Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children

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National Institute for Health and Clinical Excellence

National Collaborating Centre for Primary Care

Sibutramine (Reductil): marketing authorisation suspended
On 21 January 2010, the MHRA announced the suspension of the marketing authorisation for the obesity drug sibutramine (Reductil). This follows a review by the European Medicines Agency which found that the cardiovascular risks of sibutramine outweigh its benefits. Emerging evidence suggests that there is an increased risk of non-fatal heart attacks and strokes with this medicine.

The MHRA advises that:

- Prescribers should not issue any new prescriptions for sibutramine (Reductil) and should review the treatment of patients taking the drug.
- Pharmacists should stop dispensing Reductil and should advise patients to make an appointment to see their doctor at the next convenient time.
- People who are currently taking Reductil should make a routine appointment with their doctor to discuss alternative measures to lose weight, including use of diet and exercise regimens. Patients may stop treatment before their appointment if they wish.

The guideline recommended sibutramine for the treatment of obesity in certain circumstances. These recommendations have now been withdrawn and healthcare professionals should follow the MHRA advice.

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Foreword

There is increasing recognition both in the UK and worldwide that there is an "obesity epidemic". This is supported by research evidence based on analyses of national surveys going back over twenty years. The issue has received much attention recently from politicians, professionals, the media and the public. Changes in lifestyle, work and leisure probably all contribute to the present situation. Estimates suggest that more than 12 million adults and 1 million children in England will be obese by 2010 if no action is taken. Currently most action has been at the individual level, with programmes of diet and exercise, and while these may have some benefit, they have made little impact on halting the rise of obesity at a national level. With so many publications and claims, and with the awareness that often success for the individual is short lived, many find it difficult to know what action is appropriate in the prevention and treatment of obesity. There is significant variation in existing service provision and, in many places, the multicomponent programmes that are required for both prevention and treatment are limited.

This full guidance and the related publications seek to produce the first comprehensive and integrated approach to prevention, maintenance and treatment. It is generally accepted that obesity is one of the major challenges to public health at this time and I hope that these publications will contribute to both informed debate and action.

While as in many areas of public health and health care the evidence is limited, we believe that the initial separate searching of the published papers on public health and clinical care, which yielded a consistency of approach, has helped to strengthen our recommendations. However we are very clear in our recommendations that there is urgent need for well designed, longer term studies with agreed outcomes carried out in normal settings in this country to provide better evidence as to what works in both prevention and treatment.

In producing the recommendations there is always a dilemma between being very prescriptive and being rather general. We have sought to be sufficiently flexible to take account of the diversity of personal life style and circumstances and to ensure that in treatment, there is recognition of clinical judgement, as well as the necessity of an agreed approach by the individual and family.

Our recommendations have been formulated with different audiences in mind: public; professionals and those in responsible positions in the health services, local government, education, partnership organisations, the workplace and the voluntary sector. Just as there is no single or simple approach that will be effective in the treatment of overweight or obesity so, a broad and comprehensive approach is required for wider public health action.

I am most grateful to all those who have contributed positively to the preparation of this guidance during the past 18 months. It has been a pleasure to work with them and it is our hope that these recommendations will provide clear and practical help. In addition to the usual skills of a range of health professionals, those involved in clinical care, and patients, we have had the advice of those in local government, voluntary and community organisations, sports and exercise and the workplace. In this guidance, for the first time, NICE Recommendations are not exclusively aimed at those in the health service.

While obesity is recognised as a priority, there are of course competing priorities, although some of these, such as diabetes and heart disease, are closely linked. However few other problems are causing such widespread concern over their increase and their impact on health and quality of life.

We have sought to produce guidance that will build on the existing services, recognising that further training and staff will be required. The report aims to be ambitious and forward looking. To do otherwise would have been irresponsible with a major health priority, which is continuing to increase in prevalence.

Professor Jim McEwen, Chair of the Guidance Development Groups

Clinical guidance

The last ten years have seen increasing recognition of the importance of obesity in the UK adult population and its association with a range of significant health problems, including type 2 diabetes. There has also been increasing concern about the rise of childhood obesity and the implications of such obesity persisting into adulthood.

As a practising GP, I know that primary care has a crucial role to play in the assessment and management of adults with obesity. In order for primary care health workers to take on this role they need to know what works and require better training and resourcing of management programmes that incorporate dietary advice, physical activity and behavioural change (multicomponent interventions). This clinical guideline offers general practitioners, practice nurses, community dietitians and others a systematic review of the evidence of weight loss interventions, with clear summaries of their effectiveness.

What is striking is that we lack good evidence of the effectiveness of a number of key interventions, particularly in children. But the recommendations themselves are clear and capable of implementation, with a clear message that management should be targeted at those with the highest potential to benefit from weight loss and that drugs should only be used to manage obesity when such multicomponent interventions have been delivered.

This guidance is a significant achievement on two counts. First, it provides integrated clinical and public health guidance on the prevention as well as the management of obesity and the overweight. It is well recognised that the epidemic of obesity cannot simply be addressed through behavioural change at individual level; population based interventions are needed to change the “obesogenic environment” of modern industrialised nations. Second, it is the result of a three year collaboration between the National Collaborating Centre for Primary Care, hosted by the Royal College of General Practitioners, who led on the clinical part of the guidance and the Centre for Public Health Excellence at

NICE, who led on the public health aspects of the guidance. The use of two guidance development subgroups (clinical and prevention), chaired by an experienced public health physician, offers a successful model for developing further integrated primary care/public health guidance for the NHS and other bodies in the future.

We must take every necessary step to tackle obesity. This publication is an important step in that effort and I commend it to clinicians and commissioners.

Professor Mayur Lakhani FRCGP,
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Abbreviations and glossary of terms

Abbreviations

ABV	alcohol by volume
BMEG	black and minority ethnic group
BMI	body mass index
BT	behaviour therapy or behavioural treatment
CBA	controlled before-and-after study
CC	collaborating centre
CCT	controlled clinical trial
CHD	coronary heart disease
CEA	cost–effectiveness analysis
CI	confidence interval
CPHE	Centre for Public Health Excellence
CUA	cost–utility analysis
CVD	cardiovascular disease
DH	Department of Health
EBQ	evidence-based question
GDG	Guidance Development Group
GP	general practitioner
GPP	good practice point
GRP	Guideline Review Panel
HAD	Health Development Agency
HDL	High-density lipoprotein
HR	hazard ratio
HTA	Health Technology Assessment
ICER	incremental cost-effectiveness ratio
IOTF	International Obesity Taskforce
ITT	intention to treat
LCD	low-calorie diet
LDL	low-density lipoprotein
LSP	local strategic partnership

NCC-PC	National Collaborating Centre for Primary Care
NHMRC	National Health and Medical Research Council (Australia)
NICE	National Institute for Health and Clinical Excellence
NSF	National Service Framework
NSP	non-starch polysaccharides
OR	odds ratio
PCT	Primary Care Trust
PICO	framework incorporating patients, interventions, comparisons, outcomes used for development of evidence-based questions
PSMF	protein-sparing modified fast
QALY	quality-adjusted life year
RCT	randomised controlled trial
RR	relative risk (or risk ratio)
SD	standard deviation
SE	standard error
SEG	Socioeconomic group
SES	Socioeconomic status
SIGN	Scottish Intercollegiate Guidelines Network
VLCD	very-low-calorie diet
WC	waist circumference
WHR	waist-to-hip ratio
WHO	World Health Organization

Glossary of terms

Active play	What children and young people do when they follow their own ideas and interests, in their own way and for their own reasons – such as 'play active games, run about, ride a bike, kick a ball around” (based on Department for Culture Media and Sport definition of play and Health Survey for England 1997 definition of active play)
Active transport / travel	A form of transport that requires physical activity eg walking or cycling.
Adult	For the purposes of this guidance, adult is defined as an individual >18 years*. *However it is not considered helpful to have absolute cut offs for ages of children/young persons since the facilities available for the transition of care from children to adult centres can vary between specialties e.g. mental health, endocrinology.
Adiposity	Body fat
Anthropometry	Measures of the human body
Bariatric surgery	Surgery on the stomach and/or intestines to help the person with extreme obesity lose weight
Behavioural intervention	See term(s) above (behavioural treatment), cognitive behaviour treatment or behaviour therapy. Refers to the use of the common components of behavioural treatment (self-monitoring, goal setting, stimulus control)
Behavioural treatment	Behavioural treatment (or behaviour therapy) draws on the principles of learning theory (stimulus–behaviour contingencies or behaviour–reward contingencies). Consists of assessment (identifying and specifying problem behaviours and the circumstances in which they are elicited), treatment (including setting specific, measurable and modest goals that are continually revised) and monitoring. Behaviour change processes include stimulus control, graded exposure, extinction and reward
Bioelectrical impedance analysis (BIA)	A way to estimate the amount of body weight that is fat and non-fat. Non-fat weight comes from bone, muscle, body water, organs and other body tissues. BIA works by measuring how difficult it is for a harmless electrical current to move through the body. The more fat a person has, the harder it is for electricity to flow through the body. The less fat a person has, the easier it is for electricity to flow

	through the body. By measuring the flow of electricity, one can estimate body fat per cent
Body mass index (BMI)	A simple index of weight for height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in meters (kg/m^2)[{4624}].
Calorie value	The number of Calories (kcal) in any given food or drink. Fat provides 9 calories per gram, alcohol provides 7 Calories per gram, carbohydrates and proteins provides 4 Calories per gram. 1 kcal = 4.2 kilojoules (kJ)
Child	For the purposes of this guidance, child is defined as an individual aged <18 years* *However it is not considered helpful to have absolute cut offs for ages of children/young persons since the facilities available for the transition of care from children to adult centres can vary between specialties e.g. mental health, endocrinology.
Cohort study	A retrospective or prospective follow-up study. Groups of individuals to be followed up are defined on the basis of presence or absence of exposure to a suspected risk factor or intervention. A cohort study can be comparative, in which case two or more groups are selected on the basis of differences in their exposure to the agent of interest
Diet	The habitual food intake of people or animals *or* A plan of food and drink set down for the loss of weight, or a prescribed plan for medical reasons
Energy-dense food	Food and drinks which provide relatively high amounts of calories per gram, millilitre and/or serving The World Health Organization (2003) states that energy-dense foods „tend to be processed foods that are high in fat and/or sugar. Low energy dense (or energy dilute) foods such as fruit, legumes, vegetables and whole grain cereals are high in dietary fibre and water.‟
Exercise	Planned bouts of physical activity usually pursued for personal health and fitness goals. Exercise is a subset of physical activity, which is planned, structured, repetitive and aimed at improvement or maintenance of any aspect of fitness or health
Fast foods	No specific definition but commonly used slang term for foods which are generally sold in retail outlets and which are high in calories, fat, saturated fat, sugar and/or salt

Fatty foods	Foods high in total fat and/or saturated fat The Food Standards Agency (FSA) provides the following guidance: 20 g fat or more per 100 g is a lot of fat 5 g saturates or more per 100 g is a lot 3 g fat or less per 100 g is a little fat 1 g saturates or less per 100 g is a little fat
Healthy diet	A healthy diet contains plenty of fruit and vegetables; is based on starchy foods such as wholegrain bread, pasta and rice; and is low in fat (especially saturated fat), salt and sugar *Specific dietary recommendations (UK)* (Population average intakes; apply to children aged 5 years and over) Total fat: maintain at 35% of food energy Saturated fat: reduce to 11% of food energy Added sugar: reduce to 11% of food energy Fibre: increase to 18 g/day Salt: reduce to no more than 6 g/day* Fruit and vegetables: increase consumption of a variety of fruit and vegetables to at least five portions per day *[1]The maximum amount of salt recommended for children is less than that for adults – see www.eatwell.gov.uk for specific recommendations.
Healthy weight	A person who has a body mass index (BMI) 18.5 -24.9
Intermediate outcomes	Results or outcomes of action that must occur prior to the final outcome and in order to produce the final outcome. Within the context of this work, relevant changes in diet or activity levels may be considered intermediate outcomes for the assessment of interventions to prevent weight or manage obesity
Life-long learning	A continuum of the learning process that takes place at all levels - formal, non-formal and informal - utilizing various modalities such as distance learning and conventional learning.
Lifestyle activity	Activities that are performed as part of everyday life, such as climbing stairs, walking (for example, to work, school or shops) and cycling. They are normally contrasted with „programmed" activities such as attending a dance class or fitness training session

Long term	For the purposes of this guidance, long term is considered 1 year or more.
Low-calorie diet	A weight loss diet containing less energy than an individual‟s energy needs – typically 1000–1500 kilocalories per day. (See reviews for details)
Low-fat diet	A diet where 30% or less of the total daily energy is derived from fat. (See reviews for details)
MET („metabolic equivalent‟)	1 MET = a person‟s metabolic rate (rate of energy expenditure) when at rest. MET values are assigned to activities to denote their intensity and are given in multiples of resting metabolic rate. For example, walking elicits an intensity of 3–6 METs, depending on how brisk the walk is, and more strenuous activity such as running would have an intensity of 7–10 METs
Multicomponent intervention	An intervention that aims to address a range of factors which may influence the outcome measure of interest. Sometimes referred to as „multifaceted‟
Observational study	An epidemiological study that does not involve any intervention, experimental or otherwise. Nature is allowed to take its course with changes in one characteristic being studied in relation to changes in other characteristics
Physical activity	The full range of human movement, from competitive sport and exercise to active hobbies, walking, cycling or activities of daily living. Physical activity varies by: Volume or quantity (total quantity of physical activity over a specified period, usually expressed as kcal or METs per day or week) Frequency of participation, typically expressed as number of sessions per day or week Intensity, usually expressed as light, moderate or vigorous. Commonly used approximations are: light intensity = less than 4 METs, for example, strolling; moderate = 4 – 6 METs, for example, brisk walking, vigorous = 7+ METs for example, running Duration – time spend on a single bout of activity Type or mode – qualitative descriptor such as brisk walking, dancing or weight training
Physical literacy	Motivation, confidence, physical competence, understanding and knowledge to maintain physical activity at an individually appropriate level, throughout life.

Protein-sparing modified fast diet	A diet which is relatively high in protein (0.8–1.5 g/kg of ideal body weight (IBW) per day), low fat and low carbohydrates. It is hypocaloric and generally contains fewer than 800 kilocalories per day. It contains supplements to meet the dietary reference values for vitamins and minerals. Often recommended only for short-term use in individuals who are obese
Psychosocial	Involving aspects of social and psychological behaviour: *a child's psychosocial development*
Quasi-experimental study	A study in which some subjects receive an experimental prevention or therapeutic product or intervention and are compared with subjects who do not, but allocation to each of the groups is not random
Randomised controlled trial (RCT)	A comparative study in which participants are randomly allocated to intervention and control groups and followed up to examine differences in outcomes between the groups
Red food	From Epstein and coworkers" traffic light diet. Consists of high in calories, low in nutrient density foods
Revisional surgery	Bariatric procedure performed to correct or modify a previous bariatric procedure
Short term	For the recommendations in this guidance, short term is defined as less than one year.
Skinfold thickness	A measure of the amount of fat under the skin; the measurement is made with a calliper. Measurements at several sites are normally required as the per cent of fat at each site varies with age, sex and ethnicity. Skinfold measurements are usually taken at the triceps, subscapular and supra-iliac sites
Snack	No specific definition. Foods consumed between meals or instead of a main meal
Social marketing	The application of commercial marketing technologies to the analysis, planning, execution, and evaluation of programmes designed to influence the voluntary behaviour of target audiences to improve their personal welfare and that of their society[1]
Sugary foods and drinks	Food and drinks high in added sugars. The FSA provides the following guidance: 10 g sugar or more per 100 g is A LOT of sugar 2 g sugar or less per 100 g is A LITTLE sugar
Traffic light diet	This is a calorie-based food-exchange system created by

	Epstein and coworkers. Foods are divided into five groups (fruits and vegetables, grains, proteins, dairy and other foods), and the foods in each group are colour coded according to nutrient density: green for „go", yellow for „eat with care", and red for „stop". Green foods are foods containing less than 20 calories per serving, yellow foods are the staple of the diet and provide most of the basic nutrition and red foods are those foods high in fat and simple carbohydrates. All sweets and sugared beverages are classified as red foods. Families are then instructed to count calories and cannot have more than four red foods a week
Travel plan	Department for Transport definition: A travel plan is a package of measures produced by employers to encourage staff to use alternatives to single-occupancy car use. Such a plan could include: car sharing schemes; a commitment to improve cycling facilities; a dedicated bus service or restricted car parking allocations. It might also promote flexible working practices such as remote access and video conferencing
Very-low-calorie diet (VLCD)	Diets generally providing between 400 calories and 800 calories per day (often 400–500 calories). (See reviews for details)
Vulnerable groups	Populations who face a greater than average risk of weight gain due to a range of factors largely beyond their control. Some of these factors may be inherent, while others may relate to the social, economic and environmental circumstances in which they live.
Waist-to-hip ratio	Waist circumference (cm) divided by hip circumference (cm). Provides a proxy measure of central distribution of fat (intra-abdominal fat)

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Registered stakeholder organisations

The list below includes all registered stakeholders to date. In the final version this list will be amended to stakeholder organisations who commented on the scope and/or consultation.

Abbott Laboratories Ltd

Action on Pre-Eclampsia

Age Concern Cymru

Aintree Hospitals NHS Trust

All Wales Dietetic Advisory Committee

All Wales Senior Nurses Advisory Group (Mental Health)

Amgen

Ashfield and Mansfield District Primary Care Trusts

Ashford and St Peter‟s Hospital NHS Trust

Association for Continence Advice

Association for Respiratory Technology and Physiology

Association for the Study of Obesity

Association of Breastfeeding Mothers

Association of British Clinical Diabetologists

Association of Clinical Biochemists, The

Association of Directors of Social Services (ADSS) – Southampton

Association of Endoscopic Surgeons of Great Britain and Ireland

Association of Surgeons of Great Britain and Ireland

Association of the British Pharmaceuticals Industry (ABPI)

Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland (AUGIS)

Atkins Nutritional Inc

Back country cardiac network

Barnet Primary Care Trust

Barnsley Primary Care Trust

Bedfordshire and Hertfordshire NHS Strategic Health Authority

Big Lottery Fund

Bolton Salford and Trafford Mental Health

Bradford South and West Primary Care Trust

Bristol University

British Association for Behavioural and Cognitive Psychotherapies (BABCP)

British Association for Counselling and Psychotherapy

British Association for Parenteral and Enteral Nutrition (BAPEN)

British Association of Plastic Surgeons

British Association of Sport and Exercise Sciences

British Dietetic Association

British Geriatrics Society

British Heart Foundation

British Lymphology Society

British National Formulary (BNF)

British Nutrition Foundation

British Obesity Surgery Patient Association

British Obesity Surgery Society

British Psychological Society, The

British Society for Paediatric Endocrinology and Diabetes (BSPED)

Cambridge City and South Cambridgeshire Primary Care Trust

Cambridge Manufacturing Co Ltd

Cambridge Neurotechnology

Cancer Research UK

CASPE (Clinical Accountability, Service Planning and Evaluation)

CEMACH (Confidential Enquiry into Maternal and Child Health)

Central Council of Physical Recreation (CCPR)

Centre for Health Services Studies

Chartered Society of Physiotherapy, The

Cheshire and Wirral Partnership NHS Trust

Child Growth Foundation

Chorley and South Ribble Primary Care Trust

CIS"ters (Childhood Incest Survivors)

City and Hackney Teaching Primary Care Trust

City Hospitals Sunderland NHS Trust

College of Occupational Therapists

Community Practitioners" and Health Visitors" Association

Confederation of Indian Organisations UK

Consumers for Health Choice

Co-operative Pharmacy Association

Cornwall Partnership Trust

Counselling and Psychotherapy Trust

Counsellors and Psychotherapists in Primary Care

Counterweight Programme, The

Craven Harrogate and Rural District Primary Care Trust

Croydon Primary Care Trust

Cumbria and Lancashire Strategic Health Authority

Cyberonics

Department for Education and Skills

Department of Academic Psychiatry – Guy"s

Department of Health

Depression Alliance

Devon Partnership NHS Trust

Diabetes UK

Diennet Ltd

Dietitians working in Obesity Management (UK)

Doncaster East Primary Care Trust

East and North Hertfordshire NHS Trust

East Hampshire Primary Care Trust

East Sussex Hospitals NHS Trust

Eating Disorders Association, The

Eli Lilly and Company Ltd

English Nature

Faculty of Dental Surgery

Faculty of Public Health

Federation of Bakers

Food Advertising Unit

Food and Drink Federation

Food Commission, The

Food Standards Agency

GeneWatch UK

Green Machine, The

Hampshire Partnership NHS Trust

Healthcare Commission

Healthier Weight Centre, The

Health Promotion Agency for Northern Ireland

Heart of England NHS Foundation Trust

Heart of Mersey

Heart UK

Heartsave

Hertfordshire Partnership NHS Trust

Hyperlipidaemia Education and Research Trust (HEART-UK) – 2nd contact

Immogenics Limited

Inamed Corporation

Independent Healthcare Forum

Infant and Dietetic Foods Association

Institute of Sport and Recreation Management

International Obesity Taskforce of the International Association for the Study of Obesity

International Size Acceptance Association

Islington Primary Care Trust

Janssen-Cilag Ltd

Johnson & Johnson Medical

KCI Medical Ltd UK

King"s College Hospital NHS Trust

Kingston Primary Care Trust

Knowsley Primary Care Trust

L"Arche UK

Leeds North East Primary Care Trust

Leeds Teaching Hospitals NHS Trust

LighterLife

Liverpool John Moores University

Luton and Dunstable Hospital NHS Trust

Medical Support Systems Limited

Medicines and Healthcare Products Regulatory Agency (MHRA)

Medtronic Europe Sarl

MEND Central Ltd

Merck Sharp & Dohme Ltd

Merton Child and Adolescent Mental Health Service

Mid Staffordshire General Hospitals NHS Trust

Mid Sussex Primary Care Trust

Move4Health

MRC Human Nutrition Research

National Association of British and Irish Millers

National Audit Office

National Centre for Eating Disorders

National Collaborating Centre for Acute Care

National Collaborating Centre for Cancer

National Collaborating Centre for Chronic Conditions

National Collaborating Centre for Mental Health

National Collaborating Centre for Nursing and Supportive Care

National Collaborating Centre for Women and Children"s Health

National Council for Disabled People, Black, Minority and Ethnic Community

National Healthy School Standard

National Heart Forum (UK)

National Institute for Mental Health in England (NIMHE)

National Nurse Consultants in Child and Adolescent Mental Health Service forum

National Obesity Forum

National Patient Safety Agency

National Public Health Service – Wales

National Youth Advocacy Service

NCH – The Children"s Charity

Nestle Clinical Nutrition

Newcastle Primary Care Trust

Newcastle-under-Lyme Primary Care Trust

Newcastle upon Tyne Hospitals NHS Trust

NHS Direct

NHS Health and Social Care Information Centre

NHS Quality Improvement Scotland

North Central London Strategic Health Authority

North Glamorgan NHS Trust – Merthyr Tydfil

North Tees and Hartlepool NHS Trust

North West London Hospitals NHS Trust

Nottingham City Primary Care Trust

Nutmeg UK Ltd

Nutrition Society

Obesity Management Association

Oxfordshire Mental Health Care NHS Trust

Overweight and Obesity Organization, The

Patient and Public Involvement Programme for NICE

PERIGON (formerly The NHS Modernisation Agency)

Pfizer Ltd

Plymouth Hospitals NHS Trust

Powys Local Health Board

Primary Care Cardiovascular Society

Primary Care Rheumatology Society

Princess Alexandra Hospital NHS Trust

Proprietary Association of Great Britain (PAGB)

Queen Victoria Hospital NHS Foundation Trust

Reckitt Benckiser Healthcare (UK) Ltd

Roche Products Limited

Rotherham General Hospitals NHS Trust

Royal Brompton and Harefield NHS Trust

Royal College of Anaesthetists

Royal College of General Practitioners

Royal College of General Practitioners Wales

Royal College of Midwives

Royal College of Nursing

Royal College of Paediatrics and Child Health

Royal College of Pathologists

Royal College of Physicians of Edinburgh

Royal College of Physicians of London

Royal College of Psychiatrists

Royal Cornwall Hospitals Trust and Peninsula Medical School

Royal Liverpool Children"s NHS Trust

Royal Pharmaceutical Society of Great Britain

Royal Society of Medicine

Royal United Hospital Bath NHS Trust

Salford Primary Care Trust

Sanofi-Aventis

Scottish Intercollegiate Guidelines Network (SIGN)

Sheffield Children"s Hospital NHS Trust

Sheffield South West Primary Care Trust

Sheffield Teaching Hospitals NHS Trust

Slender Thoughts

Slim-Fast Foods Ltd

Slimming World

Society for Academic Primary Care

Society for Endocrinology

South Asian Health Foundation

South East Sheffield Primary Care Trust

South West London Strategic Health Authority

South Yorkshire Strategic Health Authority

Sport England

St George"s Healthcare NHS Trust

Stroke Association, The

Sure Start Ashfield

Sure Start Tamworth

Sustain: The alliance for better food and farming

Sustrans

Sutton and Merton Primary Care Trust

Tanita UK Ltd

Thames Valley Strategic Health Authority

Tissue Viability Society (UK)

TOAST (The Obesity Awareness and Solutions Trust)

University College London – Cancer Research UK Health Behaviour Unit

UK National Screening Committee

UK Public Health Association

University College London NHS Trust

University of Leeds

Vale of Aylesbury Primary Care Trust

Walsall Primary Care Trust

Wareney Primary Care Trust

Weight Concern

Weight Loss Surgery Information and Support

WeightWatchers UK

Welsh Assembly Government

West Midlands Specialised Services Agency

West Norfolk Primary Care Trust

West of Cornwall Primary Care Trust

West Hertfordshire Hospitals Trust

World Cancer Research Fund International

Wyre Forest Primary Care Trust

Working with people to prevent and manage overweight and obesity: the issues

Preventing and managing overweight and obesity are complex problems, with no easy answers. This guidance offers practical recommendations based on the evidence. But staff working directly with the public also need to be aware of the many factors that could be affecting a person‟s ability to stay at a healthy weight or succeed in losing weight.

- People choose whether or not to change their lifestyle or agree to treatment. Assessing their readiness to make changes affects decisions on when or how to offer any intervention.
- Barriers to lifestyle change should be explored. Possible barriers include:
  - lack of knowledge about buying and cooking food, and how diet and exercise affect health
  - the cost and availability of healthy foods and opportunities for exercise
  - safety concerns, for example about cycling
  - lack of time
  - personal tastes
  - the views of family and community members
  - low levels of fitness, or disabilities
  - low self-esteem and lack of assertiveness.
- Advice needs to be tailored for different groups. This is particularly important for people from black and minority ethnic groups, vulnerable groups (such as those on low incomes) and people at life stages with increased risk for weight gain (such as during and after pregnancy, at the menopause or when stopping smoking).

Working with children and young adults

- Treating children for overweight or obesity may stigmatise them and put them at risk of bullying, which in turn can aggravate problem eating. Confidentiality and building self-esteem are particularly important if help is offered at school.

- Interventions to help children eat a healthy diet and be physically active should develop a positive body image and build self-esteem.

Person-centred care: principles for health professionals

When working with people to prevent or manage overweight and obesity, health professionals should follow the usual principles of person-centred care.

Advice, treatment and care should take into account people‟s needs and preferences. People should have the opportunity to make informed decisions about their care and treatment, in partnership with their health professionals.

Good communication between health professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient‟s needs. Advice, treatment and care, and the information patients are given about it, should be non-discriminatory and culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

For older children who are overweight or obese, a balance needs to be found between the importance of involving parents and the right of the child to be cared for independently.

If a person does not have the capacity to make decisions, health professionals should follow the Department of Health guidance – „Reference guide to consent for examination or treatment‟ (2001) (available from www.dh.gov.uk). From April 2007 healthcare professionals will need to follow a code of practice accompanying the Mental Capacity Act (summary available from www.dca.gov.uk/menincap/bill-summary.htm

Training

Staff who advise people on diet, weight and activity – both inside and outside the NHS – need appropriate training, experience and enthusiasm to motivate people to change. Some will need general training (for example, in health promotion), while those who provide interventions for obesity (such as dietary treatment and physical training) will need more specialised training. In the recommendations, the term „specific" is used if the training will be in addition to staff"s basic training. The term „relevant" is used for training that could be part of basic professional training or in addition to it.

Section 1: Executive summary, introduction and methods

1 Executive summary and recommendations

1.1 Aims of the guidance

This is the first national guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children in England and Wales. The guidance aims to:

- stem the rising prevalence of obesity and diseases associated with it
- increase the effectiveness of interventions to prevent overweight and obesity
- improve the care provided to adults and children with obesity, particularly in primary care.

The recommendations are based on the best available evidence of effectiveness, including cost effectiveness. They include recommendations on the clinical management of overweight and obesity in the NHS, and advice on the prevention of overweight and obesity that applies in both NHS and non-NHS settings.

The guidance supports the implementation of the „Choosing health" White Paper in England, „Designed for life" in Wales, the revised GP contract and the existing national service frameworks (NSFs). It also supports the joint Department of Health, Department for Education and Skills and Department for Culture, Media and Sport target to halt the rise in obesity among children under 11 by 2010, and similar initiatives in Wales.

Rationale for integrated clinical and public health guidance

Public health and clinical audiences share the same need for evidence-based, cost-effective solutions to the challenges in their day-to-day practice, as well as to inform policies and strategies to improve health. Complementary clinical and public health guidance are essential to address the hazy divisions between prevention and management of obesity.

The 2004 Wanless report „Securing good health for the whole population" stressed that a substantial change will be needed to produce the reductions in

preventable diseases such as obesity that will lead to the greatest reductions in future healthcare costs. In addition to recommending a more effective delivery framework for health services providers, the report proposed an enhanced role for schools, local authorities and other public sector agencies, employers, and private and voluntary sector providers in developing opportunities for people to secure better health.

It is unlikely that the problem of obesity can be addressed through primary care management alone. More than half the adult population are overweight or obese and a large proportion will need help with weight management. Although there is no simple solution, the most effective strategies for prevention and management share similar approaches. The clinical management of obesity cannot be viewed in isolation from the environment in which people live.

1.2 Key priorities for implementation

The prevention and management of obesity should be a priority for all, because of the considerable health benefits of maintaining a healthy weight and the health risks associated with overweight and obesity.

Public health

NHS

- Managers and health professionals in all primary care settings should ensure that preventing and managing obesity is a priority, at both strategic and delivery levels. Dedicated resources should be allocated for action.

Local authorities and partners

- Local authorities should work with local partners, such as industry and voluntary organisations, to create and manage more safe spaces for incidental and planned physical activity, addressing as a priority any concerns about safety, crime and inclusion, by:

  - providing facilities and schemes such as cycling and walking routes, cycle parking, area maps and safe play areas
  - making streets cleaner and safer, through measures such as traffic calming, congestion charging, pedestrian crossings, cycle routes, lighting and walking schemes
  - ensuring buildings and spaces are designed to encourage people to be more physically active (for example, through positioning and signing of stairs, entrances and walkways)
  - considering in particular people who require tailored information and support, especially inactive, vulnerable groups.

Early years settings

- Nurseries and other childcare facilities should:
  - minimise sedentary activities during play time, and provide regular opportunities for enjoyable active play and structured physical activity sessions
  - implement Department for Education and Skills, Food Standards Agency and Caroline Walker Trust* guidance on food procurement and healthy catering.

Schools

- Head teachers and chairs of governors, in collaboration with parents and pupils, should assess the whole school environment and ensure that the ethos of all school policies helps children and young people to maintain a healthy weight, eat a healthy diet and be physically active, in line with existing standards and guidance. This includes policies relating to building layout and recreational spaces, catering (including vending machines) and the food and drink children bring into school, the taught curriculum (including PE), school

*see www.cwt.org.uk

travel plans and provision for cycling, and policies relating to the National Healthy Schools Programme and extended schools.

Workplaces

- Workplaces should provide opportunities for staff to eat a healthy diet and be physically active, through:
  - active and continuous promotion of healthy choices in restaurants, hospitality, vending machines and shops for staff and clients, in line with existing Food Standards Agency guidance
  - working practices and policies, such as active travel policies for staff and visitors
  - a supportive physical environment, such as improvements to stairwells and providing showers and secure cycle parking
  - recreational opportunities, such as supporting out-of-hours social activities, lunchtime walks and use of local leisure facilities.

Self-help, commercial and community settings

- Primary care organisations and local authorities should recommend to patients, or consider endorsing, self-help, commercial and community weight management programmes only if they follow best practice (see recommendation 1 in section 1.6.9.2 for details of best practice standards).

Clinical care

Children and adults

•Multicomponent interventions are the treatment of choice. Weight management programmes should include behaviour change strategies to increase people‟s physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person‟s diet and reduce energy intake.

Children

•Interventions for childhood overweight and obesity should address lifestyle within the family and in social settings.

•Body mass index (BMI) (adjusted for age and gender) is recommended as a practical estimate of overweight in children and young people, but needs to be interpreted with caution because it is not a direct measure of adiposity.

•Referral to an appropriate specialist should be considered for children who are overweight or obese and have significant comorbidity or complex needs (for example, learning or educational difficulties).

Adults

The decision to start drug treatment, and the choice of drug, should be made after discussing with the patient the potential benefits and limitations, including the mode of action, adverse effects and monitoring requirements and their potential impact on the patient‟s motivation. When drug treatment is prescribed, arrangements should be made for appropriate health professionals to offer information, support and counselling on additional diet, physical activity and behavioural strategies. Information about patient support programmes should also be provided.

Bariatric surgery is recommended as a treatment option for adults with obesity if all of the following criteria are fulfilled:

- they have a BMI of 40 kg/m2 or more, or between 35 kg/m2 and 40 kg/m2 and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight

- all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months

- the person has been receiving or will receive intensive management in a specialist obesity service

- the person is generally fit for anaesthesia and surgery

- the person commits to the need for long-term follow-up

Bariatric surgery is also recommended as a first-line option (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m2 in whom surgical intervention is considered appropriate.

1.3 Clinical care pathways

Figure 1.1 Clinical care pathway for children (see also the NICE NHS Quick Reference Guide)

(BMI, body mass index; HCP, healthcare professional)

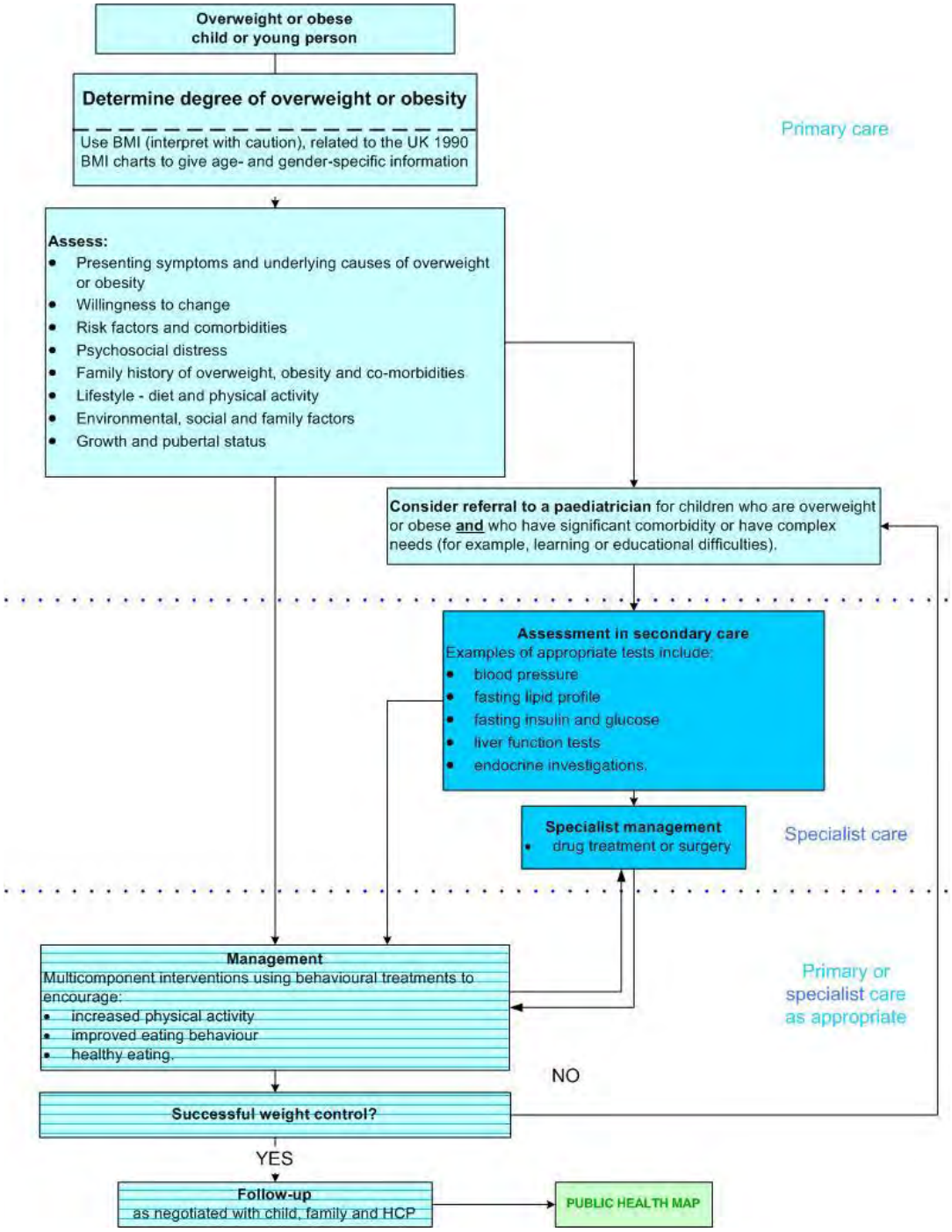
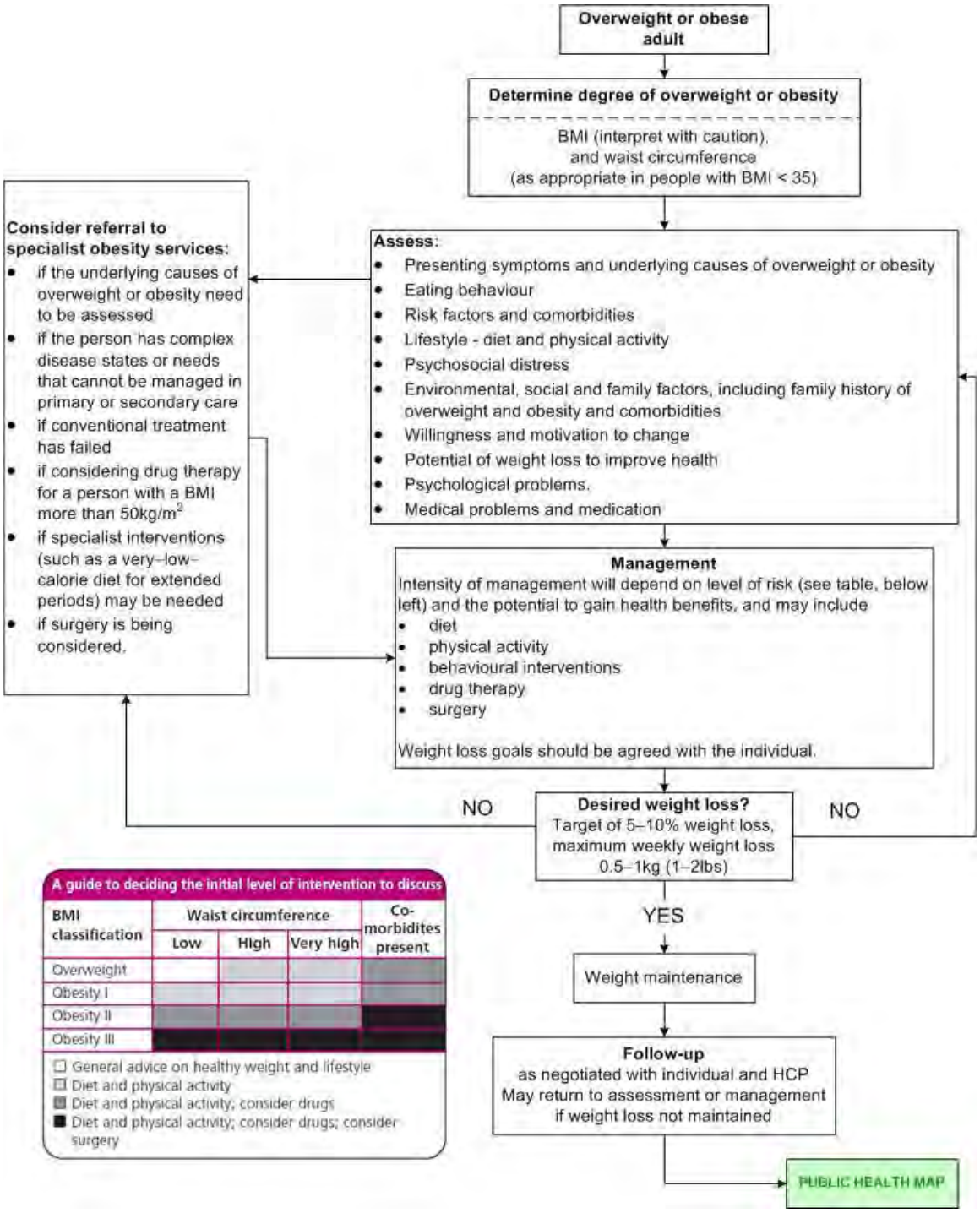


Figure 1.2 Clinical care pathway for adults (see also the NICE NHS Quick Reference Guide)

(BMI, body mass index; BP, blood pressure; HCP, healthcare professional)



1.4 Public health map

Figure 1.3a Public health map – children and young people

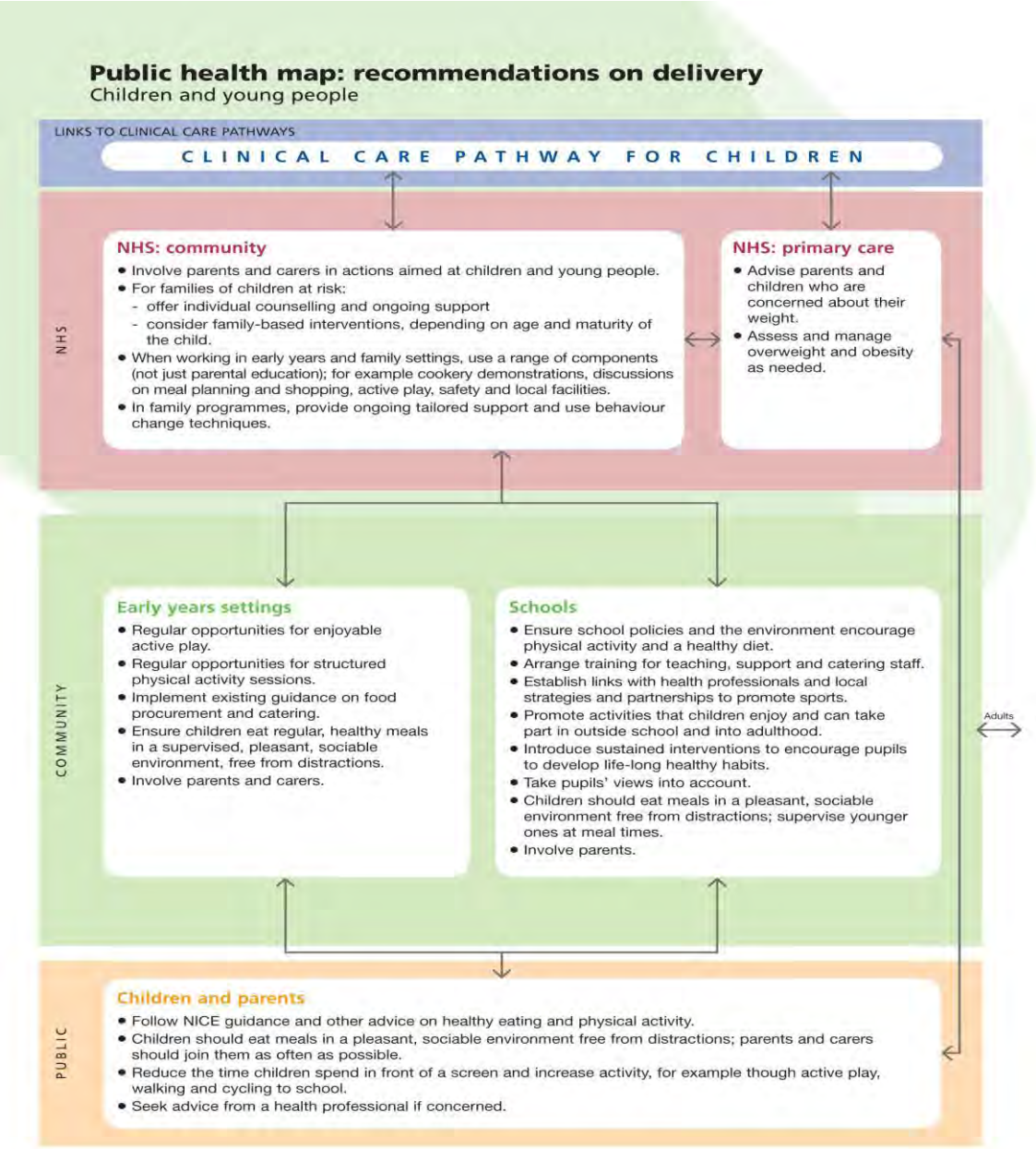
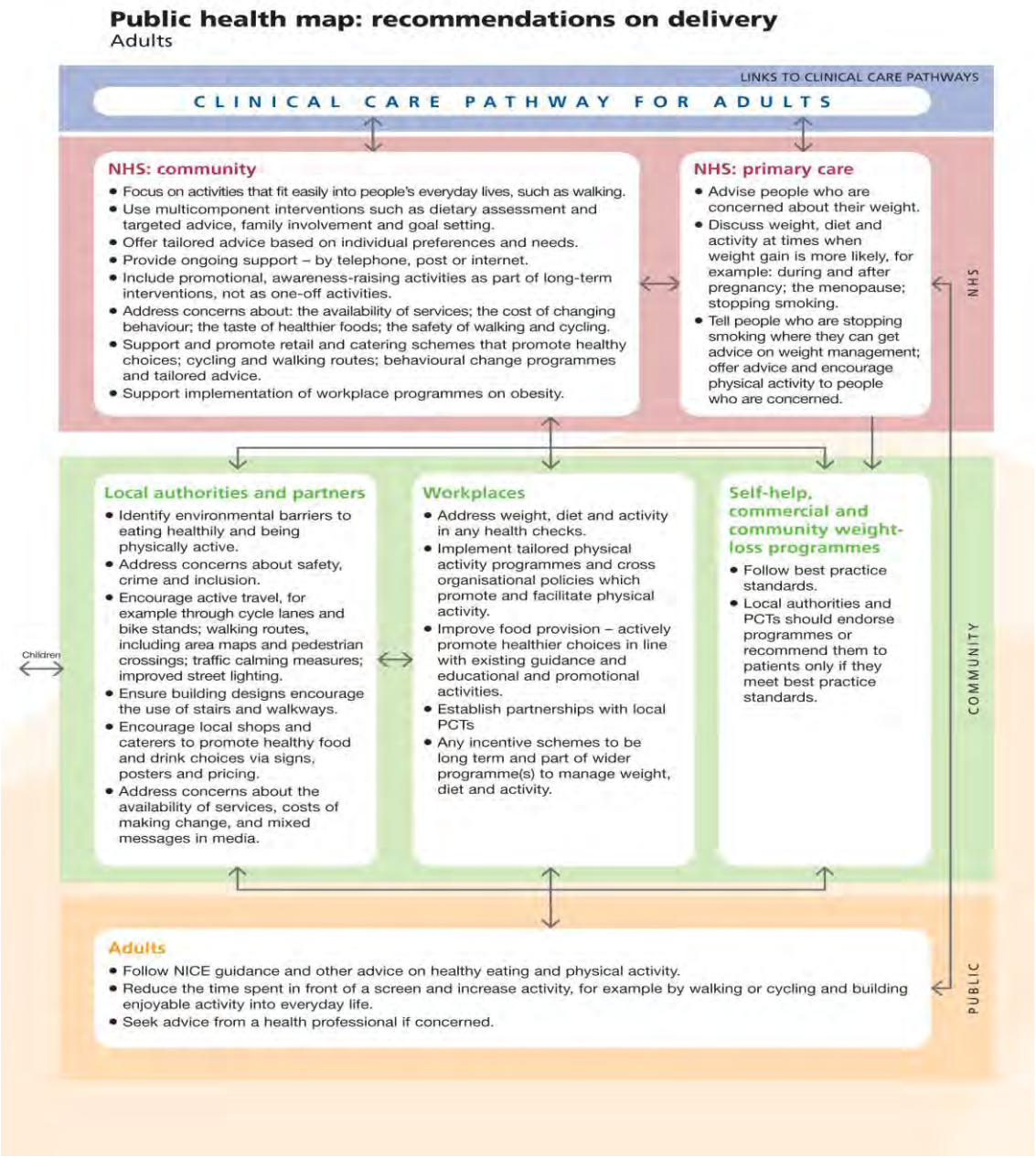
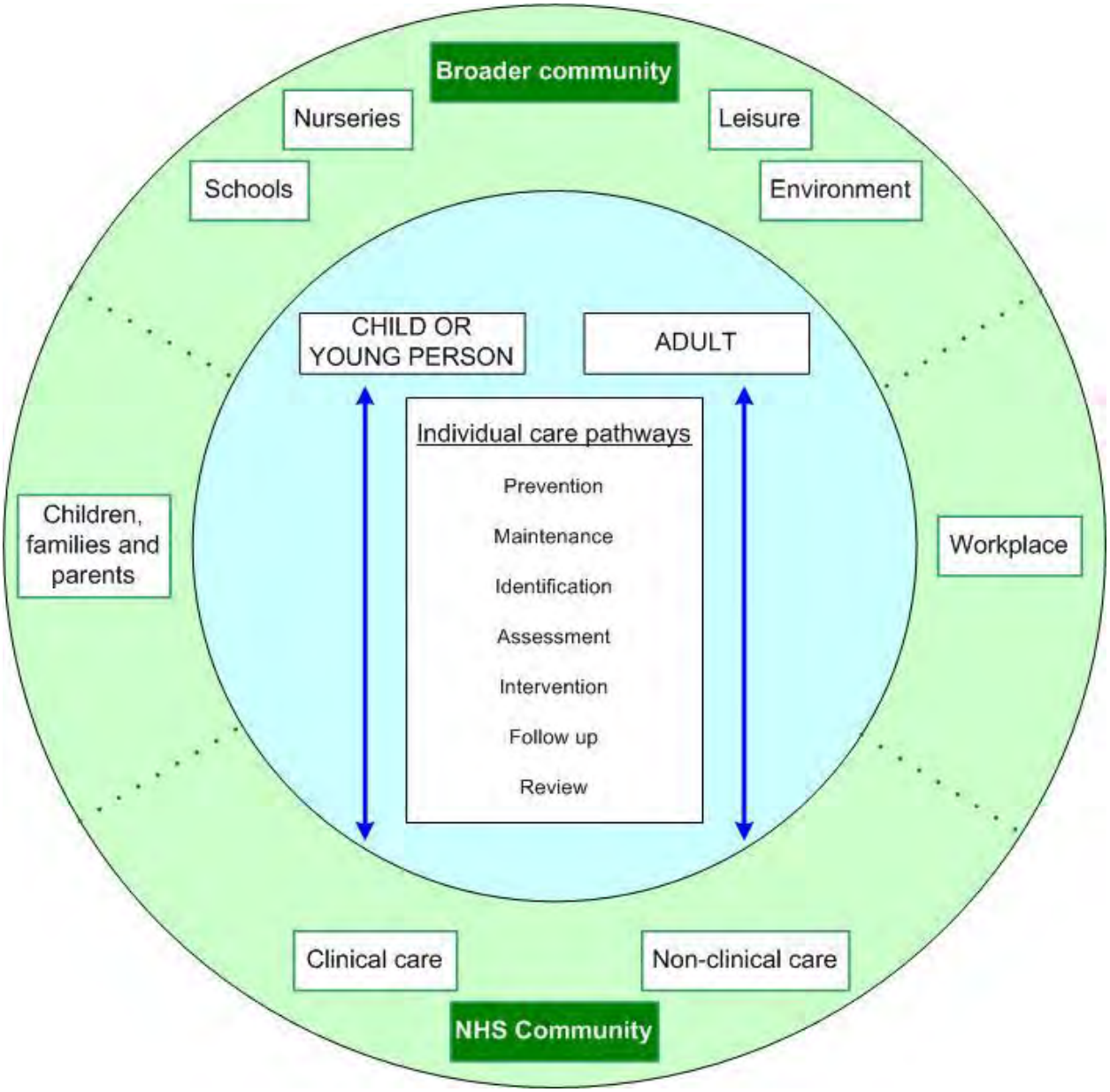


Figure 1.3b Public health map – adults



1.5 Links between public health and clinical care

Figure 1.4 Links between public health and clinical care



1.6 Public health recommendations

1.6.1 Existing guidance

The following is a brief overview of current pubic health guidance on diet, physical activity and the prevention of obesity. Key sources of further information are highlighted.

All recommendations should be viewed within the context of existing guidance and the 2004 public health White Paper „Choosing health".[2]

1.6.1.1 Diet

Standard UK population recommendations on „healthy eating" are based on the recommendations of the Committee on the Medical Aspects of Food Policy (COMA)[4–6] and subsequently the Scientific Advisory Committee on Nutrition (SACN).[7] The recommendations can be summarised as shown in Table 1.1.

Table 1.1 Standard population dietary recommendations

Nutrient/food	Recommendation
Total fat	Reduce to no more than 35% food energy
Saturated fat	Reduce to no more than 11% food energy
Total carbohydrate	Increase to more than 50% food energy
Sugars (added)	Reduce to no more than 11% food energy
Dietary fibre	Increase non-starch polysaccharides to 18 g per day
Salt	Reduce to no more than 6 g salt per day[a]
Fruit and vegetables	Increase to at least five portions of a variety of fruit and vegetables per day

[a] The maximum amount of salt recommended for children is less than that for adults – see www.salt.gov.uk

These recommendations do not apply to children under 2 years of age. Between 2 and 5 years of age, a flexible approach to the timing and extent of dietary change should be taken. By the age of 5 years children should be consuming a diet consistent with the recommendations for adults.[5]

This advice is reflected in the „National food guide, the balance of good health" (Figure 1.5).

Figure 1.5 The balance of good health

Reproduced by kind permission of the Food Standards Agency (FSA).

The Food Standards Agency summarises the advice as:

- Base your meals on starchy foods.
- Eat lots of fruit and vegetables.
- Eat more fish – including a portion of oily fish each week.
- Cut down on saturated fat and sugar.
- Try to eat less salt – no more than 6 g a day for adults.[†]

[†] The maximum amount of salt recommended for children is less than that for adults – see www.eatwell.gov.uk for specific recommendations.

- Get active and try to be a healthy weight.
- Drink plenty of water.
- Don"t skip breakfast.
- And remember to enjoy your food!

With specific reference to the prevention of obesity the World Health Organization (WHO) concluded in 2003[8] that „there is convincing evidence that a high intake of energy dense foods promotes weight gain" and that „the majority of studies show that a high intake of NSP (dietary fibre) promotes weight loss". The report highlighted that „energy dense foods tend to be high in fat (eg butter, oils, fried foods), sugars or starch, while energy dilute foods have a high fibre and water content (eg fruit and vegetables, whole grain cereals)". The report also concluded that there was „probable" evidence on increased consumption of sweetened drinks and large portion sizes increasing risk of weight gain and obesity.

Regarding alcohol intake, the Department of Health advises that men should not drink more than 3–4 units of alcohol per day, and women should drink no more than 2–3 units of alcohol per day. These daily benchmarks apply whether individuals drink every day, once or twice a week, or occasionally. The FSA also advises consumers that „There is nothing wrong with having the occasional drink. But drinking too much can cause problems. Alcohol is also high in calories, so cutting down could help you control your weight." A unit is half a pint of standard strength (3% to 5% ABV) beer, lager or cider, or a pub measure of spirit. A glass of wine is about 2 units and „alcopops" are about 1.5 units.

1.6.1.2 Physical activity

Advice on physical activity has existed for several years, and the Chief Medical Officer"s (CMO"s) report „At least five times a week" examined its validity in the light of evidence on the links between physical activity and health. The NICE guidance on obesity does not alter the current guidelines.

Adults

The current recommendations on physical activity for **general health benefits** are for adults to achieve a total of at least 30 minutes of at least moderate intensity physical activity, on 5 or more days of the week. These recommendations are also appropriate for older adults but it is highlighted that specific activities that promote improved strength, coordination and balance are particularly beneficial for older people. Achieving these levels of activity will represent a substantial increase in energy expenditure for most people.

To prevent obesity - in the absence of a reduction in energy intake, many people may need 45–60 minutes moderate activity each day .

To **prevent regaining weight** following weight loss among people who have been obese - 60–90 minutes moderate activity a day may be needed.

Children and young people

For children and young people, it is accepted that the evidence base is far from complete and the amount of activity that is required to prevent obesity is unclear. Currently it is recommended that children and young people should achieve a total of at least 60 minutes of at least moderate intensity physical activity each day, although it may be that this is inadequate to prevent the development of obesity. Between 60% and 70% of children[10] meet the current recommendations yet the prevalence of obesity continues to rise.

At this time of rapid growth and development, it is recommended that at least twice a week activities should include those aiming to improve bone health, muscle strength and flexibility. These guidelines are intended to help deliver the **general health benefits** from a physically active lifestyle.

Types of activity

Sport England highlights that the definition of moderate intensity level physical activity varies according to the fitness level of the individual. A person doing moderate intensity activity will usually experience an increase in breathing rate, an increase in heart rate

and a feeling of increased warmth. Moderate intensity activities can include everyday activities such as brisk walking or cycling, structured exercise or sport.

All forms of bodily movement contribute to energy expenditure and so can contribute to the maintenance of a healthy weight or weight loss. This can therefore include activities which can easily fit into an individual‟s daily routine such as walking or cycling to work or school, walking a dog, housework and gardening.

The daily physical activity recommendations may be achieved through several short bouts of moderate intensity activity of 10 minutes or more, or by doing the activity in one session.

Examples of moderate-intensity activities

- brisk walking
- cycling
- swimming (with moderate effort)
- stair climbing (with moderate effort)
- gardening – digging, pushing mower or sweeping leaves
- general house cleaning
- painting and decorating
- general callisthenics (sit-ups, push-ups, chin-ups)
- gentle racquet sports such as table tennis and badminton (social)
- golf – walking, wheeling or carrying clubs.

NICE guidance on physical activity

The NICE guidance „Four commonly used methods to increase physical activity: brief interventions in primary care, exercise referral schemes, pedometers and community based exercise programmes for walking and cycling‟ (2006) recommends that inactive individuals should be identified by using a validated tool, such as the Department of Health‟s general practice physical activity questionnaire (GP PAQ).

Potential risks

The wide range of health benefits of physical activity significantly outweigh the risks (for example, from injury or accidents), particularly at the levels of activity required to promote and maintain health. The CMO"s 2004 report[9] states that „the people who will benefit most from physical activity are inactive people who begin to take part in regular moderate intensity activity. If these people increase their level of activity gradually, they are unlikely to face undue risks. The greatest risks from physical activity are faced by:

- people who take part in vigorous sports and exercise
- people who do excessive amount of exercise, and
- people with existing musculoskeletal disease or at high risk of disease."

The report also highlights that many injuries that occur during physical activity are avoidable.

Sources of further information on existing guidance and trends

- http://www.fph.org.uk/policy_communication/publications/toolkits/obesity/default.asp
- www.foodstandards.gov.uk/
- www.eatwell.gov.uk/
- www.dh.gov.uk/
- www.5aday.nhs.uk/
- www.nhsdirect.nhs.uk/
- www.sportengland.org/

1.6.2 Division of the following recommendations

The public health recommendations are divided according to their key audiences and the settings they apply to:

- the public
- the NHS
- local authorities and partners in the community
- early years settings
- schools
- workplaces
- self-help, commercial and community programmes.

Some of the recommendations are at a strategic level (primarily for those involved in planning and management of service provision and policies), and others are at delivery level (for individual staff, teams and team managers).

1.6.3 Recommendations for the public

1.6.3.1 Background

Although body weight and weight gain are influenced by many factors, including genetics and the environment in which people live, research shows that the individual decisions people make will influence whether or not they are able to maintain a healthy weight.

- An individual needs to be in „energy balance" to maintain a healthy weight – that is, when energy intake (calories from food) does not exceed energy expended (for example, through everyday activities and exercise).

- Many people find it difficult to maintain a healthy weight through their lives.

- People tend to gain weight gradually, over a long period of time, and such a pattern may go unnoticed.

- People tend to gain weight with age – and may find it harder to maintain a healthy weight as they get older. Many people may accept weight gain with age as inevitable but this does not have to be the case. Although physical changes related to ageing can contribute to age-related weight gain to some extent, the main reason is the small, gradual changes in people's everyday lives (such as a tendency to being less active, or small changes to diet).

- People often gain weight during particular stages of their life, such as during and after pregnancy, during the menopause or after stopping smoking.

Small, gradual changes to daily habits, which are maintained over a long period of time, can help or hinder the ability of an individual to maintain a healthy weight. However, the effort required to gradually change long-standing behaviours cannot be underestimated. This situation is not helped by the range of (often conflicting) information available on the best options for maintaining a healthy weight.

The everyday habits that can help people maintain their weight are likely to have wider health benefits – such as reducing the risk of coronary heart disease, type 2 diabetes and some cancers.

1.6.3.2 Recommendations for all

Recommendation 1

Everyone should aim to maintain or achieve a healthy weight, to improve their health and reduce the risk of diseases associated with overweight and obesity, such as coronary heart disease, type 2 diabetes, osteoarthritis and some cancers.

Opinion of the GDG

Recommendation 2

People should follow the strategies listed in box 1, which may make it easier to maintain a healthy weight by balancing „calories in" (from food and drink) and „calories out" (from being physically active). Sources of advice and information are listed in 1.6.1.

Box 1 Strategies to help people achieve and maintain a healthy weight

Diet

Base meals on starchy foods such as potatoes, bread, rice and pasta, choosing wholegrain where possible.

Eat plenty of fibre-rich foods – such as oats, beans, peas, lentils, grains, seeds, fruit and vegetables, as well as wholegrain bread and brown rice and pasta.

Eat at least five portions of a variety of fruit and vegetables each day, in place of foods higher in fat and calories.

Eat a low-fat diet and avoid increasing your fat and/or calorie intake.

Eat as little as possible of:

- fried foods
- drinks and confectionery high in added sugars
- other food and drinks high in fat and sugar, such as some take-away and fast foods.

Eat breakfast.

Watch the portion size of meals and snacks, and how often you are eating.

For adults, minimise the calories you take in from alcohol.

Activity

Make enjoyable activities – such as walking, cycling, swimming, aerobics and gardening – part of everyday life.

Minimise sedentary activities, such as sitting for long periods watching television, at a computer or playing video games.

Build activity into the working day – for example, take the stairs instead of the lift, take a walk at lunchtime.

Evidence statements, Energy balance: 3, 3b, 4, 5, 8, 9

Recommendation 3

All adults should be encouraged to periodically check their weight, waist measurement or a simple alternative, such as the fit of their clothes.

Opinion of the GDG

Recommendation 4

People who have any queries or concerns about their – or their family"s – diet, activity levels or weight should discuss these with a health professional such as a nurse, GP, pharmacist, health visitor or school nurse. They could also consult reliable sources of information, such as those listed in 1.6.1.

Evidence statements, Identification: 6, 10
Evidence statements, Community 1: 16

1.6.3.3 Recommendations for adults considering dieting to lose weight

The following recommendation applies to adults only. Children and young people concerned about their weight should speak to a nurse or GP.

Recommendation 5

Weight loss programmes (including commercial or self-help groups, slimming books or websites) are recommended only if they:

- are based on a balanced healthy diet
- encourage regular physical activity
- expect people to lose no more than 0.5–1 kg (1–2 lb) a week.

Programmes that do not meet these criteria are unlikely to help people maintain a healthy weight in the long term.

People with certain medical conditions – such as type 2 diabetes, heart failure or uncontrolled hypertension or angina – should check with their general practice or hospital specialist before starting a weight loss programme.

Opinion of the GDG

Recommendations for parents and carers

Recommendation 6

In addition to the recommendations in box 1, parents and carers should consider following the advice in box 2 to help children establish healthy behaviours and maintain or work towards a healthy weight. These strategies may have other benefits – for example, monitoring the amount of time children spend watching television may help reduce their exposure to inappropriate programmes or advertisements.

Box 2 Helping children and young people maintain or work towards a healthy weight

Diet

- Children and young adults should eat regular meals, including breakfast, in a pleasant, sociable environment without distractions (such as watching television).
- Parents and carers should eat with children – with all family members eating the same foods.

Activity

- Encourage active play – for example, dancing and skipping.
- Try to be more active as a family – for example, walking and cycling to school and shops, going to the park or swimming.
- Gradually reduce sedentary activities – such as watching television or playing video games – and consider active alternatives such as dance, football or walking.
- Encourage children to participate in sport or other active recreation, and make the most of opportunities for exercise at school.

Evidence statement, Raising awareness: 11
Evidence statements, Energy balance: 3, 3b, 4, 5
Evidence statements, Early years: 10, 12, 15, 16

1.6.4 NHS: health professionals

The following recommendations are specifically for health professionals. Recommendations in other sections may also be relevant to health professionals.

1.6.4.1 Background

NHS organisations are **strongly advised** to implement the following recommendations. The recommendations fall under „developmental standards" – standards which the NHS is expected to achieve over time.

Audience

Senior managers, GPs, commissioners of care and Directors of Public Health have a key role.

Personnel involved in the identified interventions – providing the evidence for recommendations – include health promotion specialists, nurses, behavioural psychologists, physiotherapists, GPs, pharmacists, trained counsellors, registered dietitians, public health nutritionists and appropriately trained exercise specialists.

„Health professional" in the recommendations below refers to all appropriately trained allied health professionals in a position to provide public health advice, based in primary care and the wider community. There may also be a role for the new „health trainers", as outlined in „Choosing health",[2] although their competencies and remit is currently unclear. Additional trained front-line staff (for example, pharmacy assistants or support staff with GP practices) may also be in position to provide advice and support provided they have received sufficient training.

The recommendations below are divided into (i) strategic level and primarily for senior managers and budget holders involved in planning and management of service provision (such as local strategic partnerships, primary care trust (PCT) boards and foundation trusts) and (ii) delivery level and primarily for health professionals (individuals, teams and/or team managers).

Implementation

Prioritising action

Obesity – and implementing the following recommendations – should be an ongoing priority and should be clearly identified as such by local strategic partnerships (LSPs), PCT boards and managers, as well as front-line staff.

Implementation of the recommendations below will contribute to the public service agreement (PSA) target to halt the year on year rise in obesity in children under 11 years of age by 2010. Recommendations can be delivered through LSPs and community strategy implementation, including the Health, Social Care and Well-being strategies in Wales, as appropriate. They can also be included in local area agreements.

Tailoring advice

Tailoring advice is fundamental to the effectiveness of interventions aimed at groups and individuals and is highlighted in many of the recommendations below. Tailoring advice to address potential barriers (such as cost, personal tastes, availability, time, views of family and community members) is particularly important for people from black and minority ethnic groups (BMEGs), vulnerable groups (such as those on low incomes) and people at life stages with increased risk for weight gain (such as during pregnancy, menopause or smoking cessation). Many of the recommendations below also highlight the need to provide ongoing support – this can be in person by phone, mail or internet (as appropriate).

It is vital that all primary care settings ensure engagement with target communities; consult locally on the best mode of delivery, settings and key partnerships and ensure that interventions are client centred. See community recommendations for more information.

Training

The evidence suggests that the type of health professional who provides the advice is not critical as long as they have appropriate training and experience, are enthusiastic and able to motivate, and are able to provide long-term support. The following recommendations include action to ensure that health professionals and additional front-line staff have the skills to be involved in the prevention and management of obesity. It is recognised that there is currently poor uptake of some training courses, geographical variation in the availability of courses, and few courses which address both diet and activity. There are opportunities for training through, for example, workforce development programmes and NHS National Workforce Group and the DH/ASO „Obesity training courses for primary care"[12] lists a range of courses.

Existing legislation

The following recommendations which refer to the planning of buildings, and stair use in particular, should be considered in the context of existing building regulations and policies, particularly in relation to inclusive access for disabled people.

Sources of further information

- National Heart Forum / Faculty of Public Health *Lightening the load: Tackling overweight and obesity* (2006): http://www.heartforum.org.uk/Publications_NHFreports_Overweightandobesitytool.aspx

- Healthier catering (FSA): http://www.food.gov.uk/healthiereating/healthycatering/

- Four commonly used methods to increase physical activity: brief interventions in primary care, exercise referral schemes, pedometers and community-based exercise programmes for walking and cycling. *NICE public health intervention guidance* no. 2 (2006). Available from: www.nice.org.uk/PHI002

Department of Health"s general practice physical activity questionnaire (GPPAQ), to identify inactive individuals – see www.doh.gov.uk specific link to be available in September.

1.6.4.2 Overarching recommendations

Recommendation 1

Managers and health professionals in all primary care settings should ensure that preventing and managing obesity is a priority at both strategic and delivery levels. Dedicated resources should be allocated for action.

Opinion of the GDG

1.6.4.3 Strategic recommendations for senior managers and budget holders

Recommendation 2

In their role as employers, NHS organisations should set an example in developing public health policies to prevent and manage obesity by following existing guidance and (in England) the local obesity strategy. In particular:

- on-site catering should promote healthy food and drink choices (for example by signs, posters, pricing and positioning of products)
- there should be policies, facilities and information that promote physical activity, for example, through travel plans, by providing showers and secure cycle parking and by using signposting and improved décor to encourage stair use.

Opinion of the GDG

Recommendation 3

All primary care settings should ensure that systems are in place to implement the local obesity strategy. This should enable health professionals with specific training, including

public health practitioners working singly and as part of multidisciplinary teams, to provide interventions to prevent and manage obesity.

Evidence statements, Community 1: 1, 2

Recommendation 4

All primary care settings should:

- address the training needs of staff involved in preventing and managing obesity
- allocate adequate time and space for staff to take action
- enhance opportunities for health professionals to engage with a range of organisations and to develop multidisciplinary teams.

Evidence statements, Community 1: 12, 13;
Opinion of the GDG

Recommendation 5

Local health agencies should identify appropriate health professionals and ensure that they receive training in:

- the health benefits and the potential effectiveness of interventions to prevent obesity, increase activity levels and improve diet (and reduce energy intake)
- the best practice approaches in delivering such interventions, including tailoring support to meet people‟s needs over the long term
- the use of motivational and counselling techniques.

Training will need to address barriers to health professionals providing support and advice, particularly concerns about the effectiveness of interventions, people‟s receptiveness and ability to change and the impact of advice on relationships with patients.

Evidence statements, Community 1: 11, 12, 14, 16, 17

1.6.4.4 Recommendations for all health professionals

Recommendation 6

Interventions to increase physical activity should focus on activities that fit easily into people‟s everyday life (such as walking), should be tailored to people‟s individual preferences and circumstances and should aim to improve people‟s belief in their ability to change (for example, by verbal persuasion, modelling exercise behaviour and discussing positive effects). Ongoing support (including appropriate written materials) should be given in person or by phone, mail or internet.

Evidence statements, Community 1: 4, 17

Recommendation 7

Interventions to improve diet (and reduce energy intake) should be multicomponent (for example, including dietary modification, targeted advice, family involvement and goal setting), be tailored to the individual and provide ongoing support.

Evidence statements, Community 1: 6, 7, 8, 11

Recommendation 8

Interventions may include promotional, awareness-raising activities, but these should be part of a long-term, multicomponent intervention rather than one-off activities (and should be accompanied by targeted follow-up with different population groups).

Evidence statements, Raising awareness: 1, 3, 6;
Opinion of the GDG

Recommendation 9

Health professionals should discuss weight, diet and activity with people at times when weight gain is more likely, such as during and after pregnancy, the menopause and while stopping smoking.

Evidence statements, BMEGs: 9, 10, 11, 12
Evidence statements, Energy balance: 6, 7

Recommendation 10

All actions aimed at preventing excess weight gain and improving diet (including reducing energy intake) and activity levels in children and young people should actively involve parents and carers.

Evidence statement, Early years: 16

1.6.4.5 Health professionals working in/with primary care settings

Recommendation 11

All interventions to support smoking cessation should:

- ensure people are given information on services that provide advice on prevention and management of obesity if appropriate
- give people who are concerned about their weight general advice on long-term weight management, in particular encouraging increased physical activity.

Evidence statement, BMEGs: 9
Evidence statement, Energy balance: 7

1.6.4.6 Health professionals working in or with broader community settings

The recommendations in this section are for health professionals working in broader community settings, including healthy living centres and Sure Start programmes.

Recommendation 12

All community programmes to prevent obesity, increase activity levels and improve diet (including reducing energy intake) should address the concerns of local people from the outset. Concerns might include the availability of services and the cost of changing behaviour, the expectation that healthier foods do not taste as good, dangers associated with walking and cycling and confusion over mixed messages in the media about weight, diet and activity.

Evidence statements, Community 1: 11, 17
Evidence statements, Community 2: 10, 12
Evidence statement, BMEGs: 21

Recommendation 13

Health professionals should work with shops, supermarkets, restaurants, cafes and voluntary community services to promote healthy eating choices that are consistent with existing good practice guidance and to provide supporting information.

Evidence statements, Community 2: 5

Recommendation 14

Health professionals should support and promote community schemes and facilities that improve access to physical activity, such as walking or cycling routes, combined with tailored information, based on an audit of local needs.

Evidence statements, Community 2: 6, 8

Recommendation 15

Health professionals should support and promote behavioural change programmes along with tailored advice to help people who are motivated to change become more active, for example by walking or cycling instead of driving or taking the bus.

Evidence statements, Community 2: 7, 8

Recommendation 16

Families of children and young people identified as being at high risk of obesity – such as children with at least one obese parent – should be offered ongoing support from an appropriately trained health professional. Individual as well as family-based interventions should be considered, depending on the age and maturity of the child.

Evidence statements, Identification: 2, 3
Evidence statement, Energy balance: 2
Evidence statements, Early years: 4, 5, 6, 14

1.6.4.7 Health professionals working in/with pre-school, childcare and family settings

Recommendation 17

Any programme to prevent obesity in preschool, childcare or family settings should incorporate a range of components (rather than focusing on parental education alone), such as:

- diet – interactive cookery demonstrations, videos and group discussions on practical issues such as meal planning and shopping for food and drink
- physical activity – interactive demonstrations, videos and group discussions on practical issues such as ideas for activities, opportunities for active play, safety and local facilities.

Evidence statements, Early years: 5,9, 12,
Opinion of the GDG

Recommendation 18

Family programmes to prevent obesity, improve diet (and reduce energy intake) and/or increase physical activity levels should provide ongoing, tailored support and incorporate a range of behaviour change techniques (see Clinical Recommendations, Lifestyle interventions). Programmes should have a clear aim to improve weight management.

Evidence statement, Early years: 4, 5, 8, 14, 16

1.6.4.8 Health professionals working in/with workplace settings

Recommendation 19

Health professionals such as occupational health staff and public health practitioners should establish partnerships with local businesses and support the implementation of workplace programmes to prevent and manage obesity.

Opinion of the GDG

1.6.5 Local authorities and partners in the local community

1.6.5.1 Background

The environment in which people live may influence their ability to maintain a healthy weight – this includes access to safe spaces to be active and access to an affordable, healthier diet. All local planning decisions may therefore have an impact on the health of the local population. Furthermore, the evidence suggests that there are fundamental barriers that need to be addressed if individuals are to change their behaviour – such as concerns about safety, transport links and services. These issues may be being addressed through other initiatives – the health impact on the local population provides further impetus for action. Effective interventions often require multidisciplinary teams and the support of a broad range of organisations. In England local authorities, LSPs and PCTs are in prime position to be able to establish effective partnerships. Therefore local authorities and LSPs, along with PCTs have a key role in the prevention of obesity. In Wales, in addition to local authorities, Health Social Care and Well-being partnerships, local health alliances, local health boards and local public health teams (LPHTs) are likely to fulfil this role.

Audience

Local authorities and LSPs are strongly encouraged to implement the recommendations below.

The recommendations below are divided into: (i) strategic level and primarily for senior managers and budget holders (primarily for those involved in the management, planning and commissioning of services, such as the provision and management open spaces and sports facilities) and (ii) delivery of specific community-based interventions.

Deployment of resources, beyond statutory requirements, are dependent on strategic leadership. Ensuring public health policies apply across local authority departments in a coordinated way requires them to be embedded in the authority"s strategic priorities and monitored.

The following recommendations apply to all those working in local authorities, LSPs and other local community partnerships – not just those with an explicit health role – including the following.

Local authorities

- Councillors and members
- Planning services
- Transport services
- Leisure services
- Catering services
- Public health
- Environmental health services
- Children"s services
- Educational services
- Housing services
- Social services
- Leisure services and trusts
- Cultural services

Partners

- Directors of public health, public health advisers and commissioners of services
- All health professionals in a position to establish partnerships with a broad range of community based organisations.

- Peer support workers and health trainers
- Local voluntary organisations
- Local community organisations and networks
- Local businesses and workplaces
- Private leisure services
- Children"s trusts
- Higher education institutions (research units)
- Other relevant government agencies and non governmental organisations (NGOs).

It is assumed that staff in local authority and community settings will have the appropriate competencies to take forward the following recommendations. Where this is not the case, training options should be considered.

Implementation

Implementation of the following recommendations is likely to contribute to local area agreements, public service agreements and comprehensive performance assessment targets. The need to work in partnership to take forward recommendations to tackle obesity should be reflected in the integrated regional strategies and reviewed on a regular basis through the regional assemblies.

Please note that NICE is developing public health programme guidance on Physical activity in the environment, due September 2007.

Supportive information from ODPM:

- „Creating healthier communities: a resource pack for local partnerships"[13]
- „Planning and policy statement 1: delivering sustainable development"[14]

Supportive information from the Health Development Agency:

- „Evaluation of community level interventions for health improvement"[15]
- „Planning across the LSP: case studies of integrating community strategies and health improvement"[16]
- „Working partnership: book 1 – introduction"[17]
- „Working partnership: book 2 – short assessment"[18]
- „Working partnership: book 3 – in-depth assessment"[19]
- „Working partnership: looseleaf worksheets"[20]
- „Partnership working: a consumer guide to resources"[21]
- Health needs assessment: a practical guide[22]
- „Evaluation resources for community food projects"[23]
- Clarifying approaches to: health needs assessment, health impact assessment, integrated impact assessment, health equity audit, and race equality impact assessment[24]

Supportive information from the Local Government Association

- Comprehensive performance assessments[25]

Supportive information from the Department for Transport:

- Accessibility Planning Guidance[26]
- Walking and Cycling[27]

The following recommendations which refer to the planning of buildings, and stair use in particular, should be considered in the context of existing building regulations and policies, particularly in relation to inclusive access for disabled people.

Local authorities and their partners are strongly encouraged to monitor and evaluate the impact of **all** local action (including action that is not directly related to health). The positive and negative impact of **all** policies should be considered. The evaluation of projects should be an integral part of funding.

1.6.5.2 Overarching recommendation

Recommendation 1

As part of their roles in regulation, enforcement and promoting wellbeing, local authorities, primary care trusts (PCTs) or local health boards and local strategic partnerships should ensure that preventing and managing obesity is a priority for action – at both strategic and delivery levels – through community interventions, policies and objectives. Dedicated resources should be allocated for action.

Opinion of the GDG

1.6.5.3 Strategic recommendations for senior managers and budget holders

Recommendation 2

Local authorities should set an example in developing policies to prevent obesity in their role as employers, by following existing guidance and (in England) the local obesity strategy.

- On-site catering should promote healthy food and drink choices (for example by signs, posters, pricing and positioning of products).
- Physical activity should be promoted, for example through travel plans, by providing showers and secure cycle parking and using signposting and improved décor to encourage stair use.

Opinion of the GDG

Recommendation 3

Local authorities (including planning, transport and leisure services) should engage with the local community, to identify environmental barriers to physical activity and healthy eating. This should involve:

- an audit, with the full range of partners including PCTs or local health boards, residents, businesses and institutions
- assessing (ideally by doing a health impact assessment) the affect of their policies on the ability of their communities to be physically active and eat a healthy diet; the needs of subgroups should be considered because barriers may vary by, for example, age, gender, social status, ethnicity, religion and whether an individual has a disability.

Barriers identified in this way should be addressed.

Evidence statements, Community 2: 10, 11, 12, 13, 15

Evidence statement, BMEGs: 21

Recommendation 4

Local authorities should work with local partners, such as industry and voluntary organisations, to create and manage more safe spaces for incidental and planned physical activity, addressing as a priority any concerns about safety, crime and inclusion, by:

- providing facilities such as cycling and walking routes, cycle parking, area maps and safe play areas
- making streets cleaner and safer, through measures such as traffic calming, congestion charging, pedestrian crossings, cycle routes, lighting and walking schemes

- ensuring buildings and spaces are designed to encourage people to be more physically active (for example, through positioning and signing of stairs, entrances and walkways)
- considering in particular people who require tailored information and support, especially inactive, vulnerable groups.

Evidence statements, Community 2: 6, 8, 9, 11
Evidence statements, Workplace: 9
Opinion of the GDG

Recommendation 5

Local authorities should facilitate links between health professionals and other organisations to ensure that local public policies improve access to healthy foods and opportunities for physical activity.

Evidence statements, Community 2: 5

1.6.5.4 Recommendations focusing on specific interventions

Recommendation 6

Local authorities and transport authorities should provide tailored advice such as personalised travel plans to increase active travel among people who are motivated to change.

Evidence statements, Community 2: 7, 8

Recommendation 7

Local authorities, through local strategic partnerships, should encourage all local shops, supermarkets and caterers to promote healthy food and drink, for example by signs,

posters, pricing and positioning of products, in line with existing guidance and (in England) with the local obesity strategy.

Evidence statements, Community 2: 5

Recommendation 8

All community programmes to prevent obesity, increase activity levels and improve diet (and reduce energy intake) should address the concerns of local people. Concerns might include the availability of services and the cost of changing behaviour, the expectation that healthier foods do not taste as good, dangers associated with walking and cycling and confusion over mixed messages in the media about weight, diet and activity.

Evidence statement, Community 2: 12

Recommendation 9

Community-based interventions should include awareness-raising promotional activities, but these should be part of a longer-term, multicomponent intervention rather than one-off activities.

Evidence statement, Raising awareness: 1,2,3,6

1.6.6 Early years settings

1.6.6.1 Background

The pre-school years (age 2-5 years) are known to be a key stage in the life course for shaping attitudes and behaviours. Lifelong habits which can have an impact on an individual‟s ability to maintain a healthy weight may be established during the pre-school years. Parents are ultimately responsible for their children‟s development but childcare providers may also play an important role by providing opportunities for children to be active and develop healthy eating habits and by acting as positive role models.

Audience

The following recommendations apply to:

- Directors of children‟s services
- Children and young people‟s strategic partnerships
- Staff, including senior management, in childcare and pre-school settings
- Children‟s trusts, Children‟s centres, Healthy Start and Sure Start teams (including Sure Start Children‟s Centres)
- Trainers and child care staff, including home based childminders and nannies

Implementation[‡]

It is assumed that staff in childcare settings will have the appropriate competencies to take forward the following recommendations. Where this is not the case, training options should be considered, as should the potential to establish partnerships with local PCTs/appropriate health professionals.

[‡] In the following recommendations, „family‟ or „parents‟ primarily refers to nuclear family members, and principal carers of children not living in a traditional family environment, although it may also include extended family members as appropriate. However, please note that the following recommendations are predominantly based on research that involved nuclear families (that is. one or more children, with one or two parents, with whom they lived).

The following recommendations will support:

- Children and young people"s plan
- Local area agreement commitments to children and young people
- Sure Start initiatives, including Sure Start Children"s Centres.
- The joint Department of Health, DfES and Department for Culture, Media and Sport (DCMS) target to halt the year on year rise in obesity among children under 11 by 2010. The recommendations may also support a range of other public service agreements
- Recommendations outlined in the National Service Framework for Children and *Every Child Matters*

Please note that NICE is currently developing *Guidance to improve the nutrition of pregnant and breast feeding mothers and children in low income households for midwives, health visitors, pharmacists and other primary care services*

Sources of information

- National Service Framework for Children http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/ChildrenServices/ChildrenServicesInformation/fs/en
- http://www.everychildmatters.gov.uk/
- The Caroline Walker Trust recommendations *Eating Well for Under 5s in Childcare* (2006):http://www.cwt.org.uk/
- Department for Education and Skills guidance on food and drink, and physical education:
- http://www.teachernet.gov.uk/wholeschool/healthyliving/foodanddrink/
- http://www.teachernet.gov.uk/wholeschool/healthyliving/physicaleducation/

1.6.6.2 Recommendations for all settings

Recommendation 1

All nurseries and childcare facilities should ensure that preventing excess weight gain and improving children"s diet and activity levels are priorities.

Opinion of the GDG

Recommendation 2

All action aimed at preventing excess weight gain, improving diet (and reducing energy intake) and increasing activity levels in children should involve parents and carers.

Evidence statement, Early years: 16

Recommendation 3

Nurseries and other childcare facilities should:

- minimise sedentary activities during play time, and provide regular opportunities for enjoyable active play and structured physical activity sessions
- implement Department for Education and Skills, Food Standards Agency and Caroline Walker Trust[§] guidance on food procurement and healthy catering.

Evidence statements, Early years : 7, 9, 11, 12, 17

[§] See www.cwt.org.uk

Recommendation 4

Staff should ensure that children eat regular, healthy meals in a pleasant, sociable environment free from other distractions (such as television). Children should be supervised at mealtimes and, if possible, staff should eat with children.

Opinion of the GDG

1.6.7 Schools

1.6.7.1 Background

The school years are known to be a key stage in the life course for shaping attitudes and behaviours. Life-long habits which can have an impact on an individual‟s ability to maintain a healthy weight may be established during the school years. Improving children‟s diet and activity levels may also have wider benefits. For example, regular physical activity is strongly associated with higher academic achievement and with improved health in childhood and later life.[28] Physical activity has also been associated with higher motivation at school, reduced anxiety and depression, which in turn has a positive impact on school work.[28] Campbell[29] has highlighted that just as poor health has a negative impact on educational attainment, so high achievement positively affects social and economic prospects and subsequent choices about health.

Parents are ultimately responsible for their children‟s development but schools also play an important role by providing opportunities for children to be active, develop healthy eating habits and by providing important role models.

All school policies have the potential to have some impact on a child‟s ability to maintain a healthy weight, eat a healthy diet and be physically active. These range from the school selection processes themselves (which may determine whether a child can walk or cycle to school), to the curriculum content such as school sports, school food policies including policies on vending, packed lunches and snacks, school travel plans, extended schools policies, anti bullying policies, training opportunities for all school staff, engagement with wider community (including local business and sports facilities), fundraising choices, and the extent to which national policies (such as the National Healthy Schools Programme and nutritional standards for school meals) are implemented.

There is no evidence to suggest that school-based interventions to prevent obesity improve diet and increase activity levels foster eating disorders or extreme dieting or exercise behaviour (see section 3, chapter 9, evidence statement 8).

Audience

The following recommendations apply to:

- Directors of children‟s services
- Staff, including senior management, in schools
- School governors
- Health professional working in or with schools
- Children and young people‟s strategic partnerships
- Children‟s trusts

Implementation**

It is assumed that staff working in schools (or with school-aged children and their families) will have the appropriate competencies to take forward the following recommendations. Where this is not the case, training options should be considered, as should the potential to establish partnerships with local PCTs/appropriate health professionals.

The following recommendations will support:

** In the following recommendations, „family‟ or „parents‟ primarily refers to nuclear family members, and principal carers of children not living in a traditional family environment, although it may also include extended family members as appropriate. However, please note that the following recommendations are predominantly based on research that involved nuclear families (ie one or more children, with one or two parents, with whom they lived).

- The joint DH, DfES and DCMS target to halt the year on year rise in obesity among children under 11 by 2010. The recommendations may also support a range of other public service agreements.
- The Physical Education, School Sport and Club Links (PESSCL) strategy.
- The National Healthy Schools Programme in England and the Welsh Network of Health Schools schemes.
- The Healthy Living Blueprint.
- Local area agreement commitments to children and young people.
- Recommendations outlined in the National Service Framework for Children and „Every child matters‟.
- Guidance on nutritional standards for school meals (due 2006).

The Healthy Schools Programme highlights that engagement of **all** staff is central to success. The Healthy Schools Programme promotes the professional development of staff by providing them with an opportunity to take responsibility for the management of a whole school project.

Ofsted, Healthy Schools and the School Food Trust have as part of their remit the monitoring and assessment of school food provision and consumption,

Existing legislation

The following recommendations which refer to the planning of buildings, and stair use in particular, should be considered in the context of existing building regulations and policies, particularly in relation to inclusive access for disabled people.

Sources of information

Food

- Whole-school approach (general): www.wiredforhealth.gov.uk/
- Whole school approach (food):
    - www.foodinschools.org/
    - www.food.gov.uk/multimedia/pdfs/foodpolicygovernor.pdf
- Catering in schools (DfES): www.dfes.gov.uk/schoollunches/
- Catering in schools (FSA):
    - www.food.gov.uk/multimedia/pdfs/bookmarknut.pdf]
    - www.food.gov.uk/multimedia/pdfs/fruittuckwales.pdf
    - www.food.gov.uk/interactivetools/educational/bashstreetdiet/further_info#h_1
- Catering in schools (School Food Trust): www.schoolfoodtrust.org.uk
- Food Standards Agency advice on healthier catering and lunchboxes: http://www.food.gov.uk/healthiereating/healthycatering/

  http://www.food.gov.uk/news/newsarchive/2004/sep/toplunchboxtips

Sport

- www.qca.org.uk/pess/pdf/pe_update_autumn_05.pdf
- www.standards.dfes.gov.uk/specialistschools/what_are/sports/
- www.youthsporttrust.org/
- www.sportengland.org/county_sports_partnerships

- www.teachernet.gov.uk/pe

Travel plans

- www.saferoutestoschools.org.uk
- www.dft.gov.uk/stellent/groups/dft_susttravel/documents/page/dft_susttravel_504055.hcsp

1.6.7.2 Overarching recommendation

Recommendation 1

All schools should ensure that improving the diet and activity levels of children and young people is a priority for action to help prevent excess weight gain. A whole-school approach should be used to develop life-long healthy eating and physical activity practices.

Opinion of the GDG

1.6.7.3 Strategic recommendations for head teachers and chairs of governors

Recommendation 2

Head teachers and chairs of governors, in collaboration with parents and pupils, should assess the whole school environment and ensure that the ethos of all school policies helps children and young people to maintain a healthy weight, eat a healthy diet and be physically active, in line with existing standards and guidance. This includes policies relating to building layout and recreational spaces, catering (including vending machines) and the food and drink children bring into school[††], the taught curriculum

[††] See www.schoolfoodtrust.org.uk

(including PE), school travel plans and provision for cycling, and policies relating to the National Healthy Schools Programme and extended schools.

Evidence statements, Schools: 1, 4, 5, 7

Recommendation 3

Head teachers and chairs of governors should ensure that teaching, support and catering staff receive training on the importance of healthy-school policies and how to support their implementation.

Evidence statement, Schools: 10;
Opinion of the GDG

Recommendation 4

Schools should establish links with relevant organisations and professionals, including health professionals and those involved in local strategies and partnerships to promote sports for children and young people.

Opinion of the GDG

Recommendation 5

Interventions should be sustained, multicomponent and address the whole school, including after-school clubs and other activities. Short-term interventions and one-off events are insufficient on their own and should be part of a long-term integrated programme

Evidence statements, Schools: 1, 4, 5, 7

1.6.7.4 Recommendations for teachers, health and other professionals, and parents

Recommendation 6

Staff delivering physical education, sport and physical activity should promote activities that children and young people find enjoyable and can take part in outside school, through into adulthood. Children"s confidence and understanding of why they need to continue physical activity throughout life (physical literacy) should be developed as early as possible.

Evidence statement, Schools: 12
Opinion of the GDG

Recommendation 7

Children and young people should eat meals (including packed lunches) in school in a pleasant, sociable environment. Younger children should be supervised at mealtimes and, if possible, staff should eat with children.

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Opinion of the GDG

1.6.7.5 Children and parents

Recommendation 8

Staff planning interventions should consider the views of children and young people, any differences in preferences between boys and girls, and potential barriers (such as cost or the expectation that healthier foods do not taste as good).

Evidence statements, Schools: 11, 12

Recommendation 9

Where possible, parents should be involved in school-based interventions through, for example, special events, newsletters and information about lunch menus and after-school activities.

Opinion of the GDG

1.6.8 Workplace

1.6.8.1 Background

In addition to fundamental health and safety policies, the workplace has considerable potential for addressing wider public health issues, such as obesity. The workplace may have an impact on an individual‟s ability to maintain a healthy weight both directly, by supporting an individual to make healthier eating choices (for example, by the provision of healthier food choices in on-site catering, including staff restaurants and vending machines) and opportunities for physical activity (such as the option to use stairs instead of lifts, staff gym, cycle parking, provision of changing and shower facilities), and indirectly, through the overall culture of the organisation (for example, through appropriate policies and incentive schemes). Although addressing obesity is not a core aim of workplaces, taking action may result in significant benefit for employers as well as employees.

Audience

The recommendations apply to a range of internal and external staff, including:

- senior managers
- health and safety managers
- occupational health staff
- unions and staff representatives
- employers‟ organisations and chambers of commerce
- health professionals working with businesses.

The recommendations below are divided into:

- those that all organisations may be able to achieve, with sufficient input and support from a range of staff, including senior management
- those that are resource intensive and which may only be fully achieved by the NHS, public bodies and larger private organisations.

It is acknowledged that the ability of a workplace to take action is strongly influenced by its size and the availability of on-site occupational health leads. The NHS, public organisations and large employers are strongly encouraged to implement the following recommendations.

Smaller organisations should consider the following recommendations as best practice. In particular, smaller organisations may be able to make a useful contribution through full consideration of any new and existing policies and procedures in the light of the recommendations below.

Implementation issues

The evidence to date suggests that workplace initiatives are more likely to be effective if:[30]

- initiatives take an interdisciplinary approach with broad representation including health and safety and human resources, and implementers from high grades and strategic positions
- initiatives are integrated into workplace objectives
- initiatives ensure staff involvement, communication and realistic objectives
- activities go beyond the superficial and address root causes (such as workplace culture in relation to working hours and lunch breaks).

In many instances the recommendations are likely to build on existing initiatives – such as:

- the impetus for workplaces to produce travel plans
- existing health at work and catering awards
- the promotion of corporate social responsibility

- Investors in People and Investors in Health (supports workplace health promotion – see http://investorsinhealth.org/)
- the Corporate Health Standard for Wales
- Department for Work and Pensions (DWP), Department of Health and HSE strategy Health, Work and Well-being – Caring for Our Future (2005)[{add reference}]

In order to implement the following recommendations it is suggested that LSPs help local businesses establish effective partnerships with organisations (including the NHS and independent providers) that may be able to provide advice and support on occupational health issues. For example, NHS Plus is a network of NHS occupational health departments which provides services for external organisations; businesses can locate local services through the website www.nhsplus.nhs.uk. Information is also available from the Faculty of Occupational Medicine (see www.facoccmed.ac.uk). In addition, it is suggested that workplaces refer to existing guidance, such as that published by the former Health Development Agency, ODPM and DWP.

The British Heart Foundation have produced a Think Fit workplace activity tool kit. http://www.bhf.org.uk/thinkfit/index.asp?SecID=1590&secondlevel=1592

Existing legislation

The following recommendations which refer to the planning of buildings, and stair use in particular, should be considered in the context of existing building regulations and policies, particularly in relation to inclusive access for disabled people.

1.6.8.2 Overarching recommendation

Recommendation 1

All workplaces, particularly large organisations such as the NHS and local authorities, should address the prevention and management of obesity, because of the considerable impact on the health of the workforce and associated costs to industry.

Workplaces are encouraged to collaborate with local strategic partnerships and to ensure that action is in line with the local obesity strategy (in England).

Opinion of the GDG

1.6.8.3 Recommendations for all workplaces

Recommendation 2

Workplaces should provide opportunities for staff to eat a healthy diet and be more physically active, through:

- active and continuous promotion of healthy choices in restaurants, hospitality, vending machines and shops for staff and clients, in line with existing Food Standards Agency guidance
- working practices and policies, such as active travel policies for staff and visitors
- a supportive physical environment, such as improvements to stairwells and providing showers and secure cycle parking
- recreational opportunities, such as supporting out-of-hours social activities, lunchtime walks and use of local leisure facilities.

Evidence statements, Workplace: 3, 4, 6, 7, 8, 9, 16
Evidence statements, Workplace: 8, 9
Evidence statement, Community 1: 4
Evidence statement, Community 2: 6

Recommendation 3

Incentive schemes (such as policies on travel expenses, the price of food and drinks sold in the workplace and contributions to gym membership) that are used in a workplace should be sustained and part of a wider programme to support staff in managing weight, improving diet and increasing activity levels.

Evidence statement, Workplace: 2
Evidence statement, Community 1: 5

1.6.8.4 Recommendations for NHS, public organisations and large commercial organisations

Recommendation 4

Workplaces providing health checks for staff should ensure that they address weight, diet and activity, and provide ongoing support.

Evidence statement, Workplace: 1

Recommendation 5

Action to improve food and drink provision in the workplace, including restaurants, hospitality and vending machines, should be supported by tailored educational and promotional programmes, such as a behavioural intervention or environmental changes (for example, food labelling or changes to availability).

For this to be effective, commitment from senior management, enthusiastic catering management, a strong occupational health lead, links to other on-site health initiatives, supportive pricing policies and heavy promotion and advertisement at point of purchase are likely to be needed.

Evidence statements, Workplace: 4, 6, 7, 14, 15, 16

1.6.9 Recommendations For The Management Of Obesity: Self Help, Commercial And Community Settings

1.6.9.1 Background

There are many providers and services that may contribute to and collaborate with local heath agencies to help address overweight and obesity. However, these are of variable quality. It is vital that these services meet minimum standards in terms of best practice, staffing and facilities.

Health and other professionals in primary care, community and local authority settings should have the appropriate knowledge and skills to take forward the following recommendations. Where this is not the case, training options should be considered.

1.6.9.2 Strategic recommendations for local strategic health agencies and local authorities

Recommendation 1

Primary care organisations and local authorities should recommend to patients, or consider endorsing, self-help, commercial and community weight management programmes only if they follow best practice[‡‡] by:

- helping people assess their weight and decide on a realistic healthy target weight (people should usually aim to lose 5–10% of their original weight)
- aiming for a maximum weekly weight loss of 0.5–1 kg
- focusing on long-term lifestyle changes rather than a short-term, quick-fix approach
- being multicomponent, addressing both diet and activity, and offering a variety of approaches

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[‡‡] Based on information from the British Dietetic Association „Weight Wise" Campaign (www.bdaweightwise.com/support/support_approach.aspx); the advice on target weights is the opinion of the Clinical Management Guidance Development Group.

- using a balanced, healthy-eating approach
- recommending regular physical activity (particularly activities that can be part of daily life, such as brisk walking and gardening) and offering practical, safe advice about being more active
- including some behaviour-change techniques, such as keeping a diary and advice on how to cope with „lapses" and „high-risk" situations
- recommending and/or providing ongoing support.

Evidence statement, Management of obesity non clinical settings: 1

Opinion of the GDG

1.6.9.3 Recommendations for health professionals (working in primary care or community settings)

Recommendation 2

Health professionals should discuss the range of weight management options with people who want to lose or maintain their weight, or are at risk of weight gain, and help them decide what best suits their circumstances and what they will be able to sustain in the long term.

Opinion of the GDG

Recommendation 3

General practices and other primary or secondary care settings recommending commercial, community and/or self-help weight management programmes should continue to monitor patients and provide support and care.

Opinion of the GDG

Recommendation 4

Health professionals should check that any commercial, community or self-help weight management programmes they recommend to patients meet best-practice standards (See recommendation 1, section 1.6.9.2).

Opinion of the GDG

1.7 Clinical recommendations

Note: **(Adult)** denotes a recommendation for adults only; **(Child)** denotes a recommendation for children only.

1.7.1 Generic principles of care

Adults and children

1.7.1.1 Regular, non-discriminatory long-term follow-up by a trained professional should be offered. Continuity of care in the multidisciplinary team should be ensured through good record keeping.

Adults

1.7.1.2 Any specialist setting should be equipped for treating people who are severely obese with, for example, special seating and adequate weighing and monitoring equipment. Hospitals should have access to specialist equipment – such as larger scanners and beds – needed when providing general care for people who are severely obese.

1.7.1.3 The choice of any intervention for weight management must be made through negotiation between the person and their health professional.

1.7.1.4 The components of the planned weight-management programme should be tailored to the person"s preferences, initial fitness, health status and lifestyle.

Children

1.7.1.5 The care of children and young people should be coordinated around their individual and family needs and should comply with national core standards as defined in the Children"s NSFs for England and Wales.

1.7.1.6 The overall aim should be to create a supportive environment that helps overweight or obese children and their families make lifestyle changes.

1.7.1.7 Decisions on the approach to management of a child‟s overweight or obesity (including assessment and agreement of goals and actions) should be made in partnership with the child and family, and be tailored to the needs and preferences of the child and the family.

1.7.1.8 Interventions for childhood overweight and obesity should address lifestyle within the family and in social settings.

1.7.1.9 Parents (or carers) should be encouraged to take the main responsibility for lifestyle changes for overweight or obese children, especially if they are younger than 12 years. However, the age and maturity of the child and the preferences of the child and the parents should be taken into account.

1.7.2 Identification and classification of overweight and obesity

1.7.2.1 Healthcare professionals should use their clinical judgement to decide when to measure a person‟s height and weight. Opportunities include registration with a general practice, consultation for related conditions (such as type 2 diabetes and cardiovascular disease) and other routine health checks.

Measures of overweight or obesity

Adults

1.7.2.2 Body mass index (BMI) should be used as a measure of overweight in adults, but needs to be interpreted with caution because it is not a direct measure of adiposity.

1.7.2.3 Waist circumference may be used, in addition to BMI, in people with a BMI less than 35 kg/m2.

Children

1.7.2.4 BMI (adjusted for age and gender) is recommended as a practical estimate of overweight in children and young people, but needs to be interpreted with caution because it is not a direct measure of adiposity.

1.7.2.5 Waist circumference is not recommended as a routine measure but may be used to give additional information on the risk of developing other long-term health problems.

Adults and children

1.7.2.6 Bioimpedance is not recommended as a substitute for BMI as a measure of general adiposity.

Classification of overweight or obesity

Adults

1.7.2.7 The degree of overweight or obesity in adults should be defined as follows.

Classification	**BMI (kg/m^2)**
Healthy weight	18.5–24.9
Overweight	25–29.9
Obesity I	30–34.9
Obesity II	35–39.9
Obesity III	40 or more

1.7.2.8 BMI may be a less accurate measure of adiposity in adults who are highly muscular, so BMI should be interpreted with caution in this group. Some other population groups, such as Asians and older people, have comorbidity risk factors that would be of concern at different BMIs (lower for Asian adults and higher for older people). Healthcare professionals should use clinical judgement when considering risk factors in these groups, even in people not classified as overweight or obese using the classification in recommendation 1.2.2.7.

1.7.2.9 Assessment of the health risks associated with overweight and obesity in adults should be based on BMI and waist circumference as follows.

BMI classification	**Waist circumference**		
	Low	**High**	**Very high**
Overweight	No increased risk	Increased risk	High risk
Obesity I	Increased risk	High risk	Very high risk
For men, waist circumference of less than 94 cm is low, 94–102 cm is high and more than102 cm is very high For women, waist circumference of less than 80 cm is low, 80–88 cm is high and more than 88 cm is very high			

1.7.2.10 Adults should be given information about their classification of clinical obesity and the impact this has on risk factors for developing other long-term health problems.

1.7.2.11 The level of intervention to discuss with the patient initially should be based as follows:

BMI classification	**Waist circumference**			**Comorbidities present**
	Low	**High**	**Very high**	
Overweight				
Obesity I				
Obesity II				
Obesity III				

	General advice on healthy weight and lifestyle
	Diet and physical activity
	Diet and physical activity; consider drugs
	Diet and physical activity; consider drugs; consider surgery

Note that the level of intervention should be higher for patients with comorbidities (see section 1.7.3 for details), regardless of their waist circumference. The approach should be adjusted as needed, depending on the patient‟s clinical need and potential to benefit from losing weight.

Children

1.7.2.12 BMI measurement in children and young people should be related to the UK 1990 BMI charts§§ to give age- and gender-specific information.

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§§ The Guideline Development Group considered that there was a lack of evidence to support specific cut-offs in children. However, the recommended pragmatic indicators for action are the 91st and 98th centiles (overweight and obese, respectively).

1.7.2.13 Tailored clinical intervention should be considered for children with a BMI at or above the 91st centile, depending on the needs of the individual child and family.

1.7.2.14 Assessment of comorbidity should be considered for children with a BMI at or above the 98th centile.

1.7.3 Assessment

This section should be read in conjunction with the NICE guideline on eating disorders (*NICE clinical guideline* no. 9; available from www.nice.org.uk/CG009), particularly if a person who is not overweight asks for advice on losing weight.

Adults and children

1.7.3.1 After making an initial assessment (see recommendations 1.7.3.7 and 1.7.3.9), healthcare professionals should use clinical judgement to investigate comorbidities and other factors in an appropriate level of detail, depending on the person, the timing of the assessment, the degree of overweight or obesity and the results of previous assessments.

1.7.3.2 Any comorbidities should be managed when they are identified, rather than waiting until the person has lost weight.

1.7.3.3 People who are not yet ready to change should be offered the chance to return for further consultations when they are ready to discuss their weight again and willing or able to make lifestyle changes. They should also be given information on the benefits of losing weight, healthy eating and increased physical activity.

1.7.3.4 Surprise, anger, denial or disbelief may diminish people‟s ability or willingness to change. Stressing that obesity is a clinical term with specific

health implications, rather than a question of how you look, may help to mitigate this.

During the consultation it would be helpful to:

- assess the person"s view of their weight and the diagnosis, and possible reasons for weight gain
- explore eating patterns and physical activity levels
- explore any beliefs about eating and physical activity and weight gain that are unhelpful if the person wants to lose weight
- be aware that people from certain ethnic and socioeconomic backgrounds may be at greater risk of obesity, and may have different beliefs about what is a healthy weight and different attitudes towards weight management
- find out what the patient has already tried and how successful this has been, and what they learned from the experience
- assess readiness to adopt changes
- assess confidence in making changes.

1.7.3.5 Patients and their families and/or carers should be given information on the reasons for tests, how the tests are performed and their results and meaning.

1.7.3.6 If necessary, another consultation should be offered to fully explore the options for treatment or discuss test results.

Adults

1.7.3.7 After appropriate measurements have been taken and the issues of weight raised with the person, an assessment should be done, covering:

- presenting symptoms and underlying causes of overweight and obesity
- eating behaviour
- comorbidities (such as type 2 diabetes, hypertension, cardiovascular disease, osteoarthritis, dyslipidaemia and sleep apnoea) and risk factors, using the following tests – lipid profile, blood glucose (both preferably fasting) and blood pressure measurement
- lifestyle – diet and physical activity
- psychosocial distress and lifestyle, environmental, social and family factors – including family history of overweight and obesity and comorbidities
- willingness and motivation to change
- potential of weight loss to improve health
- psychological problems
- medical problems and medication.

1.7.3.8 Referral to specialist care should be considered if:

- the underlying causes of overweight and obesity need to be assessed
- the person has complex disease states and/or needs that cannot be managed adequately in either primary or secondary care
- conventional treatment has failed in primary or secondary care
- drug therapy is being considered for a person with a BMI more than 50 kg/m^2
- specialist interventions (such as a very-low-calorie diet for extended periods) may be needed, or
- surgery is being considered.

Children

1.7.3.9 After measurements have been taken and the issue of weight raised with the child and family, an assessment should be done, covering:

- presenting symptoms and underlying causes of overweight and obesity
- willingness and motivation to change
- comorbidities (such as hypertension, hyperinsulinaemia, dyslipidaemia, type 2 diabetes, psychosocial dysfunction and exacerbation of conditions such as asthma) and risk factors
- psychosocial distress, such as low self-esteem, teasing and bullying
- family history of overweight and obesity and comorbidities
- lifestyle – diet and physical activity
- environmental, social and family factors that may contribute to overweight and obesity and the success of treatment
- growth and pubertal status.

1.7.3.10 Referral to an appropriate specialist should be considered for children who are overweight or obese and have significant comorbidity or complex needs (for example, learning or educational difficulties).

1.7.3.11 In secondary care, the assessment of overweight and/or obese children and young people should include assessment of associated comorbidities and possible aetiology, and investigations such as:

- blood pressure measurement
- fasting lipid profile
- fasting insulin and glucose levels
- liver function
- endocrine function.

These tests need to be performed, and results interpreted, in the context of the degree of overweight and obesity, the child"s age, history of comorbidities, possible genetic causes and any family history of metabolic disease related to overweight and obesity.

1.7.3.12 Arrangements for transitional care should be made for young people who are moving from paediatric to adult services.

1.7.4 Lifestyle interventions

The recommendations in this section deal with lifestyle changes for people actively trying to lose weight; recommendations about lifestyle changes and self-management strategies for people wishing to maintain a healthy weight can be found in section 1.1.1.

General

Adults and children

1.7.4.1 Multicomponent interventions are the treatment of choice. Weight management programmes should include behaviour change strategies (see recommendations 1.7.4.15–17) to increase people‟s physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person‟s diet and reduce energy intake.

1.7.4.2 When choosing treatments, the following factors should be considered:

- the person‟s individual preference and social circumstance and the experience and outcome of previous treatments (including whether there were any barriers)
- their level of risk, based on BMI and waist circumference (see recommendations 1.7.2.9 and 1.7.2.11)
- any comorbidities.

1.7.4.3 The results of the discussion should be documented, and a copy of the agreed goals and actions should be kept by the person and the healthcare professional or put in the notes as appropriate. Healthcare professionals should tailor support to meet the person‟s needs over the long term.

1.7.4.4 The level of support offered should be determined by the person‟s needs, and be responsive to changes over time.

1.7.4.5 Any healthcare professional involved in the delivery of interventions for weight management should have relevant competencies and have undergone specific training.

1.7.4.6 Information should be provided in formats and languages that are suited to the person. When talking to patients and carers, healthcare professionals should use everyday, jargon-free language and explain any technical terms. Consideration should be given to the person‟s:

- age and stage of life
- gender
- cultural needs and sensitivities
- ethnicity
- social and economic circumstances
- physical and mental disabilities.

1.7.4.7 To encourage the patient through the difficult process of changing established behaviour, healthcare professionals should praise successes – however small – at every opportunity.

1.7.4.8 People who are overweight or obese, and their families and/or carers, should be given relevant information on:

- overweight and obesity in general, including related health risks

- realistic targets for weight loss; for adults the targets are usually
  maximum weekly weight loss of 0.5–1 kg[***]
  aim to lose 5–10% of original weight
- the distinction between losing weight and maintaining weight loss, and the importance of developing skills for both; the change from losing weight to maintenance typically happens after 6–9 months of treatment
- realistic targets for outcomes other than weight loss, such as increased physical activity, healthier eating
- diagnosis and treatment options
- healthy eating in general (see appendix D)
- medication and side effects
- surgical treatments
- self care
- voluntary organisations and support groups and how to contact them.

There should be adequate time in the consultation to provide information and answer questions.

1.7.4.9 If a person (or their family or carers) does not want to do anything at this time, healthcare professionals should explain that advice and support will be available in the future whenever they need it. Contact details should be provided, so that the person can make contact when they are ready.

Adults

1.7.4.10 The person"s partner or spouse should be encouraged to support any weight management programme.

[***] Based on the British Dietetic Association „Weight Wise" Campaign. Greater rates of weight loss may be appropriate in some cases, but this should be undertaken only under expert supervision

1.7.4.11 The level of intensity of the intervention should be based on the level of risk and the potential to gain health benefits (see recommendation 1.7.2.11).

Children

1.7.4.12 Single-strategy approaches to managing weight are not recommended for children or young people.

1.7.4.13 The aim of weight management programmes for children and young people may be either weight maintenance or weight loss, depending on their age and stage of growth.

1.7.4.14 Parents of overweight or obese children and young people should be encouraged to lose weight if they are also overweight or obese.

Behavioural interventions

Adults and children

1.7.4.15 Any behavioural intervention should be delivered with the support of an appropriately trained professional.

Adults

1.7.4.16 Behavioural interventions for adults should include the following strategies, as appropriate for the person:

- self monitoring of behaviour and progress
- stimulus control
- goal setting
- slowing rate of eating
- ensuring social support
- problem solving
- assertiveness

- cognitive restructuring (modifying thoughts)
- reinforcement of changes
- relapse prevention
- strategies for dealing with weight regain.

Children

1.7.4.17 Behavioural interventions for children should include the following strategies, as appropriate for the child:

- stimulus control
- self monitoring
- goal setting
- rewards for reaching goals
- problem solving.

Although not strictly defined as behavioural techniques, giving praise and encouraging parents to role-model desired behaviours are also recommended.

Physical activity

Adults

1.7.4.18 Adults should be encouraged to increase their physical activity even if they do not lose weight as a result, because of the other health benefits physical activity can bring, such as reduced risk of type 2 diabetes and cardiovascular disease. Adults should be encouraged to do at least 30 minutes of at least moderate-intensity physical activity on 5 or more days a week. The activity can be in one session or several lasting 10 minutes or more.

1.7.4.19 To prevent obesity, most people should be advised they may need to do 45–60 minutes of moderate-intensity activity a day, particularly if they do not reduce their energy intake. People who have been obese and have lost weight should be advised they may need to do 60–90 minutes of activity a day to avoid regaining weight.

1.7.4.20 Adults should be encouraged to build up to the recommended levels for weight maintenance, using a managed approach with agreed goals.

Recommended types of physical activity include:

- activities that can be incorporated into everyday life, such as brisk walking, gardening or cycling
- supervised exercise programmes
- other activities, such as swimming, aiming to walk a certain number of steps each day, or stair climbing.

Any activity should take into account the person"s current physical fitness and ability.

People should also be encouraged to reduce the amount of time they spend inactive, such as watching television or using a computer.

Children

1.7.4.21 Children and young people should be encouraged to increase their physical activity even if they do not lose weight as a result, because of the other health benefits exercise can bring, such as reduced risk of type 2 diabetes and cardiovascular disease. Children should be encouraged to do at least 60 minutes of at least moderate activity each day. The activity can be in one session or several lasting 10 minutes or more.

1.7.4.22 Children who are already overweight may need to do more than 60 minutes‟ activity.

1.7.4.23 Children should be encouraged to reduce sedentary behaviours, such as sitting watching television, using a computer or playing video games.

1.7.4.24 Children should be given the opportunity and support to do more exercise in their daily lives (such as walking, cycling, using the stairs and active play). The choice of activity should be made with the child, and be appropriate to their ability and confidence.

1.7.4.25 Children should be given the opportunity and support to do more regular, structured physical activity, such as football, swimming or dancing. The choice of activity should be made with the child, and be appropriate to their ability and confidence.

Dietary advice

Adults and children

1.7.4.26 Dietary changes should be individualised, tailored to food preferences and allow for flexible approaches to reducing calorie intake.

1.7.4.27 Unduly restrictive and nutritionally unbalanced diets should not be used, because they are ineffective in the long term and can be harmful.

1.7.4.28 People should be encouraged to improve their diet even if they do not lose weight, because there can be other health benefits.

Adults

1.7.4.29 The main requirement of a dietary approach to weight loss is that total energy intake should be less than energy expenditure.

1.7.4.30 Diets that have a 600 kcal/day deficit (that is, they contain 600 kcal less than the person needs to stay the same weight) or that reduce calories by lowering the fat content (low-fat diets), in combination with expert support and intensive follow-up, are recommended for sustainable weight loss.

1.7.4.31 Low-calorie diets (1000–1600 kcal/day) may also be considered, but are less likely to be nutritionally complete.

1.7.4.32 Very-low-calorie diets (less than 1000 kcal/day) may be used for a maximum of 12 weeks continuously, or intermittently with a low-calorie diet (for example for 2–4 days a week), by people who are obese and have reached a plateau in weight loss.

1.7.4.33 Any diet of less than 600 kcal/day should be used only under clinical supervision.

1.7.4.34 In the longer term, people should move towards eating a balanced diet, consistent with other healthy eating advice.

Children

1.7.4.35 A dietary approach alone is not recommended. It is essential that any dietary recommendations are part of a multicomponent intervention.

1.7.4.36 Any dietary changes should be age appropriate and consistent with healthy eating advice.

1.7.4.37 For overweight and obese children and adolescents, total energy intake should be below their energy expenditure. Changes should be sustainable.

1.7.5 Pharmacological interventions

This section contains recommendations that update the NICE technology appraisals on orlistat and sibutramine (*NICE technology appraisal guidance* no. 22 and *NICE technology appraisal guidance* no. 31); see section 6 for details.

General: indications and initiation

Adults and children

1.7.5.1 Pharmacological treatment should be considered only after dietary, exercise and behavioural approaches have been started and evaluated.

Adults

1.7.5.2 Drug treatment should be considered for patients who have not reached their target weight loss or have reached a plateau on dietary, activity and behavioural changes alone.

1.7.5.3 The decision to start drug treatment, and the choice of drug, should be made after discussing with the patient the potential benefits and limitations, including the mode of action, adverse effects and monitoring requirements, and their potential impact on the patient‟s motivation. When drug treatment is prescribed, arrangements should be made for appropriate healthcare professionals to offer information, support and counselling on additional diet, physical activity and behavioural strategies. Information on patient support programmes should also be provided.

1.7.5.4 Prescribing should be in accordance with the drug‟s summary of product characteristics.

Children

1.7.5.5 Drug treatment is not generally recommended for children younger than 12 years.

The marketing authorisation for sibutramine has been suspended. See front cover for details.

1.7.5.6 In children younger than 12 years, drug treatment may be used only in exceptional circumstances, if severe life-threatening comorbidities (such as sleep apnoea or raised intracranial pressure) are present. Prescribing should be started and monitored only in specialist paediatric settings†††.

1.7.5.7 In children aged 12 years and older, treatment with orlistat or sibutramine is recommended only if physical comorbidities (such as orthopaedic problems or sleep apnoea) or severe psychological comorbidities are present. Treatment should be started in a specialist paediatric setting, by multidisciplinary teams with experience of prescribing in this age group.

1.7.5.8 Orlistat or sibutramine should be prescribed for obesity in children only by a multidisciplinary team with expertise in:

- drug monitoring
- psychological support
- behavioural interventions
- interventions to increase physical activity
- interventions to improve diet.

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††† At the time of publication (December 2006), orlistat and sibutramine do not have UK marketing authorisation for use in children. Prescribers should be aware of the special considerations and issues when prescribing for children.

The marketing authorisation for sibutramine has been suspended. See front cover for details.

1.7.5.9 Orlistat and sibutramine should be prescribed for young people only if the prescriber is willing to submit data to the proposed national registry on the use of these drugs in young people (see also Section 8).

1.7.5.10 After drug treatment has been started in specialist care, it may be continued in primary care if local circumstances and/or licensing allow.

Continued prescribing and withdrawal

Adults and children

1.7.5.11 Pharmacological treatment may be used to maintain weight loss, rather than continue to lose weight.

1.7.5.12 If there is concern about the adequacy of micronutrient intake, a supplement providing the reference nutrient intake for all vitamins and minerals should be considered, particularly for vulnerable groups such as older people (who may be at risk of malnutrition) and young people (who need vitamins and minerals for growth and development).

1.7.5.13 People whose drug treatment is being withdrawn should be offered support to help maintain weight loss, because their self-confidence and belief in their ability to make changes may be low if they did not reach their target weight.

Adults

1.7.5.14 Regular review is recommended to monitor the effect of drug treatment and to reinforce lifestyle advice and adherence.

1.7.5.15 Withdrawal of drug treatment should be considered in people who do not lose enough weight (see recommendations 1.7.5.19 and 1.7.5.24 for details).

The marketing authorisation for sibutramine has been suspended. See front cover for details.

1.7.5.16 Rates of weight loss may be slower in people with type 2 diabetes, so less strict goals than those for people without diabetes may be appropriate. These goals should be agreed with the person and reviewed regularly.

Children

1.7.5.17 If orlistat or sibutramine is prescribed for children, a 6–12-month trial is recommended, with regular review to assess effectiveness, adverse effects and adherence.

Orlistat

Adults

1.7.5.18 Orlistat should be prescribed only as part of an overall plan for managing obesity in adults who meet one of the following criteria:

- a BMI of 28.0 kg/m^2 or more with associated risk factors
- a BMI of 30.0 kg/m^2 or more.

1.7.5.19 Therapy should be continued beyond 3 months only if the person has lost at least 5% of their initial body weight since starting drug treatment. (see also recommendation 1.7.5.16 for advice on targets for people with type 2 diabetes.)

1.7.5.20 The decision to use drug treatment for longer than 12 months (usually for weight maintenance) should be made after discussing potential benefits and limitations with the patient.

1.7.5.21 The coprescribing of orlistat with other drugs aimed at weight reduction is not recommended.

The marketing authorisation for sibutramine has been suspended. See front cover for details.

Sibutramine

Adults

1.7.5.22 Sibutramine should be prescribed only as part of an overall plan for managing obesity in adults who meet one of the following criteria:

- a BMI of 27.0 kg/m^2 or more and other obesity-related risk factors such as type 2 diabetes or dyslipidaemia
- a BMI of 30.0 kg/m^2 or more.

1.7.5.23 Sibutramine should not be prescribed unless there are adequate arrangements for monitoring both weight loss and adverse effects (specifically pulse and blood pressure).

1.7.5.24 Therapy should be continued beyond 3 months only if the person has lost at least 5% of their initial body weight since starting drug treatment. (See also recommendation 1.7.5.16 for advice on targets for people with type 2 diabetes.)

1.7.5.25 Treatment is not currently recommended beyond the licensed duration of 12 months.

1.7.5.26 The coprescribing of sibutramine with other drugs aimed at weight reduction is not recommended.

1.7.6 Surgical interventions

This section updates the NICE technology appraisal on surgery for people with morbid obesity (*NICE technology appraisal guidance* no. 46); see section 6 for details.

The marketing authorisation for sibutramine has been suspended. See front cover for details.

Adults and children

1.7.6.1 Bariatric surgery is recommended as a treatment option for people with obesity if all of the following criteria are fulfilled:

- they have a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and 40 kg/m^2 and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight

- all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months
- the person has been receiving or will receive intensive management in a specialist obesity service
- the person is generally fit for anaesthesia and surgery
- the person commits to the need for long-term follow-up.

See recommendations 1.7.6.12 and 1.7.6.13 for additional criteria to use when assessing children, and recommendation 1.7.6.7 for additional criteria for adults.

1.7.6.2 Severely obese people who are considering surgery to aid weight reduction (and their families as appropriate) should discuss in detail with the clinician responsible for their treatment (that is, the hospital specialist and/or bariatric surgeon) the potential benefits and longer-term implications of surgery, as well as the associated risks, including complications and perioperative mortality.

1.7.6.3 The choice of surgical intervention should be made jointly by the person and the clinician, and taking into account:

- the degree of obesity
- comorbidities
- the best available evidence on effectiveness and long-term effects
- the facilities and equipment available
- the experience of the surgeon who would perform the operation.

1.7.6.4 Regular, specialist postoperative dietetic monitoring should be provided, and should include:

- information on the appropriate diet for the bariatric procedure
- monitoring of the person‟s micronutrient status
- information on patient support groups
- individualised nutritional supplementation, support and guidance to achieve long-term weight loss and weight maintenance.

1.7.6.5 Arrangements for prospective audit should be made, so that the outcomes and complications of different procedures, the impact on quality of life and nutritional status, and the effect on comorbidities can be monitored in both the short and the long term.

1.7.6.6 The surgeon in the multidisciplinary team should:

- have undertaken a relevant supervised training programme
- have specialist experience in bariatric surgery
- be willing to submit data for a national clinical audit scheme.

Adults

1.7.6.7 In addition to the criteria listed in 1.2.6.1, bariatric surgery is also recommended as a first-line option (instead of lifestyle interventions or

drug treatment) for adults with a BMI of more than 50 kg/m2 in whom surgical intervention is considered appropriate.

1.7.6.8 In people for whom surgery is recommended as a first-line option, orlistat or sibutramine can be used to maintain or reduce weight before surgery if it is considered that the waiting time for surgery is excessive.

1.7.6.9 Surgery for obesity should be undertaken only by a multidisciplinary team that can provide:

- preoperative assessment, including a risk–benefit analysis that includes preventing complications of obesity, and specialist assessment for eating disorder(s)
- providing information on the different procedures, including potential weight loss and associated risks
- regular postoperative assessment, including specialist dietetic and surgical follow-up
- management of comorbidities
- psychological support before and after surgery
- providing information on, or access to, plastic surgery (such as apronectomy) where appropriate
- access to suitable equipment, including scales, theatre tables, Zimmer frames, commodes, hoists, bed frames, pressure-relieving mattresses and seating suitable for patients undergoing bariatric surgery, and staff trained to use them.

1.7.6.10 Surgery should be undertaken only after a comprehensive preoperative assessment of any psychological or clinical factors that may affect adherence to postoperative care requirements, such as changes to diet.

The marketing authorisation for sibutramine has been suspended. See front cover for details.

1.7.6.11 Revisional surgery (if the original operation has failed) should be undertaken only in specialist centres by surgeons with extensive

1.7.6.12 experience because of the high rate of complications and increased mortality.

Children

1.7.6.13 Surgical intervention is not generally recommended in children or young people.

1.7.6.14 Bariatric surgery may be considered for young people only in exceptional circumstances, and if they have achieved or nearly achieved physiological maturity.

1.7.6.15 Surgery for obesity should be undertaken only by a multidisciplinary team that can provide paediatric expertise in:

- preoperative assessment, including a risk–benefit analysis that includes preventing complications of obesity, and specialist assessment for eating disorder(s)
- information on the different procedures, including potential weight loss and associated risks
- regular postoperative assessment, including specialist dietetic and surgical follow-up
- management of comorbidities
- psychological support before and after surgery
- information on or access to plastic surgery (such as apronectomy) where appropriate
- access to suitable equipment, including scales, theatre tables, Zimmer frames, commodes, hoists, bed frames, pressure-relieving mattresses and

seating suitable for patients undergoing bariatric surgery, and staff trained to use them.

1.7.6.16 Surgical care and follow-up should be coordinated around the young person and their family"s needs and should comply with national core standards as defined in the Children"s NSFs for England and Wales.

1.7.6.17 All young people should have had a comprehensive psychological, education, family and social assessment before undergoing bariatric surgery.

1.7.6.18 A full medical evaluation including genetic screening or assessment should be made before surgery to exclude rare, treatable causes of the obesity.

2 Development of the guidance

2.1 Public health and clinical context

2.1.1 Rationale for integrated clinical and public health guidance

In 2003, the then National Institute of Clinical Excellence and Health Development Agency (HDA) were commissioned by the Department of Health and the National Assembly for Wales to develop guidance on the prevention and management of obesity in children and adults. This was the first time NICE had been tasked to work in collaboration with an external body. Crucially, it was also the first time that the applicability of existing NICE methodology to public health evidence and recommendations was to be fully considered. Since April 2005, with the transfer to NICE of the functions of the HDA and the creation of the new Centre for Public Health Excellence (CPHE) within the Institute, the audiences for NICE guidance have extended beyond the National Health Service (NHS). Yet even before April 2005, NICE and the HDA shared audiences inside and outside the NHS, because their work programmes concerned interventions at different stages in the evolution of the same diseases and conditions. Public health and clinical audiences share the same need for evidence-based solutions to the challenges they face in their day-to-day practice as well as to inform policies and strategies that lead to health improvement. Obesity is a prime example of a condition where complementary clinical and public health guidance are essential to address the hazy divisions between prevention and management and the sliding scale of risk. The opportunities to intervene therefore include population-wide initiatives to support healthy lifestyles and prevent ill health, as well as interventions targeted at vulnerable groups, through to individual lifestyle advice on prevention and management in the clinical setting.

The 2004 Wanless report „Securing good health for the whole population"[31] highlighted that a step change will be required to lift us on to the „fully engaged" trajectory to reduce preventable illness and deaths from diseases such as obesity, which would lead to the greatest reduction in future healthcare costs. Apart from a more effective delivery framework for health service providers nationally and locally, the report stressed an

enhanced role for schools, local authorities and other public sector agencies, employers, and private and voluntary sector providers in developing opportunities for people to play their part in securing better health. Crucially, the report considered that there was no reason why the cost effectiveness of prevention interventions should not be assessed in the same way as disease-management strategies. The analysis would allow commissioners of services to compare the relative merits of prevention and treatment strategies, and would allow them to develop a business case for purchasing a balanced portfolio of interventions.[32]

Littlejohns and Kelly have highlighted that the new responsibilities of NICE mean that, for the first time, there is the opportunity to assess the comparative value of multiple approaches to improving specific health issues, and it is hoped that the public health recommendations in NICE guidance can also re-emerge as an integral component of clinical practice, at the same time ensuring that public health practice, based on sound evidence, infuses through lifestyle decisions by people and those responsible for the environment in which they live. Such an approach is vital for tackling obesity. With over half of the population now known to be either overweight or obese, addressing the problem of obesity through primary care management alone is likely to be impossible. Based on around 20% of the adult population being obese and around 50% overweight, it has been extrapolated that in a typical population of 100,000 there will be about 30,000 adults of working age who need help with weight management.[33]

Furthermore, although it is clear that there is no simple – or single – solution, it is likely that the most effective strategies for prevention and management will share fundamental approaches and the clinical management of obesity cannot be viewed in isolation to the „obesogenic" environment in which people live.

The inequalities that are seen in many aspects of health and illness are all too apparent in relation to obesity, where social determinants play a key role in the choices that individuals are able to make concerning their diet and activity. This guidance highlights interventions to identify populations that are vulnerable to the risk factors for obesity, as well as individuals who are at greater risk for weight gain at particular life stages. As

such, the recommendations refer to the need for interventions to be tailored both to different populations and to individual circumstances. However, relatively little is known about the differential effectiveness of interventions in tackling obesity among different vulnerable groups, hence the focus for one of the research recommendations.

2.2 Who is the guidance for?

The guidance covers the care provided by NHS health professionals working with overweight and obese adults and children in primary, secondary and, where appropriate, tertiary care (specialised morbid obesity services). The guidance also addresses areas that require collaboration between primary, secondary and tertiary care. Of course, the role of NHS staff in prevention and health promotion forms a key component too.

In line with the remit of the CPHE within NICE, the guidance also covers a broad range of non-NHS settings including local authorities, government agencies, schools and private and voluntary organisations. Some recommendations have also been made for individuals, recognising that although body weight and weight gain are influenced by many factors, including genetics and the environment in which people live, the individual choices people make will influence whether they are able to maintain a healthy weight.

The integrated nature of the guidance is fundamental. In particular, clinicians should not ignore the public health aspects of the guidance and all audiences should note the importance of multidisciplinary teams and partnerships working for the effective implementation of the recommendations.

2.3 Structure of the guidance documentation

The guidance is divided into sections which cover in detail specific topics relating to the public health and clinical management of overweight and obesity. The recommendations are presented in the executive summary only (Section 1, Chapter 1). The recommendations are supported by summary evidence statements which provide the basis on which the Guidance Development Group made its recommendations. A narrative review of the evidence base is provided (including the health economic

evidence) in sections 2-6 and detailed evidence tables are annexed. Important general methodological issues are flagged as appropriate.

2.4 Scope

The guidance was developed in accordance with the scope prepared by the Institute, the HDA and National Collaborating Centre for Primary Care (NCC-PC), and published by the Institute in 2004 (see Appendix 1). The scope sets the remit of the guidance – specifying those aspects of obesity prevention and management to be included and excluded – and is outlined below.

2.4.1 Population groups

2.4.1.1 Groups that are covered

This guidance covers adults and children aged 2 years or older, either a healthy weight, overweight or obese. This includes adults and children with established comorbidities, and those with or without risk factors for other medical conditions. The following special groups are considered, where there is good evidence of effectiveness of interventions targeted at these groups:

- black and minority ethnic groups
- lower socioeconomic groups
- vulnerable groups, including older people and women of child-bearing age.

2.4.1.2 Groups that are not covered

- Children aged less than 2 years.
- The medical management of related medical conditions. However, links will be made to other appropriate NICE guidance, such as that for type 2 diabetes and eating disorders.

2.4.2 Areas covered

2.4.2.1 Clinical management of overweight and obesity in adults and children aged 2 years or older

(i) The identification of overweight and obesity in adults and children in primary and secondary care. This includes advice on the following;

- The best way to discuss weight in the clinical setting.
- The role of body mass index (BMI) and waist circumference as a method of measuring overweight and obesity, including an appropriate definition of overweight and obesity.
- The role of serial measurements of height and weight in the clinical setting.

(ii) The assessment of overweight and obesity in adults and children in primary and secondary care. This includes advice on the following:

- Assessment of any weight-related comorbidities (for example, diabetes, coronary heart disease), including the adult"s or child"s clinical need to lose weight.
- Assessment of risk factors strongly associated with overweight and obesity.
- Determining the adult"s or child"s readiness and motivation to try to lose weight.
- Consideration of lifestyle factors that are likely to explain why energy imbalance has occurred, including weight control history, usual dietary habits and physical activity levels.

(iii) The management of overweight and obesity in adults and children in primary and secondary care. This includes advice on the following:

- How practitioners should develop goals and treatment strategies with the adult or child with overweight or obesity (and their parent/family as appropriate). This will include, as appropriate, the goal of weight maintenance as well as weight loss.

- The role of non-pharmacological interventions. Where there is good evidence of effectiveness, the following interventions are considered:
    - dietary advice including the role of low-fat, low-carbohydrate and very-low-energy diets, the role of meal replacements and the role of „slimming clubs‟
    - physical activity
    - psychological therapies
    - professionally organised alternative therapies.[‡‡‡]
- The role of pharmacological interventions. This is limited to orlistat and sibutramine. These are currently the only anti-obesity drugs listed in the „British national formulary‟ and available on prescription. The guidance updates the current NICE technology appraisals for these agents and when the final guidance has been published the technology appraisals will be withdrawn.
    - National Institute for Clinical Excellence (2001). „Guidance on the Use of Orlistat for the Treatment of Obesity in Adults‟. *NICE technology appraisal* no. 22.
    - National Institute for Clinical Excellence (2001). „Guidance on the Use of Sibutramine for the Treatment of Obesity in Adults‟. *NICE technology appraisal* no. 31.

Note that guidance recommendations will fall within licensed indications: exceptionally, and only where clearly supported by evidence, can use outside a licensed indication be recommended. The guidance will assume that prescribers will use the Summary of product characteristics to inform their decisions for individual patients.

[‡‡‡] These are defined as: acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy (Select Committee on Science and Technology Sixth Report . London: The UK Parliament [House of Lords], 2000).

(iv) Morbid obesity in adults (BMI > 40 kg/m^2) and children will be discussed in sufficient detail to inform primary and secondary care practitioners on best practice for referral to tertiary care (specialised morbid obesity services) and to identify key aspects of care for people with morbid obesity in tertiary centres. The following aspects of care will be considered:

- The identification of morbid obesity in adults and children in primary and secondary care.
- The criteria that should be used to determine when adults and children with morbid obesity should be referred to tertiary care.
- The assessment of morbid obesity in adults and children in tertiary care, including a health risk assessment based on presence of comorbidities.
- The management of morbid obesity in adults and children in tertiary care, including the role of an integral management approach aimed at weight loss and weight maintenance. The role of surgical treatment of morbid obesity will be addressed. The guidance will update the NICE technology appraisal on the use of surgery; when the guidance has been published the technology appraisal will be withdrawn.
    - National Institute for Clinical Excellence (2002). „Guidance on the Use of Surgery to Aid Weight Reduction for People with Morbid Obesity". *NICE technology appraisal* no. 46.
- The prevention of overweight and obesity in adults and children aged 2 years or older, who are currently of a healthy weight.

(v) The role of primary prevention approaches intended to support adults and children in maintaining a healthy weight. These approaches will be aimed mainly outside the clinical setting and include advice on the following:

- Raising awareness of what constitutes a healthy weight range and the need to stay within such a range.

- Identifying adults and children who should participate in prevention programmes based on their risk factors for obesity and readiness and opportunities to change their behaviour.
- Maintaining energy balance in adults and children of a healthy weight through a healthy diet and physical activity.
- Developing local strategies to prevent obesity and support weight maintenance in adults and children of a healthy weight. These will focus on multicomponent interventions including:
    - community-based services including those to which people are referred from primary care services
    - broader environmental interventions in the community
    - interventions in workplaces
    - interventions in schools
    - interventions targeted at children aged 2–5 years
    - interventions targeted at black and minority ethnic groups, at vulnerable groups and at individuals at vulnerable life stages.

2.4.3 Areas not covered

The guidance does not cover the following areas of clinical practice:

- Population-based screening programmes for overweight or obesity.
- Complementary therapy approaches to the treatment of overweight and obesity that are not included in the definition of „professionally organised alternative therapies".
- Eating disorders, including binge-eating disorder.

- In adults and children, the prevention or management of comorbidities (for example, type 2 diabetes) associated with overweight or obesity.
- In children, the diagnosis and management of childhood syndromes (for example, Prader–Willi syndrome) or childhood diseases (for example, hypothyroidism) that lead to obesity.
- In terms of prevention of overweight and obesity, the guidance will contribute to the evidence base leading to subsequent recommendations in national government or European policies, including fiscal policy, food labelling policy and food advertising and promotion. The guidance is intended to support local practice whereas national or „upstream" action will be addressed in the context of wider work, as outlined in the „Choosing health" White Paper.

2.5 Plans for guidance revision

The process of reviewing the evidence is expected to begin 4 years after the date of issue of this guidance. Reviewing may begin before this if significant evidence that affects the guidance recommendations is identified. The updated guidance will be available within 2 years of the start of the review process. However, please note that this process is currently under review and may change following consultation.

3 Obesity

3.1 Introduction

Obesity and overweight have been dubbed a „global epidemic" by the World Health Organization (WHO).[34] Obesity should not be considered to be simply a consequence of an unhealthy lifestyle: it is a condition in which weight gain has reached the point where it poses significant risks to health. Obesity may be considered as a disease and a risk factor for other diseases. In adults, obesity is associated with an increased risk of diseases that are a major cause of morbidity and mortality, notably type 2 diabetes, coronary heart disease (CHD), hypertension, many cancers and osteoarthritis (Table 3.1).

Table 3.1 Relative risk of other diseases in obese adults

Disease	**Relative risk**	
	Women	**Men**
Type 2 diabetes	12.7	5.2
Hypertension	4.2	2.6
Heart attack	3.2	1.5
Colon cancer	2.7	3
Angina	1.8	1.8
Gall bladder disease	1.8	1.8
Ovarian cancer	1.7	
Osteoarthritis	1.4	1.9
Stroke	1.3	1.3

Source: National Audit Office. Tackling obesity in England. London: The Stationery Office, 2001.

In children and teenagers, the associated morbidities include hypertension, hyperinsulinaemia, dyslipidaemia, type 2 diabetes, psychosocial dysfunction, and exacerbation of existing conditions such as asthma. However, in children the persistence of obesity into adulthood is the most important concern; the risk of persistence increases with increasing age of the child and severity of obesity.

There are strong cultural pressures for both children and adults, particularly girls and women, to remain slim, and overweight and obesity may also have psychosocial penalties,[37] especially for children, who may be bullied as a consequence of their obesity.

It is therefore unsurprising that obesity imposes a considerable economic burden. The Health Select Committee (HSC)[33] reported that the cost of obesity in England is between £3.3 and £3.7 billion per year. This figure is 27% to 42% higher than the previous estimate by the National Audit Office (NAO)[35] due to higher NHS and drug costs, the availability of more accurate data, the inclusion of comorbidities and increased prevalence of obesity. The HSC estimate includes £49 million for treating obesity, £1.1 billion for treating the consequences of obesity, and indirect costs of £1.1 billion for premature death and £1.45 billion for sickness absence. The cost of obesity plus overweight is estimated between £6.6 and £7.4 billion per year.

The fundamental cause of overweight and obesity is „energy imbalance"; without periods of increased energy intake and/or decreased physical activity, a person will not gain weight, no matter what their genetic make up. However, the causes of this energy imbalance, which result in weight gain, remain unclear. It has been hypothesised that numerous behavioural, psychological, social and environmental factors determine the increasing prevalence of obesity seen throughout the world. Small, virtually unnoticeable changes in lifestyle can result in significant weight gain: just 50–60 calories a day in excess – from increased calorie intake and/or reduced physical activity – can result in over 2.4 kg increase in weight at the end of a year.[33,34{4625}].

The tendency for weight gain to occur over extended periods of time (years or decades for most people) means that it may go virtually unnoticed until a person is already overweight or obese and showing signs of associated comorbidities. Similarly there is some evidence that parents may fail to recognise excess weight gain and obesity in their children as overweight and obesity become more common in society.[36]

Weight gain resulting in overweight and obesity is associated with increased health risk, and intentional weight loss reduces morbidity and mortality.[37] However, whereas it can

be easy to gain body weight, considerable effort may be required to lose it. For adults to lose 1 kg of fat requires an energy deficit of around 7000 calories. Therefore, to lose 0.5–1 kg per week would required an energy deficit of between 500 and 1000 calories per day.

It is unusual for an obese person to seek medical help in the first instance;[37] they are likely to have tried an array of „self-help" measures before approaching a health professional. The search for the most successful – or most fashionable – means of losing weight or preventing weight gain, is never ending and has become big business. Entering obesity into „Google" results in more than 35 million hits; there are few health topics where there is greater media interest, conflicting advice, self-help manuals, popular myths, mis-information and unsubstantiated celebrity endorsements.

3.2 Prevalence

In adults, body mass index (BMI, kg/m^2) is frequently used as a measure of overweight and obesity, with overweight being defined as a BMI 25–29.9 kg/m^2 and obesity as a BMI equal to or greater than 30 kg/m^2. Epidemiological surveys of England indicate that the prevalence of overweight and obesity in adults has trebled during the past 25 years. In 1980, 8% of adult women and 6% of adult men were classified as obese; by 2004[38] this had increased to approximately 24% of men and women, with a further 46% of men and 35% of women being overweight. Therefore, around two-thirds of men and women, almost 24 million adults, were either overweight or obese in 2004. Furthermore, 0.9% of men and 2.6% of women are classified as morbidly obese, with BMIs over 40 kg/m^2.[38]

In adults, central adiposity is frequently measured by waist circumference, with raised waist circumference defined as equal to or greater than 102 cm in men and equal to or greater than 88 cm in women. In 2004, approximately 31% of men and 41% of women were classified as having a raised waist circumference.[38]

The NAO[35] summarised that the prevalence of obesity:

- increases with age
- is more prevalent among lower socioeconomic and lower-income groups, with a particularly strong social class gradient among women
- is more prevalent among certain ethnic groups, particularly among African Caribbean and Pakistani women
- is a problem across all regions in England but shows some important regional variations.

Adults at greater risk of becoming obese also include those who were previously overweight and who have lost weight; smokers who have stopped smoking and those who change from an active to an inactive lifestyle.[37]

In children, the prevalence of obesity (defined as a BMI above the 95th percentile) is also rising. The latest figures[10] suggest that over 16% of boys and girls aged 2–15 years were obese compared with 10% of boys and around 12% of girls in 1995. A further 14% of boys and girls were estimated to be overweight (defined as a BMI between the 85th and 95th percentiles) compared with around 13% of males and females in 1995. There are social inequalities in the prevalence of obesity in children[10] and children with at least one overweight or obese parent are at greater risk of obesity.[37]

Children‟s weight tends to „track‟ from childhood to adulthood and children who are overweight or obese are at greater risk of being obese in adulthood. Although obesity in childhood is an important risk factor for adult obesity, the majority of obese adults were not obese children. This suggests that factors throughout the life course have an impact on the development of obesity.[39]

Epidemiological studies suggest that there are critical periods in the life course when weight gain is greatest and may be associated with excess weight gain. These include:

- Prenatal period – research by Jackson and coworkers,[40] among others, suggests that fetal nutrition has permanent effects on later growth, body shape, fatness and energy regulation.

- Rapid growth in infancy.[41]

- Adiposity rebound – a rapid period of growth and increase in BMI between the ages of 5 and 7 years which may lead to increased risk of obesity later in life (for example, Rolland-Cachera and coworkers,[42] Prokopec and coworkers[43]). In this period children are also exposed to new environments and patterns of behaviour which have an effect on food and activity patterns.

- Adolescence – tends to be associated with increased autonomy when individuals may have irregular meals, changed food habits and periods of inactivity during leisure combined with physiological changes which promote increased fat deposition, particularly in girls.[44]

- Young adulthood – often correlates to a period of reduced physical activity. For men and women this occurs at different times. In women this usually occurs between the ages of 15 and 19 years but in men it maybe as late as when they are in their early thirties).[45]

- Pregnancy – although on average, women gain less than 1 kg after each pregnancy, excessive weight gain during pregnancy may result in retention of weight gain after the baby is born, particularly with early cessation of breastfeeding (see for example, Williamson and coworkers[46]).

- Menopause – tends to be associated with weight gain, particularly around the abdomen (see for example, Williamson and coworkers[46]). Hormonal changes are thought to be partly responsible for the increased susceptibility to weight gain during the menopause, although the exact process is not fully understood and changes have also been attributed to changes in metabolism and reduced physical activity levels.

3.3 Existing service provision

There is considerable variability in the management of overweight and obese people in the NHS. In 2001, the NAO[35] identified no central guidance on the management of obesity and, at local level, only 28% of health authorities had taken action to address obesity as a health problem. It was also noted that primary care played an important role in the management of obesity but that general practitioners (GPs) and practice nurses used a wide range of methods to manage overweight and obese patients and many were uncertain as to which interventions were most effective. A more recent survey by Dr Foster in 2005[47] on obesity management services found that although there appeared to be an increased willingness to address the problem of obesity, the provision of services remained limited and inconsistent. Despite 55% of primary care organisations (PCOs) believing that prevention and treatment of obesity was a top priority, only 31% had established a weight management clinic. The report found that PCOs have developed a number of innovative approaches to the management of obesity, including partnerships with local authority and commercial weight loss organisations, but there is considerable regional variation in service provision.

The prevalence of obesity was not monitored by 76% of PCOs. The majority did not allocate specific funds to obesity prevention and management. Only a minority of PCOs were able to estimate the amount of money spent on obesity prevention and treatment; and when they were, the amounts were shown to be low. In 15% of PCOs, the service was provided by privately managed services such as slimming clubs, dietary advice, leisure services and independent dietitians.

The majority of PCOs do not monitor the effectiveness of interventions for obesity. Just 19% monitor outcomes for surgery, 39% drug treatment, 45% weight loss and 15% for other interventions including dietetic and nutrition, physical activity programmes and exercise on prescription. Moreover, 91% offer exercise on prescription and 59% advice on „healthy shopping".

There is also some evidence that health professionals may question their own ability to motivate patients to change behaviour and their patients ability to change. Garrow and

Summerbell[37] have noted that most GPs have had little or no training on how to manage obesity.

3.3.1 Multidisciplinary approach and partnership working

The NAO in 2001[35] also highlighted the need for joint working with different agencies to facilitate cross-government initiatives to prevent obesity at both national and local level and the need to consider the broader environment in terms of its potential to support behavioural change. As the key representative for health in local strategic partnerships, primary care trusts (PCTs) in England and local health boards in Wales have a role to play that goes beyond the clinical setting and extends into the wider community through work in schools, workplaces and neighbourhoods.

In 2006, the Audit Commission, the Healthcare Commission and the National Audit Office published *Tackling Child Obesity – First Steps.* This contains a number of recommendations directed at local authorities and their partners.

3.4 Key public health audiences and settings

3.4.1 General public

Although body weight and weight gain are influenced by many factors, including genetics and the environment in which we live, research shows that the individual choices people make may influence whether or not they are able to maintain a healthy weight. Furthermore, the lifestyle choices associated with a healthy weight are likely to have wider health benefits – such as reducing the risk of heart disease and some cancers.

3.4.1.1 Awareness

The NAO in 2001[35] found that around half of GP surgeries made information about the weight management available to all patients, usually via leaflets or information displays in the waiting room, and three-quarters provided information on physical activity and healthy eating. Despite this, there is some evidence that the general public may not

always recognise a healthy weight[36] or appreciate the health risks of obesity.[48] Furthermore, although surveys suggest that most people know what constitutes a healthy diet, few are putting this information into practice).[49,50] Similarly, the „Active for life" campaign during the 1990s found that while the campaign increased awareness of the moderate activity message this did not appear to be translated into action[51]

However, a lack of awareness of an issue may not be the main barrier to people changing their behaviour. „Choosing health" recognises that health messages can be inconsistent or „out of step" with the way people live their lives.[2] The HSC enquiry into obesity probed a range of experts into „why the message was not getting through".[33] The multifactorial nature of obesity and the complex factors involved in determining individual"s health behaviours were apparent in the evidence gathered by the committee. Factors such as the cost of a healthy diet, lack of cooking skills, the opportunity to be physically active in a safe environment, and the effects of foods advertising were all given as examples of factors that contributed to individuals not being able to maintain a healthy weight.

The benefit of interventions that are designed to provide information alone has been questioned by health professionals – and certainly few health education campaigns over the past decade have relied on imparting information alone.

This guidance predominantly focuses on interventions which are locally led. However, in assessing the effectiveness of interventions to raise awareness, it is not always possible to delineate between those which are nationally or locally led. For example, a national mass media of short duration may be intended to provide a focus for the ongoing work of local health professionals. In addition, it is not always possible to separate out the effects of the awareness raising element of a broader-based intervention from the effects of other aspects of the same intervention.

3.4.1.2 'Self-help' and non-clinical management of overweight and obesity

The most recent national diet and nutrition survey of adults aged 19–64 years,[50] found that 24% of women and 10% of men were dieting to lose weight, and the survey of young people[52] found that 16% of girls aged 15–18 years were trying to lose weight.

It is unusual for an overweight or obese person to seek medical help in the first instance[37] – they are likely to have tried an array of „self-help" measures to manage their weight before approaching a health professional. Furthermore, although studies have shown that the most trusted source of nutrition information is their GP, most consumers get their nutrition information through the media.[53]

Diet and weight management has for many years been an area of intense media interest. The proliferation of different diet, fitness and weight loss regimens – which are widely marketed and often sponsored by or attributed to various celebrities, coupled with the relatively recent development of e-technologies such as the internet, hand-held computers, and mobile phones and interactive television – has made access to information on diet and weight loss widely available. The quality and reliability of some of the information available through the media can sometimes be a cause for concern to health professionals.

„Self-help" strategies may include:

- slimming clubs – including commercial programmes and local not-for-profit groups based in local settings such as churches or community centres
- interactive programmes using new technologies (including web, interactive television and mobile phones)
- specifically formulated weight loss products such as meal replacements and low-calorie" meals and snacks
- popular diet books and magazines
- one-to-one counselling/coaching by dietitians, nutritional therapists, exercise specialists, personal trainers
- alternative therapies (such dietary supplements, hypnosis, acupuncture, homeopathy).

The quality of the advice and support provided by these approaches, the cost to the individual and ultimately the impact on long-term weight management varies tremendously. The fact that many users of such interventions self-refer and self-manage their weight, and do so in the absence of a health professional, means that some of the interventions above are unlikely to be widely evaluated or be the subject of good-quality research. However, there are increasingly examples of health professionals using traditional „self-help" strategies to address the management of overweight and obesity in the local population. For example, a GP or practice nurse may formally „refer" patients to an exercise programme at a local sports centre, informally recommend a commercial slimming club, and/or run or support a weight management programme based in a community health centre or workplace.

3.4.2 Pre-school children

The pre-school years are not only critical for physical and emotional development, they are also likely to be important for learning attitudes and practices related to healthier lifestyles.[54] Lifelong habits which can have an impact on an individual's ability to maintain a healthy weight may be established during the pre-school years.

The family environment has a tremendous influence on a child's development, their eating and activity habits, and predisposition to overweight.[55–57] Similarities within families are documented in relation to eating and exercise behaviour and body weight.[55] This clustering of family characteristics suggests the value of the family as a critical unit upon which obesity prevention and intervention strategies can be developed. For example, the nutrient quality of the diets of 2–5-year-old children is influenced by the eating patterns of their parents.[58] Children's eating behaviours are influenced by the family food environment, including parental food preferences and beliefs; children's food exposure; role modelling; media exposure and child/parent interactions around foods.[56,59,60] Similarly, children's activity levels will be strongly influenced by, for example, parental decisions on car use and walking, family television viewing habits, leisure time activities.

Although parents are primarily responsible for their child‟s nutrition and activities, child care providers can also play an important role by providing opportunities for children to be active and develop healthy eating habits and by acting as important role models. Crucially, a child‟s positive experience in childcare outside the home may influence their behaviours in the home and thus help promote healthy lifestyles to the family as a whole.[61]

Assessing the diet and activity levels of young children is not straight forward, particularly due to concerns of bias from self-reported measures. Young children find it difficult to recall food intake and physical activities, potentially lead to mis-reporting. For very young children, the use of parents or carers to provide reports may also introduce error – in particular, they may over report intakes in an aim to give „socially desirable‟ responses. The data available suggest that trends in children‟s diet and activity levels may be placing them at risk of excess weight gain and obesity.

In relation to activity, approximately two-thirds of boys and girls aged 2–5 years achieve at least 60 minutes moderate intensity physical activity each day.[10] However, there are many current threats to children‟s activity levels, including greater access to computers and television and other sedentary activities and parental reliance on car use and reluctance to allow outdoor play.

By 5 years of age children should be consuming a diet consistent with the population dietary recommendations for adults. Between the ages of 2 and 5 years a flexible approach to the timing and extent of dietary change should be taken.[5] However, the National Diet and Nutrition Survey[62] found that the diets of children aged 1.5–4.55 years were generally less than ideal, for example, children tended to have low intakes of fruit and vegetables (particularly children from lower-income and one parent families) and high intakes of added sugars (18.7%).

3.4.3 Schools

The school years are known to be a key stage in the life course for shaping attitudes and behaviours. Indeed life-long habits which can have an impact on an individual‟s ability to maintain a healthy weight may be established during the school years. All

school policies have the potential to have some impact on a child‟s ability to maintain a healthy weight, eat a healthy diet and be physically active. These range from the school selection processes themselves (which may determine whether a child can walk or cycle to school), to the curriculum content, school food policies, training opportunities for all school staff, engagement with wider community and the extent to which national policies are implemented.

School-aged children‟s diet and activity practices are less than ideal. In 2002, around 70% of boys and 61% of girls aged 2–15 years were active for at least an hour a day.[10] Participation in physical activity in girls begins to decline at age 10 years and that by the age of 15 years the level of recommended physical activity was only achieved by 50% of girls. The number of children who travel to school by car has doubled over the past 20 years, with a corresponding fall in those who walk or cycle.[63] In terms of diet, fewer than half school-aged children meet the dietary recommendation for total fat intake and only 8% the recommendation for saturated fat intake. Over half exceed the maximum recommended salt intake and only 15% meet the maximum recommended intake for added sugars. On average, children eat two portions of fruit and vegetables each day, compared with the recommended five, with those from low-income households consuming half the amount of those in the highest-income households.[52]

Addressing obesity (and wider health issues) in children and young adults is a major focus of government policy. There is a national target to halt the year on year increase in obesity in children aged under 11 years, as part of a broader strategy to reduce obesity in the population as a whole. This target will contribute to the government‟s overarching strategy for children, „Every child matters: change for children‟ which aims to allow every child, whatever their background or circumstances, to have the support they need to be healthy, stay safe, enjoy and achieve, make a positive contribution, and achieve economic well-being.

Recognising the importance of introducing good dietary and activity habits early in life and the opportunity the school environment provides, a raft of government policy

initiatives and interventions which aim to improve children‟s diets and activity levels have been introduced in recent years. These include:

- **The National Healthy Schools Programme**: promotes a „whole-school approach‟ to specific health themes within schools; with all participating school now having to work on healthy eating and physical activity.
- **The Food in Schools Programme**: good practice guidance for schools wishing to implement the various initiatives which can contribute to a whole-school approach to promoting healthy eating.
- **The School Fruit and Vegetable Scheme**: entitles all 4–6-year-olds in local education authority (LEA)-maintained infant, primary and special schools in England, to a free piece of fruit or vegetable on each school day.
- **School meals**: Nutritional standards due 2006 and from 2005 part of Ofsted inspection on healthy eating in schools.
- **School travel plans**: By 2010**,** all schools will be required to have active travel plans which aim to reduce car use and encourage children and their parents to walk or cycle to school where possible.
- **Physical education (PE) and sport in schools and beyond –** There is a national target to increase the percentage of children spending a minimum of 2 hours each week in high-quality PE and sport both in and outside school hours, from 25% in 2002 to 75% in 2006 and 85% in 2008.
- **Extended schools**: offering „wraparound childcare‟ in the form of breakfast and after-school clubs (including, for example, cooking, sports, physical activities).
- **School nurses/personal health plans**: „Choosing health‟ makes a commitment to extend the role of the school nurse and dietitians, so that families and young people can access individual support and advice to promote healthy eating and physical activity and to prevent obesity.

Although some of these initiatives are relatively new, others have been in development, or operating for several years. Some have been trialled as part of the development process for these government-based initiatives and others have been operating independently as part of ongoing health promotion activities or as part of research programmes.

3.4.4 Workplace

In addition to fundamental health and safety policies, the workplace has considerable potential for addressing wider public health issues, such as obesity. In 1986, the WHO[64] identified the workplace as a key setting for health promotion (along with cities, neighbourhoods and schools). The workplace has potential as a setting for improving the health of the adult population because of:

- ease of access to a large number of people
- a potentially low level of attrition as the population is relatively stable
- cohesion of the working community which can offer benefits such as peer support
- established channels of communication which can be used to publicise programmes, encourage participation and provide feedback.

More recently, „Choosing health"[2] set out a range of the action that employers, employees, government and others can take to extend healthy choices in the workplace by:

- reducing barriers to work to improve health and reduce inequalities through employment
- improving working conditions to reduce the causes of ill health related to work
- promoting the work environment as a source of better health.

The workplace may have an impact on an individual"s ability to maintain a healthy weight both directly, by supporting an individual to make healthier choices (for example,

by the provision of healthier food choices in on-site vending machines, providing changing and shower facilities), and indirectly, through the overall culture of the organisation (for example, through appropriate policies and incentive schemes).

Although addressing obesity is not a core aim of workplaces, taking action may result in significant benefit for employers as well as employees. Collaboration with local employers as part of the local strategic partnership (LSP) will enable the development of appropriate targeted work in this area. There is also potential to have a local area agreement target addressing a reduction in days lost through sickness absence.

The UK workforce

- Among 16–74-year-olds in England and Wales 41% work full time and 12% work part time, and 8% are self-employed and 3% are unemployed. The NHS is the largest employer in the UK with 1.3 million staff. Most employees (12.5 million) work in small- or medium-sized enterprises (employing 5–249 people).[65]

- Most people travel to work by car (61%, including passengers). Around 14% of people use public transport (bus, train, etc) to travel to work. Only a minority walk (10%) or cycle (3%).[65]

- The average lunch break is 27 minutes with fewer than one in five workers taking a full hour and one in five (20%) working through their lunch.[66]

- A third of employees would like staff catering facilities offering healthier eating options, a quarter would like on-site fitness facilities or gym memberships, 1 in 8 would welcome 15-minute workplace exercise sessions and 1 in 10 would back a ban on the sale of high-fat snacks, drinks and confectionery at work.[66]

3.4.5 Community

The environment in which people live may influence their ability to maintain a healthy weight – this includes access to safe spaces to be active and access to an affordable, healthier diet. Examples of community based interventions in the UK to prevent obesity, improve diet and/or increase activity levels include:

- improved information and access to healthier food choices for example, partnerships with small and large retailers improving access to major stores and better provision at local shops, establishment of food co-ops, community cafes, growing clubs

- improved knowledge and skills on healthy eating and food preparation, for example, supermarket tours, cook and eat classes

- community voucher schemes for example, for local sport facilities

- improving support for example, walking groups
- safer walking and cycling routes (for example, cycle ways, improved lighting, bike parks, pedestrian crossings).

However, all local planning decisions may therefore have an impact on the health of the local population. A variety of work may also be ongoing which has other aims but may also have an impact on weight, diet and/or activity levels, such as traffic calming, congestion charging, the positioning of shops and public transport routes, building design. Furthermore, the fundamental concerns of local users may influence whether they are likely to change their behaviour, such as concerns about safety, transport links and services.

Community interventions for health are a range of very varied initiatives, programmes, projects and activities emerging out of and overlapping with a range of areas including public health, community development, activities addressing health inequalities, attempts to increase „social capital", and health partnerships, among others. Most community level interventions start from a broad definition of health. With a growing awareness of the multiple factors that affect health many community-based interventions that seek to address other factors – unemployment, crime, poor education standards – can also be seen to have a potential impact on health even if indirectly. Therefore, distinguishing interventions with specific health aims from those with more general employment or environmental aims is often not easy and therefore judging the „effectiveness" of community-based work is not necessarily straightforward.[67]

Personnel involved in public health interventions to prevent or manage obesity may include nurses, GPs (the new General Medical Services [GMS] contract requires practices to offer relevant health promotion advice to patients), health promotion specialists, behavioural psychologists, physiotherapists, pharmacists, dietitians, public health nutritionists and appropriately trained exercise specialists. Additional trained front line staff (for example, pharmacy assistants) may also be in position to provide opportunistic advice if sufficiently trained.

Effective interventions often require multidisciplinary teams and the support of a broad range of organisations; local authorities and PCTs are in prime position to be able to establish effective partnerships. Local authorities, along with PCTs therefore have a key role in the prevention of obesity. Two key policy documents require much greater joint working and partnership between PCTs, local authorities, NHS foundation trusts, NHS trusts, independent sector and voluntary organisations:

- „National standards, local action"[68] sets out the framework for all NHS organisations and social service authorities to use in planning over the next financial three years. It looks to PCTs and local authorities to lead community partnership by even closer joint working (with LSPs) to take forward the „NHS improvement plan".
- The „NHS improvement plan"[69] set out the next stage of the government"s plans for the modernisation of the health service. It signalled three big shifts:
    - putting patients and service users first through more personalised care
    - a focus on the whole of health and well-being, not only illness
    - further devolution of decision-making to local organisations.

Local area agreements form part of the developing agenda for local government. Under the local government power of well-being, coordination of local service delivery and joined-up working by local partners have become key contributions to the promotion of health.

3.5 Key clinical audiences and settings

3.5.1 Primary care

The primary healthcare team, chiefly GPs, practice nurses and health visitors, have an important role in the identification, assessment and management of overweight and obese adults, children and young people. A „typical" NHS general practice with a list size of 6000 will have approximately 1000 adults who are obese (BMI ≥ 30 kg/m^2), 50 adults

who have severe obesity (BMI ≥ 40 kg/m^2) and approximately 200 children (aged 2–15 years old) who are obese (BMI above 95th centile).[38,70]

Obesity in adults within the primary care setting is broadly managed in three ways, depending on the degree of obesity and the extent of clinical comorbidities (for example, diabetes, hypertension, osteoarthritis):[35]

- General advice within the surgery, and personal advice by a GP or practice nurse on weight control, diet and physical exercise aimed at influencing lifestyle.
- Personal advice on weight loss and lifestyle change by a GP or practice nurse supported by drug therapy prescribed by the general practitioner.
- Onward referral by a GP to a weight loss specialist, possibly involving drug therapy and, in extreme cases, surgery.

Surveys have, however, identified a number of barriers to the effective management of obesity in adults in primary care, notably in relation to GPs reporting uncertainty about three areas: the effectiveness of lifestyle interventions, the appropriateness and effectiveness of drug therapy and the effectiveness of referral options.[35,71]

There is a lack of published surveys reporting current practice in the management of obesity in children and young people in primary care.

Recent changes to the structure of primary care in the UK may help facilitate better management of obesity in adults and children by the primary healthcare team. The new GMS contract[3] has since April 2004 required practices to offer consultation for chronic disease and related health problems; offer relevant health promotion advice to patients; and to refer patients to other treatment that may be necessary. Under the new contract PCOs are also able to commission enhanced services from practices, these could include commissioning obesity clinics from NHS or non-NHS providers. Another key aspect of the new GMS contract is the Quality and Outcomes Framework (QoF). The QoF currently includes a quality marker for the recording of BMI in patients with diabetes. From April 2006 the QoF will also include a quality marker for practices to set

up a register of patients aged 16 and over who have a BMI equal to or greater than 30 kg/m^2.[72]

3.5.2 Secondary care

Obesity in adults and children is managed in secondary care as part of a treatment programme for patients with specific comorbidities (for example,, type 2 diabetes in adults and endocrine disorders in children). There is, however, little specific obesity-related activity in the NHS at secondary care level.[35]

3.5.3 Specialist obesity services

In 2002, the Department of Health issued a definition as to what should constitute specialist morbid obesity services for adults and children.[73] It recommended an integral management approach for patients aimed at weight loss and weight maintenance. Programmes should be drawn up by a multidisciplinary team and may include some or all of the following: weight loss goals, diet, behaviour management, physical activity, drug treatment and bariatric surgery.

- Surgery is an effective intervention to aid weight loss.[74] It should only be undertaken in specialist centres and by surgeons who work in collaboration with a physician with expertise in this area and who carry out the required number of procedures to ensure optimum outcomes. The main surgical procedures currently undertaken in the UK are: restrictive (laparoscopic gastric banding), restrictive/malabsorptive (gastric bypass) and malabsorptive/restrictive (duodenal switch with biliopancreatic diversion). All patients receive diet and behaviour advice following any surgical procedure as part of a programme encouraging a change in lifestyle.

- Since the Department of Health‟s 2002 report it has been noted that specialist obesity services remain poorly distributed across England and Wales and that few people with severe obesity can access services on the NHS. There are currently seven NHS-operated specialist obesity clinics for adults and six NHS-operated specialist obesity clinics for children. The number of surgeons undertaking obesity surgery is unknown. Specialist services for children are likely to be even more limited.[73]

3.6 Addressing inequalities in health

3.6.1 Social status

Data on health inequalities are primarily based on data that show marked differences in health from top to bottom of the occupational hierarchy. Similar differences are captured in measures of people"s socioeconomic circumstances, which are based on education, income and housing tenure. Policy responses have focused on addressing:

- those in the poorest circumstances and the poorest health (that is, the most socially excluded, with the most risk factors and those most difficult to reach. If effective such interventions only help a relatively small part of the population.

or

- the broader social gradient in health recognising that it is not only the poorest groups and communities who have poorer health. There are large numbers of people who although they could not be described as socially excluded are relatively disadvantaged in health terms.[75]

The core objective of current public health policy is to improve health and to reduce health differences between groups in society (by tacking the wider determinants of health inequalities).

In most developed countries there is an inverse relation between measures of social status, such as income and education level and obesity, particularly among females. The HSE[38] found that the proportion of men and women who were obese was lower among those in managerial and professional households, and in intermediate households, than in the other three national statistics socioeconomic status groups. The trend was particularly strong in women, with 18.7% of managerial and professional women classified as obese compared with 29.1% of women in routine occupations. A similar pattern was seen in the distribution of raised waist circumference in men, and with income in women (but not men). Differences in prevalence of obesity between social groups are also observed in children.[10]

Parental social class may have an enduring effect on offspring‟s risk of overweight and obesity in adulthood (see for example, Langenberg et al 2003{add reference}. It has been argued that that cheaper foods are usually high in fat and energy dense, and those with less financial resources spend more time in sedentary activities, such as watching television.[77]

Disadvantage is associated with:

- lower consumption of healthier food options. Compared with higher social groups, lower social groups have 50% lower intakes of fruit and vegetables, lower intakes of protein, fibre and many vitamins and minerals.[2,50]
- poor access to sports facilities
- less physical activity outside work and less participation in sport, for example, the HSE[78] found that 66% of men and 67–69% of women with the lowest incomes participated in some physical activity of at least moderate intensity in the past 4 weeks compared to 87–88% of men and 83–84% of women in the two highest income quintiles.

The 2004 Wanless report[31] stated that:

> „Public health policy has recognised the growing importance of the wider determinants of health such as income, education, employment, housing and the environment as well as their effect on lifestyle. Highlighted by the Black report and Acheson report, much of government policy now seeks to address these issues that have traditionally been outside the health domain‟.

The Acheson report[79] highlighted that:

> „Studies have shown that people on a low income can describe a healthy diet as well as those on higher incomes. Food poverty, affordability and access to ah healthy and varied diet have been identified as possible barriers‟.

The guidance for implementing the preventive aspects of the NHS framework on CHD [80] noted that issues around access:

> „should not be seen purely in terms of physical proximity and other kinds of access need to be considered for example financial access, knowledge and information (HEA 1998a). In areas where a large proportion of the population is unemployed, on low income or in receipt of benefits, interventions to improve people"s access to a healthier diet are likely to be a key priority".

The guidance also stated that the characteristics of good practice on work on physical activity and inequalities (HEA 1999a)[{add reference}] include proactive outreach work; taking a multidisciplinary approach; involving targeted communities; and developing new partnerships with professionals who have good access to hard to reach groups.

However, low socioeconomic status groups and ethnic minority groups are frequently under represented in community trials and different strategies may be needed to target these groups.[81]

3.6.2 Ethnicity

Obesity (as defined as a BMI ≥ 30 kg/m^2) is less common in men from other minority ethnic backgrounds than the general population in England, with the exception of black Caribbean men (25% obese) and Irish men (23.6% obese).[38] Among women, the prevalence of obesity among black Caribbean, black African and Pakistani women is substantially higher than the general population (with the prevalence of obesity in these groups at 32.1%, 38.5% and 28.1%, respectively). There are also variations by ethnicity in the prevalence of raised waist circumference (as defined as ≥ 102 cm for men and 88 cm for women). For men, the prevalence of raised waist circumference was only higher than the general population for Irish men (33%). For women, the prevalence of raised waist circumference was higher than the general population for black Caribbean (47%), black African (53%), Pakistani (48%), Bangladeshi (43%) and Irish (43%) women.[38]

Differences in obesity rates and fat distribution between ethnic groups are believed to be due to a genetic predisposition, which becomes apparent when such groups are

exposed to unhealthy diet and lifestyle patterns. Dietary patterns may vary between first and second generation migrants to the UK, with second generation offspring of former migrants appearing to adopt British patterns, increasing fat and reducing fat and vegetable, fruit and pulse consumption compared with first generation migrants.[82] McKeigue and coworkers[83]) showed that Indian immigrants showed increased levels of weight gain and obesity after entering the UK. Behaviours and attitudes may differ between ethnic groups. For example, African American women have been shown to have higher fat intakes, be less likely to participate in physical activities than white women and may not experience the same cultural pressures to be slim.[84]

The „Health survey for England"[38] shows that adherence to physical activity recommendations varies by ethnic group: 26% of Bangladeshi men, 30% of Indian men and 37% of black Caribbean men met physical activity recommendations compared with 37% of men in the general population; and 11% of Bangladeshi women, 23% of Indian women and 31% of black Caribbean women met the recommendations compared with 25% of women in the general population.

The results of short questionnaires included in the most recent „Health survey for England" (2004)[38] suggest that all minority ethnic groups (except the Irish) consumed significantly more fruit and vegetables and significantly less fat than the general population. However, more rigorous analysis of dietary intake by ethnicity is not available from the most recent national diet and nutrition survey (2000).[50]

Graham and Kelly[75] have noted that socioeconomic disadvantage is a major contributor to the poorer health of African Caribbean, Bangladeshi and Pakistani groups and exposure to racism is an important part of why they are more disadvantaged than the wider population.

The considerably higher risk of cardiovascular disease (CVD) for South Asian men and women in England and Wales (22% and 60% higher than Europeans, respectively) suggests that the potential gains from controlling major establish risk factors for CVD – such as obesity – could be substantial for South Asians and greater than in Europeans.[85]

The guidance for implementing the preventive aspects of the NHS framework on CHD[80] noted that the Acheson report (1998):

> „recommended that the needs of black and ethnic minority ethnic groups be considered specifically. The HEA (2000) found that among black and minority ethnic groups understanding of healthy eating messages varied widely across groups and knowledge of food high in complex carbohydrates, fibre, fat and saturated fat was often poor across all ethnic groups. There is therefore a need to raise awareness of the links between diet and CHD among these groups and to promote culturally specific messages‟. In relation to physical activity, the guidance also noted that „barriers to participation in physical activity among black and minority ethnic groups tend to be similar to many of those in other groups including lack of time and concerns about body shape. Additional barriers include racism, cultural inappropriateness (eg lack of single sex provision) the importance of family responsibilities and language issues (HEA 1997a).‟

3.6.3 Other vulnerable groups

3.6.3.1 People with learning disabilities and serious mental health problems

Obesity is more common in people with learning disabilities than in the general population: estimates range from 17% to 51% for adults[86,87], Linehan et al 2004) and 24% for children (based on 95th percentile for age).[88] Obesity is a particular issue for women and people living in more independent settings in the community rather than in institutions.[89,90] Higher levels of obesity among people with learning disabilities has been attributed to inadequate diet and low levels of physical activity, particularly among people with more severe impairments in more institutional settings.[90–92] Problems that people face in addressing obesity include insufficient income, transport problems, unclear policy guidelines in residential and day service provision, and staffing constraints.[92,93]

It is estimated that the prevalence of obesity is approximately 50% higher in people with serious mental health problems compared with the general population.[94–95] It is well established that weight gain is associated with both newer and more traditional antipsychotic medication and weight gain increases over time.[97,98] However, poor diet and lack of exercise are also likely to be contributing factors.[99]

3.6.3.2 Looked after children

Looked after children may have poor access to adequate healthcare and health promotion information. The Caroline Walker Trust[100,101] has highlighted that „Their diets are a particular cause for concern because many of them will already have experienced deprivation and poor health care before they arrived in care‟. However, there is very little information about the physical health of looked after children and young people despite evidence that they are at increased risk of ill health in adulthood.

3.7 Assessment of the evidence base

Garrow and Summerbell[37] have highlighted that:

> „A convenient, but imperfect, measure of the effectiveness of obesity treatment is the weight loss achieved during treatment, and the extent to which it is maintained after active treatment ceases. Ideally, such measurements should be made over a period of several years. It is difficult to achieve high follow-up rates over long periods, so most trials of obesity treatment are characterised by a rather high drop-out rate, and a large variability in weight loss within a group of patients on the same treatment. This makes design of good randomised control trials (RCTs) very difficult.‟

From the outset of the development of this guidance, it was known that the evidence base on effective interventions to prevent overweight and obesity was extremely limited [102, 103]. For example, based on UK data published after 1990, the Scottish Intercollegiate Guidelines Network (SIGN) 2003[103] concluded that „no study has appropriately examined specific environmental factors, such as low habitual physical activity and inappropriately high energy intake which are believed to have causal roles in the current epidemic of child obesity‟.

The WHO[34] report „Obesity: preventing and managing the epidemic‟ discussed the problems of evaluating obesity prevention programmes, noted that „at present prevalence rates of obesity are the most commonly used measures of success or failure of interventions aimed at controlling obesity. However, these have a number of serious limitations when used in isolation.‟ These include:

- the prevalence of obesity in a population is unlikely to decline in the short term
- a long time often elapses before environmental, societal and behavioural changes are reflected in population weight status
- estimates of the prevalence of and trends in obesity are often unreliable because small sample sizes reduce their accuracy.

The report concluded that „a more practical and useful outcome indicator for evaluating obesity prevention would be to combine the assessment of changes in the prevalence of overweight with short term indicators such as standardised measures of dietary change and of physical activity levels‟.

The WHO[8] subsequently reviewed the evidence on specific activity and dietary components which might promote or protect against obesity in adults and children over 2 years of age (Table 3.2).

Table 3.2 Activity and dietary components that may influence development of obesity

Evidence	Decreased risk	No relationship	Increased risk
Convincing	Regular physical activity High dietary intake of non-starch polysaccharides (dietary fibre)		Sedentary lifestyles High intake of energy-dense foods
Probable			High intake of sugar-sweetened soft drinks and fruit juices
Possible	Low glycaemic index foods	Protein content of the diet	Large portion sizes
Insufficient	Increased eating frequency		Alcohol

It was therefore agreed that the development of public health guidance on obesity should consider the effectiveness of interventions in relation to dietary and physical activity outcomes in addition to measures of weight.

4 Methodology

4.1 Introduction

This chapter sets out in detail the methods used to generate the recommendations that are presented in the subsequent chapters.

The work for this guidance was split between two project teams to give full consideration to (i) the clinical and (ii) the broader public health issues. However, the complementary nature of the work was recognised from the outset; the teams worked closely throughout the process, had the same Chair, and the final recommendations (including cost considerations) were developed jointly.

The methods are largely in accordance with those set out by the National Institute for Health and Clinical Excellence (NICE) in „Guideline Development Process – Information for National Collaborating Centres and Guideline Development Groups‟ (available at www.nice.org.uk). Where necessary, the methods were adapted as appropriate for the development for public health guidance. Where possible, it was ensured that the methods used by the project teams were consistent.

4.2 The developers

4.2.1 Clinical management

4.2.1.1 The National Collaborating Centre for Primary Care

The National Collaborating Centre for Primary Care (NCC-PC) is based at the Royal College of General Practitioners (RCGP) and has an academic partner, the Clinical Governance Research and Development Unit (CGRDU), Department of Health Sciences, University of Leicester. Its other partner organisations are the Royal Pharmaceutical Society of Great Britain and the Community Practitioners‟ and Health Visitors‟ Association. The Collaborating Centre was set up in 2000, to undertake commissions from NICE to develop clinical guidelines for the National Health Service (NHS) in England and Wales.

This guidance was developed jointly by the CGRDU, Department of Health Sciences, University of Leicester and the College Managed Unit of the NCC-PC. The NCC-PC project team consisted of the Project Lead (Clinical Director of the NCC-PC/Senior Lecturer in General Practice), one Senior Systematic Reviewer (Research Fellow, University of Leicester), one Systematic Reviewer (Research Fellow, NCC-PC, College Managed Unit, RCGP), one Information Librarian (Research Associate, University of Leicester), one Health Economist (NCC-PC, College Managed Unit, RCGP) and one Project Manager (NCC-PC, College Managed Unit, RCGP).

4.2.2 Public health

4.2.2.1 The Centre for Public Health Excellence

The Centre for Public Health Excellence (CPHE) was established when the functions of the Health Development Agency (HDA) transferred to NICE. The project team which initiated the development of the guidance at the HDA transferred directly to the CPHE. The project team included the Director of the CPHE, a Technical Lead (an Analyst at CPHE), analysts within the CPHE, and the Associate Director for Methodology at the CPHE.

4.2.2.2 Collaborating centres and external contractors

The CPHE was supported in collating the evidence on which the public health recommendations were based by two public health collaborating centres (PHCCs), one based at Cardiff University and the other based at the University of Teesside. Each PHCC produced a series of evidence reviews on a range of sub-topics to address the public health questions identified by the Guidance Development Group (GDG). On an approximately 12-weekly cycle, each PHCC searched for and synthesised the evidence base for a particular sub-topic as agreed with the CPHE and the GDG. **Two PHCCs were appointed so that the evidence could be provided to the GDG prevention subgroup meetings at 6 weekly intervals.** Members of the PHCC attended each GDG meeting.

An additional evidence review was commissioned from the Centre for Reviews and Dissemination at the University of York on the management of obesity in non-clinical

settings. A review of the available health economic evidence and subsequent modelling was undertaken by the Health Economics Consortium at the University of York.

4.2.3 Joint working

The Scope for this work was developed jointly by the HDA and the NCC-PC. A joint CPHE/NCC-PC steering group for the guidance was subsequently established which consisted of the Chair of the GDG and members of the NCC-PC and CPHE project teams. The final draft guidance was written jointly by the NCC-PC and the CPHE project teams (the latter supported by the CPHE collaborating centres). Editorial responsibility for the guidance rested solely with the project teams.

4.2.4 The Guidance Development Group

To address the broad nature of the task, the GDG consisted of two subgroups which functioned as two separate GDGs – one addressing clinical management and the other addressing prevention and public heath issues. One Chair, a senior public health physician of national standing, identified jointly by the NCC-PC and HDA, oversaw the work of both groups.

Nominations for group members were invited from various stakeholder organisations, selected to ensure an appropriate mix of members. For the clinical subgroup this included healthcare professionals and patient representatives. For the public health subgroup this included health professionals and planning, local government, school, physical activity and consumer representatives. In view of the number of organisations that needed to contribute to the guidance, nominations were also received for co-opted experts. Each nominee was expected to serve as an individual expert in their own right and not as a representative of their parent organisation, although they were encouraged to keep their nominating organisation informed of the process. Co-optees contributed to aspects of the guidance development but did not sit on the GDG and were not involved in the final wording of recommendations. Group membership and co-optee details can be found in the preface to the guidance.

The GDG met on 14 occasions, at approximately 6-weekly intervals over 16 months to review the evidence identified by the project teams, to comment on its quality and completeness and to develop recommendations for practice based on the available evidence. In order to generate separate recommendations for adults and children, the clinical GDG was divided into adult and child subgroups. Each subgroup met to discuss the evidence reviews and to make preliminary recommendations.

Three joint GDG meetings were held to ensure consistency in the development of the clinical and public health guidance. The final recommendations were agreed by the full GDG. All GDG members made a formal „Declaration of interests" at the start of the guidance development and provided updates throughout the development process.

4.3 Developing key questions

The first step in the development of the guidance was to refine the Scope into a series of key questions. The key questions formed the starting point for the subsequent evidence reviews and facilitated the development of recommendations by the GDG.

In relation to the clinical arm of the work, the key questions reflected the clinical care pathway for children and adults. For public health, the key questions reflected stages through the life course and/or settings providing opportunities for intervention. Furthermore, the public health questions specifically addressed (i) the evidence in relation to weight outcomes and (ii) the evidence in relation to diet and activity outcomes.

The key questions were developed by the GDG with assistance from the project teams. As necessary, the questions were refined into specific research questions by the project teams to aid literature searching, appraisal and synthesis. The full list of key questions is shown in Appendix 2.

It was clear from the outset that a full literature search and critical appraisal could not be undertaken for all key questions due to the time and resource limitations within the guidance development process. The GDG and project teams therefore agreed

appropriate review parameters (inclusion and exclusion criteria) for each question or topic area.

4.4 Identifying the evidence

4.4.1 Literature search and evidence reviews

The aim of the literature review was to identify the most relevant, published evidence in relation to the key clinical questions generated by the GDG. Due to time constraints, full systematic reviews were not undertaken. However, the evidence reviews were undertaken using systematic, transparent approaches. The methods used by the clinical and public health project teams to search and review the literature varied to some extent, but overall consistency was ensured, as outlined below. Details of all literature searches for clinical reviews are available from the NCC-PC; details of all specific searches for public health reviews are annexed with review tables. Further references were also suggested by the GDG. Evidence submitted by stakeholder organisations that was relevant to the key questions and was of at least the same level of evidence as that identified by the literature searches was also included.

4.4.1.1 Clinical

In line with the Scope, literature searches were undertaken to produce an evidence review on each of the following key topic areas:

- Identification and classification of children and adults who were overweight or obese
- Lifestyle interventions for the management of overweight and obesity
- Pharmacological interventions for the management of overweight and obesity
- Surgical interventions for the management of overweight and obesity
- Professionally led complementary medicine interventions for the management of overweight and obesity

Other more restricted reviews were undertaken for the remaining key clinical questions. The findings of each of the reviews are summarised in Sections 2 and 5.

The specific search strategy for each topic area varied and was agreed with the Methods Team (with input from the GDG as necessary). A pragmatic approach was taken in defining the time period for searches and the included study types and outcome measures. The review parameters were agreed with the GDG and aimed to provide the best available evidence**. Where specific parameters were applied, the details are reported in the evidence review.**

In summary, reviews included:

- systematic reviews from 1995 and single studies (predominantly randomised controlled trials (RCTs) and non-randomised trials). No time restriction was applied for the Adult reviews, but Child reviews were limited to studies published since 1985
- studies which reported outcome measures of weight change (in kilograms for adults, and using any appropriate measure for children)
- studies with at least 12 months follow-up for adults, and 6 months for children.

Updated searches were conducted for references published during the course of the guidance development and a final search date of 1st December 2005 was agreed across all of the reviews. Because of the amount of literature reviewed and identified in the Update searches, only those studies where evidence statements (and therefore recommendations) needed substantial revisions were added in detail. Where studies were relevant, but did not alter the evidence summaries, these were noted in the narrative.

4.4.1.2 Public health

In line with the Scope, literature searches were undertaken to produce an evidence review on each of the following topic areas:

- Identification of children and adults at risk of obesity
- Raising awareness of weight, diet and activity
- Determinants of energy balance
- Interventions among children aged 2–5 years and families
- School-based interventions
- Workplace-based interventions
- Community-based interventions led by health professionals
- Broader community-based interventions
- Interventions among black and minority ethnic groups, vulnerable groups and at life stages with increased risk for weight gain.
- Management of obesity in non-clinical settings.

The findings of each of the reviews are summarised in Sections 2–4.

Reviews were undertaken over approximately 10–12 weeks. The specific search strategy for each topic area varied and was agreed with the CPHE (with input from the GDG as necessary). A pragmatic approach was taken in defining the time period for searches and the included study types and outcome measures. The review parameters were agreed with the GDG and aimed to provide the best available evidence in the time available. **The parameters are shown in detail in Appendix 2.** In summary, reviews included:

- systematic reviews from 1995 and single studies (predominantly RCTs and non-randomised trials) from 1990 – reflecting the period in which obesity has increased most significantly in England.
- studies which had outcome measures of weight, diet and/or physical activity.

- UK-based „corroborative"-type evidence (such as surveys, cases studies and qualitative work) to assess issues such as barriers and facilitators to implementation.

In line with the clinical reviews, a final search to December 2005 was undertaken and the reviews were updated accordingly.

A key difference in the review parameters between the clinical and public health reviews was that the clinical reviews tended to only include interventions with at least 1 year follow-up whereas the public health reviews included interventions with at least 3 months" follow-up. Three months would generally be regarded as being too short for confident measurement of changes in body fatness in **individuals**. However, the public health reviews focus on the measurement of **group** changes over time; these are measurable over a period as short as 3 months.

4.4.2 Health economics

Separate clinical and public health reviews were conducted to assess the state of the economic evidence, given that in the main searches this evidence was limited. The reviews were undertaken by the health economists in each project team, liaising with other members of the project teams as appropriate. Given the limited economic evidence in the area it was decided to perform a broad search for evidence that was designed to identify information about the costs or resources used in providing a service or intervention and/or the benefits that could be attributed to it. No criteria for study design were imposed a priori. In this way the searches were not constrained to RCTs or formal economic evaluations. Papers included were limited to papers written in English and health economic information that could be generalised to UK on obesity prevention and management.

4.5 Reviewing and grading the evidence

The titles and abstracts of records retrieved by the searches, suggested by the GDG or submitted by stakeholders were scanned for relevance to the key questions. Any potentially relevant publications were obtained in full text. These were reviewed to

identify the most appropriate evidence to help answer the key questions and to ensure that the recommendations were based on the best available evidence. This process required four main tasks: selection of relevant studies; assessment of study quality; synthesis of the results; and grading of the evidence. The methods used by the project teams are outlined below.

For both groups, the primary outcome measure was BMI, weight and/or waist circumference. Other reported anthropometric outcomes (such as skinfold thickness) were also considered where available. As discussed earlier, dietary and physical activity outcomes which may promote or protect against obesity were also considered key outcome measures within the public health reviews. In the clinical reviews, such measures were considered secondary outcomes, as were any relevant health indicators, such as measurements of blood pressure or blood cholesterol. Any additional information on factors which may have influenced the study results and had an impact on the wider implementation of an intervention, such as participants‟ age, ethnicity or social status; the staff involved in the intervention; dropout rates and payments or rewards given to participants, were recorded in the evidence tables considered by the GDG.

4.5.1 Review of the clinical evidence

The searches were first sifted by the systematic reviewers to exclude papers that did not relate to the scope of the guidance. The abstracts of the remaining papers were scrutinised for relevance to the key questions under consideration. Initially both systematic reviewers reviewed the abstracts independently. This proved impractical as the guidance progressed and the task was delegated to the systematic reviewer responsible for each section. The project lead was asked to review the abstracts in cases of uncertainty.

The papers chosen for inclusion were obtained and assessed for their methodological rigour against a number of criteria that determine the validity of the results. These criteria differed according to study type and were based on the checklists included in the NICE Technical Manual, „Guideline Development Methods – Information for National

Collaborating Centres and Guideline Developers„ (available from www.nice.org.uk). Critical appraisal was carried out by the systematic reviewers. Further appraisal was provided by the GDG members at and between the GDG meetings.

The data were extracted to standard evidence table templates. The findings were summarised by each systematic reviewer into a series of evidence statements and an accompanying narrative review. Where appropriate, a quantitative synthesis was conducted and checked by a consultant statistician.

4.5.2 Review of the public health evidence

Each evidence review:

- critically appraised the included studies
- identified what components are effective for which groups and in which settings
- identified the inputs and process issues which had an impact on the development and delivery of effective interventions

The hits from the database search were saved. Papers that were clearly inappropriate were excluded at this stage. Full copies of papers that could not be excluded with confidence at this stage were ordered. The full papers were reviewed against an IN/OUT form. Papers were categorised into (i) excluded (ii) included (iii) unclear/require further information. Each included paper was critically appraised using the relevant NICE checklist (except longitudinal studies within some reviews which were appraised using the tool developed by Tooth and coworkers 2005[106}; and the studies in the „energy balance" review were not critically appraised due to the quality element of the inclusion criteria – see review for details). In addition, data from each paper was extracted onto a proforma. Relevant information from the checklist and the proforma for each included study was then summarised for GDG members in evidence tables, evidence statements and narrative summaries. Critical appraisal and data extraction was carried out by one reviewer and any queries discussed with another reviewer. Data

extraction into standard evidence tables was also double checked against the original study papers.

The evidence tables, statements and summaries provided the GDG with:

- synthesis of key findings
- discussion of the strengths and weaknesses of the evidence
- identification of any gaps in the evidence base
- an assessment of how up to date the evidence is
- identification of consensus or dispute around the evidence
- an initial assessment of the available evidence on cost effectiveness.

Only a few public health RCTs met the NICE critical appraisal criteria in full and it was rarely possible to be certain that, as required by the NICE critical appraisal processes, the overall effect was due to the study intervention. Studies often lacked (or failed to report) a description of the randomisation process, concealment allocation and/or an intention to treat (ITT) analysis. Following agreement with NICE and the public health GDG, RCTs with no ITT but with 80% or more follow-up were downgraded in quality assessment but not downgraded to non-randomised controlled trials (CCTs). Studies with no ITT and less than 80% follow-up were downgraded to CCTs. The lack of description of randomisation and/or concealment allocation also led to a downgrading but not automatic rejection. Detailed guidance for appraisers on the use of the critical appraisal forms for public health research studies is under discussion within NICE.

4.5.3 Grading the evidence

The findings were summarised into a series of evidence statements by the project teams. The evidence statements were graded according to an established hierarchy of research designs (Table 4.1). The grades were considered by the GDG and amended if necessary.

Table 4.1 Levels of evidence for intervention studies

Level of evidence	Type of evidence
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs or RCTs with a low risk of bias)
1–	Meta-analyses, systematic reviews of RCTs or RCTs with a high risk of bias[a]
2++	High-quality systematic reviews of non-RCT, case–control, cohort, CBA or ITS studies
	High quality non-RCT, case–control, cohort, CBA or ITS studies with a very low risk of confounding, bias or chance and a high probability that the relation is causal
2+	Well-conducted non-RCT, case–control, cohort, CBA or ITS studies with a very low risk of confounding, bias or chance and a moderate probability that the relation is causal
2–	Non-RCT, case–control, cohort, CBA or ITS studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal[a]
3	Non-analytic studies (for example, case reports, case series)
4	Expert opinion, formal consensus

[a] Studies with a level of evidence „–" should not be used as a basis for making a recommendation.

RCT – randomised controlled trial; CBA – controlled before-and-after; ITS – interrupted time series

For each question, the highest level of evidence was selected. If a systematic review, meta-analysis or RCT existed in relation to the question being asked, studies of a weaker design were ignored. Where the evidence base was limited questions were addressed by the identification of published expert narrative reviews by the project team and/or the GDG which formed the basis of discussion papers written either by the project lead or by a member of the GDG.

4.5.3.1 Additional considerations for clinical management

Due to paucity of evidence for interventions in children, the GDG recommended that we considered lower levels of evidence throughout the reviews because of the limitations of the higher-level evidence available. Similarly in the reviews on surgical interventions for adults, we considered longer-term case series (lower-level evidence) in addition to higher level RCTs to provide the GDG with evidence on the long-term complications for each procedure.

Summary results and data are presented in the guidance text. More detailed results and data are presented in the evidence tables.

A number of key clinical questions could not appropriately be answered using a systematic review, for example, where the evidence base was very limited. These questions were addressed by the identification of „published expert" narrative reviews by the project team and/or GDG which formed the basis of discussion papers written either by the project lead or the systematic reviewers.

4.5.3.2 Additional considerations for public health

A parallel scale for grading evidence for public health, policy and practice does not exist at present. A review of the grading of public health evidence and recommendations[104] indicated general agreement that the RCT has the highest internal validity and, where feasible, is the research design of choice when evaluating effectiveness. However, it was acknowledged that „gold standard" RCTs cannot be readily performed in public health interventions (particularly community-based programmes) for feasibility, cost and practical reasons. Furthermore, RCTs tend to be limited to questions of efficacy; they are less useful, and hence less appropriate, when considering external validity and issues of implementation. Thus reviews of evidence for public health interventions tend to be dominated by „lower" levels of evidence.

NICE is currently considering the methods used to assess evidence and prioritise recommendations that may be applied across all types of question, leading to both clinical and public health recommendations (see www.nice.org.uk/pdf/boardmeeting/brdnov05item4.pdf). In relation to the development

of public health recommendations on obesity, it was also agreed that the rapid reviews of the evidence should actively incorporate corroborative evidence (from observational and qualitative studies) for the feasibility and likelihood of success of an intervention if implemented in the UK.

4.6 Developing recommendations

For each key question, recommendations were derived from the evidence summaries and statements presented to the GDG.

Each recommendation was linked to an evidence statement. The GDG was able to agree recommendations through informal consensus, taking cost effectiveness considerations into account. Where there was a lack of evidence of effectiveness, but the GDG was of the view that a recommendation was important based on the GDG members" own experience and/or the availability of UK-based corroborative evidence (such as surveys, case studies), this was highlighted as „opinion of the GDG" .

4.6.1 Clinical

Clinical recommendations were drafted for the NHS only.

4.6.2 Public health

Public health recommendations were drafted for both the NHS and non-NHS settings. Recommendations were developed with five separate groups in mind, based on their status and ability to implement recommendations (Table 4.3).

Table 4.3 Details of the five groups for which the public health recommendations were drafted

Group 1	NHS	NHS organisations are **strongly advised** to implement recommendations. Recommendations fall under „developmental standards" – standards which the NHS is expected to achieve over time

Group 2	Public bodies; local authorities; government, government agencies and arms length bodies; forces, prisons and police service	Organisations are **strongly encouraged** to implement recommendations
	Schools, colleges and childcare in early years settings	Public organisations and schools were previously outside the remit of NICE. However, with the remit of the new organisation, discussions between NICE, the Department of Health and relevant organisations on the status of recommendations directed at this group are ongoing
Group 3	Private and voluntary organisations: large employers (more than 250 employees)	Organisations are **strongly encouraged** to implement recommendations. Large private and voluntary organisations are outside the remit of NICE It should be noted that although reducing obesity is not the main aim of most workplaces, and that workload and time pressures for staff and organisations is substantial, addressing these issues is in line with standard business „good practice" approaches such as good corporate citizenship, reducing staff ill health and reducing workplace costs due to sickness and absences
Group 4	Private and voluntary organisations: small and medium employers (fewer than 50 and fewer than 250 employees, respectively)	Organisations outside the remit of NICE are advised that the recommendations outlined are **best practice** The difficulties for small organisations in implementing some recommendations is recognised, particularly for those without an occupational health worker
Group 5	Consumers including parents, the media and others providing advice for individuals/population groups	Recommendations directly for parents and consumers are ***best practice***. The role of the media and other non health professionals in the provision of advice/awareness raising is recognised through a number of recommendations.

4.7 Relation between the guidance and technology appraisals

This guidance was required to update the following NICE technology appraisals:

- National Institute for Clinical Excellence (2001). „Guidance on the Use of Orlistat for the Treatment of Obesity in Adults‟. *NICE technology appraisal* no. 22.
- National Institute for Clinical Excellence (2001). „Guidance on the Use of Sibutramine for the Treatment of Obesity in Adults‟. *NICE technology appraisal* no. 31.
- National Institute for Clinical Excellence (2002). „Guidance on the Use of Surgery to Aid Weight Reduction for People with Morbid Obesity‟. *NICE technology appraisal* no. 46.

The objective for the GDG in updating these appraisals was to determine whether any new evidence that had become available since the publication of the appraisal warranted a change to the original recommendations. To achieve this the NCC-PC health economist updated the models of the original appraisal (when available from NICE). Changes to the original appraisal recommendations are clearly documented in the full version of the guidance. The guidance recommendations resulting from this update process are graded as considered appropriate by the guidance developers. Once the Obesity Guidance is published the existing technology appraisals will be withdrawn by NICE.

4.8 Relation between the guidance and national service frameworks

The existing national service frameworks (NSFs) contain standards which are of relevance to the prevention and management of obesity, particularly those on CHD, cancer, diabetes, and children. However, the aims of the guidance and the NSFs differ. The guidance aims to assist decisions about appropriate healthcare or preventive strategies for clinical and public health settings. Conversely, the NSFs are primarily concerned with service delivery, which is outside the Scope of the guidance.

4.9 Relation between the guidance and 'Choosing health'

The 2004 Public Health White Paper, „Choosing health",[2] reiterated the commitment for NICE to publish guidance on the prevention and management of obesity. A commitment was also made to producing a care pathway for the local management of obesity; the pathways to be circulated by the Department of Health will be superseded by the care pathways presented in the final version of this NICE guidance. In many instances the recommendations made in this guidance will support the implementation of other commitments made in „Choosing health".

4.10 External review

The guidance has been developed in accordance with the NICE guideline development process. This has included allowing registered stakeholders the opportunity to comment on the Scope and the draft guidance. In additional the first draft was reviewed by an independent Guideline Review Panel (GRP) established by NICE.

The comments made by stakeholders, peer reviewers and the GRP were collated and presented anonymously for consideration by the GDG. All comments were considered systematically by the GDG and the Project Team recorded the agreed responses.

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Section 2: Identification and classification

Identification and classification

5.1 A: Clinical

5.1.1 Evidence statements

5.1.1.1 Children (Table 5.1)

Table 5.1 Evidence statements and grading

No.	Evidence statement	Grade
Body mass index (BMI)		
1	BMI is a widely accepted and practical estimate of general adiposity in children	2++
2	Different classifications using BMI centile cut-offs have been proposed for children, but there is no evidence on which are the most appropriate in practice	2++
3	There is limited evidence on which BMI measure (BMI, percentage change BMI, BMI z-score or BMI centile) is best at measuring adiposity change	3
4	Some evidence suggests that the IOTF/Cole and the WHO BMI-based systems have high specificity which can lead to fewer non-overweight adolescents being classified as overweight	3
5	There is no evidence on ethnicity differences in the association of proxy measures of obesity with morbidity in children in UK populations	N/A

No.	Evidence statement	Grade
Waist circumference		
6	There is limited evidence on the utility of waist circumference compared with BMI in children, but its use is not widely accepted. Expert consensus is that waist circumference alone is not recommended in children, due to problems with measurement validity and reliability	4 (expert opinion)
1.1.7	There are no proposed evidence-based cut-offs for waist circumference measurements in children	2++
Bioimpedance		
8	There is no evidence on the utility of bioimpedance compared with BMI in children	N/A

IOTF, International Obesity Taskforce; NA, not applicable; WHO, World Health Organization.

5.1.1.2 Adults (Table 5.2)

Table 5.2 Evidence statements and grading

No.	Evidence statement	Grade
Body mass index (BMI)		
1	BMI is a widely accepted measure of general adiposity in adults	2++
2	Adults with a BMI of 25 kg/m^2 or over are overweight. Adults with a BMI of 30 kg/m^2 or over are obese	2++
3	Further classifications of obesity by BMI in adults are as follows: Obesity, class I 30–34.9 Obesity, class II 35–39.9 Obesity, class III ≥40	4

No.	Evidence statement	Grade
4	There is no accepted definition for classification using BMI in older people.	2++
Waist circumference		
5	Waist circumference is a useful measure of central adiposity in adults	3
6	Men with a waist circumference of 94 cm or more are at increased risk of health problems. If their waist circumference is 102 cm or more, even at a healthy weight (BMI 18.5–25 kg/m^2) they are at increased risk	2++
7	Women with a waist circumference of 80 cm or more are at increased risk of health problems. If their waist circumference is 88 cm or more, even at a healthy weight (BMI 18.5–25 kg/m^2) they are at increased risk	2++
Other measurements		
[The Guidance Development Group (GDG) wanted evidence on the diagnostic accuracy of other anthropometric measurements and bioimpedance compared with the gold standard of BMI.]		
8	Waist-to-hip ratio is a useful measure of central adiposity in adults, but is more difficult to measure	3
9	There is no evidence on the utility of bioimpedance compared with BMI in adults	N/A
Opportunistic screening		
10	There is no evidence on the effectiveness of opportunistic screening	N/A
Different cut-offs in different ethnic groups		
11	In first generation migrants from Pakistan to the UK, a given BMI is associated with greater truncal adiposity than in the white population	3

No.	Evidence statement	Grade
12	In South Asians (of Pakistani, Bangladeshi and Indian origin) living in England, a given waist circumferences tends to be associated with more features of metabolic syndrome than in Europeans (for example, higher triglycerides and lower HDLs in females and higher serum glucose in males)	2
13	In South Asians living in South Asia, a given BMI tends to be associated with higher percentage body fat than in European populations	3
14	In black populations, for a given BMI, percentage body fat tends to be higher in those living in the USA than in Jamaica. It also tends to be higher in Jamaicans compared with rural Nigerians	2

HDL, high-density lipoprotein; NA, not applicable.

5.1.2 Methodology

We searched for high-quality systematic reviews of the evidence, and these are summarised below. We also searched for evidence published since the cut-off dates of the included reviews and evidence to answer key clinical questions not addressed in the reviews. Where appropriate, expert opinion is cited. Details can be found in the evidence review for each section. We did not retrieve any study from the update searches that modified any of the recommendations.

5.1.3 Evidence review on different anthropometric measures for the identification of individuals who are overweight or obese

There is growing evidence that links body composition, specifically the levels of fat tissue in the human body, with increased health risks and the development of certain diseases (see also section 5.1.5). The amount of body fat in the human body is called adiposity. Adiposity is defined as the amount of body fat expressed as either the absolute fat mass (in kilograms) or as the percentage of total body

mass. Absolute adiposity is highly correlated with body mass, but percentage adiposity is relatively uncorrelated with body mass.[1]

There are many methods of **directly** measuring the amount of fat in the human body. These usually involve complicated procedures that can only be carried out in specialist laboratories.

Indirect methods, based on the relation between height and weight, can be used in everyday clinical practice to estimate adiposity. The most common and accepted, at least in adults, measures are those of body mass index (BMI) and waist circumference.

BMI is calculated as the weight (in kilograms) divided by the height (in metres) squared. For example, an individual who weighs 95 kg and is 180 cm tall has a BMI = $95/(1.80 \times 1.80) = 95/3.24 = 29.32$ kg/m^2. So the person's BMI is approximately 29 kg/m^2.

A simple measure of fat distribution is waist circumference. This can be related to the overall body shape of the individual by calculating the ratio of the waist to the hip (waist-to-hip ratio).

Different methods may be appropriate in different circumstances. For example, waist-to-hip ratio may be the most accurate predictor of risk of myocardial infarction,[2] and waist circumference may be the most accurate predictor of risk of type 2 diabetes.[3]

5.1.3.1 Identification and measurement of children who are overweight or obese

We were not able to find any other systematic reviews that addressed the accuracy of anthropometric measures or bioimpedance to diagnose obesity compared with the use of BMI in children.

The National Health and Medical Research Council (Australia) (NHMRC)[4] stated that although there was no evidence to recommend specific cut-offs, it recommended that BMI should be the standard measure for children. BMI is a measure of weight adjusted for height and is highly correlated with adiposity.

Limitations of the BMI, include: not being able to distinguish between fat or lean mass, not necessarily reflecting fat distribution (which may or may not be associated with age), and not necessarily describing the same levels of body fat in different populations because of different body proportions. Both the United States Preventive Services Task Force (USPSTF) 2005[5] and Freedman and coworkers[6] reiterated these limitations. Freedman and coworkers[6] pointed out pitfalls in their assessment of the relation of BMI to levels of fat mass and fat-free mass among healthy 5–18-year-olds. By measuring fat and fat-free mass by dual-energy X-ray absorptiometry they found that the correlation of BMI to fat mass was clearly non-linear, and that substantial differences in fat mass were only observed at BMI levels equal to or more than the 85th percentile. Thus, the authors contended that despite BMI-for-age being a good estimate of excess fat mass, BMI differences among thinner children can be partly associated with fat-free mass.[6]

For measurement of central adiposity, waist circumference was recommended but, as for BMI, no cut-offs were specified. The role of bioimpedance was reviewed and several limitations were highlighted: equations used to convert resistance to body fat should be population specific but these may not always be available; it may add little to anthropometric measures; hydration status can affect results; results can be unreliable at extremes of body weight. Concern was also raised that bioimpedance may be used by operators who are not aware of these limitations.[4] The USPSTF also stated that 'indirect measures of body fat, such as skinfold thickness, bioelectrical impedance analysis, and waist-hip circumference, have potential for clinical practice, treatment, research, and longitudinal tracking, although there are limitations in measurement validity, reliability, and comparability between measures'.[5]

The Scottish Intercollegiate Guidelines Network (SIGN) guidelines[7] only considered the use of BMI as 'there is no clear threshold for waist circumference associated with morbidity outcome in children'. However, the strict use of BMI in children can underestimate the prevalence of obesity in young people. McCarthy and coworkers[8;9] compared changes in waist circumference and BMI in British youth through cross-sectional surveys in 1977, 1987 and 1997. They found that

trends in waist circumference significantly exceeded the figures for BMI in the past 10–20 years. Another study published by Rudolf and coworkers,[10] followed a cohort of British schoolchildren for 6 years, and found that both BMI and waist circumference increased significantly.

The clinical practice guidelines of the Ministry of Health of Singapore recommended BMI-for-age and gender charts to be used in children.[11]

A recent study published by Neovius and coworkers[12] in which a cross-sectional analysis was performed in 474 healthy adolescents aged 17 years, showed that both BMI and waist circumference had strong correlation with percentage body fatness in both girls and boys, but that the correlation was not so apparent for waist to hip ratio. Moving on from this the authors contended that for BMI and waist circumference, sensitive and specific cut-offs of obesity can be derived, whilst larger trade-offs were required to detect overweight in girls.

5.1.3.2 Identification and measurement of adults who are overweight or obese

The NHMRC[13] reviewed the evidence for different anthropometric measures in the identification of overweight or obesity in adults.

On the basis of the evidence, the NHMRC concluded that:

- BMI was highly, but not perfectly, correlated with adiposity
- limitations of the BMI included not being able to distinguish between fat or lean mass, not necessarily reflecting fat distribution (which may or may not be associated with age), and not necessarily describing the same levels of body fat in different populations because of different body proportions.

Because of these limitations, they recommended that:

> ‘BMI is an acceptable approximation of total body fat at the population level and can be used to estimate the relative risk of disease in most people. However, it is not always an accurate predictor of body fat or fat distribution, particularly in muscular individuals, because of differences in body-fat proportions and distribution.’[13]

The evidence on waist circumference showed a positive correlation with risk of disease. However, when the BMI was greater than 35 kg/m^2, waist circumference did not add to the absolute measure of risk. The conclusions reached were:

> 'waist circumference is a valid measure of abdominal fat mass and disease risk in individuals with a BMI less than 35. If BMI is 35 or more, waist circumference adds little to the absolute measure of risk provided by BMI.'[13]

No evidence on the use of bioimpedance was reported.

Similarly, the National Institutes of Health (NIH) guidelines[14] found that BMI gave a reasonable approximation of adiposity in most people and that waist circumference was the most practical measurement for assessing abdominal fat. Again, bioimpedance was not considered.[14]

In older people,[15] the evidence was summarised as follows:

> 'Primary limitations to use of BMI in diagnosing obesity in the elderly include a lower correlation with percentage body fat in the old than in the young, and a weaker association with cardiovascular mortality, as well as several intermediaries of cardiovascular morbidity than measures of central adiposity (waist circumference or waist-to-hip ratio).
>
> While the correlation between BMI and body fat percentage drops with age, most data show a reasonable correlation persists. In addition, body fat percentage is generally more closely correlated with BMI or waist circumference than other common obesity diagnostic tests in the elderly. Likewise, BMI is the diagnostic measure linked with the broadest range of subsequent health states. Some of these outcomes (e.g., incident functional disability) have not been evaluated by waist-to-hip ratio or waist circumference; others (e.g., hip fracture incidence in women) are linked with BMI, but not with waist-to-hip ratio or waist circumference (likely reflecting that generalized, not central, obesity is important in their aetiology).'[15]

We were not able to find any other systematic reviews that addressed the accuracy of anthropometric measures or bioimpedance to diagnose obesity compared with the gold standard of BMI in adults.

We found several primary studies that assessed the utility of waist circumference and/or waist-to-hip ratio to classify people as obese or overweight compared with classification by BMI.[16-26]

None of the included studies scored highly when quality assessed (using diagnostic study criteria), as blinding was not done, which was assumed to be a practical problem with this type of measurement. This may have affected the accuracy of the measurements, particularly with waist circumference. However, most studies did report that the assessors were trained, and in some cases, the results were validated.

Overall, the utility of other measures compared with BMI varied, particularly with sex and age. In general, the use of measures such as waist circumference or waist-to-hip ratio only would not classify someone as overweight or obese who was not. However, the use of these measures would miss a proportion of people who were at increased risk if assessed using BMI alone. The use of waist-to-hip ratio appeared to be less useful than waist circumference.

Since we initially reviewed the evidence, the National Guideline Clearing House has produced a synthesis of guidelines relating to obesity in adults,[27] and a comparison of the different recommendations relating to measurement can be seen in Table 5.3.

Table 5.3 Comparison of recommendations in the key measures (weight, body mass index (BMI), waist circumference)[a]

ACP (2005)	No recommendations offered. ACP refers to the USPSTF guidelines for screening for obesity in adults
ACPM (2001)	Periodic measurement of BMI (weight in kilograms/height in metres^2) is recommended for all adults

AGA (2002)	A medical evaluation is needed to identify patients who either have, or are at risk for, obesity-related medical complications. This assessment should include a careful history, physical examination (including determination of BMI), and laboratory tests to identify eating and activity behaviours, weight history and previous weight loss attempts, obesity-related health risks, and current obesity-related medical illnesses
BWH (2003)	*BMI*. The BMI is the recommended approach for assessing body size in the clinical setting, providing a more accurate measure of body size than weight alone. However, it can overestimate body fat in people who are very muscular, very short, or who have oedema, and it underestimates it in people who have lost muscle mass, such as the elderly. *Waist circumference*. Excess abdominal fat carries particularly elevated health risks. Waist circumference is the most practical marker of abdominal fat. (Many patients understand this concept as ‘apple’ versus ‘pear’ shaped.) A waist circumference greater than 88 cm (> 35 inches) raises cardiovascular disease risk in women Ethnic and age-related variations in distribution of body fat affect the predictive value of waist circumference. Waist circumference may be a better indicator of risk than BMI for estimating obesity-related disease risk among certain populations, such as Asian–Americans and older people. Waist cut-offs designed for the general population may not apply to very short women (under 1.5 m [5 feet])

Singapore MOH (2004)	BMI is the recommended index to define overweight and obesity. It is minimally correlated with height and highly correlated with body fat percentage and levels of disease risk of comorbidities. Body weight alone can be used to follow weight loss and to determine efficacy of therapy (grade B, level III) Waist circumference is the most practical anthropometric measurement for assessing a patient's abdominal fat content before and during weight loss treatment. Gender-specific waist circumference cut-offs should be used in conjunction with BMI to identify increased disease risk (grade B, level III)
USPSTF (2003)	The USPSTF found good evidence that BMI, calculated as weight in kilograms divided by height in metres squared, is reliable and valid for identifying adults at increased risk for mortality and morbidity due to overweight and obesity Central adiposity increases the risk for cardiovascular and other diseases independent of obesity. Clinicians may use the waist circumference as a measure of central adiposity. Men with waist circumferences greater than 102 cm (> 40 inches) and women with waist circumferences greater than 88 cm (> 35 inches) are at increased risk for cardiovascular disease. The waist circumference thresholds are not reliable for patients with a BMI greater than 35 kg/m^2

[a] Adapted from the National Guideline Clearinghouse guideline synthesis on the assessment and treatment of obesity and overweight in adults.[27]

ACP, American College of Physicians; ACPM, American College of Preventive Medicine; AGA, American Gastroenterological Association; BWH, Brigham and Women's Hospital; MOH, Ministry of Health; USPSTF, United States Preventive Services Task Force.

5.1.3.3 Effectiveness of opportunistic screening on health outcomes

We did not find any guidelines that issued recommendations on the effectiveness of opportunistic screening in the identification of people who are overweight or obese.

We identified randomised controlled trials (RCTs) from the Cochrane review[28] on improving management for people who are overweight or obese that may have had an element of opportunistic screening in the intervention arm of the trial. Only one was considered relevant, but follow-up was less than our inclusion criteria of 12 months so was subsequently excluded.[29] We also searched for RCTs citing a Little 1998 paper,[30] which concluded that measurement of obesity in the general population was not likely to improve risk assessment or patient knowledge significantly. Again, no RCTs were identified that evaluated the effectiveness of opportunistic screening.

Other policy initiatives

GMS2 contract

Two indicators in the Quality and Outcomes Framework[31] (QOF) of the revised contract for general practitioners (GMS2) require an assessment of obesity:

OB1: The practice can produce a register of patients aged 16 and over with a BMI greater than or equal to 30 in the previous 15 months.

DM 2 The percentage of patients with diabetes whose notes record BMI in the previous 15 months.

The rationale given for DM 2 was that:

> ‘Weight control in overweight subjects with diabetes is associated with improved glycaemic control. There is little evidence to dictate the frequency of recording but it is general clinical practice that BMI is assessed at least annually.’[31]

National Service Frameworks

The National Service Framework for Coronary Heart Disease (www.dh.gov.uk) stated that general practitioners and primary care teams should identify all people with established cardiovascular disease and offer them appropriate advice and treatment to reduce their risks.

The National Service Framework for Diabetes (www.dh.gov.uk) stated that the opportunistic screening of people with multiple risk factors for diabetes can lead to the identification of some individuals with previously undiagnosed diabetes.

The rationale given for this was that:

> 'People who have multiple risk factors for diabetes – family history, obesity, ethnic background, increasing age – also require advice and support to decrease their risk of developing diabetes and information about the symptoms and signs of diabetes. Moreover, opportunistic screening will identify those who are unaware of their condition. Opportunistic screening can help, although there is the need for a more systematic approach to administer screening.'

National Screening Committee

The National Screening Committee (www.nsc.nhs.uk) does not currently recommend screening for obesity for children or adults.

5.1.4 Evidence review on the classification of overweight and obesity

[This is intended as a discussion paper to highlight any areas where there is disagreement or controversy in the defined cut-offs used to classify people who are overweight/obese. Because the associated key clinical question does not lend itself easily to an evidence-based approach, we have referred to key references which are mainly expert opinion and authoritative statements.]

5.1.4.1 Classification of overweight or obesity in children

Despite the rising problem of weight and weight-related problems among children, there is no universally accepted classification system for childhood obesity. Thus, the absence of a universally accepted measure causes difficulties in monitoring the development of the obesity epidemic and for comparing between studies.[32]

Several attempts have been made to establish BMI-based classification systems, although such systems are difficult to define with any precision. This problem is related to children having less obesity-related disease than adults (in the short term) and that the dose–response curve connecting obesity and outcome is linear

over a wide range of adiposity in children (Cole and Rolland-Cachera cited by Neovius et al., p107[32]).

The evidence reviews below report how BMI and waist measurements can be used to classify the weights and body shapes of individuals into groups at increased risk of health problems (Table 5.4).

Table 5.4 Classification of overweight and obese (BMI) from key references

Source	Classification	Definition and notes	
RCPCH/NOF 2002[33]	Overweight	British childhood BMI charts show 91st, 98th and 99.6th centile lines	'Body mass index (BMI) is the most practical measure of obesity/overweight, provided values are related to reference standards for age'
	Obese	The 2002 charts show IOTF cut-offs corresponding to adult definitions of overweight and obesity	
NHMRC 2003[4]	Overweight	> 85th centile (CDC 2002)	CDC BMI percentile charts recommended for use (in the clinical setting) until local BMI charts are developed (Australia)
	Obese	> 95th centile (CDC 2002)	
SIGN 2003[7]	Overweight	≥ 91st centile (UK 1990)	'Despite … limitations, there is widespread international support for the use of BMI to define obesity in children, expressed in non-systematic reviews and consensus statements'
	Obese	≥ 98th centile (UK 1990)	

Source	Classification	Definition and notes	
AAP 2003*	At risk of overweight	BMI between 85th and 95th percentile for age and sex	
	Overweight or obese	BMI ≥ 95th percentile	
Singapore MOH 2004	'BMIs-for-age and gender equivalent to adult WHO BMI cut-offs for obese and overweight (at ≥ 30.0 or ≥ 25.0 kg/m^2) respectively can be used as thresholds, although BMI cut-offs for action among Asians of 27.5 kg/m^2 and 23.0 kg/m^2 respectively may be eventually used'		
AHA 2005	Overweight	≥ 95th percentile (CDC age- and sex-specific nomograms for BMI)	'By late adolescence, these percentiles approach those used for adult definitions; the 95th percentile is approximately 30 kg/m^2'
RNAO 2005	Overweight	BMI > 85th percentile and < 95th percentile	'Research studies often use recommended international cut-offs corresponding to a BMI of 25-29.9 used in adults'

* The AAP 2003, Singapore MOH 2004, AHA 2005, RNAO 2005 and USPSTF 2005 are all adapted from the National Guideline Clearinghouse guideline synthesis on the assessment and treatment of obesity and overweight in children and adolescents.

Source	Classification	Definition and notes	
	Obese	BMI for age and sex above 95th percentile using CDC growth curves	'There is no direct measure of body fat in childhood that is readily applicable in the clinical setting …. A new international cut-off for BMI which corresponds to the adult levels of 25 and 30 for overweight and obesity respectively are recommended for population studies'
USPSTF 2005	At risk of overweight	BMI between the 85th and 94th percentile for age and sex	'BMI percentile for age and sex is the preferred measure for detecting overweight in children and adolescents because of its feasibility, reliability, and tracking with adult obesity measures'
	Overweight	Overweight as a BMI at or above the 95th percentile for age and sex	

AAP, American Academy of Pediatrics; AHA, American Heart Association; CDC, Centers for Disease Control and Prevention; MOH, Ministry of Health; NOF, National Obesity Forum; NHMRC, National Health and Medical Research Council (Australia); RCPCH, Royal College of Paediatrics and Child Health; RNAO, Registered Nurses Association of Ontario; SIGN; Scottish Intercollegiate Guidelines Network; USPSTF, United States Preventive Services Task Force.

In children, weight must be adjusted for height. These adjustments are made by comparing the child's measurements with reference standards. BMI varies with body proportions, age and puberty status. To assess individual children, measurements need to be adjusted to compare them with those of other children of the same age.

There are different ways of making these adjustments and they are all made with the same aim: to strengthen the relation between weight and adiposity.

Concern surrounding issues of sensitivity and specificity of classification systems were also explored in Neovius and coworkers'[34] assessment of the International Obesity Taskforce (IOTF/Cole) and the World Health Organization BMI-based systems. The results were then compared with a national (Swedish) BMI reference, and BMI cut-offs maximising the sum of sensitivity and specificity were also derived from the group. The results suggested that, on the one hand the international classification systems have high specificity, resulting in few cases of non-overweight adolescents being classified as overweight. On the other hand, the sensitivity was very low in adolescent girls, thus illustrating how overweight girls would be missed in intervention programmes that use BMI as inclusion criteria.

The authors concluded that:

> 'an international reference is a compromise to obtain acceptable, comparable prevalence estimates at the global level. At the national level, given the probable population differences in relative risks at certain BMI values, the seriousness of the adolescent obesity problem, and its character as a major cost driver through obesity-related illnesses, customized systems derived from national data are likely to be more efficient'.[34]

Different growth reference charts can be used to assess the degree of overweight or obesity of a child. These are calculated to allow for age, sex and height.

The Growth Reference Review Group, a working group convened by the Royal College of Paediatrics and Child Health concluded that for most clinical purposes the UK 1990 charts were superior and recommended that:

- For children under the age of 2 years, the UK 1990 reference charts are the only suitable reference charts for weight, length and head circumference.
- For children over the age of 2 years, both the UK 1990 and the Buckler–Tanner references are suitable for assessing cross-sectional height in

isolation, but the UK 1990 charts should be used where both weight and height are being evaluated. The UK 1990 BMI reference is the only suitable reference for assessing weight relative to height.[35]

The NHMRC guidelines for children[4] highlighted several difficulties with the BMI-for-age percentile cut-offs:

- Data are derived from a reference population.
- Classifying a child as overweight or obese on the basis of BMI being above a certain percentile is an arbitrary decision and not based on known medical or health risk.

These difficulties have resulted in different BMI centiles being used. For example, the Centres for Disease Control and Prevention define the cut-offs as over 95th percentile as overweight, the 85–95th percentile as risk of overweight, and under the 5th percentile as underweight. The NHMRC guidelines[4] recommended that BMI above the 95th percentile (on the CDC charts) is indicative of obesity and a BMI above the 85th percentile is indicative of overweight. Again, the guidelines stressed that these classifications are arbitrary. The SIGN guidelines[7] used yet another classification, with obese children with a BMI at the 98th percentile or over (on the UK 1990 charts), and overweight children with BMI at the 91st percentile or over. The authors of the evidence review on which these guidelines were based stated that:

> ‘A BMI cut off in the upper end of the BMI range (for example, above the 85th centile) was specific for obesity (low false positive rate). This avoids problems associated with stigmatising children or providing unnecessary treatment.
> When using BMI > 91st centile on the UK 1990 charts for British children, sensitivity is moderately high and specificity high. In practice, clinical assessment of obesity in British children using British BMI centile charts will be robust provided that an appropriate cut off (for example, BMI > 98th centile) is used. Serial measures of BMI, plotted on the chart, can assess changes over time.[36]
>
> ‘One British study reported improved screening ability (higher sensitivity; high specificity) when national (UK) reference data were

> used, compared to use of the international reference data. Sensitivity of the definition of obesity using the international reference data differed significantly between the sexes, with low sensitivity in girls and extremely low sensitivity in boys. International BMI cut offs for BMI in children have not been related to obesity related morbidity in childhood.'[37]
>
> 'They require further testing, with evidence of external validity, before they are adopted.'[36]

The Growth Reference Review Group, a working group convened by the Royal College of Paediatrics and Child Health, published a review of growth reference charts for use in the UK.[35] The Group considered the data on which the references were based and their current validity, and made recommendations about which reference was to be used in defined settings.

Viner and Nicholls[38] made clear their use of the IOTF cut-offs to identify obesity. As there is no accepted definition of obesity they considered those with a BMI of greater or equal to 3 standard deviations (SD) above the mean (≥ 99.86th centile) as extremely obese and at potential high risk. Moreover, they acknowledged the use of waist circumference as an additional indicator of potentially high risk of abdominal obesity.[38]

Cole and coworkers[39] aimed to identify the best possible BMI measure for change (BMI, BMI%, BMI z-score or BMI centile) for children across a range of adiposity. To do so, they measured BMI three times over a period of 9 months in 135 Italian preschool children aged 29–68 months.

The authors concluded that BMI centile is (i) useful for classifying children's adiposity, although poor at quantifying change in adiposity and (ii) sensitive to changes in the middle of the adiposity range but insensitive to changes at the extremes. BMI z-score is also useful for assessing adiposity cross-sectionally, and, unlike BMI centile it can be summarised across populations for statistical purposes. Despite these, disadvantages appear as its variability gets progressively smaller the more obese the child.[39]

Cole and co-workers also analysed percentage change in BMI, stating that it performs better than BMI centile or z-score. They stated that, in practice, adiposity change over time is virtually equivalent when measured either with percentage change BMI or BMI. Thus, both can be used interchangeably. To conclude, Cole and co-workers contended that adiposity change should be measured in BMI (kg/m^2) or BMI (%). Nevertheless they acknowledged that this should be qualified, as the adiposity measures for change over time are all highly associated and the advantage of BMI or BMI% over BMI z-score is tenuous.[39]

In 2002, the 'Health survey for England'[40] focused on the health of children and young people, and on the health of infants (aged under 1 year) and their mothers. One of the 'core topics', which is included in all health surveys, was anthropometry.

Emmanuel Stamatakis produced a chapter for 'Health survey for England' on the anthropometric measurement of overweight and obesity in children.[41] He discussed the establishment of a standard definition for child overweight and obesity using BMI reference data from six different countries around the world.[42] This linked childhood and adult obesity/overweight standards using evidence of clear associations between the adult BMI cut-off values of 25 kg/m^2 and 30 kg/m^2 and health risk. However, Stamatakis reported that a re-analysis of children's BMI data using similar methods to the international classification but UK-only reference data showed that the international BMI cut-offs exaggerated the differences in overweight and obesity prevalence between boys and girls by underestimating prevalence in boys. Other possible limitations of the international classification included concerns about its sensitivity (ability to identify all obese children as obese), the limited sample size of the reference population and the lack of BMI cut-off points for underweight. However, in summary, the report concluded that 'the issue of childhood obesity definition is far from resolved and there is an urgent need for further work'.[41]

5.1.4.2 Classification of overweight and obesity in adults

This section describes how BMI and waist measurements can be used to classify the weights and body shapes of individuals into groups at increased risk of health problems (Tables 5.5 and 5.6).

Table 5.5 Classification of overweight and obese (body mass index [BMI][a]) from key references

Source		Classification (BMI[a])
		Adult
NOF 2002[43]	Overweight	≥ 25
	Obese	≥ 30
NHMRC 2003[13]	Overweight	≥ 25
	Obese	≥ 30
		(≥ 40 severely obese)
NIH 1998[14]	Overweight	≥ 25
	Obese	≥ 30

[a] BMI unit of measurement: $kg/m^{2.}$

NOF, National Obesity Forum; NHMRC, National Health and Medical Research Council (Australia); NIH, National Institutes of Health.

Table 5.6 Classification of overweight and obese (waist circumference) from key references

Source	Classification (waist circumference)	Additional comments
	Adult	
NOF 2002[43]	Men > 102 cm	Associated with 'substantially increased health risk'
	Women > 88 cm	
NHMRC 2003[13]	Men ≥ 102 cm (≥ 94 cm increased risk)	Associated with 'substantially increased' risk of metabolic complication Waist circumference is a valid measure of abdominal fat mass and disease risk in individuals with a BMI less than 35 kg/m^2. If BMI is 35 or more, waist circumference adds little to the absolute measure of risk provided by BMI
	Women ≥ 88 cm (≥ 80 cm increased risk)	
NIH 1998[14]	Men > 102 cm	Associated with high risk to health Although waist circumference and BMI are interrelated, waist circumference provides an independent prediction of risk over and above that of BMI. It is particularly useful in patients who are categorised as normal or overweight on the BMI scale
	Women > 88 cm	

BMI, body mass index; NOF, National Obesity Forum; NHMRC, National Health and Medical Research Council (Australia); NIH, National Institutes of Health.

As for measurement above, the National Guideline Clearing House synthesis of adult guidelines summarised classification as follows (Table 5.7).

Table 5.7 Classification of obesity in adults

ACPM (2001)	By criteria of the International Obesity Taskforce, overweight is classified as BMI > 25 kg/m^2 Obesity is categorised as class I (BMI 30–34.9), class II (BMI 35–39.9) and class III (BMI ≥ 40)
AGA (2002)	A BMI of 25.0–29.9 is classified as overweight. Obesity is categorised as class I (BMI 30–34.9), class II (BMI 35–39.9) and class III (BMI ≥ 40)
BWH (2003)	The National Heart, Lung, and Blood Institute Overweight and Obesity Classification by BMI (in kg/m^2): Normal weight 18.5–24.9 Overweight 25.0–29.9 Obesity class 1 30.0–34.9 Obesity class 2 35.0–39.9 Obesity class 3 ≥ 40.0 *Waist circumference*. A waist circumference > 88 cm (> 35 inches) raises cardiovascular disease risk in women. Waist cut-offs designed for the general population may not apply to very short women (under 1.5 m [5 feet])

Singapore MOH (2004)	Current World Health Organization and international guidelines recommend BMI cut-offs of 25 kg/m^2 and 30 kg/m^2 to define overweight and obesity, respectively. Based on body fat equivalence and comorbid disease risk, BMIs of 23 kg/m^2 and 27.5 kg/m^2, respectively have been recommended as cut-off points for public health action in Asians (grade C, level IV). *Note*: BMI cut-off points are currently being reviewed in the light of new data Current international guidelines recommend waist circumference cut-offs of 102 cm and 88 cm to define excess risk in males and females, respectively. Based on an Asian-Pacific consensus and our national health survey and comorbid disease risk, cut-offs of 90 cm and 80 cm, respectively, are probably more appropriate for Asians (grade C, level IV)
USPSTF (2003)	The USPSTF found good evidence that BMI, calculated as weight in kilograms divided by height in metres squared, is reliable and valid for identifying adults at increased risk for mortality and morbidity due to overweight and obesity Persons with a BMI between 25 kg/m^2 and 29.9 kg/m^2 are overweight, and those with a BMI of $\geq$ 30 kg/m^2 are obese. There are three classes of obesity: class I (BMI 30–34.9), class II (BMI 35–39.9) and class III (BMI 40 and above). Men with waist circumferences > 102 cm (> 40 inches) and women with waist circumferences > 88 cm (> 35 inches) are at increased risk for cardiovascular disease. The waist circumference thresholds are not reliable for patients with a BMI > 35 kg/m^2

ACPM, American College of Preventive Medicine; AGA, American Gastroenterological Association; BMI, body mass index; BWH, Brigham and Women's Hospital; MOH, Ministry of Health; USPSTF, United States Preventive Services Task Force.

BMI

There is little disagreement about the classification of overweight and obese using BMI in adults; a BMI between 18.5 kg/m^2 and under 25 kg/m^2 is accepted to be within normal ranges, whereas a BMI of between 25 kg/m^2 and under 30 kg/m^2 is classified as overweight and a BMI of 30 kg/m^2 and over as obesity. Further classifications, linked with morbidity, can be seen in Table 5.8.

Table 5.8 Classifications of obesity[44]

Classification	BMI (kg/m^2)	Risk of co-morbidities
Underweight	< 18.5	Low[a]
Healthy weight	18.5– 24.9	Average
Overweight (or pre-obese)	25–29.9	Increased
Obesity, class I	30–34.9	Moderate
Obesity, class II	35–39.9	Severe
Obesity, class III	≥ 40-	Very severe

[a] Other health risks may be associated with low body mass index (BMI).,

These cut-offs are based on epidemiological evidence of the link between mortality and BMI in adults.

Waist circumference and waist-to-hip ratio

This agreement on classification is also reflected in the cut-offs used for waist circumference: a waist circumference of 102 cm or over in men and 88 cm or over in women is associated with substantially increased health risks (Table 5.9).

Table 5.9 Classification using waist-to-hip ratio and waist circumference[44;45]

At increased risk	Men	Women
Waist-to-hip ratio	> 1.0	> 0.85
Waist circumference (increased risk)	≥ 94 cm	≥ 80 cm
Waist circumference (greatly increased risk)	≥ 102 cm	≥ 88 cm

BMI and waist circumference

The WHO recommended that an individual's relative risk could be more accurately classified using both BMI and waist circumference. These can be seen in Table 5.10.

Table 5.10 Combining body mass index (BMI) and waist measurement to classify the risks of type 2 diabetes and cardiovascular disease[13;44]

		Waist circumference (cm)		
Classification	**BMI (kg/m^2)**	**Men**	94–102	> 102
		Women	80–88	> 88
Underweight	< 18.5		–	–
Healthy weight	18.5–24.9		–	Increased
Overweight	25–29.9		Increased	High
Obesity	> 30		High	Very high

The Agency for HealthCare Research and Quality (AHRQ) undertook a systematic review of the diagnosis and treatment of obesity in older people.[15] The review addressed the following questions:

- Are there limitations in diagnosing obesity in the elderly[†] with BMI?
- Should another measurement be used with BMI or in place of BMI for diagnosing obesity in the elderly?

The review concluded that:

> 'Overall, among office-based diagnostic tests for obesity, BMI and WC showed very similar correlation with body fat percentage in men and women.… While WC correlates closely with body fat percentage and aims to measure central adiposity, it showed low sensitivity when used as a single tool to identify older patients with either generalized (by BMI) or central (by WHR) obesity. Gender did not appear to strongly affect these analyses' diagnostic accuracy, but the utility of diagnostic measures may differ across ethnic/racial groups.'

[†] Defined as people aged 60 years or older.

However, no specific cut-offs were suggested for any of the measures evaluated in this group of people.

One systematic review assessed the link between BMI and risk in older people.[46] In studies where an association was found, a BMI of 27 kg/m^2 or over was associated with increased all-cause and cardiovascular mortality among people aged 65–74 years. For people aged 75 years or over, a BMI of 28 kg/m^2 or over was associated with an increased all-cause mortality. The authors suggested that future guidelines may wish to consider the evidence for specific groups when establishing standards for healthy weight.

5.1.5 How do BMI and waist circumference correlate with morbidity and mortality in different ethnic groups?

5.1.5.1 Classification of obesity in children from different ethnic groups

Background

BMI, besides not being able to distinguish between fat mass and lean (or muscle) mass, does not reflect body fat distribution or differences in body fat associated with different body proportions in different ethnic groups.[47]

The concept of different cut-offs for different ethnic groups has been proposed by the WHO, but there is ongoing debate[48-51] and at present, there are no commonly accepted cut-offs or indeed, methods to determine specific cut-offs.[52]

In the UK, a secondary analysis[53] of the 1999 health survey for England found that Afro-Caribbean and Pakistani girls (aged 2–20 years) were more likely to be obese than girls in the general population (odds ratio [OR] 2.74, 95% confidence interval [CI] 1.74 to 4.31 and OR 1.71, 95% CI 1.06 to 2.76, respectively), with Afro-Caribbean girls also more likely to be overweight (OR 1.73, 95% CI 1.29 to 2.33). Indian and Pakistani boys were more likely to be overweight (OR 1.55, 95% CI 1.12 to 2.17 and OR 1.36, 95% CI 1.01 to 1.83), but not obese. Conversely, Chinese girls were less likely to be overweight or obese and Chinese boys less likely to be overweight. The degree of overweight or obesity was assessed using the IOTF standard definition for international use[42](see International evidence below).[53]

In another study of UK adolescents aged 11–14 years,[54] the prevalence of overweight and obesity was found to be highest for black African girls and lowest for Bangladeshi and Pakistani girls. In boys, the prevalence of overweight and obesity was highest for Indian boys and lowest for black African and Pakistani boys. But the differences between ethnic groups were not significant overall. There were some significant differences between the white British population and the different ethnic groups. Indian boys were significantly more likely to be overweight and Pakistani and black African boys were significantly less likely to be overweight (using the IOTF international cut-offs[42]). One limitation of this study is that the survey was not a national one, but restricted to East London. However, the response rate was high and the authors felt that that sample was representative.

Studies have found that Asian Indian children have higher body mass adjusted pressure levels than white children,[55] and are predisposed to insulin resistance syndrome (IRS),[56] which is associated with excess body fat, abdominal adiposity, and excess truncal subcutaneous fat.[57] This association between IRS and ethnicity was also found in a cross-sectional study of 3642 children in the UK.[58]

However, it is not yet clear how influential maternal nutrition and intergenerational effects will be on the relation between ethnicity and obesity over time.

Methods

The evidence review is based on relevant, identified systematic reviews and primary studies that assessed whether the association between BMI, waist circumference and bioelectrical impedance and morbidity is different between different ethnic groups in UK populations.

Owing to the lack of evidence and ongoing international debate on this topic, we asked experts[‡] in the area to suggest any additional references. These were scanned and included as appropriate.

[‡]Professor Philip James and Dr Kamlesh Khunti.

UK evidence

No studies investigating ethnicity differences in the association of proxy measures of obesity with morbidity in children in UK populations were found. However, there is evidence that young adult South Asians tend to have greater truncal adiposity than their European counterparts.

One study developed body mass reference curves based on a representative sample of the UK population from birth to 23 years.[59] However, it was not stated if ethnicity was considered in ensuring the sample was representative.

International evidence

The WHO review of obesity in the Asia-Pacific region published in 2002 stated that the international standard for BMI-for-age chart[42] was unlikely to be appropriate for Asian and Pacific children.[60]

Summary

Some evidence appears to suggest that Afro-Caribbean and black African girls might be at greater risk of overweight and obesity. This is also observed in some Indian boys. Evidence also suggests that Indian children have higher body mass adjusted pressure levels than white children, and are predisposed to IRS, which is associated with excess body fat, abdominal adiposity and excess truncal subcutaneous fat.

5.1.5.2 Classification of obesity in adults from different ethnic groups

Background

It is now generally accepted that the different ethnic groups have higher cardiovascular and metabolic risks at lower BMIs, and this may be because of differences in body shape and fat distribution.

In 2001, an international meeting of researchers discussed the simplified use of anthropometry to assess the risk of chronic disease associated with overweight and body fat distribution in adults.[61] The researchers concluded that:

> ‘for its potentially important role in health promotion and primary health care activities, WC [waist circumference] should be adopted as

> a valuable tool for assessing the health risks of overweight**, provided that appropriate cut-off points are established'**.[61] (Our emphasis)

Although ethnicity was discussed, the main groups were those not directly applicable to the UK. Although the UK data included in the pooled evidence presented at the meeting did include people of South Asian ancestry, no detailed discussion of this group was reported.

The concept of different cut-offs for different ethnic groups has also been proposed by the WHO, but there is ongoing debate[62-66] and at present, there are no commonly accepted cut-offs or indeed, methods to determine specific cut-offs.[66;67] However, research is currently being undertaken,[68] and any update of this guidance will consider this new evidence as appropriate. For this guidance, we have therefore looked for evidence on how different cut-offs are associated with mortality and morbidity in ethnic populations (appropriate to the UK) both in the UK and in the countries of origin.

The Newcastle Heart project[69] compared coronary heart disease (CHD) risk factors in Indians, Pakistanis and Bangladeshis, and also compared South Asians (as a group) with people of European origins. The participants were aged between 20 and 74 years, and lived in Newcastle, UK. Measurements included biochemical markers (including fasting insulin, lipids, blood glucose) and anthropometry, and other clinical factors (including blood pressure and electrocardiograms). Another aim of the project was to determine the association between ethnic and socioeconomic inequalities, physical activity, social networks and cardiovascular risk factors.[70-74]

The authors reported (in several papers) that:

- The risk of CHD was not uniform among South Asians but that, overall, South Asians had a higher level of CHD than Europeans.[69]
- South Asians did not appear to have higher levels of lipoprotein (a) levels (which, in combination with high insulin resistance, was hypothesised to explain the increased level of heart disease).[74]

- South Asians had lower levels of habitual physical activity than Europeans, and this was likely to contribute to the higher levels of diabetes and cardiovascular risk.[72]

The authors suggested that for South Asians living in Newcastle, the European pattern of inequalities (where social class, education and deprivation were associated with disease and risk factors) were becoming established, with different rates of establishment occurring in different ethnic groups.[70] When different models of predicting cardiovascular disease were applied to the different ethnic groups, a variety of results were seen. However, overall, the authors concluded that 'the potential gains from controlling major established risk factors could be substantial in South Asians and greater than in Europeans'.[75]

There remains uncertainty about how ethnic, migrant populations may or may not adapt over time to the patterns of risk of the indigenous population. Lean and co-workers compared anthropometric measures and behavioural associations in migrant and British-born South Asians and Italians and the general population of British women living in the west of Scotland. No differences were found in anthropometry between the British-born South Asian women and the general population women. The authors concluded that these results offered 'hope that some of the high cardiovascular risks in South Asians in Britain may be overcome by lifestyle modification, and that the risks may reduce over generations through acculturation'.[76] The influence of maternal nutrition, birth weight and initial weight gain on future health and risk of obesity in adulthood is also unclear (although evidence is emerging).[77-79]

Methods

The evidence review was based on relevant, identified systematic reviews and primary studies assessing whether the association between BMI and waist circumference and morbidity is different between different ethnic groups in UK populations. This review considered only Asian and black populations. Due to the lack of evidence and ongoing international debate on this topic, we asked

experts[§] in the area to suggest any additional references. The suggested references were scanned and included as appropriate.

Asian population

UK evidence

Five studies were identified that investigated the measurement of obesity in ethnic groups in the UK population. Three of these associated proxy indicators of obesity with morbidity[80-82] and the remaining two investigated the correlation between BMI and skinfold thickness.[83;84] The key findings were as follows:

- For equivalent BMIs, Pakistani adult males were found to have significantly more truncal adiposity and total adiposity than white males as measured by skinfold thickness.[83;84]
- Significant differences were found in associations between proxy measures of obesity and features of the metabolic syndrome with regard to:
    - waist-to-hip ratio and triglycerides in European and Chinese women
    - waist circumference, waist-to-hip ratio and waist-to-height ratio and triglycerides and HDL cholesterol in European and South Asian (Indian, Pakistani or Bangladeshi origin) women
    - waist circumference and waist-to-hip ratio and serum 2-hour glucose in European and South Asian males.[81]
- For equivalent waist-to-hip ratios, South Asian males (Sikh, Punjabi Hindu, Gujarati Hindu and Muslim) were found to have significantly higher diabetes prevalence and serum insulin (excluding people with diabetes) but not significantly different HDL cholesterol, triglyceride and systolic blood pressure.[80]
- However, another study found no relation between central or generalised adiposity and plasma triacylglycerol (TAG) in Sikh men. Although there was a

[§] Professor Philip James and Dr Kamlesh Khunti

positive association between central body fat and insulin resistance, this was less strong for Sikh men than for white men.[82]

- Waist circumference and waist-to-height ratio were more consistently associated with features of metabolic syndrome than waist-to-hip ratio when comparing across European, Chinese and South Asian groups.[81]

In another series of papers,[85;86] the health and coronary risk of a British Punjabi population was compared with that of the general population in Glasgow. However, this was a cross-sectional survey with physical measures, and was not a study to determine the level of association between the different anthropometric measures and risk, so was not included in the detailed review.

International evidence

These findings are broadly consistent with studies and reviews of studies of Asian population groups outside the UK.[87-93] In 2004, a WHO expert consultation[94] reviewed the scientific evidence relevant to recommending BMI cut-off points for determining overweight and obesity in Asian populations. Combining 11 data sets for Asian populations (China, Hong Kong, India, Indonesia, Japan, Republic of Korea, Malaysia, Philippines, Singapore, Taiwan and Thailand) the consultation found that for the same age and percentage of body fat, BMI was 1.3 kg/m^2 ($\pm$0.1) lower in females and 1.4 kg/m^2 in males compared with their European counterparts. However, these differences varied substantially between different Asian populations.

> ‘From the analyses undertaken, Hong Kong Chinese, Indonesians, Singaporeans, urban Thai, and young Japanese had lower BMIs at a given body fat compared with Europeans, whereas Beijing (northern) Chinese and rural Thai had similar values to those of Europeans. These differences across Asian groups might be because of the methods used, but might also reveal real differences among the ethnic groups’[94]

The key conclusions were that:

- On the basis of available data in Asia, Asians generally have a higher percentage of body fat than white people of the same age, sex and BMI.
- The proportion of Asian people with risk factors for type 2 diabetes and cardiovascular disease was substantial even below the existing cut-off point of 25 kg/m^2.
- Current (WHO) cut-off points do not therefore provide an adequate basis for taking action on risks related to overweight and obesity in many populations in Asia.

However, the available data do not necessarily indicate one clear BMI cut-off point for all Asian population groups for overweight or obesity. Cut-offs for observed risk varied from 22 kg/m^2 to 25 kg/m^2 and for high risk from 26 kg/m^2 to 31 kg/m^2.

Two key recommendations were as follows:

- Trigger points for public health action should be 23 kg/m^2 (increased risk) and 27.5 kg/m^2 (high risk).
- Where possible, in populations with a predisposition to central obesity and related increased risk of developing the metabolic syndrome, waist circumference should also be used to refine action levels on the basis of BMI.

There is some limited evidence that for a given BMI or waist circumference, morbidity risk in South Asian populations (of Pakistani, Bangladeshi and Indian origin) resident in the UK may be higher.

Black population

UK evidence

Only one UK-based study was found that investigated the measurement of obesity in the male black population.[80] However, the focus of this study was on differences in the relation of central obesity with cardiovascular risk, insulin resistance and diabetes prevalence between European and South Asian populations. The sample size of the Afro-Caribbean group was considerably

smaller (European = 1515, South Asian = 1421, Afro-Caribbean = 209). Unlike the European and South Asian groups, data on risk factors for the Afro-Caribbean group were not controlled for waist-to-hip ratio so it is difficult to say whether the findings have a bearing on appropriate cut-offs for Afro-Caribbeans. However, a general comparison of the Afro-Caribbean population sample with the European population found that:

- waist-to-hip ratio was not significantly different but BMI was significantly higher
- diabetes prevalence was significantly higher but serum insulin levels were not significantly different
- median systolic and diastolic blood pressures were significantly higher
- plasma triglyceride was significantly lower and HDL cholesterol significantly higher.

International evidence

Elsewhere, a large-scale study[95] of the relation between BMI and body fat in black populations in Nigeria, Jamaica and the USA concluded that within populations bioelectrical impedance analysis as a measure of percentage body fat was not a better predictor of blood pressure, or waist or hip circumference. However, for similar levels of BMI, body fat varied substantially. Nigerians had a greater fat-free mass than Jamaicans and Jamaicans had a greater proportion than African Americans. The study did not make comparisons with white populations.

A smaller-scale study[96] set in the USA compared the association between upper body obesity and cardiovascular and diabetic risk in white and black pre-menopausal women. This found that upper body obesity (as assessed by waist-to-hip ratio) is not as potent a risk factor for diabetes and coronary heart disease in black women as it is in white women. Also, whereas in white women upper body obesity was associated with significantly greater glucose intolerance, hyperinsulinaemia and insulin resistance, this was not significant in black women

(that is, upper body fat distribution has less impact on carbohydrate metabolism). The sample size for this study was small (black women = 22, white women = 20).

Summary

In summary, the evidence base for differences in the association of BMI, waist circumference and bioimpedance with morbidity is limited, particular in black ethnic groups. Available evidence for South Asian groups was consistent with findings from studies in populations living in South Asia. This may not be surprising as UK studies have focused particularly on first generation migrants.

The findings on South Asian populations in the UK were consistent with those from the WHO expert consultation which assessed populations living in South Asia (although these also included a wider range of populations).

Therefore, there is probably insufficient evidence to make any clear recommendations about separate cut-offs for ethnic groups in the UK, as distinct to the cut-offs recommended for Asian populations by the WHO.

5.2 B: Public health

The following is based on an evidence review produced by Cardiff University.

Detailed evidence tables and supporting information are in Appendix 3.

5.2.1 Evidence statements (Table 5.12)

Table 5.12 Evidence statements and grading

No.	Evidence statement	Grade	Evidence
Observational longitudinal studies			
Children			
1	Limited evidence suggests that attempting to identify children at risk of obesity before 2 years of age has poor predictability	3	One longitudinal study (3) (Toschke et al. 2004[97])
2	Children at risk of becoming overweight or obese may be identified from opportunistic monitoring using growth charts after 2 years of age	3	Two longitudinal studies (both 3) (Guo 2002,[98] He and Karlberg 2002[99])
3	There is some evidence that children at risk of overweight or obesity may be identified by assessing measures of habitual activity levels and diet	3	Two longitudinal studies (both 3) (Barba 2001[100] as addition to anthropometric measures, Metcalf et al. 2002[101])
4	There is some evidence that measures in addition to BMI – height and waist circumference – may aid the identification of children at risk of overweight and obesity	3	Three longitudinal studies (two of which linked; all 3) (Maffeis et al. 2001,[102] Freedman et al. 2001,[103] Freedman 2002 et al.[104])
5	Based on two studies, schools may provide an opportunity for monitoring the growth and activity levels of children	3	Two longitudinal studies (both 3) (Barba et al. 2001,[100] Metcalf et al. 2002[101])
Adults			
6	There is some evidence that considering an individual's weight history (for example, previous weight gain or loss, previous attempts at dieting) and monitoring more recent weight gain may help identify adults	3	Two longitudinal studies (both 3) (Kroke et al. 2002,[105] St Jeor et al. 1997[106])

No.	Evidence statement	Grade	Evidence
	at risk of becoming overweight or obese in the future		

Existing guidance and recommendations

UK based			
7	There is no existing UK guidance on the identification of children and adults at risk of obesity	N/A	N/A
8	There is a lack of consensus in existing UK-based 'recommendation' papers on whether to regularly monitor or screen BMI, particularly in children	4	No clear link to evidence or low quality; expert opinion
9	Two of the three UK-based recommendation papers have suggested schools as an appropriate setting if regular monitoring is considered	4	No clear link to evidence or low quality; expert opinion
Non-UK based			
10	The majority of non-UK guidance and recommendation documents suggest that periodic monitoring of weight status and BMI and waist circumference measurements should be routinely undertaken	4	No clear link to evidence or low quality; expert opinion

BMI, body mass index; N/A, not applicable.

See Appendix 3 for associated evidence tables.

5.2.2 Methodology

Database searches were carried out in June/July 2005 for papers published from 1990 onwards (1995 onwards for systematic review level evidence). An additional range of databases were searched for guidelines (see Appendix 3). A final update search was completed on 1 December 2005 on a reduced number of databases. From an initial 1404 hits, 114 papers were assessed in detail, of which 10 papers met the critical appraisal criteria for inclusion in

evidence tables. An additional 561 guidelines were identified, of which 44 were assessed in detail and of which 14 met the criteria for inclusion (5 clinical practice guidelines, 2 recommendation statements, 4 policy statements, 2 reports and 1 briefing paper).

The inclusion and exclusion criteria for the review adhered to the standard public health review parameters for interventions. In addition, it was agreed with the Guidance Development Group (GDG) that studies should only be included in this review if:

- the paper reports an intervention to identify adults and/or children who are potentially at risk for developing obesity and who would benefit from participation in a prevention/public health intervention to manage weight
- the paper is a recommendation or guideline for identifying adults and/or children who are potentially at risk for developing obesity and who would benefit from participation in a prevention/public health intervention to manage weight
- the paper concludes that the tools evaluated have the potential for use in identification interventions.

Tooth et al 2005[107] was used to appraise observational longitudinal studies and the AGREE instrument (www.agreecollaboration.org/instrument) was used to appraise guidelines and recommendation documents. For the purposes of this review a clinical or practice guideline was defined as a document that aimed to identify, summarise and evaluate the best evidence and was based on a systematic review of the current research evidence. Public/policy statements and recommendations were defined as documents that aimed to provide advice or recommendations and were likely to have been developed based on consensus agreement by an expert panel.

Please note that the Department of Health (DH) has recently issued ‘Measuring childhood obesity: guidance to primary care trusts’. However as this was published in January 2006 (that is, after the agreed search dates) it

has not been appraised for this version of the review. The DH guidance will be appraised before final publication of this NICE guidance.

5.2.3 Identification of individuals who may benefit from participation in public health interventions to manage weight

There is limited evidence on the effectiveness of interventions to identify children and adults who are likely to become overweight or obese and would benefit from interventions. This is particularly the case in adults. All studies had some confounders. Only one study[101] was carried out in the UK. No UK-based corroborative data were identified other than one accelerometer study, but it is likely that the findings are applicable to the UK. No cost-effectiveness data were identified.

5.2.3.1 Children

Eight moderate quality observational longitudinal studies in children[97–104] suggest that those at risk of becoming overweight or obese may be identified from opportunistic monitoring of growth charts after 2 years of age (including larger than expected weight gain and early 'rebound'),[98,99] potentially using anthropometric measures in addition to BMI (height and waist circumference) and from assessing measures of habitual activity levels (for example, through an accelerometer) and diet.[101] Attempting to identify children at risk before 2 years of age had poor predictability.[97] Of the four studies measuring anthropometric measures, one[102] concluded that measurement of waist circumference at age 8 may be a promising index to predict overweight at puberty, and two linked studies[103,104] concluded that a measurement of height at age 7–8 could be used to identify more accurately children who are likely to become overweight adults, although this may only be true for those children already overweight. A further study,[100] which measured anthropometric measures and examined lifestyle factors such as diet and physical activity, concluded that large-scale involvement of primary schools in screening programmes could identify those children at risk of being overweight and obese in adulthood and for whom strategies to prevent overweight and obesity would be most effective. No studies were found which considered identifying children by their parent's weight/obesity.

5.2.3.2 Adults

Two studies with some confounders,[105,106] one large retrospective cohort study and one relatively small ongoing prospective study, examined interventions to identify adults at risk of overweight and obesity. The results suggest that considering an individual's weight history (for example, previous weight gain or loss, previous attempts at dieting) and monitoring more recent weight gain (for example over 2.3 kg) may help identify adults at risk of becoming overweight or obese in future.

5.2.4 Existing guidelines and recommendations

There is currently no available formal guidance in the UK and there is a lack of consensus in the existing 'recommendation' papers on whether to regularly monitor or screen BMI, particularly in children. No corroborative data were identified, but it is likely that the findings are applicable to the UK. No cost data were identified.

5.2.4.1 UK-based guidance and recommendations

No usable UK guidelines were identified. Following the advice of SIGN, the existing SIGN guidelines for adults[108] were not considered due to methodological problems. These guidelines will be updated in the future. SIGN guidance for children[7] was considered, but excluded as it discussed identification of overweight and obesity only.

The conclusions of three UK recommendation papers suggest that there is currently no consensus available for the screening of children for unhealthy weight gain. A policy statement form the UK's National Screening Committee in 2005,[109] based on expert consensus opinion, recommended that screening should not be offered whereas the evidence from a briefing paper prepared by the Child Growth Foundation[110] firmly recommended universal serial BMI assessments for children at least until the end of primary school. One further report from the House of Commons Select Committee on Health in 2004,[111] supported the guidance suggested by the Child Growth Foundation and suggested that BMI measures should be recorded annually for school-aged children.

The evidence underpinning the identified recommendations is not available or is of lower-level quality. According to the AGREE instrument for the appraisal of guidelines only two publications would be recommended (National Screening Committee 2005,[109] Child Growth Foundation 2004[110]), one with provisos (National Screening Committee[109]).

5.2.4.2 Non-UK-based guidance and recommendations

Of the 11 identified non-UK guidance documents, overall evidence from nine recommendations suggests that periodic monitoring of weight status and BMI and waist circumference measurements should be routinely undertaken.

Five clinical practice evidence-based guidelines were identified, of which four recommended recurrent screening for weight gain. Three of these were from the USA, one from Canada and one from Australia. Of the US-based recommendations, one recommended that height, weight and BMI measurements be taken annually for mature adolescents and adults,[112] one) recommended that adults who are not overweight or who have no history of overweight should be screened for weight, BMI and waist circumference every 2 years,[113] and one firmly recommended against screening for obesity for asymptomatic adults.[114] The Canadian guidance, based on expert opinion, advocated the inclusion of monitoring and surveillance data on nutrition, physical activity and measures of adiposity for children in public health policies.[115] The Australian guidance recommended recurrent measurement of height and weight in a nationally representative sample of children and adolescents.[116] Supporting evidence for clinical practice guidelines was obtained from controlled comparative studies, observational data and expert judgement from clinical experience. According to the AGREE appraisal criteria all five clinical practice guidelines would be strongly recommended.

Two recommendation statements, one US-based and one from Canada, gave conflicting advice. The Canadian evidence-based statement concluded that there was insufficient evidence to recommend for or against BMI measurement in the periodic health examination of the general public,[39] whereas the US-based statement proposed an algorithm to determine a

child's BMI at health visits.[117] No supporting evidence for the US statement is available and the frequency for health visits is not indicated.

Three policy statements all supported serial assessments for weight monitoring. Two US-based statements recommended recurrent measurement of BMI, one of which[118] recommended annual routine assessments to calculate and plot BMI measurements for children and the assessment of eating and activity patterns for excessive weight gain relative to linear growth. The other US-based statement[119] recommended periodic BMI measurement for all adults, independent of weight or BMI, along with consistent counselling about healthful dietary and physical activity patterns from general practitioners. There are no apparent links to supporting evidence for either of these statements. One evidence-based collaborative policy statement from Canada suggested that repeated height and weight measurements be part of scheduled well-baby and well-child health visits and that health maintenance visits for children be organised according to a child's immunisation schedule.[120] Continued growth monitoring on an annual basis at primary care visits for older children and adolescents was also recommended. These recommendations were based on expert opinion only. BMI-for-age screening from age 2 onwards to track and predict future risk of being overweight was also advised.

According to the AGREE appraisal criteria the five recommendation and policy statements are broadly recommended with provisos although one[117] is an identification algorithm only for children and adolescents and would not be recommended as a guideline.

One taskforce report from Australia recommended, as part of its national action agenda, regular tracking of height and weight status in the community as well as monitoring of knowledge, attitudes, intentions, behaviours and other indicators of healthy eating and active living.[121] The recommendation from this report is not evidence based.

5.3 Review limitations

No review level or controlled trial evidence was found for this review question, resulting in an evidence base of observational longitudinal studies.

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Section 3: Prevention

6 Prevention evidence summary: determinants of weight gain and weight maintenance ('energy balance')

The following is based on an evidence review produced by the University of Teesside. Detailed evidence tables and supporting information are in Appendix 4.

6.1 Evidence statements (Table 6.1)

Table 6.1 Evidence statements and grading

No.	Statement	Grade	Evidence
Weight outcomes			
1	There are limited data from cohort studies on the factors associated with weight gain in children	N/A	N/A
2	There is a body of evidence which suggests that the offspring of overweight and obese parent(s) are at increased risk of themselves becoming overweight or obese in childhood or adulthood	2+	Parsons et al. 1999[1] (2++) and Klesges et al. 1995[2] Reilly et al. 2005[3], Burke et al. 2005[4] (no significant association found in Thompson et al. 2004[5] and O'Loughlin et al. 2000[6])
3	Cohort studies suggest that children who increase calorie intake, increase fat intake, consume "junk food", "takeaways" and "carbonated drinks" and/or do not eat breakfast, tend to gain weight.	2+	Moore et al. 2003[7], Klesges et al. 1995[2] (2+), GUT study[8;9–10] (2+) (O'Loughlin et al. 2000[6] [2+] and Bogaert et al. 2003[11] [2+] found no significant association with fat and calories), Burke et al. 2005[4] found inverse relationship between % energy from fat and BMI); Reilly 2005[3] (junk food); Burke 2005[4] (takeaways); Phiilips 2004[12] (carbonated drinks); Elgar et al. 2005[13] (snacking associated with obesity but did not predict change in BMI), Philips et al. 2004 found no significant
	The evidence on 'snacking' is limited and inconsistent		

No.	Statement	Grade	Evidence
			relationship between BMI z-score or % body fat and total energy-dense snack consumption).
3b	There is limited evidence from prospective cohort studies over at least one year for the relationship between regular meals, portion size or snacking with weight in children	2+	McConahy et al. 2004[14] (portion size); Elgar et al. 2005[13] (skipping meals)
4	Cohort studies suggest that children who do not participate in sport outside school and who are the least active appear to gain more weight than their more active peers	2+	Burke et al. 2005[4], Elgar et al. 2005[13], Moore et al. 2003[7], O'Loughlin et al. 2000[6] (2+), GUT study[9–10] (2+), Klesges et al. 1995[2] (2+), Datar et al. 2004[15] (2+)
5	The evidence from cohort studies is inconsistent on the associations between television viewing and weight gain. Some but not all identified studies found a significant association between greater television viewing and weight gain	2+	Supportive: Viner et al. 2005[16], Burke et al. 2005[4], Elgar et al. 2005[13], Reilly et al. 2005[3], Moore et al. 2003[7], Kaur 2003 et al[17](2+), GUT study[9–10] (2+) Not supportive: Robinson et al.1993[18] (2+), Bogaert et al. 2003[11] (2+) Inconsistent: O'Loughlin et al. 2000[6] (2+)
6	Among adults, there is a body of evidence from cohort studies that pregnancy, menopause and smoking cessation are key stages in the life-course associated with weight gain. The evidence on the importance of other life stages, such as marriage, divorce and a change in work patterns (for example, shift working)	2+	*Pregnancy* (all 2+) Supportive: Williamson et al. 1994[19], Smith et al. 1994 (CARDIA),[20] Linne et al. 2003 (SPAWN),[21] Olson and Strawderman 2003,[22] Rosenberg et al. 2003[23], Wolfe et al. 1997,[24] Sowers et al. 1998[25] *Menopause* (all 2+) Supportive: Macdonald et al. 2003,[26] Nagata et al. 2002,[27] Blumel et al.

No.	Statement	Grade	Evidence
	remains unclear		2001[28] Not supportive: Wing et al. 1991,[29] Burnette et al. 1998[30] (two papers on same cohort) *Smoking* (all 2+) Supportive: Williamson et al.1991[31] (short term only) Gerace and George 1996,[32] Swan and Carmelli 2005,[33] Froom et al. 1999,[34] Burnette et al. 1998[30] in Burke et al. 2000[35] (small % variance) *Marriage* (all 2+) Supportive: Kahn and Williamson 1990,[36] Rauschenbach et al. 1995[37] and Gerace and George1996[32] *Shift work* (2+) Supportive: Yamada et al. 2001[38]
7	There is limited evidence from cohort studies that increasing physical activity may minimise the weight gain associated with smoking cessation	2+	Kawachi et al. 2005[39] (2+)
8	There is a body of evidence from cohort studies that adults are more likely to maintain a healthy weight if they maintain an active lifestyle and reduce sedentary behaviours such as television viewing	2++	Body of evidence (all 2+) Two reviews (both 2++): Williamson 1996[40] and Saris et al. 2003.[41] In Saris, 9 of 11 studies (2++) showed significant inverse associations between PAL and BMI/weight Body of individual studies (2+): Nooyens et al. 2005[42], Klesges 1992[43] and Owens 1992,[44] Gerace 1996,[32] DiPietro 1998,[45] Martikainen 1999,[46] NHS II,[47] Ball 2002,[48] Bell 2001,[49] Droyvold 2004,[50] Sundquist 1998,[51] Wagner 2001,[52] CARDIA,[53–54] Lissner 1997,[55] Kahn 1990[36]
9	There is a body of evidence from cohort studies that adults are more likely to maintain a healthy weight if	2+	Body of evidence (all 2+) Rissanen et al.1991[56] and Klesges et al. 1992[43] (both for women only,

No.	Statement	Grade	Evidence
	they consume a low-fat diet containing less 'takeaway' foods, more fruit and vegetables, salad and fibre and little alcohol. Reducing consumption of confectionary and drinks high in sugar may also help to prevent weight gain		out of Williamson 1996[34] review) French et al. 1994,[57] Kahn et al. 1997,[58] Parson et al. 2005,[59] Sammel et al. 2003,[60] Ball et al. 2002,[48] CARDIA,[61], Greenlund, 1996 4388 /id}–[54] He et al. 2004[62], Schulze et al. 2004,[63] Koh-Banerjee et al. 2003,[64] Martikainen and Marmot 1999[46], Schulz et al. 2005[65], Quatromoni et al. 2002[66], Nooyens et al. 2005[42]

BMI, body mass index.

See Appendix 4 for associated evidence tables.

6.2 Methodology

Database searches were carried out in March 2005 for papers published from 1990 onwards (1995 onwards for systematic reviews). A final update search of MEDLINE captured papers published up to 1st December 2005. The review parameters for inclusion and exclusion were adapted for this review which focused primarily on observational studies. Prospective cohorts of at least 12 months duration that assessed factors potentially associated with weight gain or weight control in adults and/or children who were not all obese at baseline and reported a weight outcome at baseline and follow-up were included. Due to time constraints, studies without weight outcomes were excluded from this review. From an initial 4988 hits, 433 papers were assessed in detail, of which 55 cohort studies and 3 systematic reviews met the criteria for inclusion in this review.

Additional searching was carried out for key cohorts on advice from the GDG and a further 3 cohorts met the criteria for inclusion in this review, including the Framingham Children's cohort, the Framingham Offspring/Spouse cohort and the ALPAC cohort. Additional and specific searches were conducted for the terms raised by stakeholders: "regular meals", "snacking" and "portion size" which

yielded another 2 cohorts. One additional reference suggested by stakeholders met our criteria for inclusion.

The World Cancer Research Fund (WCRF) database at the University of Teesside was searched for any potentially relevant studies. A further 2 cohorts were identified which fit the criteria for inclusion in this review. It had originally been hoped that this review could supplement the energy balance review. However the WCRF review will not now be published until after the guidance is published.

The final update search plus additional searching produced 11 cohorts that met the criteria for inclusion in this review.

Given the quality element of the inclusion criteria (ie only prospective and controlled cohort studies), the included papers were not critically appraised and all studies were graded 2+.

6.3 Weight outcomes: children

One systematic review examined the role of childhood predictors of adult obesity and a further 11 prospective cohorts assessed factors influencing weight gain in childhood.[1] Children tended to be over 8 years of age and although follow-up varied, the majority of studies lasted 1–3 years. Based on the parameters of this review, the evidence identified regarding determinants of weight gain in children was limited. A broad range of factors were considered but the majority were only assessed by single cohorts. Where there are more than one cohort that assesses a particular factor (that is, fat and calorie intake, hours in activity and television viewing) the evidence was often inconsistent. There was no body of evidence underpinning any of the factors found to be associated with weight change in children.

6.3.1 Parental obesity

A systematic review identified eight cohort studies that considered factors in childhood which may influence the development of obesity in adulthood.[1] Offspring of obese parent(s) were consistently seen to be at increased risk of overweight or obesity, although few studies have looked at this relation over longer periods of childhood and into adulthood. Data from one study suggested that this relation may be stronger between mothers and their offspring than fathers and offspring, and that the mother–offspring relation strengthens over time. One study found that parental obesity was a more important predictor of offspring obesity earlier in childhood (< 6 years becoming less important with increasing age. Data from another study showed that parental obesity influences tracking of the offspring's own obesity, which is much stronger if both parents are obese. The reviewers highlighted that the relative contributions of genes and inherited lifestyle factors to the parent–child fatness association remains unclear.

6.3.2 Dietary factors

Eleven longitudinal prospective cohorts and one cross-sectional study specifically assessed the association between weight and dietary factors, and the cross-sectional study (McConahy 2004[14]) focused on portion size.

Three of the cohorts were set in the UK([3,13,16]), six were set in the USA (GUTS[8-10;67-70]; Framingham Children's Cohort[7,71,72]; Phillips 2004[12]; Klesges 1995[2]; Thompson 2004[5]; McConahy 2004[14]), one in Canada[6] and two in Australia[4,11]

The studies identified suggest that children of normal weight, who do not eat breakfast, increase calorie intake, increase fat intake and eat more 'fast foods' appear to gain more weight than their peers.

Higher baseline levels of percentage of calories from fat among children aged 3–5 years were associated with greater increases in body mass index (BMI) as

were recent increases in the percentage of intake as fat.[2] Among 9–14-year-old children of normal weight, not eating breakfast was associated with weight increase over 1 year [69] as were higher reported caloric intake (girls only). For both boys and girls a larger rise in caloric increase predicted larger BMI increases[9]. The effects of milk and dietary calcium intake on weight appeared to be explained by energy intake; however skimmed milk intake in girls remained marginally significant after adjustment for energy intake (GUTS[8] Moore (2003)[7] investigated the relationships between physical activity level, TV viewing and change in body fat in 106, 3-5-year-olds from the Framingham Children's Study over a period of eight years. Children with high fat diets (>34% calories from fat) exacerbated body fat gain in children watching TV for more than 3 hours per day. They gained approximately 30mm of body fat (sum of five skinfolds) compared with children who watched least TV (<1.75h per day) and consumed a lower-fat diet (<34% calories from fat). Burke (2005)[4] investigated the relationships between different food categories and BMI at 8 years in 340 Australian children. An inverse relationship was found for 'cereals' and '% energy from total fat' ($p = 0.046$ and $p = 0.025$ respectively).

Whilst cross-sectional data showed children were less likely to be overweight if they ate dinner most days with their family, this relationship was not apparent in the longitudinal analyses over 2 years(GUTS[67])

Thompson and coworkers[5] followed up 9-year-old girls over an average of 6 years. Girls who ate 'quick-service food' (that is, food from 'fast food' outlets, ice cream parlours, street vendors, etc.) twice a week or more at baseline had the greatest mean increase in BMI z-score at follow-up, and this change was significantly different from that seen in girls who ate quick-service food once or twice a week or not at all. Burke (2005)[4] investigated the relationships between different food categories and BMI at 8 years in 340 Australian children. A positive relationship was identified between weight gain and 'takeaways' ($p = 0.025$). Reilly (2005)[3] examined 25 risk factors for obesity from the inter-uterine period to

7 years in the ALSPAC cohort (UK). Eight factors were associated with risk of obesity. None were dietary, although a 'junk food type dietary pattern' (not defined further) at 3 years was significant at the 10% level.

Elgar (2005)[13] found that skipping meals and snacking (not further defined) were associated with obesity, but did not predict change in BMI between the ages of 11-12 and 15-16 years in 355 Welsh adolescents. Phillips (2004)[12] investigated the relationship between energy dense snacks (EDS) and BMI z-scores in 196 non-obese pre-menarcheal girls 8 to 12 years old for four years. Categories of EDS foods considered were baked goods, ice cream, chips, sugar-sweetened carbonated drinks and sweets. No relationship was found between BMI z-score or % body fat and total EDS food consumption. However, carbonated drinks were the only EDS food significantly related to BMI z-score over the 10-year study period (p-value for trend <0.001), but it was not related to % body fat.

McConahy (2004)[14] looked at dietary behaviours in 5447 children aged 2-5 years from the Continuing Survey of Food Intakes by Individuals across the US, over a two year period. Based on parental self-report, this cross-sectional study found that body weight, food portion size, number of eating occasions and number of foods accounted for 38% of the variance in 2-3-year-olds and 39% in 4-5-year-olds. Portion size as a single predictor explained 17% of the variance in 2-3-year-olds and 19% in 4-5-year-olds.

No significant associations were observed between weight change and fat intake, calorie intake, fruit and vegetable intake or snacking in the other cohorts identified.[4,6–10]

6.3.3 Physical activity

Eight prospective cohorts specifically assessed the association between weight and physical activity[2;4;6;7;9;11;13;15;68]. The studies suggest that children who do not

participate in sport outside school and who are the least active appear to gain more weight than their more active peers.

Only one study failed to find significant correlation between BMI and measures of energy expenditure although children's activity levels were correlated with their parents activity levels.[11] Other cohorts found that no sports outside school [6] and fewer hours of physical activity (not defined)[9;68] were associated with increases in BMI in 3–5-year-old boys and girls, whereas higher aerobic activity and increased leisure activity were associated with BMI decrease.[2] Overweight 5–7-year-old girls (but not normal weight children or overweight boys) had reduced BMI with an additional 1-hour per week physical education (PE) in school.[15] Elgar (2005)[13] assessed the relationship between physical activity and change in BMI in 355 Welsh adolescents who were part of the Health Behaviour of School-aged Children Study. Physical activity questions were from the HBSC questionnaire and hours of sports participation was associated with lower increases in BMI ($p<0.05$) over the four year period (from 11-12 to 15-16 years). Details about amount of hours of sport were not reported.

Burke (2005)[4] used parental questionnaires to assess levels of physical activity in 1430 Australian children at 6 years. Playing organised sport at age 6 was not predictive of BMI at age 8, but 'being slightly active' and 'active' at 8 years were (OR 0.44; 95 CI 0.28, 0.70 ($p<0.001$) and OR 0.23; 95 CI 0.14, 0.38 ($p<0.001$)) respectively. Duration of physical activity was not reported.

Moore (2003)[7] examined 106 children aged 3-5 years from the Framingham Children's Study with Caltrac motion sensors to assess physical activity levels. Children were categorised as having low, medium or high activity levels (based on average number of counts per hour and then averaged over the eight year study period). Children in the highest tertile for daily physical activity had consistently smaller gains in BMI, triceps and sum of 5 triceps throughout childhood. By 11 years, sum of 5 skinfolds was 95.1mm, 94.5mm and 74.1mm for the low, medium and high tertiles respectively (p-value for trend = 0.045).

This relationship was evident for both sexes. Children with the lowest levels of PA and highest levels of TV viewing gained nearly 40 mm of body fat than children with highest levels of PA and least TV by 11 years.

The evidence on television viewing and weight gain was inconsistent with some but not all cohort studies finding a significant association between greater time television viewing and weight gain. Ten prospective cohorts assessed television viewing as a potential predictor of weight change. [4;6;11;17;18;68;13;7;3;16].

Seven studies, including 3 UK-based studies, with children entering the studies at ages ranging from 3 years to adolescence reported a significant association with increased television/video viewing/computer games and weight gain from 2 to 30 years' follow-up. [3;4;7;13;16;17;68] One study reported inconsistent findings; O'Loughlin and coworkers[6] reported that playing video games every day was significantly associated with increase in BMI in 9-12 year old girls but not in boys. One study in 6–9-year-old children[11] and one study in 12-year-old children[18] did not find any significant associations.

Viner (2005) [16] UK conducted an analysis of the 1970 British Birth cohort of over 8000 subjects followed up at 5, 10 and 30 years (30 year follow-up self-reported) examining the relationship between television viewing and BMI change. Clearer relationships were found from ages 5 to 10 years than to 30 years. Using obesity at 10 as the outcome in logistic regression, each additional hour of TV watched on weekdays at 5 years increased the risk of obesity by 12% (OR 1.12; 95 CI 1.04, 1.21; p = 0.002); and each additional hour at weekends increased risk by 10% (OR 1.10; 95 CI 1.03, 1.18; p = 0.003). Weekend but not weekday TV viewing in early childhood independently predicted increased adult BMI.

6.4 Weight outcomes: adults

There is more evidence regarding determinants of weight gain in adults than in children. Two reviews and 49 cohorts were considered, which addressed factors in adulthood associated with weight gain and maintenance. The size of studies and length of follow-up varied enormously, for example, Olson and Strawderman[22] followed up 600 women for 2 years after pregnancy whereas Parsons and coworkers[59] reported the results of the 1958 birth cohort which includes 16,000 men and women followed up at 33 and 42 years of age. Many determinants identified are interdependent and can only partially account for variation in weight between individuals.

6.4.1 Menopause

Five cohorts assessed a number of variables with weight change during menopause. The findings suggest that weight gain during menopause transition is itself inconsistent and may indicate underlying behavioural variables contributing to weight change. According to Macdonald and coworkers[26] who analysed 1064 Caucasian women in the UK for 6 years, mean weight was influenced more by reduced energy expenditure than increased energy intake. Nagata and coworkers,[27] who analysed a cohort of Japanese women for 6 years, reported that nutrient intakes were not significantly associated with difference in weight change between premenopausal and postmenopausal women. They did not find a significant association between weight and exercise, However the Massachusetts Women's Health Study[73] a cohort of 400 women followed for 3 years, found that reduced exercise was more strongly related to weight gain than menopause transition.

Both the Healthy Women's Study,[29;30] which followed 500 US women for 3–4 years and a study which analysed 271 Chilean women for 5 years[28] found a significant increase in weight during the menopause. Blumel and coworkers[28] concluded that weight gain in the perimenopausal period appears independent of the menopause.

6.4.2 Pregnancy

Seven cohorts examined weight change and pregnancy. Pregnancy appears to be a risk factor for persistent weight gain, and probability of weight gain rises with increase in parity for some women and this was shown in studies of Caucasian and African American women. Those who gained more weight or ate more during pregnancy were more likely to retain weight gain after pregnancy.

The findings of two large US-based cohorts[20;24;74] following women for 4–10 years suggests that the probability of weight gain appears to rise with increase in parity. For African American women this tends to occur after the first child and for white women this tends to occur after the second child.[24] African American women gained more weight over 10 years than white women (5.5 kg vs 4.4 kg).[24] Black women demonstrated greater adverse changes in adiposity than did white women at each level of parity.[74] Another cohort suggests that weight gain is greater for the first child compared to subsequent children and weight gain increases with increasing baseline BMI.[23]

An additional small US-based cohort followed women who breastfed for 18 months to compare baseline pregnancy with post-pregnancy weight following the subsequent pregnancy.[25] On average, cases weighed 1.3 kg more after the subsequent pregnancy than they weighed following the baseline pregnancy.

The SPAWN study, which examined long-term weight development after pregnancy of 1423 women from Sweden over 15 years, reported that women who started to eat more irregularly retained more weight at 1-year postpartum.[21] Olson and coworkers[22] – following 622 healthy US women – found less physical activity was significantly related to excessive gestational weight gain, and in the SPAWN study[21] women who started to exercise less frequently after their pregnancies retained more weight 1-year postpartum.

Williamson (1994)[75] examined 2547 white women aged 25-45 years from the first National Health and Nutrition Examination Survey. The risk of becoming overweight was increased by 60-110% in women having live births over the 12-

year study period. Over 12 years average weight gain whilst having children was modest in US white women, but for some women the risks of major weight gain and becoming overweight are increased in association with childbearing.

6.4.3 Marriage

Three cohorts considered weight change and marital status. Rauschenbach and coworkers[37] reported that women but not men who entered marriage had greater weight gain than their peers who remained unmarried and lost less weight than those who remained married. For men (but not women) there was a significant interaction such that those with more education who became separated or divorced were likely to gain more weight. Another cohort reported that men who became married during the 10-year study period showed a trend towards a greater gain in BMI when compared with men who were consistently married.[36] Those men whose marriage ended appeared to experience a relative loss in BMI. Among a work-based cohort married or cohabiting men gained less weight than their peers.[32]

6.4.4 Smoking

Five US and one Israeli cohort suggest that those who quit smoking for at least a year experience greater weight gain than their peers who continue to smoke. However the results of the National Health and Nutrition Examination Survey 1 (NHANES 1)[31] suggest that ‘significant’ weight gain only occurs in a minority and Kawachi and coworkers[39] found that weight gains may be minimised if cessation was accompanied with moderate increase in levels of physical activity. The amount of weight gained with cessation may differ by age, social status and other behaviours.[33] Among a work-based cohort quitters who had been heavy smokers (20+/a day) appeared to gain more weight than those who smoked less.[32]

Stopping smoking during menopause was associated with greater weight gain[32;73] and relatively more women who became overweight during pregnancy had stopped smoking.[21;32]

6.4.5 Occupation- and work-based cohorts

Eleven cohorts assessed weight change among occupation- or work-based groups. The six cohorts which assessed diet suggest that a lower risk of becoming obese or gaining excess weight is found among those with the highest fruit and vegetable intake[62] consumption of at least one portion of cereals per day[76] lower consumption of sugar sweetened beverages[63] more favourable intakes of fat and fibre[64] slower pace of eating and less 'nibbling'[32] and with a 'good' diet.[46] Men in the US physicians[64] and UK Whitehall II cohorts[46] who were more active were less likely to gain in waist circumference or BMI, respectively. Among fire fighters[32] greater recreational activity was associated with lower weight gain, although self-reported activity levels at baseline were not. In the Nurses Health Study II vigorous physical activity was protective against weight gain.[47] Physical inactivity was associated with weight gain.

Other studies reported that weight gain was associated with long (12-hour) work shifts,[38] lower employment grade,[46] overtime working,[77] job insecurity,[78] and periods of unemployment.[79] The Whitehall II study reported that it was the element of perceived control rather than the employment grade per se that was significantly associated with weight gain (that is, less control more weight gain).[46]

6.4.6 General population cohorts

A total of 24 general population cohorts considered factors associated with weight in adulthood. Results from 12 general population cohorts specifically addressing diet reflected the findings of other cohorts. Lower risk of weight gain was associated with lower consumption of chips and fried foods;[59] higher fruit and vegetable intake and lower confectionary consumption;[42;60] higher fat intake (women with obese parents only,[80] women who were sedentary only[55]); and less restrictive eating practices and infrequent consumption of takeaway foods[48] or infrequent fast food restaurant use.[61] A diet containing more fibre,[42;81] little alcohol[50] and less sugar-containing drinks also appears to help prevent weight gain. There was no independent association of frequency of eating with

prospective weight change over the preceding 8–10 years in the NHANES I Epidemiologic Follow-up Study (NHEFS) cohort.[82] In the Danish MONICA study of 3000 Danish adults, obese women with night eating experienced a greater average 6-year weight gain.[83]

Quatrimoni (2002)[66] found that in 737 non-overweight women from the Framingham Offspring/Spouse cohort, the likelihood of becoming overweight at 12 years follow-up was approximately 29%. The relative risk of developing overweight was RR 1.4; (95 CI 0.9, 2.2) in women who ate an 'Empty Calorie' diet that was rich in sweets and fats with fewer servings of nutrient-dense fruits, vegetables, and lean food choices, compared with women who ate a lower-fat, nutritionally varied 'Heart Healthy' diet.

Schulz (2005)[65] looked at food patterns and subsequent weight gain nearly 25,000 subjects from the German cohort in the EPIC study. Those with a food pattern of a high consumption of whole-grain bread, fruits, fruit juices, grain flakes/cereals, and raw vegetables, and of low consumption of processed meat, butter, high-fat cheese, margarine, and meat were less likely to gain weight. Mean annual weight gain gradually decreased with increasing pattern score (higher score indicates healthier diet) (p-value for trend < 0.0001), i.e., subjects scoring high for the pattern maintained their weight or gained significantly less weight over time compared with subjects with an opposite pattern. However the prediction of annual weight change by the food pattern was significant only in non-obese subjects, ie dietary patterns predicted weight gain in normal weight subjects by not in those already obese.

On balance it appears that an active daily lifestyle can help maintain weight. The UK 1958 birth cohort found no relation between activity level (assessing **change** in activity level) and change in weight.[59] Data from one small study also found no significant association between weight and physical activity.[60]

The other cohorts reported reduced risk of excess weight gain with lower sedentary activity[48] higher baseline activity levels and lower television viewing,[45] high level of physical activity,[50] and higher frequency of active travel to work and recreational activities.[52] In men from the NHANES I and NHEFS cohorts,[36] the incidence of major weight gain was lowest among men who reported high levels of physical activity or whose baseline BMI was between 24.0 kg/m^2 and 27.8 kg/m^2.

Nooyens (2005)[42] investigated the effects of retirement on lifestyle and weight and waist circumference in 288 Dutch men. Over five years increases in weight and waist circumference were associated with a decrease in several physical activities, such as household activities, bicycling ($p = 0.03$), and walking ($p = 0.02$). Increase in body weight and waist circumference was higher among men who retired from active jobs (0.42 kg per year and 0.77 cm per year, respectively) than among men who retired from sedentary jobs (0.08 kg per year and 0.23 cm per year, respectively).

Heavy work-related activity in Chinese adults was associated with reduced risk of weight gain[49] and greater levels of exercise endurance were significantly correlated with lower rates of weight gain in a small group of premenopausal women.[84] A high-fat diet combined with a sedentary lifestyle predicted weight gain in women but not a high-fat diet combined with higher levels of activity.[55] Decreased fitness during young adulthood was strongly associated with increased weight [54] and men who stopped exercising had larger increases in BMI than regular exercisers.[51]

Other factors associated with lower weight gain included lower anxiety scores[60] and low dietary restraint and higher self-esteem.[85] A 7-year follow-up of young US adults showed that parents' body size was positively associated with a participant's BMI and father's education was inversely associated with BMI.[53]

Viner (2005)[16] UK conducted an analysis of the 1970 British Birth cohort of over 8000 subjects followed up at 5, 10 and 30 years (30 year follow-up self-reported) examining the relationship between television viewing and BMI change. Weekend but not weekday TV viewing in early childhood independently predicted increased adult BMI. Each additional hour of TV watched on weekends at 5 years increased risk of adult obesity by 7%.

6.5 Sub questions

6.5.1 Variation by gender, age, ethnicity, religious practices or social group

6.5.1.1 Gender

Two studies among children suggest gender differences; Berkey and coworkers[68] reported larger annual increases in BMI in girls than in boys who reported a higher calorie intake and less physical activity in the year between BMI measurements. Datar and Sturm[15] reported that additional physical education in primary school was associated with reduced BMI in overweight girls but not boys. Among adults, one small study suggests gender differences in the rate of weight change following change in marital status such that women but not men experienced greater weight change following marriage and lost less weight than those who remained married.[37]

6.5.1.2 Age

Among adults, one cohort of men found that ‘super gainers’ of weight during smoking cessation tended to be younger in age.[32] Two cohorts reported that adults tended to gain weight with age.[86,87] Tremblay and coworkers[87] noted that lifestyle changes observed during (12-year) follow-up should have favoured body weight maintenance but adiposity significantly increased with ageing suggesting age-related effects on fat balance largely dominated lifestyle changes that should have promoted fat loss.

6.5.1.3 Ethnicity

Among children, two cohorts examined ethnicity and weight change, with one reporting that only 0.3% variation in follow-up BMI was explained by ethnicity.[17] Ambrosius and coworkers[88] reported that the rate at which BMI increased in black children was significantly greater than in the white children ($p < 0.0001$).

Among adults, no study specifically assessed the effects of ethnicity. However, the findings available suggest that ethnicity appears to be a risk factor for weight gain for some women during/following pregnancy, as shown in studies of Caucasian and African American women.[23,53] At each level of parity, black women demonstrated greater adverse changes in adiposity than did white women.[53] This was supported by results of parity from women in the NHANES I and NHEFS.[24]

One cohort found that Mexican Americans compared to non-Hispanic whites had greater risk of weight gain with smoking cessation but this racial difference contributed only slightly to overall contribution to weight gain.[35] Another cohort found that black non-Hispanic fire-fighters/paramedics gained 7.1 kg (15.7 lb) compared with white Hispanics who gained 4.0 kg (8.9 lb) and white non-Hispanics who gained 3.0 kg (6.7 lb) ($p < 0.001$).[32]

Spiegelaere reported that adiposity rebound before age 5 was inversely related to body mass at age 3 and was independent of social status.[89] Among adults, low family income may be related to excessive gestational weight gain but is not as influential as increasing food intake.[53] Lower job control was associated with increased weight gain in the Whitehall II study.[46] Low socioeconomic status also associated with ‘super gainers’ of weight during smoking cessation in men.[33] Kahn and Williamson[36] reported a significant increase in mean BMI change for American men with lower education levels compared with those who had gone beyond 12th grade education.

6.5.2 Influence of previous weight loss

No data were identified regarding weight history of children and few data were available in adults. Previous weight change is a potential confounder of the relation between diet and subsequent weight change in prospective observational studies. The Nurses Health Study II[47] reported that women who lost greater than or equal to 10% of their weight between 1989 and 1991 subsequently gained more weight between 1991 and 1995 than their peers who did not lose weight.

6.5.3 Potential negative impact

None were reported.

6.6 Limitations of the review

Time limitations in the preparation of this review necessitated pragmatic decisions regarding the search strategy. It is difficult to limit a search to identify only cohort designs and so the review was limited to cohorts where the main focus of the paper was on the physiology of weight gain. It is possible that key cohorts may have been excluded by the search strategy if the paper used different terms for weight gain (for example, cohorts that explored the determinants of increases in BMI). A high-quality systematic review of observational cohorts exploring the relation between various behavioural factors and weight has been commissioned by the WCRF and will be published in 2006.

Studies assessing associations between menopause and changes in weight had a maximum 6-year follow-up despite the fact that menopause may span up to 8–10 years.

At times it was difficult to ascertain which data were longitudinal and which were cross-sectional (and therefore weaker). As large cohorts were sometimes used for various analyses and reported in multiple publications, it was sometimes difficult to marry up publications pertaining to the same cohort.

Cohort studies can only examine associations, which may not be causal in direction. All cohorts report outcomes at latest follow-up, and in some studies with follow-up over long period (that is, 15 years) with little interim measurement, it is difficult to ascertain if the correlations between dietary and physical activity variables are linear. It might be the case that issues within the design of cohorts produces inconsistent results and results that intuitively do not make sense (that is, increased physical activity or lower calorie intake associated with weight gain). Furthermore, many cohorts rely on self-reported data, which are fraught with bias.

7 Prevention evidence summary: interventions to raise awareness

The following is based on an evidence review produced by the University of Teesside. Detailed evidence tables and supporting information are in Appendix 5.

7.1 Evidence statements (Table 7.1)

Table 7.1 Evidence statements and grading

No.	Statement	Grade	Evidence
Weight outcomes			
1	There is limited evidence to show that a multi-component intervention including a public health media campaign, can have a beneficial effect on weight management, particularly among individuals of higher social status	2+	One 2+ (Wardle et al. 2001[90]) One 2– showing no effect but concerns about validity (Tudor-Smith et al. 1998[91]
2	The effectiveness of promotional campaigns focusing on education alone remains unclear	1+	One RCT 1+ (O'Loughlin et al.[92]) in low-income, low-literacy volunteers in Canada suggest education alone ineffective
Diet outcomes			
3	There is a body of evidence that promotional campaigns including media interventions can increase awareness of what constitutes a healthy diet and may subsequently improve dietary intakes	2+	Five studies: O'Loughlin et al. 1998[92] (1+), Department of Health 2003[93] (2±), Wardle et al. 2001[90] (2+), Tudor-Smith et al. 1998,[91] (2–) Van Wechem 1997[94] (2–)
4	There is a body of evidence that food promotion can have an effect on children's food preferences, purchase behaviour and consumption. The majority of food promotion focuses on foods high in fat, sugar and salt and therefore tends to have a	2+	One systematic review 2+ (Hastings et al. 2003[95])

No.	Statement	Grade	Evidence
	negative effect. However, food promotion has the potential to influence children in a positive way		
Physical activity outcomes			
5	It remains unclear whether media interventions can influence participation in physical activity. There is some evidence that interventions may be more successful if they target motivated subgroups	2++	One systematic review of CBAs (Cavill and Bauman 2004[96] [2++]) plus one RCT (O'Loughlin 1998[92] [1+]), 2 BAs grade (2+) (Huhman et al. 2005,[97] Merom 2005 et al.[98]) and a BA grade 2– (Tudor-Smith et al. 1998[91])
6	Promotional campaigns including media interventions can improve knowledge, attitudes and awareness of physical activity. Levels of awareness are likely to vary according to type of medium used and the scale of the campaign	2++	One systematic review of CBAs (Cavill and Bauman 2004[96] [2++]) plus one RCT (O'Loughlin 1998[92] [1+]), two BAs (2+) (Huhman et al. 2005,[97] Merom 2005 et al.[98]) and a BA grade 2– (Tudor-Smith et al. 1998[91])
Generalisability			
7	The majority of the identified interventions are generalisable to the UK	2+	Hillsdon et al. 2001[99] (2+), Wardle et al. 2001[90] (2+), Wimbush et al. 1998[100] (2–), Tudor-Smith et al. 1998[91] (2–), Department of Health 2000[93] (2±)
8	There is a paucity of evidence on the effectiveness of interventions among lower socioeconomic groups and BMEGs	N/A	N/A
9	There is a paucity of evidence in children and young people; the generalisability of evidence in adults to children and young people remains unclear	N/A	N/A
10	The effectiveness of	2+	Wardle et al. 2001[90] (2+),

No.	Statement	Grade	Evidence
	interventions vary by age, gender, social status and ethnicity		Hillsdon et al. 2001[99] (2+), Huhman 2005[97] (2+)
Implementation			
11	Parents are important role models for children and young people in terms of behaviours associated with the maintenance of a healthy weight	3	One survey (McCullough 2004[101])
12	Books, magazines and television programmes are an important source of information and actively involving media providers may improve the effectiveness of interventions	3	One survey ('Family food survey' 2003[102]), one CBA (2+) (Wardle et al. 2001[90])
13	A significant proportion of parents may not recognise that their child is overweight and may have a poor understanding of how to translate general advice into specific food choices	3	One survey (Jeffery 2005[103])

BA, before-and-after study; BMEGs, black and minority ethnic groups; CBA, controlled before-and-after study; N/A, not applicable; RCT, randomised controlled trial.

See Appendix 5 for associated evidence tables.

7.2 Methodology

Database searches were carried out in September 2005 for papers published from 1990 onwards (1995 onwards for systematic review level evidence). A final update search was completed on 1 December 2005 on a reduced number of databases. The inclusion and exclusion criteria for the review adhered to the standard public health review parameters. Priority was given to systematic reviews and to studies conducted within the UK. From an initial 3147 hits, 66

papers were assessed in detail of which 20 papers met the critical appraisal criteria for inclusion in evidence tables. In line with the review parameters, studies considering knowledge, attitudes and awareness were only included if they also had a measure of weight, diet and/or activity. However, findings on knowledge, attitudes and awareness per se were considered in the studies identified. Towards the end of the reviewing process an additional review conducted for *Safe*food, the Food Safety Promotion Board, Island of Ireland, on the impact of social marketing interventions and knowledge, perceptions and behaviour in relation to nutrition and food safety (McDermott, unpublished data, 2006) was received. Although the findings were considered (and are noted below), because of time constraints, the review could not be fully appraised alongside the other identified papers. However, the review did not include any additional studies that met the agreed review parameters.

7.3 Weight outcomes

Three studies were identified with weight outcomes: one short, but good-quality randomised controlled trial (RCT) of an education-only intervention in Canada[92] and two UK-based multi-component before-and-after studies – Fighting Fat, Fighting Fit campaign (FFFF)[90] and Health Promotion Wales in the Heartbeat Wales campaign.[91]

The FFFF campaign[90] aimed to raise public awareness of the need for obesity prevention, healthy eating and increased physical activity among UK adults. The campaign was broadcast during peak and daytime programming across BBC 1 and BBC 2, BBC radio 1 and local BBC radio programmes, and was supported by a website, Ceefax, book, video, telephone lines and national and regional press coverage.

The Welsh-based community intervention aimed to prevent cardiovascular disease by modifying smoking, diet and exercise. It consisted of public health education campaigns, including specially developed television programmes, catering awards and a worksite health promotion programme.[91]

All three studies were in adults and used self-reported data. Research staff provided the intervention in all three studies alongside the BBC education department in the FFFF campaign[90] and Health Promotion Wales in the Heartbeat Wales campaign.[91]

7.3.1 Education only

The low-intensity education-only intervention, providing pamphlets to Canadians households, with the aim of raising awareness of healthy weight and healthy eating, did not show an effect on body mass index (BMI) at 10 weeks.

7.3.2 Multi-component interventions

One of the two multi-component before-and-after studies – FFFF – found that the 7-week intervention to raise public awareness of the need for obesity prevention, healthy eating and increased physical activity had a positive effect on weight 3 months after the intervention.[90;104] The campaign demonstrated an average post-campaign weight of 2.3 kg lower than before the campaign for the full random sample (people who requested an information pack and returned the baseline questionnaire, assuming non-completers of follow-up questionnaire returned to baseline weight) and 4.2 kg lower for completers only ($p < 0.001$). Forty-four per cent of the full sample and 78% of completers lost weight. Although the campaign aimed to target groups with higher prevalence of obesity (those in socioeconomic groups III M and IV), participants were more likely to be female, obese and higher socioeconomic status compared with the British adult population.

The Heartbeat Wales campaign did not show a positive change in overweight, with a 2.5 percentage point change in Welsh adults compared with a 1.1 percentage point change in the control community at 5-years' follow-up for BMI (at least 24 for women and 25 for men). However, this study was of poor quality, with evidence that there was contamination in the control area.

The studies with a weight outcome considered by the Food Safety Promotion Board (McDermott, unpublished data, 2006) are considered within other public health evidence reviews (principally pre-school, school and community reviews).

7.3.3 Evidence of corroboration

One UK-based cross-sectional study considered awareness of weight issues in UK parents (with children of mean age 7.4 years).[103] The results suggest that general awareness of the importance of healthy weight among adults and their children in the UK is low. Among overweight parents, 40% of mothers and 45% of fathers judged their own weight 'about right' and 27% of mothers and 61% of fathers were unconcerned about their weight. Only a quarter of parents recognised overweight in their child. Parents were less likely to identify overweight in sons than in daughters. More mothers than fathers correctly assessed their child's weight. Maternal weight status did not affect mothers' awareness of children's weight but only 74% of overweight fathers compared with 85% normal weight fathers were correct. Of parents who were unaware their child was overweight, 86% were also unconcerned. Parents' perception of their child's weight did not vary by socioeconomic status.

7.4 Diet and activity outcomes

One RCT[92] and three before-and-after studies,[90,93,94] which reported dietary outcomes in adults, were identified. Three of the studies – FFFF, Heartbeat Wales and the 5 A DAY[93] pilot to increase awareness and consumption of fruit and vegetables – were UK based. With the exception of one study, an education-only programme,[92] the interventions were multi-component.

One high-quality systematic review[96] of mass media campaigns with an explicit focus on physical activity was identified. The 15 studies identified in the systematic review were predominantly before-and-after studies. Follow-up ranged from a few weeks to 7 years. Three of the 15 studies were conducted in the UK: a walking campaign in Scotland,[92;100] the Active for Life campaign in England promoting moderate physical activity[99] and the FFFF campaign.[90] The

studies included in the review varied considerably in their focus (some targeting whole populations, other subgroups) and content (with five considered multi-component interventions). A range of ages were included although the majority were targeted at adults. Two additional studies in adults were identified.[91,92] Two additional studies in children were also identified; the US-based VERB campaign,[97] aiming to increase awareness of physical activity among 9–13-year-olds, and an Australian Walk Safely to School Day campaign.[105]

Providers of the interventions with diet and activity outcomes were research staff often in collaboration with government, health promotion and/or media bodies.

7.4.1 Diet

The findings of all identified studies suggest that interventions can result in improvements in various dietary outcomes, including a decrease in high fat consumption, increase in fruit and vegetable intake, and decrease in fried foods and snacking.

7.4.1.1 Education only

The RCT on healthy weight/eating pamphlets[106] reported that the frequency of consumption of high-fat foods decreased in the intervention group but remained stable in the control group ($p = 0.02$) 2 weeks after the 8-week campaign. Intervention participants also reported more improvements in their eating habits than the controls ($p = 0.02$).

7.4.1.2 Multi-component campaigns

The UK-based FFFF campaign demonstrated statistically significant improvements in diet 5 months after the campaign in a random survey of people who registered for more information (1% of the cross-sectional population survey, therefore limiting generalisability).[90;104] Significant improvements ($p < 0.001$) were reported in fruit and vegetable intake (increased by 0.8 [1.3] portions/day), 13% increase in respondents eating the recommended five portions a day and 16% increase in participants eating fried food less than once a week. Significant

improvements ($p < 0.001$) were also observed in consumption of fat spreads, lower fat milk, removal of fat from meat, snacking and consumption of starch-based meals.

One-year follow-up of the community-based five-a-day pilot projects[93] demonstrated that the intervention had stemmed a fall in fruit and vegetable intake against the national trend. Overall the intervention had a positive effect on people with the lowest intakes. Those who ate fewer than five portions a day at baseline increased their intake by one portion over the course of the study. In contrast, those who ate five or more portions a day at baseline decreased intakes by about one portion per day.

The 'Fat Watch' campaign in the Netherlands reported no significant difference in fat consumption between the intervention and control community at approximately 8 months' follow-up.[94] However, more respondents in the intervention community (32%) than in the control community (24%) reported that they had tried to lower their dietary fat intake in the past 6 months ($p < 0.01$). In the intervention community, a small but significant decrease (3%) in fat consumption was found ($p < 0.04$) between baseline and follow-up, compared to no change in the control community. The intervention was a pilot and took place within a framework of a nationwide 'fat watch' campaign, which may have confounded the results.

The one study that did not show significant differences between intervention and control (Heartbeat Wales[91]) showed improvement from baseline in both intervention and control communities with evidence of contamination in the control area.

These findings are consistent with the conclusions of the Food Safety Promotion Board review (McDermott, unpublished data, 2006) that there is strong evidence that social marketing interventions can bring about dietary improvements. Twenty-three of the 28 included studies reported at least one significant dietary improvement. The review reported that:

- There is strong evidence that social marketing interventions can improve outcomes associated with fruit and vegetable intake.
- There is moderate evidence that social marketing interventions can improve outcomes associated with fat intake. However, when the results of a subset of five studies which compared both fruit and vegetable intake **and** fat intake outcomes were examined, there was evidence that interventions could be as effective in terms of fat outcomes as they were in relation to fruit and vegetable outcomes.
- There is strong evidence that social marketing interventions can improve other dietary behaviours (identified studies included consumption of water, dairy products, 'unhealthy foods' and sweets).
- There is some evidence that social marketing interventions can have an effect on diet-related health but in limited circumstances.

7.4.1.3 Evidence of corroboration

A systematic review by Hastings and coworkers[95] considered the effectiveness of food promotion to children. The review included both experimental and cross-sectional designs of various durations, the majority of which were conducted in North America; no UK-based studies were identified. Although the included studies did not meet the criteria for inclusion for effectiveness, it was agreed that the review be included for evidence of corroboration.

The review concluded that food promotion can have and is having an effect on children, particularly in the areas of food preferences, purchase behaviour and consumption. Most studies uncover an effect that will be harmful. However, there is evidence that promotion can have a beneficial effect. Food promotion has the potential to influence children in a positive way. The review found that:

- All seven studies identified found that exposure to food promotion had an influence on, or was significantly associated with, the specific purchase-

related behaviour measured in each study (for example, sales, household purchase).

- Eleven studies investigated the effects of exposure to food promotion on children's food consumption behaviour. Overall the studies provide evidence of an effect of food promotion on consumption behaviour. Effects were sometimes inconsistent and were not found in all the studies, but were found in sufficient studies to suggest that food promotion influences children's food consumption.

- Studies suggest that food promotion or television viewing significantly influences children's food behaviour and diet independently of other factors known to influence children's food behaviour and diet. However there is little evidence to show whether the influence of food promotion on children's food behaviour and diet is greater or lesser than that of other factors.

Additional UK surveys suggest that although there are high levels of general awareness of healthy eating – and parents rate it as an important issue – there is poor understanding of how general advice translates into specific food choices.[92,101;102;107,107,108] Parents are an important source of information on nutrition for children and parents themselves have reported that doctor/health professional was their main source of information on nutrition.[101] However, in another survey 43% of parents said that their main source of nutrition information was from books and magazines and 15% relied on family and friends.[102]

7.4.2 Physical activity

A systematic review of mass media campaigns with an explicit focus on physical activity reported that 5 of 15 studies showed significant increase in physical activity at the population level.[96] Whereas 10 of the 15 identified studies reported no significant increases in measures of physical activity at the population level, 4 reported significant increases in activity among subgroups. Of the three UK-based campaigns included in the review only one (FFFF) showed significant improvements in physical activity; overall 39% of full sample and 74% of

completers increased their activity levels and the proportion undertaking regular moderate exercise increased from 29% to 45% (29–60% for completers only).[90]

The authors of the systematic review were unable to determine reliably the extent to which many of the studies represented true ‘community-wide’ campaigns and as a result it is difficult to separate out the effect of the mass media component in addition to any community activity. The scale of the ‘dose’ of the intervention (expenditure, media exposure or outputs for the campaigns) was unclear in 10 of the 15 campaigns. It was also difficult to ascertain how much attention was paid to the physical activity component in the five studies that covered factors other than physical activity (notably healthy eating). The authors note that for instance in the Stanford 5 City project physical activity messages appeared only once every 6 weeks on average and in the Minnesota Heart Health programme physical activity was included alongside prevention of hypertension, healthy eating and non-smoking. Therefore the authors were unable to explore any potential relations between dose, number of components included in the campaign, community and media elements, and effectiveness.

Many of the included campaigns were single events, others were integrated parts of community-wide cardiovascular education, and few were sustained and focused physical activity initiatives over a number of years. The authors identify a range of mass media and communications strategies employed, including paid television commercials, public service announcements, radio, newspaper and unpaid media publicity techniques. All campaigns mentioned link to other activities but it is not possible to ascertain the extent to which these were truly ‘community wide’ and the authors were unable to separate out the effect of the media component from any community activity.

The two additional studies in adults reflect these mixed results. The RCT of healthy weight/eating pamphlets demonstrated that intervention participants were 2.7 times more likely than control to change from reporting no exercise at baseline to exercising once or more a week at follow-up (2 weeks after the

8-week campaign).[92] In contrast, 'Heartbeat Wales' demonstrated no significant difference between intervention and control communities for physical activity outcomes.[91] The problems with this RCT have been noted previously.

Among children, the VERB campaign found that levels of activity increased in line with awareness of the campaign. Those 9–10-year-olds who were aware of the campaign engaged in 34% more free-time physical activity sessions per week than those who were unaware. However, no overall effect on free-time physical activity sessions was detected at the population level.[97] The Australian Walk Safely To School Day attributed a relative, short-term increase of 31% among children walking to school to the campaign; on a population level this equates to a 6.8% increase in walking to school.[98,105]

7.5 Knowledge, attitudes and awareness

Five campaigns and one systematic review provide equivocal evidence that awareness is translated into action in terms of diet and exercise. The majority of studies reported good awareness of campaigns but the impact on behaviour change is unclear. However, it has been suggested that people who are more motivated and active at baseline may be more likely to become more active following an awareness-raising campaign.[99]

7.5.1 Diet

The UK-based 5 A DAY campaign resulted in a 17% increase in the proportion of the intervention group that correctly reported that five portions a day was the optimal fruit and vegetable intake compared with 8% in the control areas.[93] In the Dutch 'Fat Watch' campaign there was no significant difference ($p > 0.05$) between the intervention and control community in the proportion of respondents that referred to the campaign as a reason for their behavioural change.[94] However, more of the intervention group (20%) than the control group (12%) intended to eat lower-fat foods in the following 6-month period ($p < 0.01$). Of those respondents who intended to eat lower-fat foods, significantly more

intervention respondents (29%) than controls (11%) referred to the campaign as a motive for this intention ($p < 0.01$).

The systematic review by Hastings and coworkers[95] concluded that food promotion influences children's food knowledge and preferences. The findings of the review were:

- Studies that have considered the influence of food advertising on nutritional knowledge provide modest evidence of an effect of food advertisements on children's nutritional knowledge. Four of the identified studies found that exposure to food promotion had a significant impact on, or was associated with, differences in nutritional knowledge.

- Fourteen studies suggested, on balance, that food promotion influences children's brand and product preference. Six of the nine high- and medium-quality studies found that promotion had significant effects on children's product and brand preferences and children were more likely to choose foods with high fat, salt or sugar than alternative 'healthy' products after viewing food adverts.

The Food Safety Promotion Board review (McDermott, unpublished data, 2006) reported that when the results from the studies were examined in terms of level of effect, it was apparent that social marketing interventions were strongly and equally effective at influencing behaviour, knowledge and psychosocial variables such as self-efficacy, attitudes and perceptions of the benefits of eating more healthily. Social marketing interventions appeared to be moderately effective at influencing stage of change in relation to diet, and to have a more limited effect on diet-related physiological outcomes such as blood pressure, body mass index and cholesterol.

7.5.2 Physical activity

A systematic review of physical activity campaigns reported outcomes in terms of awareness of campaign messages and awareness of knowledge, attitudes or

beliefs about physical activity.[96] Campaigns achieved high recall with a median 70% (range 38–97%) of target group aware of the campaign. Six of 15 studies reported measures of knowledge or beliefs, of which three found significant increases in measures. Intention to be more active was measured in seven campaigns, with three finding an increase in intention to be active against four that found no change or a decrease. One of the campaigns included in the systematic review[109] reported that 'advice from social network and mass media' was related to trying to be more active ($p < 0.001$). The UK Active for Life campaign included in the review reported that those aware of the campaign at 1 year had been more active at baseline than those not aware of the campaign.[99] The walking campaign in Scotland reported that, at a population level, the campaign had a notable impact on knowledge about walking but had little impact on behaviour.[100]

The additional VERB campaign targeted at 9–13-year-olds found that 90% of children who were aware of VERB also demonstrated understanding of the messages. A significant positive relation was detected between the level of awareness of VERB and weekly median sessions of free-time physical activity ($p < 0.05$).[97]

7.6 Sub questions

7.6.1 Variation by gender, age, ethnicity, religious practices or social group

The results suggest that the effectiveness of campaigns to raise awareness may vary by age, gender, ethnicity and social status. The findings of the general population survey following the BBC's 'Fighting fat, fighting fit' campaign suggest that men, people under 25 years, lower socioeconomic status groups and black and minority ethnic groups (BMEGs) may require specifically targeted campaigns as significantly fewer participants in these groups failed to complete the follow-up survey (registrants survey). These findings are reflected in the 'Active for life' campaign where greatest awareness was found among 16–24-year-olds (65%)

and lowest awareness among 65–74-year-olds (25%).[99] Men were more aware than women as were those with children living at home and those from lower social grades. Changes in the proportion of participants who knew about the recommendations were higher in women, older age groups and social grades C II/DE. The VERB campaign aimed at 9–13-year-olds was found to be more effective for younger children, girls, white children (compared with Latino/Hispanic and black children from lower-income households and children living in high-density urban areas.[97]

The Food Safety Promotion Board review (McDermott, unpublished data, 2006) also reported that there was some evidence that particular population subgroups (for example, males and females, different age groups, different ethnic groups) respond in different ways to social marketing interventions. However, no clear picture emerged, and there were too few studies to examine differential impact more rigorously. The review concluded that interventions with more specifically defined target groups appeared to be more effective than those with more broadly defined target groups.

7.6.2 Influence of previous weight loss

It was not possible to answer this question from the evidence identified.

7.6.3 Source and mode of delivery

No evidence of effectiveness was identified to answer how best to engage people. Many of the other campaigns identified could be generalisable to the UK, particularly for motivated Caucasian females of higher socioeconomic status.

The systematic review of 15 mass media campaigns with an explicit focus on physical activity found that levels of awareness are likely to vary according to type of medium used and scale of the campaign.[96] The importance of measuring the dose of the intervention was highlighted, as there is a strong relation between amount of media exposure of a campaign message and the resulting level of awareness. The scale of expenditure, media exposure or outputs from the

campaigns was unclear in 10 of 15 campaigns studied. Of the UK studies included in the review, both the Health Education Board for Scotland and the FFFF campaigns found that awareness was greater for associated television programmes than radio programmes. For example, in the FFFF campaign, 87% of respondents said they were introduced to the campaign through television compared with 14% by radio.[90;96,104] The FFFF campaign was organised by media providers themselves rather than media space purchased at commercial rates which may have had an impact on the success of the campaign.

The Food Safety Promotion Board review (McDermott, unpublished data, 2006) concluded that interventions could be effective in all settings identified but it was not possible to explore any relation between setting type and effectiveness. Effectiveness seemed to be improved where the choice of setting appeared to have been carefully considered and was integral to the intervention strategy as opposed to being selected with little strategic purpose. These results suggest that the effects of social marketing interventions are likely to be enhanced if careful consideration is paid to the choice of setting and features of the setting are harnessed to add value to the intervention.

7.6.4 Potential negative impact

The systematic review of the effectiveness of food promotion to children concluded that food promotion can have and is having an effect on children, particularly in the areas of food preferences, purchase behaviour and consumption.[95] Most studies uncover an effect that will be harmful (because foods promoted are predominantly high in fat, salt and/or sugar) but there is evidence that promotion can have a beneficial effect.

7.7 Limitations of the review

The major limitation to the review was the design of the studies. There were few controlled before-and-after studies (CBAs) and many of these were evaluated cross-sectionally. Also the data pertaining to weight and behaviour are self-reported, which gives cause for concern regarding bias.

A range of large studies have not been included in this review due to a lack of evaluation or evaluation that did not meet the parameters of this review, including ‘The big fat problem’ and ‘Walking way to health’.

8 Prevention evidence summary: interventions for pre-school children and family-based interventions ('early years')

The following is based on an evidence review produced by the University of Teesside. Detailed evidence tables and supporting information are in Appendix 6.

8.1 Evidence statements (Table 8.1)

Table 8.1 Evidence statements and grading

No.	Statement	Grade	Evidence
Weight outcomes			
1	There is limited evidence that interventions which focus on the prevention of obesity through improvements to diet and activity appear to have a small but important impact on body weight that may aid weight maintenance	1+	Five RCTs, three of which prevented gain (Fitzgibbon et al.[110–111] [Hip-Hop; 1+], He 2004[112] [1+], STRIP[113–114] [1+]) and two found no difference between intervention and control (Healthy Start[115–116] [2++], Dennison et al. 2004[117] [1+])
2	Improvements in the food service to pre-school children can result in reductions in dietary intakes of fat and improved weight outcomes	1+	Body of evidence 1+: one systematic review (Worsley 2004[118])
3	No family studies were identified among children under 5 years of age	N/A	N/A
4	Family-based interventions that target improved weight maintenance in children and adults, focusing on diet and activity, can be effective, at least for the duration of the intervention	1++	Body of evidence 1++: one systematic review (MCLean et al. 2003[119] [1++]) and one RCT (Hopper 1996[120] [1+])

No.	Statement	Grade	Evidence
5	The effectiveness of interventions tends to be positively associated with the number of behaviour change techniques taught to both parents and children	1++	Body of evidence 1++: one systematic review (McLean et al. 2003[119])
6	It remains unclear whether the age of the child influences the effectiveness of family-based interventions compared with individual interventions	N/A	One study (Brownell et al. 1983[121]) in a systematic review (McLean et al. 2003[119] [1++]) suggested that more family interventions may be more effective in younger children
Diet and activity outcomes			
7	Interventions which do not identify favourable changes in weight outcomes may identify favourable changes in diet and/or activity outcomes (where recorded). The reasons for this are unclear	1+	Body of evidence, majority 1+: seven of the nine studies (Dennison et al. 2004[117] [1+], He 2004[112] [1+], Healthy Start[115–116] [2++], Koblinsky et al. 1992[122] [2+], McGarvey et al. 2004[123] [2+], Reilly and McDowell 2003[124] [grade to be checked on publication of full study], STRIP[113–125] [1+]) reporting significant effects, concurrent with conclusions of systematic review (Worsley 2004[118] [1+]). One study showed mixed results (Hip-Hop[110–111] [1+])
8	There is some evidence that interventions which do not focus on preventing obesity, but aim to bring about modest changes in dietary	2+	Healthy Start[115– 116] (2++) and Dennison et al. 2004[117] (1+) (Although STRIP[113–125]

No.	Statement	Grade	Evidence
	and physical activity behaviour, are unlikely to demonstrate an impact on body weight. However, there is evidence from cohort studies that people who habitually eat healthy diets and are physically active are more likely to maintain their weight over the long term		[1+] – aimed to improve cardiovascular disease – showed positive results for weight for girls) See energy balance statements with regard to cohort studies
9	There is evidence for small but important beneficial effects of interventions that aim to improve dietary intake (such as videos, interactive demonstrations, and changing food provision at nursery school) so long as these interventions are not solely focused on nutrition education alone	2+	Eight of the nine studies (Dennison et al. 2004[117] [1+], He 2004[112] [1+], Healthy Start[115–116] [2++], Hip-Hop[110–111] [1+], Koblinsky et al. 1992[122] [2+], McGarvey et al. 2004[123] [2+], Reilly and McDowell 2003[124] [1+], STRIP[113–125] [1+]) One CBA on education alone showed no effect (Horodynski et al. 2004[126] [2–])
10	The provision of regular meals in a supportive environment free from distractions may improve dietary intakes	4	Opinion of GDG
11	There is limited evidence that structured physical activity programmes within nurseries can increase physical activity levels	Grade pending	One RCT: 1+ (Reilly and McDowell 2003[124]) (grade to be checked on publication of full study)
12	Interventions which involve parents in a significant way may be particularly effective and can improve parental engagement in active play with children and a child's dietary intake	2+	Body of evidence 2+ (majority of studies included parents but McGarvey et al. 2004[123] [2+] Koblinsky et al. 1992[122] [2+]) specifically

No.	Statement	Grade	Evidence
			aimed at parents)
Generalisability			
13	The majority of interventions identified were conduced in the USA. However the findings are likely to be generalisable to the UK population	4	Opinion of reviewers and GDG
14	Interventions should be tailored as appropriate for lower-income groups	1+	Body of evidence 1+ and 2++: two RCTs (Dennison et al. 2004[117] [1+], Hip-Hop[110–111] [1+]) and one CCT (Healthy Start[115–116] [2++])
15	2–5 years is a key time to establish good nutritional habits especially when parents are involved.	1+	Body of evidence 1+: one systematic review (Worsley 2004 [118])
Implementation			
16	Interventions require some involvement of parents or carers	1+	Body of evidence 1+: virtually all included RCTs involved parents
17	There is limited evidence that interventions to increase opportunities for children to be active can be incorporated into nurseries and implemented by nursery staff	Grade pending	One RCT 1+ (Reilly and McDowell 2003;[124] grade to be checked on publication of full study)

CBA, controlled before-and-after study; CCT, controlled clinical trial; GDG, Guidance Development Group; N/A, not applicable; RCT, randomised controlled trial; STRIP,Turku Coronary Risk Factor Intervention Project for Children.

See Appendix 6 for associated evidence tables.

8.2 Methodology

Database searches were carried out in December 2004 for papers published from 1990 onwards (1995 onwards for systematic review level evidence). A final update search was completed on 1 December 2005 on a reduced number of databases. The inclusion and exclusion criteria for the review adhered to the standard public health review parameters. From an initial 5487 hits, 106 papers were assessed in detail of which 13 papers met the critical appraisal criteria for inclusion in evidence tables.

8.3 Weight outcomes

8.3.1 2–5-year-olds

Five interventions were identified among 2–5-year-old children and their families which reported a weight outcome. Of these, only two studies were designed specifically for the prevention of obesity.[110,112] Five of the six studies were/are being conducted in a nursery or childcare setting, but all had/have some degree of family involvement. The STRIP (Turku Coronary Risk Factor Intervention Project for Children) study was conducted in well-infant clinics in Finland.[113] Due to the limited evidence available on 2–5-year-olds, the paper by He[112] was included despite the fact that the children were overweight at baseline (the paper met the other inclusion criteria for this review).

Three[110–113] of the five studies found some evidence that the intervention prevented unhealthy weight gain leading to obesity, compared with controls. Ethnic minority children in Head Start programmes in Chicago who received a 14-week diet and physical activity intervention had significantly smaller increases in body mass index (BMI) compared with control children at 1-year ($p = 0.01$) and at 2-year ($p = 0.02$) follow-up (after adjustment for baseline age and BMI).[110] Girls (but not boys) who received the intervention in the Finnish STRIP study gained significantly less weight between the ages of 2 and 3 years compared with controls.[113] Chinese children who received the highly intensive intervention in the study by He[112] gained much less weight over time compared with controls.

Two US-based studies reported no significant differences in weight between intervention and control children.[115–116]

8.3.2 Family-based interventions for 5–18-year-olds

One systematic review[119] and one additional randomised controlled trial (RCT)[120] considered the efficacy of interventions targeted at 5–18-year-olds, and their families/carers, in terms of helping children maintain a healthy weight/prevent overweight or obesity.

The systematic review found that in children aged 5–12 years, five of the seven interventions reported no significant difference in weight outcomes at follow-up ranging from 1 to 5 years.[119] The effectiveness of interventions tended to be positively associated with the number of behaviour change techniques taught to both the parents and children. The additional RCT reported that two school-based studies, one among children aged 9 years and one among children aged 12 years, resulted in no significant differences between groups in post-intervention weight or skinfold thickness at 6 and 8 weeks follow-up.[120]

Among adolescents, one study reported that treating the mother and child separately appeared to be more effective than treating them together, or treating the child alone.[121]

8.4 Diet and activity outcomes

8.4.1 2–5-year-olds

The five studies with weight outcomes among 2–5-year-olds also reported diet and/or physical activity outcomes. Four additional studies assessing dietary and physical activity outcomes among 2–5-year-olds were also identified, all of which were conducted in a nursery or childcare setting, and had a degree of family involvement.[122–126]

Eight of the nine identified studies reported that a range of self-reported diet and physical activity outcomes improved following intervention. It is of note that

although all five of the studies with weight outcomes reported improvements in some indicators of diet and/or physical activity following intervention only three reported improvements in weight outcomes.[110,112,113] The reason for this disparity remains unclear.

8.4.1.1 Diet

Mean fat intake at 5 years of age was significantly lower in the intervention group of the STRIP study compared with the control group.[113] Similarly, the Hip-Hop to Health Jr. study demonstrated significant difference in per cent of calories from saturated fat at 1-year follow-up between intervention and control children (11.6% vs 12.8%, $p = 0.002$).[110–111] Differences were not observed for the other dietary variables assessed.

Koblinsky and coworkers[122] reported that a US-based parent education programme focusing on nutrition-related behaviour resulted in the intervention group consuming significantly more fruits, vitamin C rich fruits, green vegetables, breads, rice/pasta and orange vegetables than the control group.

McGarvey and coworkers[123] reported that attending educational sessions significantly improved the frequency of parents offering their child water. The results of a systematic review[118]) support the results of these individual studies. Two of the five studies of relevance showed beneficial effects on nutritional content of daycare menus[127] and dietary fat intake was significantly reduced in the intervention group of the STRIP study[113] (included in both systematic review and individual studies).

The only study that reported no effectiveness of the intervention[126] focused solely on nutrition education; the authors concluded that a change in knowledge and attitudes is insufficient to change eating habits.

8.4.1.2 Physical activity

The UK-based MAGIC (Movement and activity Glasgow intervention in children) pilot study reported that a nursery-based structured physical activity programme

resulted in a significant improvement in children's physical activity level (based on accelerometry output). McGarvey and coworkers[123] reported that attending educational sessions significantly improved the frequency of parents engaging active play with their child. The UK-based study by Dennison and coworkers[117] was successful in significantly reducing television viewing (the primary aim of the study) but did not show significant improvements in snacking or watching television during dinner (specific findings not reported).

8.4.2 Family-based interventions for 5–18-year-olds

Hopper[120] reported the findings of two interventions. Both treatment groups in the first intervention scored significantly higher than the control group on exercise knowledge and obtained a lower proportion of their energy from fat. In the second intervention, the treatment group scored higher than the control group on post-intervention fitness and nutrition knowledge as well as consuming more servings of fruit and vegetables. Within the treatment group a measure of the degree of family involvement significantly correlated with a reduction in intake of fat and cholesterol.

8.5 Sub questions

8.5.1 Variation by gender, age, ethnicity, religious practices or social group

The included studies provided little information on how the effectiveness of interventions varied by gender, age, ethnicity or socioeconomic status of the children or families. Three studies were conducted with low-income families, and the interventions were tailored accordingly.[110,115,117] Two studies reported no significant differences by gender[110,115] and one study reported no significant differences by age.[110–111] One study considered effectiveness by ethnicity and reported that there was a significant difference in weight-to-height ratio for white participants but not for African American or Hispanic participants.[115]

8.5.2 Influence of previous weight loss

It was not possible to answer this question from the evidence identified.

8.5.3 Source and mode of delivery

The evidence identified suggests that many of the interventions cited could be implemented in the UK. It seems reasonable to assume that such interventions could be implemented within the existing programmes and services. However, the evidence identified does not provide a firm answer on the most effective source of delivery. The majority of interventions took place in daycare or clinic settings. The data suggest that interventions work best where they are focused on preventing obesity (rather than simply improving diet and levels of physical activity) and delivered by researchers. In terms of the mode of delivery, the evidence identified suggests that intensive interventions work best and education alone is ineffective.

8.5.4 Potential negative impact

None of the identified papers reported negative impacts/harms.

8.6 Limitations of the review

There is a dearth of controlled studies that met the inclusion criteria for this review and no UK studies with weight and height outcome data were identified (one study [MAGIC] is expected to be published by May 2006). Potentially useful corroborative data from national programmes which are implemented locally, such as Sure Start, were not identified.

9 Prevention evidence summary: school-based interventions

The following is based on an evidence review produced by the University of Teesside. Detailed evidence tables and supporting information are in Appendix 7.

9.1 Evidence statements (Table 9.1)

Table 9.1 Evidence statements and grading

No.	Statement	Grade	Evidence
Weight outcomes			
1	The evidence on the effectiveness of multi-component school-based interventions to prevent obesity (addressing the promotion of physical activity, modification of dietary intake and reduction of sedentary behaviours) is equivocal. Some identified interventions demonstrated a reduction in mean BMI and the prevalence of obesity while the intervention was in place, but this finding was not universal. UK-based evidence in particular is lacking	2+	Four studies, two 1+ RCTs (Sallis et al. 2003[128] [boys; girls NS], Gortmaker et al. 1999[129] [girls; boys NS]) and two 2+ CCTs (Graf et al. 2005,[130] Kain et al. 2004[131] [boys; girls NS]) Six did not show significant improvements in weight/BMI (Warren et al. 2003 [132] [1+], Sahota et al. 2001[133][1+], Caballero et al. 2003[134] [1+], Donnelly et al. 1996[135] [2+], Neumark-Sztainer et al.[136] 2003 [2+], Story et al. 2003[137] [1+])
2	School-based physical activity interventions (physical activity promotion and reduced television viewing) may help children maintain a healthy weight		Flores 1995[138] (1+), Robinson 1999[139] and one CCT (2+) (Stephens 1998[140]) Six physical activity studies did not show improvement in weight (Pate et al. 2005[141] [1+], Schofield et al. 2005[142] [2+], Jamner et al. 2004[143] [2+], Sallis et al. 1993/7 [144,145] [1+], Pangrazi et al. 2003[146] [2+], Trudeau et al. 2000/1[147,148] [2–]) one showed trends in improvement with age in BMI

No.	Statement	Grade	Evidence
			in girls (Mo-suwan et al.[149] 1998 [1+])
3	There is limited evidence from one UK-based study to suggest that interventions to reduce consumption of carbonated drinks containing sugar may have a role in reducing the prevalence of overweight and obesity	1++	One 1++ RCT (James et al. 2004[150])
Diet and activity outcomes			
4	There is a body of evidence that school-based multi-component interventions addressing various aspects of diet and/or activity in the school, including the school environment are effective in improving physical activity and dietary behaviour, at least while the intervention is in place. However, UK-based evidence to support multi-component interventions (the 'whole-school approach') is limited	1+	Eight studies 1+: Simon et al. 2004,[151] Pate et al. 2005,[141] Caballero et al. 2003,[134] Leupker et al. 1996,[152] Trevino et al. 2004/5,[153,154] Sahota et al. 2001,[133] Warren et al. 2003,[132] Vandongen et al. 1995 [155] Four studies 2+: Donnelly et al. 1996,[135] Manios 1998/99/2002,[156–157] Anderson 2000 from Woolfe and Stockley 2005 review[158] (2+)
5	There is a body of evidence to suggest that short- and long-term school-based interventions to improve children's dietary intake may be effective, at least while the intervention is in place. This includes interventions aiming to increase fruit and (and to a lesser extent) vegetable intake, improve school lunches and/or promote water consumption	1+	Two non-systematic reviews (French and Wechsler 2004[159] [2+], Woolfe and Stockley 2005[158] [2+]) Ten RCTs 1+: James et al. 2004.[150] Perry et al. 2004,[160] Caballero et al. 2003,[134] Sallis et al. 2003,[128] Sahota et al. 2001,[133] Warren et al. 2003,[132] Leupker et al. 1996,[152] Vandongen et al. 1995,[155] Gortmaker et al. 1999,[129] Trevino 2004/5 et al.[153,154] Four studies 2+: Bere et al. 2005,[161] Loughridge and Barratt 2005,[162] Donnelly et al. 1996,[135] Manios et al. 1998, 1999, 2002[156–157]

No.	Statement	Grade	Evidence
			One study 2–: Horne et al. 2004[163]
6	UK-based evidence suggests that school children with the lowest fruit and vegetable intakes at baseline may benefit more from the school-based interventions than their peers	2+	Bere et al. 2005[161] (2+), Horne et al. 2004[163] (2–), Woolfe and Stockely 2005 review[158] (2+)
7	There is evidence from multi-component interventions to suggest that both short- and long-term physical activity focused interventions may be effective, at least while the intervention is in place	1+	Six multi-component studies supportive Five studies 1+: Simon et al. 2004,[151] Pate et al. 2005,[141] Caballero et al. 2003,[134] Leupker et al. 1996,[152] Trevino et al. 2004/5[153,154] One study 2+: Manios et al. 1998/9/2002[156–157]
Other outcomes			
8	No negative outcomes were reported in the identified studies. One multi-component study showed that measures of extreme dieting behaviour remained unchanged	1+	Two papers (both 1+) from one study: Gortmaker et al. 1999[129] and Austin et al. 2005[164]
Generalisability			
9	Most of the evidence for school-based interventions is non-UK based. However, it is likely that the findings are generalisable to the UK	4	GDG and reviewers' opinion
Implementation			
10	There is limited UK evidence to indicate that in terms of engaging schools it is important to enlist the support of key school staff	2+	One paper (Anderson 2000, 2+) included in review by Woolfe and Stockley 2005[158] (2+)
11	There is a body of evidence to suggest that young people's views of barriers and facilitators to healthy eating indicated that effective interventions would (i) make healthy food choices accessible, convenient	1++	EPPI-[165,166]

No.	Statement	Grade	Evidence
	and cheap in schools, (ii) involve family and peers, and (iii) address personal barriers to healthy eating, such as preferences for fast food in terms of taste, and perceived lack of will-power		
12	There is a body of evidence to suggest that young people's views on barriers and facilitators suggest that interventions should (i) modify physical education lessons to suit their preferences, (ii) involve family and peers, and make physical activity a social activity, (iii) increase young people's confidence, knowledge and motivation relating to physical activity, and (iv) make physical activities more accessible, affordable and appealing to young people	1++	EPPI[167,168]

BMI, body mass index; CCT, controlled clinical trial; EPPI, ; GDG, Guidance Development Group; NS, not significant; RCT, randomised controlled trial; EPPI: Evidence for Policy and Practice Information and Co-ordinating Centre.

See Appendix 7 for associated evidence tables.

9.2 Methodology

Database searches were carried out in October 2004 for papers published from 1990 onwards (1995 onwards for systematic review level evidence). A final update search was completed on 1 December 2005 on a reduced number of databases. The inclusion and exclusion criteria for the review adhered to the standard public health review parameters. A range of UK government, government agency and non-governmental organisation websites were also searched.

From an initial 9387 hits, 92 papers were assessed in detail, of which 40 papers met the critical appraisal criteria for inclusion in evidence tables.

9.3 Weight outcomes

Twenty-five studies were identified which reported weight outcomes among school children aged 4.5–15.8 years. The majority of studies were conducted in primary school children; only eight were definitely conducted in secondary school children.[129,136,138,141–144,155] The majority of the studies were conducted in America; three were conducted in UK primary schools.[132,133,150]

The results suggest that such interventions may have the potential to prevent excess weight gain and obesity in children. Interventions may be more effective in primary school children than older children. Although the evidence from UK-based studies is limited many of the identified non-UK-based interventions could be generalisable to the UK.

9.3.1 Dietary interventions

One high-quality, UK-based randomised controlled trial (RCT) that aimed to help 7–11-year-old children reduce their consumption of carbonated drinks reported a 7.5% increase in overweight and obesity in the control group at 12 months compared with a 0.2% decrease in the intervention group.[150] No difference was observed in mean body mass index (BMI).

9.3.2 Physical activity interventions

Ten interventions, five RCTs and five controlled clinical trials (CCTs), aimed to increase physical activity levels.[138–141;144,147–149] No UK-based interventions were identified, with the majority undertaken in the USA. The evidence suggests that such interventions may help children maintain a healthy weight by preventing them from becoming overweight, but the evidence is inconsistent. The results suggest that interventions appear more successful in primary school children than in secondary school children.

Of the 10 studies identified, 4 showed statistically significant improvements in mean BMI following a physical activity intervention.[138,139,149,169] Of these four studies, two reported significant differences for girls only.[138,149] With the

exception of Flores' study,[138] participants in these studies tended to have a mean age less than 10 years of age.

Robinson[139] reported that a 6-month intervention to encourage reduction in television watching among 9-year-olds resulted in a significant reduction in BMI, skinfold thickness, waist circumference and waist-to-hip ratio in intervention children compared with controls. Stevens and coworkers[169] reported that a 15-week physical activity intervention in low-income, minority school children (approximately age 8) demonstrated significantly more weight gain among controls and significant decreases in skinfold thickness among intervention children. Flores[138] reported that a 12-week aerobic dance programme significantly reduced BMI but only among 10–13-year-old girls. Mo-suwan and coworkers[149] reported mixed results for a 30-week aerobic exercise programme – encouraging a pre-class walk and three 20-minute aerobic sessions a week – in kindergarten children (aged 4–5 years) in Thailand. Although a reduction in BMI occurred in both intervention and control groups and was not significantly different between groups, the intervention girls had lower likelihood of having an increased BMI slope than the control girls (odds ratio: 0.32; 95% confidence interval [CI]: 0.18 to 0.56). This was not found for boys.

Six of the studies did not report significant improvements in mean BMI. Three studies among female adolescents in secondary schools – a 6-month intervention promoting a supportive school environment and programme champion,[141] a 12-week intervention targeting moderate activity (walking) in low active girls[142] and a 4-month intervention promoting additional PE classes[143] – demonstrated no difference in percentage overweight[141] or mean BMI.[142,143] Two studies among children (average age 9–10 years) – a 12-week physical activity programme supplementary to usual physical education (PE)[146] and a 2-year specialist physical activity promotion programme[144;145] – found no difference in mean BMI between control and intervention groups. One poor-quality, 22-year follow-up of a sub-sample of adults who participated in a 6-year physical activity

intervention as primary school children[147;148] showed no significant differences between groups on any anthropometric measure.

9.3.3 Diet and physical activity

Ten school-based interventions included diet and physical activity components and aimed to prevent obesity. [128,130, 131, 132,133, 134, 135 , 136, 137,129;164]

Three further studies aimed to prevent cardiovascular disease[152,155,156;157;170] and one aimed to prevent diabetes. [153;154] The findings are inconsistent, but overall suggest that such interventions may help children maintain a healthy weight by preventing them becoming overweight. It remains unclear why some of the studies were effective whereas others were not, though the range of components in the intervention, and the extent of dietary change and amount of physical activity promoted may play a role.

Four of the 10 studies, all non-UK-based, showed significant improvements in mean BMI in the intervention groups compared with the control groups. Graf and coworkers[130] reported that in the STEP 2 programme in primary school children (approximate age 8) the increase in BMI and waist circumference tended to be lower in those undergoing intervention than controls. Two interventions found significant differences in mean BMI between intervention and control groups in 11-year-old[131] and US grades 6–8[128] boys only -– Kainand coworkers[131]) following a 6-month intervention in Chile and Sallis et al.[128] following a 2-year environmental, policy and social marketing intervention in middle school (mean age not available). The 2-year Planet Health programme among US 12-year-olds, promoting physical activity, improved diet and reduction of sedentary behaviours (with a strong emphasis on reducing television viewing), resulted in a reduction in the prevalence of obesity in intervention girls (but not boys) compared with controls.[129;164]

Two of the six studies which found no significant difference in mean BMI between intervention and control children were UK based. Sahota and coworkers[133] reported that an intervention involving the whole school community (including

parents, teachers and catering staff), which aimed to improve school meals, tucks shops, the curriculum, PE and playground activities, resulted in no difference in BMI between intervention and control children at 1 year. The other UK-based intervention among primary school children was insufficiently powered to detect differences in BMI at 14 months' follow-up.[132]

Four non-UK-based studies reported that intervention had no effect on BMI. Callabero and coworkers[134]) reported that a 3-year intervention among US primary school children resulted in no significant difference in mean weight, BMI, per cent body fat or skinfold thickness. A 2-year US-based intervention showed significant increase in BMI in both intervention and control from baseline to follow-up but no significant difference between groups in a small sub-sample with complete data.[135] Two further interventions were among girls only. Neumark-Sztainer and coworkers[136] reported that a physical education programme (dance classes) incorporating (to a limited extent) personal, behavioural and nutritional elements resulted in no significant difference in mean BMI at 8-month follow-up. A short-term feasibility study in African American girls – lunchtime clubs promoting nutrition and physical activity – showed no significant differences in anthropometric measures between intervention and control.[137]

Three additional school-based interventions focused on dietary intake and physical activity to improve cardiovascular health. One high-quality Greek-based CCT demonstrated significant improvement in mean BMI and skinfold at 3 years ($p < 0.005$) and 6 years ($p < 0.05$) follow-up.[156;157;170] Conversely, two RCTs[155,152]) found no significant different in mean BMI between intervention and control at 1- and 3-year follow-up, respectively). One additional study aimed to improve physical fitness and prevent diabetes in low-income Mexican American 9-year-olds included a parent education and involvement programme, a classroom health and physical education curriculum, a student after school health club and a school cafeteria programme.[153;154] No difference in per cent body fat was observed at 8 months (interim follow up for on-going study).

9.4 Diet and activity outcomes

Two systematic reviews and 18 RCTs/CCTs reported diet outcomes and 18 RCTs/CCTs reported activity outcomes. The age of children within the studies ranged from 4.5 years to 15.8 years, with the majority of studies being undertaken among children 12 years and under. The majority of studies could be considered multi-component, aiming to address a range of dietary and/or activity measures. The majority of identified studies were not undertaken in the UK but the results are likely to be generalisable to the UK.

The majority of interventions were shown to be effective. The results suggest that both short- and long-term interventions are effective, including multi-component interventions, although the effects may not be maintained once the intervention has ended.

9.4.1 Diet

9.4.1.1 Fruit and vegetable intake

All but one study in a review of five high-quality US-based CCTs over a minimum of 1 year[159] reported significant increases in daily fruit and vegetable intake in intervention versus control school children (of various ages). Increases in fruit intake ranged from 0.2 to 0.6 servings per day and vegetable intake from 0 to an increase of 0.3 servings per day. A further review of five school-based multi-component interventions to increase fruit and vegetable intake in UK-based primary and secondary schools showed positive and significant increases in intake, especially of fruit, in primary school children.[24] Children with the lowest intakes at baseline appeared to benefit the most from the intervention.

The results of the two reviews are mirrored in the additional studies that focused solely on fruit and vegetable consumption.[160,161,163,171] Analysis of the UK national school fruit scheme[171] showed that 4–6-year-old children receiving school fruit had a significantly higher daily intake than controls (117 g/day compared to 67 g/day, respectively) but this difference was not maintained 2 years after

intervention when free fruit was no longer available. Similarly, children receiving free fruit through the Norwegian School fruit scheme consumed significantly more fruit and vegetables at 9-month follow-up, with the strongest effects observed in children with the lowest intakes at baseline.[161] No significant differences were observed between children in paid and the no fruit groups. A 2-year cafeteria-based intervention aimed at primary school children significantly improved children's total fruit and vegetable intake, predominantly due to increases in fruit consumption (no significant increases juices or vegetables was observed).[160] The poor quality UK-based 'Food dudes' video intervention among socially deprived primary school children demonstrated that the 16-day intervention resulted in significant improvements in fruit and vegetables intake at 4-month follow-up compared with the controls.[163]

A US-based intervention[172] focusing on nutrition lessons for adolescents, newsletters for parents and some school modification to increase consumption of fruit and vegetables and low-fat foods, reported no significant differences in intake between control and intervention schools at 2-years' follow-up.

9.4.1.2 School lunches and associated food provision

Three large-scale interventions aimed to modify school lunch provision: one significantly reduced children's total energy and fat intake;[152] one reduced children's fat intake but not total energy intake in school lunch observations[134]) and the last showed no difference in fat intake.[135] One additional study within the fruit and vegetable intervention review showed that reducing relative prices on low-fat snacks was effective in promoting lower-fat snack purchases from vending machines in adolescents over 1 year.[159]

A review of five UK school-based interventions concluded that all five interventions considered (fruit tuck shops, CD-ROM, art/play therapy, whole-school approach and a family-centred school-based activity) have the potential to be incorporated into a health promoting school approach and could be more

effective than stand-alone interventions.[158] The authors highlighted the importance of actively engaging schools for the success of the intervention.

9.4.1.3 Water

Two UK-based interventions focused on water intake were identified, one aiming to reduce consumption of carbonated drinks in primary schools over 12 months[150] and the other comparing access of cooled filtered water with and without associated promotion over 3 months in secondary schools.[162] The findings suggest that such interventions can significantly increase water intake, particularly when actively promoted. The authors reported that the children enjoyed the cooled filtered water and that the intervention was relatively inexpensive and sustainable.

9.4.1.4 Multi-component studies

Eight of the 11 studies considering multi-component interventions demonstrated some significant improvements in dietary behaviour (either total energy intake or fat intake).

Two UK-based multi-component interventions were identified. Sahota et al.[133] reported that 7–11-year-old children in schools adopting a whole-school approach were consuming significantly more vegetables at 1-year follow-up (weighted mean difference 0.3 portions/day, 95% CI 0.2 to 0.4).

Warren and coworkers[132] reported that 5–7-year-old children in the intervention group consumed significantly more vegetables ($p < 0.05$) and fruit (girls only) ($p < 0.01$). No significant differences were observed in children's consumption of confectionary or crisps or their parents' diet (as measured by food frequency questionnaire).

Two US-based multi-component interventions focused on modification to school lunches. A large 3-year intervention[134] in American Indian primary school children resulted in significantly lower total daily energy intake (1892 kcal vs 2157 kcal) and percentage energy from fat (31.1% vs 33.6%) in intervention versus control.

Donnelly and coworkers[135]) reported that a 2-year US-based intervention resulted in lunches containing significantly less fat and sodium and more fibre but 24-hour recall showed significant differences in actual intake between groups for sodium only.

A 2-year US-based intervention promoting modification of dietary intake, physical activity and a reduction of sedentary behaviours (with a strong emphasis on reducing television viewing) among 11–12-year-old children reported significant increases in fruit and vegetable consumption and reduced total energy intake among intervention girls only.[129]

Three large, long- to medium-term studies aimed at reducing therisk of cardiovascular disease demonstrated significant reductions in energy and fat intake. A 6-year intervention among 5–7-year-olds in Crete resulted in intervention children consuming significantly less total energy intake, total fat and total saturated fat compared with control children ($p < 0.05$ for all).[156;157;170] Similarly, Luepker and coworkers[152]) reported that, among 8–9-year-old American children, significant reductions in the percentage of fat and energy in lunches resulted in self-reported energy intake ($p < 0.01$) and per cent energy from fat (32.7% to 30.3%) ($p < 0.001$) being significantly lower among intervention children compared with control at 3-year follow-up. A 1-year Australian programme focusing on school- and home-based interventions among 10–12-year-olds resulted in a significant decrease in saturated fat intake (girls only).[155]

Three interventions did not appear to be effective in terms of dietary intake. A 2-year US-based environmental, policy and social marketing intervention in middle school students showed no differences in fat intake at the school level but no actual data was reported.[128] An intervention encouraging reduction in television watching did not produce a significant difference in daily servings of high-fat foods between the intervention and control groups at 6 months.[139] An ongoing intervention among low-income Mexican American 9-year-olds aiming to improve

physical fitness and prevent diabetes and incorporating a dietary component reported that dietary fat intake did not differ between groups (p = 0.52) at 8-month interim follow-up.[153;154]

9.4.2 Physical activity

9.4.2.1 Active play

Two studies aimed to increase active play. A 12-week, high-quality US-based intervention promoting active play supplementary to usual PE among 9-year-olds showed significant improvements in the intervention children compared with the controls, particularly among girls (p < 0.001).[146] Similarly, Warren and coworkers[132]) reported that a small but high-quality intervention over 14 months resulted in 5–7-year-old children in the intervention group being more active in the playground than the control group children.

9.4.2.2 Pedometers

A pilot study among inactive 15–16-year-old girls in Australia reported that mean 4-day step count was significantly higher in the pedometer group versus control at 12 weeks' follow-up (p = 0.03).[142] There were no significant changes in moderate or vigorous physical activity.

9.4.2.3 PE classes

Four studies promoted additional structured activity in schools. Of these, one reported significant increases in activity levels,[143] two reported equivocal findings[135,136]) and one reported no effect.[144;145]

Jamner and coworkers [143] reported significant increases in moderate physical activity among female adolescents (p = 0.007), particularly 'lifestyle' activity, at 4-month follow-up, following the promotion of 60-minute PE classes 5 days a week and associated education classes.

Two interventions reported equivocal results. Donnelly and coworkers[135] reported that although structured 30–40-minute activity classes three times a week for 9-

year-olds resulted in intervention children being 6% more active in the classroom at 2 years' follow-up, outside the classroom, the intervention children's activity levels were 16% less than the control group. However, overall change in physical activity was not reported. Neumark-Sztainer and coworkers[136] reported that an obesity programme for adolescent girls, focusing on the replacement of usual low-impact PE classes with high aerobic dance classes, resulted in a progression in physical activity stage based on the Stages of Change Model ($p = 0.004$) at 8-month follow-up. However, there were no significant differences between intervention and control in actual physical activity level or sedentary behaviour.

A 2-year physical education intervention among 9–10-year-old children promoting three 30-minute activity sessions a week, parental newsletters and weekly 30-minute 'self-management' training, reported no significant groups differences on physical activity level outside school.[144;145]

9.4.2.4 Television viewing

Two US-based interventions aimed to reduce television viewing. A 2-year multi-component intervention among 11–12-year-olds with a focus on sedentary activities resulted in a significant reduction in television viewing.[129] However, no information was provided on overall changes in activity levels. A 6-month intervention among 9-year-olds significantly decreased children's reported television viewing but did not significantly increase daily physical activity levels (although the intervention did not appear to promote alternative activities).[139]

9.4.2.5 Multi-component interventions

Eight of the identified studies could be considered as multi-component and focusing on various aspects of the school (and home and/or wider community) environment. The majority (six) of these interventions demonstrated significant increases in physical activity levels in the intervention compared with control.[134;141;151-154;157;170;173]

A large 3-year physical activity and dietary intervention in American Indian primary school children, including structured activity sessions, exercise break

time between lessons and class room curriculum as well as dietary intervention, resulted in self-reported physical activity levels being significantly higher among intervention compared to control.[134] Two studies aiming to improve cardiovascular health also provide long-term results. An intervention among children in Crete, including class room curriculum and two 45-minute structured physical activity sessions per week, showed a significant increase in reported time spent in leisure time physical activity in intervention children than controls ($p < 0.05$).[156;157;170] Similarly, a large 3-year US-based intervention among 8–9-year-olds, including both a school and home element, with enhanced PE at school, curriculum information, training of teachers and family education packs, resulted in significantly more daily vigorous physical activity reported by intervention children than controls ($p < 0.003$).[152]

There is evidence that interventions are also effective over shorter time periods. Pate and coworkers[141] reported that a high-quality, US-based intervention among adolescent girls, which included a supportive school environment for physical activity and a programme champion, demonstrated a significant increase in self-reported vigorous activity among intervention girls compared with control girls at 6 months. Simon and coworkers[151] reported that a whole school/community intervention among French 11–12-year-olds resulted in a significant reduction in the proportion of intervention children not engaging in physical activity, significant increase in leisure time activity and significant reduction in sedentary activities, in both boys and girls at 6-month (interim) follow-up. A study among low-income Mexican American 9-year-olds, which aimed to improve physical fitness and prevent diabetes, reported that pre- and post-intervention physical fitness score was significantly different between intervention and control at 8-month (interim) follow-up.[153;154]

Two interventions were largely ineffective. A study of a US-based 2-year environmental, policy and social marketing intervention in middle school students reported that although intervention schools increased physical activity over time at a greater rate than control schools, survey data of a sample of individual

children suggested that the intervention had no significant impact on reported physical activity or participation in sedentary behaviours.[128] A UK-based RCT considering a 'whole-school approach' to obesity among 7–11-year-olds found that a whole-school approach resulted in no significant difference in sedentary behaviour or physical activity at 12 months.[133]

9.4.2.6 Corroborative evidence

Corroborative evidence is available from four large-scale systematic reviews that evaluated barriers and facilitators to healthy eating and physical activity among children and adolescents.[165-168] Only some of the included studies were conducted in the UK.

Diet

Young people's views of barriers and facilitators to healthy eating indicated that effective interventions would (i) make healthy food choices accessible, convenient and cheap in schools, (ii) involve family and peers, and (iii) address personal barriers to healthy eating, such as preferences for fast food in terms of taste, and perceived lack of will-power.[165] The success of school-based interventions[166] appeared to depend to a large extent on the enthusiasm of staff and parents. Interventions were well-received in most cases, although a recurring theme was that schools lacked the time and resources for such projects. One of the identified interventions met with resistance from teachers and waning enthusiasm from students and parents. In this case, more training for the teachers might have provided more motivation, enthusiasm and skill. One study noted that young women tended to enjoy the intervention more than young men, and that peer leaders were particularly well received.

In general teachers found it difficult to fit nutrition education in to the curriculum and were concerned that they lacked the skills, training and support to deliver high-quality nutrition lessons. Fruit tuck shops were considered valuable to other areas of learning, such as English and art through promotion exercises, and maths via the handling of money.

Activity

The main barrier identified by staff developing school-based interventions was a lack of time, resources and adequate training. Young people's views on barriers and facilitators suggest that interventions should:

- modify PE lessons to suit their preferences
- involve family and peers, and make physical activity a social activity
- increase young people's confidence, knowledge and motivation relating to physical activity
- make physical activities more accessible, affordable and appealing to young people.[166;166-168]

Interventions should address the barriers and facilitators to participation in physical activity identified by children:

- providing activities that are enjoyable, in a social atmosphere, giving children some choice, and making children aware of how sedentary activities such as television watching are
- involving parents in interventions
- improving children's access to physical activity opportunities.

Three additional studies provide corroborative evidence. A cross-sectional analysis in urban primary schools reported that being driven to school did not affect the overall physical activity levels of 5-year-olds.[166;174] However, the generalisability of these findings is limited given that the time spent walking to school at 5 years of age is likely to be a very small proportion of overall activity levels. The authors reported that social status was not a confounding factor (but data were not presented). A randomised trial of advice on school travel plans[175] (which did not meet inclusion criteria for efficacy but are included for corroboration) showed that at 1-year follow-up the proportion of children walking,

cycling or using public transport on the school journey was similar in intervention and control schools. One small-scale short-term study in UK schools evaluated the effects of painting a school playground with bright and colourful markings on physical activity in primary school children.[176] Although the markings successfully increased activity levels in intervention children, the results are confounded by the fact that the control school also increased availability of skipping ropes and balls.

9.5 Essential elements of a 'whole-school' approach

The National Healthy Schools Programme (NHSP) advocates that a whole-school approach addresses:

- leadership, management and managing change
- policy development
- curriculum planning and resourcing including external agencies
- teaching and learning
- school culture and environment
- giving pupils a voice
- provision of pupils' support services
- staff professional development needs, health and welfare
- partnerships with parents/carers and local communities
- assessing, recording and reporting pupils' achievements.

The NHSP has only recently recognised the potential contribution of the whole-school approach to obesity prevention and so far there is little formal evaluation of this approach. Caution has been taken in retrospectively assessing any of the schools studies using a definition of 'whole-school approach'. However, many of

the interventions identified could be considered as taking a whole-school approach (particularly those which were multi-component and addressing elements of the whole of the school [and in some instances wider community] environment).

Only one UK-based study explicitly reported adopting a whole-school approach to implementing a diet and physical activity intervention.[133] The intervention was underpinned by the Health-Promoting Schools philosophy and the intervention involved the whole school community including parents, teachers and catering staff. At 1 year, there was no difference in change in BMI between the children in the two groups. Two UK-based studies, one study aiming to increasing fruit and vegetable consumption (Anderson in Woolfe and Stockley's review[158]) and one study aiming to provide 'healthier' vending[158;177] were shown to be effective. However, the elements of the approach which contributed to effectiveness were not identified.

9.6 Sub questions

9.6.1 Variation by gender, age, ethnicity, religious practices or social group

There appears to be a trend for primary school girls to do better regarding weight outcomes in physical activity interventions and for boys to do better in diet and physical activity interventions to prevent obesity. Further unpicking of the type of interventions that appeal to boys and girls is warranted.

The findings suggest that interventions may be effective in lower income ethnically diverse groups although the data are limited. The majority of interventions were in Caucasian children although six US-based studies were conducted in an ethnically diverse sample,[129;138;140;141;143;152;158;177] one in low-income African American girls,[137] one in American Indian primary school children,[134] and one in low-income Mexican American school children.[153;154] One study also stated it took place in a low-income population[169] and in another three studies[131;135;144] at least one third of the children received free school lunches.

Additional evaluation of UK school breakfast clubs[178] reported that the positive impact of the intervention (including small but important beneficial effect on dietary intake, social interaction and learning) is reaching many families whose members are at risk of, or are actually experiencing, social exclusion.

9.6.2 Influence of previous weight loss

It was not possible to answer this question from the evidence identified.

9.6.3 Source and mode of delivery

An overview of five school-based UK dietary interventions indicated that in terms of engaging schools it was important to list the support of school gate keepers (secretaries).[158] The commitment of schools affects the success of projects and this was particularly demonstrated with tuck shop interventions. A hindrance to engaging schools is the design of research interventions where there is selection to control. If schools are asked to ‘buy-into’ future initiatives this may lead to increased commitment compared to a research scenario. A feasibility study by the Health Education Trust[177] suggests that children will choose healthier options from vending machines even when ‘healthier’ products are set alongside usual provision. The key to success appears to be pupil involvement, positioning the vending machine close to the dining area, and continuity of provision.

9.6.4 Potential negative impact

Gortmaker and coworkers[129]) and Austin and coworkers[164]) reported that analysis of girls only using self-report showed a reduced risk of using self-induced vomiting, laxatives or diet pills to control weight within the previous 30 days. An additional 12-month weight maintenance intervention among adolescent girls[179] resulted in significantly greater decreases in bulimic symptoms compared with controls at 12 months ($p = 0.004$) despite demonstrating significant increases in healthy eating at 12 months and exercise intensity at 6 months ($p < 0.001$) among intervention compared with control.

9.7 Limitations of the review

It remains questionable whether some of the studies were adequately powered to detect differences between the intervention and control groups. It also remains questionable whether some of the interventions would be sufficient to produce a change weight/BMI, total activity levels or per cent dietary energy and/or fat intake (for example, included interventions promoting 3 × 30-minute physical activity sessions a week and/or one additional piece of fruit each day).

The majority of studies were conducted outside the UK although many are generalisable to the UK setting. There were more data for primary school children than secondary school children. No evidence of effectiveness was identified regarding strategies to engage schools to undertake interventions, nor whether effectiveness varied by ethnicity, religious practices or social group – although some studies did include mixed groups and reported being beneficial for all.

Only one study was included to address the question on the whole-school approach as there is currently a lack of evidence prospectively assessing the use of a whole-school approach in the field of obesity prevention. However, many of the interventions identified could be considered as taking a whole-school approach (particularly ‘multi-component’ interventions addressing the whole of the school environment).

10 Prevention evidence summary: workplace interventions

The following is based on an evidence review produced by Cardiff University. Detailed evidence tables and supporting information are in Appendix 8.

10.1 Evidence statements (Table 10.1)

Table 10.1 Evidence statements and grading

No.	Statement	Grade	Evidence
Weight outcomes			
1	Worksite behaviour modification programmes, that include health screening with counselling/education can result in short-term weight loss. Weight loss may be regained post intervention	1+	Body of evidence variable but largely supportive: 10 RCTs and 1 CCT. Majority 1+ Five RCTs (all 1+): Proper et al. 2003,[180] Gomel et al. 1993,[181] Shannon 1987 (data from Hennrikus and Jeffery 1996[182]), Erfurt et al. 1991,[183] Brownell et al. 1985[184] One CCT (2+): Cockcroft et al. 1994[185] support Three RCTs show positive trend (all 1+): Gemson 1995,[186] Peterson et al. 1985,[187] Rose et al. 1983[188] Twp RCTs do not support: Hanlon et al. 1995[189] (1++), Braeckman 1999[190] (1+)
2	Payroll incentive schemes (such as free gym membership) are either only effective in the short term (during the period of the intervention) or ineffective for weight control	1+	Body of evidence variable: three RCTs (all 1+) Forster et al. 1985,[191] Jeffery et al. 1985[192] effective in short term Jeffery et al. 1993[193] ineffective

No.	Statement	Grade	Evidence
3	There is inconclusive evidence for the effectiveness of workplace-based physical activity interventions on weight outcomes	N/A	Body of evidence variable: four RCTs (all 1+) and one CBA (2++) One RCT supports: Pritchard et al. 1997[194] (1+) One RCT shows trend: Grandjean et al. 1996[195] (1+) Two RCTs (both 1+) (Grønningsater et al. 1992,[196] Lee and White 1997[197]) and one CBA (2++) (Cook et al. 2001[198]) do not support but amount of activity prescribed in interventions considered insufficient
4	The effectiveness of healthier food provision in workplaces on weight outcomes remains unclear	2++	One CBA (2++) found no significant effect: Cook et al. 2001[198]
5	No studies were identified which considered the provision of water in the workplace, active travel schemes and stair use on weight outcomes	N/A	N/A
Diet and activity outcomes			
6	Worksite behaviour modification programmes, such as health screening followed by counselling and, sometimes, environmental changes, can lead to improvements in nutrition and physical activity while the intervention is in place	1+	Body of evidence variable but largely supportive: one systematic review and six RCTs (majority 1+) One systematic review (1+) (Janer et al. 2002[199]) supports for diet and physical activity Four RCTs for diet – three support: Sorensen et al. 1996[200] (1+), Sorensen et al. 1999[201] (1+), Sorensen

No.	Statement	Grade	Evidence
			et al.1998[202] (1±); one does not support: Sorensen et al. 2002[203] (1+) Two RCTs for physical activity (one supports: Emmons et al. 1999[204] (1+); and one does not support: Nichols et al. 2000[205] (1±)
7	There is a body of evidence that the provision of healthier food choices can encourage consumption of a healthier diet	2++	Body of evidence variable but largely supportive. One systematic review and two RCTs One systematic review (2++) (Seymour et al. 2004[206]) and one RCT (1+) (Beresford et al. 2001[207]) support One RCT (1±) (Steenhuis et al. 2004[208]) does not support
8	Workplace physical activity programmes can have a positive effect on physical activity	1++	Body of evidence from single 1++ systematic review (Proper et al. 2003[209]) supports
9	Environmental improvements in stairwells, such as decoration, motivational signs and music may increase stair use. Posters alone may be ineffective or effective only while the posters are in place	2+/++	Body of evidence variable. Two ITS and one BA One ITS supports: (Kerr et al. 2004[210] (2++); one BA of posters plus email supports in the short term only: Vanden Auweele 2005 et al.[211] (2+) One ITS of posters alone does not support: Kerr 2001[212] (2++)
10	No studies were identified which considered the provision of water in the workplace on	N/A	N/A

No.	Statement	Grade	Evidence
	diet or activity outcomes		
11	It is unknown whether incentive schemes improve dietary intakes or increase physical activity levels	2+	One CBA only considering diet (2+ quality): French et al. 2001[213]
Generalisability			
12	It remains unclear whether the effectiveness of interventions varies by age, gender, socioeconomic or ethnic group	N/A	Of 63 studies identified only one RCT (Braeckman 1999[190] [1+]) and one cross-sectional survey (Fleming et al. 1997[214] [3+]) considered social status and gender, respectively
Implementation			
13	There is little evidence on the most effective strategies for attracting workplaces to invest in the heath and activity of their staff, with the exception of weak evidence of reduced sick leave as a result of physical activity programmes	N/A	One CBA (2++) found reduced sick leave: Kerr 1993 [215] One RCT (1++) showed no difference: Nurminen 2002[216]
14	A body of UK-based case studies suggests that factors most likely to make a canteen-style five-a-day intervention work are: commitment from the top, enthusiastic catering management, a strong occupational health lead, links to other on-site health initiatives, free or subsidised produce and heavy promotion and advertisement at point of purchase	3	Two sets of case studies: Healthlinks 2003,[217] Holdsworth et al. 2004[218]
15	A body of UK-based case studies suggests that the more successful behaviour modification/education techniques include an	3	Body of 16 case studies (3): Health Development Agency 2002[219]

No.	Statement	Grade	Evidence
	interdisciplinary approach with broad representation including health and safety and human resources, and implementers from high grades and strategic positions; initiatives integrated into worksite objectives; staff involvement, communication and realistic objectives; activities that go beyond the superficial and address root causes		
16	A UK-based survey of Heartbeat Award schemes, recommended improved promotion and better integration with other health programmes	3	One cross-sectional survey: The Research Partnership 2000[220]

BA, before-and-after study; CBA, controlled before-and-after study; CCT, controlled clinical trial; ITS, interrupted time series; N/A, not applicable; RCT, randomised controlled trial.

See Appendix 8 for associated evidence tables.

10.2 Methodology

Database searches were carried out in October 2004 for papers published from 1990 onwards (1995 onwards for systematic review level evidence). A final update search was completed on 1 December 2005 on a reduced number of databases. The inclusion and exclusion criteria for the review adhered to the standard public health review parameters. From an initial 16695 hits, 298 papers were assessed in detail of which 61 papers met the critical appraisal criteria for inclusion in evidence tables.

10.3 Weight outcomes

10.3.1 Worksite behaviour modification programmes

Evidence from 10randomised controlled trials (RCTs) and one controlled non-randomised trial (CCT) suggests that worksite behaviour modification programmes, such as a 'health check' followed by counselling can result in short-term weight or body fat loss although there was a tendency for weight regain after the intervention. Eight of these RCTs and one CCT noted reductions in body mass/body fat relative to control with five RCTs and the CCT noting statistically significant reductions[180–185] and three RCTs recording a positive trend.[186–188] There were a wide range of results for the amount of weight lost.

A recent UK-based individual RCT looking at a single health check with 5-month follow-up found no significant difference in body mass index.[189] Another UK-based RCT looking at workplace-supported dietary approaches found that, although there was no difference in weight loss between the diets, a daily energy deficit diet (reduction of 600 kcal) might be considered preferable to a more demanding low-calorie diet (1500 kcal) since compliance was better.[221]

A weak RCT among male blue collar workers in Belgium resulted in an increase in body mass index (BMI) in the intervention compared with the control group despite a reported reduction in calorie and per cent fat intake.[190]

10.3.2 Healthier food provision

One controlled before-and-after study (CBA) of nutrition displays and a monthly 30-minute workshop over 6 months found there was no significant self-reported difference in mean BMI or waist circumference at 12-month follow-up.[198]

10.3.3 Physical activity programmes

There is inconclusive evidence for the effect of physical activity interventions on body weight, BMI and body fat. Of four RCTs[194–197] and one CBA identified,[198] only one study, an RCT, found a significant difference in body weight between intervention and control groups[194] with another RCT noting a significant before

and after difference in the exercise group with no significant difference in the control group.[195] However, the amounts of exercise prescribed in the RCTs did not meet the UK recommended levels.[222]

10.3.4 Incentives

Three US-based RCTs suggested that payroll incentive schemes were either only effective in the short term (that is, during the intervention) or ineffective for weight control.[191–193] Follow-up data suggested that any weight loss was regained 6–12 months after the intervention.[191] The schemes included weigh in, health education/group sessions and the provision of self-motivating materials.

10.3.5 Other initiatives

No studies with weight outcomes were identified for stair use, water provision or active travel to and from work.

10.4 Diet and activity outcomes

There is evidence from a systematic review of trials and six additional RCTs that worksite behaviour modification programmes can lead to improvements in nutrition and physical activity. Evidence of longer-term, post-intervention benefits is limited.

10.4.1 Diet

10.4.1.1 Worksite behaviour modification programmes

A systematic review found that worksite behaviour modification programmes can show a positive effect on dietary fat intake (up to 3% decrease in percentage of energy from fat).[199] Programmes can also increase consumption of fruit and vegetables from 0.09 to 0.5 portions per day. Successful programmes included a wide range of educational interventions (such as health check followed by counselling) sometimes accompanied by environmental changes. Information about long-term effects was limited.

Of the four additional RCTs identified, three supported the findings of the systematic review. Only one trial monitored post-intervention effects 1 year after the 2-year intervention and noted significant decreases in fat intake and increases in fruit and vegetable intake.[200] It appeared from this study that longer, interactive intervention efforts (contests and classes) resulted in more positive outcomes than one-time events or more passive efforts (use of printed materials). One study found a significant improvement when a family component was added to the worksite intervention.[201]

10.4.1.2 Healthier food provision

One systematic review concluded that worksite intervention studies targeting healthier food provision by information strategies such as labelling and/or changes in food availability or cost can encourage healthier eating.[206] Two additional RCTs reported conflicting results.[207,208] The US study reported an increase in fruit and vegetable intake by 0.3 portion per day at 3, 8 and 12 months post intervention ($p < 0.05$).[207] However, the study in the Netherlands, which looked at combinations of educational and food supply programmes, found no significant effects on consumption data.[208]

10.4.1.3 Incentives

One CBA concluded that, when prices of low-fat snacks in 55 vending machines were reduced by 10%, 25% and 50%, the total number of items sold increased by 9%, 39% and 93%, respectively.[213] The effect on calorie consumption was unknown.

10.4.1.4 Other initiatives

No studies were identified on water provision.

10.4.2 Physical activity

10.4.2.1 Worksite behaviour modification programmes

A systematic review concluded that there are significant effects of workplace-based educational sessions and informative materials on levels of

physical activity.[199] Details were not provided of the type of physical activity promoted in each trial. Out of nine trials using educational sessions and informative materials, and evaluating outcomes directly related to physical activity, four reported significant changes. Two additional RCTs noted significant increases in physical activity in the intervention group[204] or significant increases in both intervention and control groups but no significant difference between groups.[205] Only the latter trial had post-intervention follow-up (6 months).

10.4.2.2 Physical activity programmes

Results from a systematic review support the implementation of worksite physical activity programmes.[209] The overall conclusion of the review, based on five RCTs (two of high quality) and three non-randomised controlled trials was that there was strong evidence for a positive effect of physical activity programmes on physical activity.

10.4.2.3 Active travel to/ from work

There is evidence from a UK-based RCT[223] and one before and after study in Finland[224] that workplace promotional strategies can increase the number of people travelling actively to work.

10.4.2.4 Increasing use of stairs

One interrupted time series (ITS) study suggests environmental improvements (such as re-decoration, motivational signs and music in the stairwell) may increase stair use.[210] Another ITS study found that posters alone were ineffective[212] but a before-and-after study that included an email reminder found a temporary improvement while the sign was in place.[211]

10.5 Sub questions

10.5.1 Variation by gender, age, ethnicity, religious practices or social group

There is little evidence comparing findings by gender, socioeconomic or ethnic groups. For behaviour modification/educational techniques, one RCT among

male blue collar workers in Belgium resulted in an increase in BMI in the intervention compared to the control group despite a reported reduction in calorie and per cent fat intake.[190] In a UK study including health checks, a lack of nutritional information was cited as a barrier to change by men whereas women predominantly cited the preferences of family members.[214] Finance was not a factor in this particular study.

10.5.2 Influence of previous weight loss

No evidence was identified.

10.5.3 Source and mode of delivery

The evidence base for strategies to influence workplaces to invest in health is inconclusive. There are some indications that sick leave is reduced in workers who have received worksite physical activity interventions.

In one UK study, individual health checks were not considered a threat for most of the participants although the results for weight loss were not significant.[225] A single set of case studies suggest that the more successful interventions include: (i) an interdisciplinary approach with broad representation including health and safety and human resources, and implementers from high grades and strategic positions; (ii) initiatives integrated into worksite objectives; (iii) staff involvement, communication and realistic objectives; (iv) activities that go beyond the superficial and address root causes.[219]

Corroborative evidence from the UK Heartbeat Award scheme reported additional data from a single set of case studies.[218] These studies found that factors most likely to make a canteen-style five-a-day intervention work are: commitment from the top, enthusiastic catering management, a strong occupational health lead, links to other on-site health initiatives, free or subsidised produce, and heavy promotion and advertisement at point of purchase.[217] The authors of a cross-sectional survey in England of Heartbeat Award managers and caterers, government and health professionals,

recommended improved promotion of the schemes and better integration with other health programmes.[220]

10.5.4 Potential negative impact

A UK-based study which aimed to increase stair use reported that posters alone caused feelings of 'laziness' and 'guilt' in many subjects.[215] An incentive study by French and coworkers[213] found that when the prices of low-fat snacks were reduced, sales of these items increased. However, it is unknown whether this had a positive or negative impact on calorie consumption.

10.6 Limitations of the review

RCTs often lacked (or failed to report) a description of the randomisation process, concealment allocation and/or an intention to treat (ITT) analysis.

According to the agreed review parameters, RCTs without ITT but 80% or more follow-up were downgraded in quality assessment but not to CCTs. Studies with no ITT and less than 80% follow-up were treated as CCTs. The lack of description of randomisation and/or concealment allocation also led to a downgrading but not automatic rejection. Where an RCT did not meet one or more of the NICE criteria, reasons are listed in the comments column of the evidence tables.

11 Prevention evidence summary: interventions led by health professionals ('Community 1')

The following is based on an evidence review produced by Cardiff University. Detailed evidence tables and supporting information are in Appendix 9.

11.1 Evidence statements (Table 11.1)

Table 11.1 Evidence statements and grading

No.	Statement	Grade	Evidence
Weight outcomes			
1	Sustained health-professional-led interventions in primary care or community settings, focusing on diet and physical activity or general health counselling can support maintenance of a healthy weight	1+	Body of evidence variable but generally supportive One systematic review and eight RCTs mostly 1+ Systematic review supports: Asikainen et al. 2004[226] (1++) Three RCTs support: Simkin-Silverman et al.2003[227] (1++), ICRF 1995[228] (1+), Murray and Kurth1990[229] (1++) Three RCTs show trend: Fries et al. 1993[230] (1+), Jeffery 1999[231] (1±), FHSG 1994[232] (1+) Two RCTs do not support: Dzator et al. 2004[233] (1+), ICRF 1994[234] (1+)
2	Interventions which provide support and advice on physical activity and diet are more likely to be effective for weight outcomes than interventions which focus on physical activity alone. There is no reliable evidence for diet alone	1+	Body of evidence variable for physical activity alone: 11 RCTs One shows weight reduction (self-reported): Stewart et al. 2001[235] (1+) Five show trend and/or changes in body composition: Taylor et al.

No.	Statement	Grade	Evidence
			1998[236] (1+), Schmitz et al. 2003[237] (1+), Coleman et al. 1999[238] (1+), Dunn et al. 1999[239] (1+), Elley et al. 2003[240] (1++) Five do not support: Hillsdon 2002[241] (1+), Pereira et al. 1998[242] (1+), Tully et al. 2005[243] (1+), Lamb et al. 2002[244] (1+), Halbert et al. 2000[245] (1++) Limited evidence for diet alone: one RCT and one CBA CBA supports: Wrieden et al. 2002[246] (2+); RCT does not support: John et al. 2002[247] (1++)
Diet and activity outcomes			
3	Interventions which do not identify favourable changes in weight outcomes may identify favourable changes in diet and/or activity outcomes (where recorded).	1+	At least four RCTs: Dzator et al. 2004[233] (1+) and John et al. 2002[247] (1++) for diet; Pereira et al. 1998[242] (1+) and Elley et al. 2003[240] (1++) for physical activity See also statements 4 and 6
4	Behavioural/educational interventions to increase physical activity can be moderately effective, particularly for walking and non-facility-based activities, although increases may not be sustained over time	1++	Body of evidence variable but largely supportive Four systematic reviews and 12 RCTs (1++/1+) Systematic reviews had variable results with some support: Hillsdon and Thorogood 1996[248] (1++), Eden et al. 2002[249] (1++), Eakin et al. 2000[250] (1++), Morgan 2005[251] (1+) Nine of 13 more recent and/or UK-based RCTs

No.	Statement	Grade	Evidence
			support: Dzator et al. 2004[233] 1+, Simkin-Silverman et al. 2003[227] (1++), Stewart et al. 2001[235] (1+), Coleman et al. 1999[238] (1+), Dunn et al. 1999[239] (1+), Pereira et al. 1998[242] (1+), Harland et al. 1999[252] (1++), Stevens et al. 1998[169] (1+), Elley et al. 2003[240] (1++) One RCT suggests positive trend: Hillsdon 2002[241] (1+) Three RCTs do not support: Jeffery 1999[231] (1±), Lamb et al. 2002[244] (1+), Schmitz et al. 2003[237] (1+) One systematic review (3) noting high attrition in exercise referral studies: Gidlow et al. 2005[253] – (Please note that this review is treated as a review of observational studies, hence grading)
5	Limited evidence suggests that using an incentive of free access to leisure facilities is likely to increase activity levels but only during the period of the intervention	1+	One RCT: Harland et al. 1999[252] (1++)
6	Moderate- or high-intensity dietary interventions most commonly report clinically significant reductions in fat intake and an increase in fruit and vegetable intake	1++	Body of evidence supportive: one systematic review, four RCTs and two CBAs Systematic review: Pignone et al. 2003[254] (1++) RCTs: Carpenter and Finley 2004[255] (1++), Havas et al. 2003[256] (1+), Dzator et al. 2004[233] (1+), Havas et al. 1998[257] (1+)

No.	Statement	Grade	Evidence
			UK CBAs: Department of Health 2003[93] (2±), Wrieden et al. 2002[246] (2+)
7	Briefer interventions, such as brief counselling/dietary advice by GPs or other health professionals, can be effective in improving dietary intake but tend to result in smaller changes than intensive interventions	1++	Body of evidence: two systematic reviews and four RCTs (1++/1+) Systematic reviews: Pignone et al. 2003[254] (1++), Ashenden et al. 1997[258] (1+) RCTs: Delichatsios et al. 2001[259] (1+), Steptoe et al. 2003[260] (1++), John et al. 2002[247] (1++), Beresford 1997[261] (1+)
8	Interventions with a greater number of components are more likely to be effective	1++	Body of evidence (1++): one systematic review (Pignone et al. 2003[254])
Generalisability			
9	The majority of interventions identified were conducted in the USA. However, the findings are likely to be generalisable to the UK population	N/A	GDG conclusions based on full range of evidence
10	Although the majority of studies included predominantly white, higher social status and reasonably motivated individuals, there is some evidence that interventions can also be effective among lower social groups and effectiveness does not vary by age or gender	1+	Body of evidence supportive for lower social groups (four RCTs and one CBA) and for age/gender (only one study, a survey, suggested variable effect in men and women) *Lower social groups*: three RCTs (Steptoe et al. 2003[260] [1++], Havas et al. 1998[257] [1+], Havas et al. 2003[256] [1+]); one CBA (Wrieden et al. 2002[246] [2+]) *Age/gender*: only one study suggested potential variation in effect a survey (Duaso and Cheung 2002[262]

No.	Statement	Grade	Evidence
			[3])
Implementation			
11	Tailoring dietary advice to address potential barriers (taste, cost, availability, views of family members, time) is key to the effectiveness of interventions and may be more important than the setting	3	Body of survey and qualitative evidence in four RCTs and one CBA support (all grade 3) Four surveys/qualitative studies in RCTs: Anderson et al. 1998,[263] Lloyd et al. 1995,[264] John and Ziebland 2004,[265] Baron et al. 1990[266] One qualitative study in a CBA: Wrieden et al. 2002[246]
12	The type of health professional who provides the advice is not critical as long as they have the appropriate training and experience, are enthusiastic and able to motivate, and are able to provide long-term support	3	Two qualitative studies and one evaluation of case studies support (all grade 3) Qualitative studies: Hardcastle and Taylor 2001,[267] Fuller et al. 2003[268] Evaluation of case studies: Biddle et al. 1994[269] Plus: GDG conclusions based on full range of evidence
13	It remains unclear whether interventions are more effective when delivered by multidisciplinary teams	N/A	Two RCTs (Elley et al. 2003[240] [1++], Lamb et al. 2002[244] [1+]) noted no significant effect on weight when two professions combined vs one; RCT with single professional suggesting weight gain (Halbert et al. 2000[245] [1++])
14	There is some evidence that primary care staff may hold negative views on the ability of patients to change behaviours, and their own ability to encourage change	3	Three qualitative studies and one survey/case study support (all grade 3) Qualitative studies: Fuller et al. 2003[268], Coggans et al. 2000[270], Benson and Cribb

No.	Statement	Grade	Evidence
			1995[271] Case study/survey: Hopper and Barker 1995[272]
15	There is a body of evidence from UK-based qualitative research that time, space, training, costs and concerns about damaging relationships with patients may be barriers to action by health professionals (GPs and pharmacists)	3	Six qualitative studies, one cross-sectional study and one survey/case study support (all grade 3) Qualitative: Fuller et al. 2003,[268] Smith et al. 1996,[273] Keene and Cervetto 1995,[274] Ursell et al. 1999,[275] Moore et al. 1995,[276] Coggans et al. 2000,[270] Benson and Cribb 1995 [271] Cross-sectional: Vernon and Brewin 1998[277] Survey/case study: Hopper and Barker 1995[272]
16	There is some evidence from the UK that patients are likely to welcome the provision of advice despite concerns by health professionals about interference or damaging the relationship with patients	3	One qualitative (Duaso and Cheung 2002[262] and one case study (Hardcastle and Taylor 2001[267]) support
17	Tailoring physical activity advice to address potential barriers (such as lack of time, access to leisure facilities, need for social support and lack of self-belief) is key to the effectiveness of interventions	1++	Body of evidence from two reviews and corroborative evidence supports One systematic review noting attrition through problems with attendance at leisure facilities: Gidlow et al. 2005[253] (3++) One systematic review noting importance of self-belief: Keller et al. 1999[278] (3++) Three qualitative studies and three surveys also

No.	Statement	Grade	Evidence
			support (all 3) Qualitative: Hardcastle and Taylor 2001,[267] Martin and Wollf-May 1999,[279] Ashley et al. 2000[280] Survey: See Tai et al. 1999,[281] Vernon and Brewin 1998,[277] Horsefall/Wealden District Council 1997[282]

CBA, controlled before-and-after study; FHSG, Family Heart Study Group; GDG, Guidance Development Group; GP, general practitioner; ICRF, Imperial Cancer Research Fund; N/A, not applicable; RCT, randomised controlled trial.

See Appendix 9 for associated evidence tables.

11.2 Methodology for review

Database searches were carried out in January 2005 for papers published from 1990 onwards (1995 onwards for systematic review level evidence). A final update search was completed on 1 December 2005 on a reduced number of databases. The inclusion and exclusion criteria for the review adhered to the standard public health review parameters. From an initial 10227 hits, 410 papers were assessed in detail of which 67 papers met the critical appraisal criteria for inclusion in evidence tables.

11.3 Weight outcomes

A total of 22 randomised controlled trials (RCTs) and one controlled before-and-after study (CBA) were identified which provided data on weight outcomes. Of these, 12 RCTs and 1 CBA were considered general public health interventions in the community, 1 systematic review and 9 RCTs were considered primary care based (including primary care referral) and 1 RCT included a cash incentive.

In all settings, the results suggest that sustained interventions which provide support and advice on diet **and** activity or general health counselling are

marginally more likely to be effective than interventions which focus on physical activity or diet alone, although some of the evidence identifies trends as opposed to statistical significance. The evidence base is less conclusive for general public health interventions than for primary care based interventions.

11.3.1 Interventions focusing on general counseling

11.3.1.1 General public health interventions

No evidence identified.

11.3.1.2 Primary care based interventions

Three UK-based RCTs were identified providing general health advice (including diet and activity) with the intensity of intervention based on participants risk score.[228,232,234] One RCT found no effect on body mass index (BMI) at 1 year, but a 1.4% reduction in BMI in the intervention group compared with the control group at 3 years ($p < 0.005$).[228,234] The two RCTs from the same study had different control groups. The Family Heart Study Group (FHSG)[232] reported that the weight of the intervention group was lower by an average 1 kg compared with controls at follow-up and the proportion of obese patients was lower in intervention than control (significance not stated).

11.3.1.3 Incentive schemes

One low-intensity US-based RCT compared education or education with incentives (entry into a US$100 lottery) against a control group.[231] After a 3-year follow-up significant differences were reported between the intervention groups and control with a higher reported frequency in healthy weight loss practices and non-significant reduced weight gain over time. However, no differences were found between the treatment groups suggesting no additional benefit of the cash incentive.

11.3.2 Interventions focusing on diet and physical activity

11.3.2.1 General public health interventions

Of the five RCTs that addressed diet **and** activity[227,229–231,233] only one,[227] an intensive intervention delivered by behavioural psychologists and nutritionists, found a significant prevention of unhealthy weight gain. However, two low-intensity interventions[220,221] noted positive but non-significant trends and one study[219] which compared two eating management and one weight loss programme with a physical activity control group, noted greater weight reduction in the weight loss group immediately after the intervention (10 weeks post-baseline) although this benefit was lost at 1-year follow-up. The results from a large US-based individualised counselling programme also suggest that participants were more likely to maintain their weight over a 48-month period than those in the control group.[283] Only one study, a relatively small RCT of Australian couples, found no evidence that the intervention prevented unhealthy weight gain despite reporting improvements in diet.[233]

11.3.2.2 Primary care based interventions

No studies identified.

11.3.3 Interventions focusing on diet alone

11.3.3.1 General public health interventions

One CBA considered diet alone. A food skills programme in deprived areas of Scotland noted a slight but significant reduction in the post-intervention weight of intervention versus control subjects.[246]

11.3.3.2 Primary care based interventions

A health check and diet-only RCT reported no difference in weight loss between intervention and control groups ($p = 0.68$) at 6 months.[247]

11.3.4 Interventions focusing on physical activity alone

11.3.4.1 General public health interventions

One US RCT of predominantly older, higher socioeconomic status, white adults found that information and support provided by trained staff and counsellors resulted in a significant reduction in self-reported BMI, compared with no change in the control group.[235] Three US-based studies of varying intensity found no difference in weight loss between the intervention and control groups but did report significant changes to fat-free mass/percentage body fat.[237–239] Two RCTs found no evidence of effect. One of these was a low-intensity UK-based trial of middle-aged adults who received 'brief negotiation' or 'direct advice'.[241] Follow up of this study was poor. Pereira and coworkers[242] also reported no weight differences at 10-year follow-up of US postmenopausal women encouraged to walk as part of the original trial, although the intervention group continued to walk significantly more than the control group.

11.3.4.2 Primary care based interventions

None of the five activity-only RCTs[236,240,243–245] showed a significant effect for weight loss at follow-up (up to 37 weeks depending on study) although positive trends were noted in two studies,[236,240] with one (a UK-based study of general practitioner [GP] exercise referral) showing a reduction in skin folds up to 16 weeks.[236] One study showed a significant weight gain in women in the intervention group ($p = 0.01$).[245] Among the three studies providing serially reinforced advice by telephone after an initial consultation, a more positive outcome was found when interventions were delivered by facilitators from more than one discipline (GP/practice nurse and exercise specialist;[240] physiotherapist and local health walks coordinator[244]) compared with intervention which was delivered by an exercise specialist only.[245]

The systematic review of exercise training in early postmenopausal women in which some of the interventions were combined with diet, found an improved body composition in 9 of the18 included studies.[226] The best effect was in the

three studies of overweight women that combined training and diet but six of the studies with positive results included some women within the normal weight range.

11.3.5 Corroborative evidence

The findings of the majority of studies are likely to be generalisable to the UK, particularly for motivated individuals of higher social status. Although UK data were limited from general public health interventions there was body of UK-based evidence from studies conducted in primary care. [228,232,234,241,244,246,247] A range of UK-based studies addressed practical issues which could influence the effectiveness of an intervention (for example, considering concerns around taste, cost, availability and time). A systematic review of exercise referral schemes found that attendance was generally poor with approximately 80% of participants dropping out before the end of the programme.[253] More women than men took up the referral (60% vs 40%) but there was no evidence of higher attendance in women.

11.4 Diet and activity outcomes

11.4.1 Dietary outcomes

On the basis of one high-quality systematic review and one moderate-quality systematic review, eight additional RCTs and two CBAs it can be concluded that general community or primary care based public health interventions, providing brief or intensive, individualised advice, in person or by mail, can result in dietary change, particularly for fat and fruit and vegetable intake. It is unclear whether a cash incentive would result in **additional** benefits for dietary interventions.

11.4.1.1 General public health interventions

A high-quality systematic review concluded that moderate- or high-intensity interventions can reduce saturated fat intake and increase fruit and vegetable intake.[254] Briefer interventions delivered by primary care professionals were also

effective but resulted in more modest changes. However, the effect size was to some extent dependent on the number of components in the intervention.

The findings of the review were supported by four additional RCTs[233,255–257] and two UK-based CBAs.[93,246] Carpenter demonstrated improvements to diet in middle-aged women from either group meetings or advice via mail or website with a larger effect from the weekly group meetings. Dzator and coworkers also found that interactive sessions and/or advice by mail to couples over a 16week period resulted in improvements to total fat, fibre and fruit and vegetable intake at 4 months and total fat intake at 12 months' follow-up.[233] Marginal improvements were reported in the high-intensity versus the low-intensity intervention but no significance values were reported. Two multi-component personalised educational RCTs in lower socioeconomic status women in the USA,[256,257] based on social marketing strategies resulted in significant increases in fruit and vegetable intake and, also, a reduction in fat and an increase in fibre in the later study.[256]

Before and after evaluation of five-a-day pilot projects in the UK concluded that the initiatives stemmed a fall in fruit and vegetable intake against the national trend,[93] but a lack of methodological detail limit the strength of this conclusion. A community food skills programme in eight deprived areas of Scotland resulted in a significant increase of one portion a week for fruit immediately after the intervention but this was not sustained at 6 months.

Three dietary studies identified barriers to change (for example, concerns around taste, cost, availability and time) that could influence effectiveness.[246,263,264]

11.4.1.2 Primary care based interventions

A systematic review reported that dietary advice trials were very mixed in interventions employed and study populations.[258] Of four included trials directly assessing dietary change by collecting data on fat and fibre intake, one found very positive results, one found no significant difference on either measure and two found significant differences for one measure but not the other.

Four RCTs published since the systematic review all reported positive effects of intervention. The RCTs had predominantly white samples (with the exception of one[260]), two were UK based[237,260] with one based in a low-income area.[260] In two studies, physicians gave dietary advice in routine consultations[259, 261] and in two advice was provided by research nurses.[247,260] Three of the RCTs[247,259,260] reported that individually tailored intervention resulted in increases in self-reported fruit and vegetable intake at 3 months[259] six months[247] and 12 months,[260] with the reported increases between 0.6[259] and 1.4 portions per day[247] compared with control groups. Steptoe and coworkers[260] reported increased consumption (at 12 months) in both a nutrition advice and tailored behaviour intervention, but the observed increase was significantly higher in the latter (0.6 portions per day, $p = 0.021$). Beresford and coworkers[261] measured changes in fat intake which were significant larger at three and 12 months in the intervention group.

11.4.1.3 Incentives

One multifaceted RCT to improve dietary habits among adult primary care patients offered a $5 incentive at the baseline and final survey for those in the intervention group.[259] The intervention group reported a positive effect for fruit and vegetable consumption (an increased of 0.6 servings a day) compared with the control group. No effect was found for dairy products.

11.4.2 Physical activity

Based on 4 systematic reviews and 10 additional RCTs it can be concluded that interventions to increase physical activity levels can be moderately effective in the short to medium term, particularly for walking and non-facility-based activities. The findings are more equivocal for primary care based than general public health interventions, although interventions tailored to participant characteristics, and which offer written materials, may be more effective.

11.4.2.1 General public health interventions

One high quality systematic review identified a lack of UK-based research[248] but was able to conclude that interventions to encourage walking and non-facility-based activity are most likely to lead to sustainable increases in physical activity (up to at least 2 years). Of the nine additional RCTs, only one[237] did not support these conclusions. The majority of studies were among motivated, higher socioeconomic status groups but were undertaken among both genders, a range of age groups, and through a range of delivery methods (for example, mailed information, brief advice, structured programmes and counselling).

Although only one RCT was undertaken in the UK[241] many of the interventions could be generalisable to the UK, particularly for motivated individuals of higher social status. In terms of walking the most significant barrier was lack of time reflecting findings of RCTs that compliance was likely to be better with less time demanding interventions (that is, home rather than facility based).

11.4.2.2 Primary care based interventions

Three systematic reviews with limited overlap,[249–251] which included four UK RCTs[169,236,244,252] and one additional RCT,[240] provide some evidence that primary care based interventions can be effective.

One systematic review concluded that counselling adults in a primary care setting is moderately effective in the short term,[250] and one[249] concluded that the evidence was inconclusive. Interventions tailored to the participant characteristics and which offered written materials to patients produced stronger results. The most recent systematic review concluded that exercise referral schemes appear to increase physical activity levels in populations that are already slightly active, in older adults and in those who are overweight but not obese.[251]

The systematic reviews were ‘unpicked’ to look at the four UK studies in more detail. Physiotherapist-led advice sessions to sedentary 40–70-year-olds, encouraging group participation in lay-led walking schemes, reported no significant between-group differences in self-reported physical activity at 12

months. However, when completers-only were analysed, the intervention was more effective than advice only.[244] An incentive study [252] offering free access to leisure facilities resulted in increased physical activity scores at 12 weeks but this was not maintained at 12 months. A personalised 10-week programme for sedentary 45–70-year-olds resulted in a significant (10.6%) reduction in the proportion of participants classed as sedentary in the intervention compared with the control group at 8 months' follow-up.[169] Taylor and coworkers[236] did not report physical activity outcomes.

The more recent RCT of oral and written advice from GPs or practice nurses plus motivational phone calls by an exercise specialist from New Zealand reported a significant difference between intervention and control including the proportion undertaking 2.5 hours/week exercise ($p = 0.003$) at 12 months.[240]

Sixteen studies offer evidence of UK corroboration. The success of programmes is influenced by the qualities of personnel in contact with participants, while the views of referring practice members or barriers such as lack of time could be significant.[267,269,273,277,284] Individual perceptions of self-efficacy ('I believe I can exercise regularly') are strongly related to exercise behaviour and clinicians can help facilitate these perceptions (Keller 1999).[285] Barriers to leisure centre attendance include social support, time, the gym environment and time spent with instructors.[267,279,281,282] Other barriers were illness and injury, work pressure, transport, programmes not appropriately tailored, lack of money. When 'not knowing where exercise facilities are' is cited as a barrier by participants at the start of the programme, the likelihood of those participants completing the programme is increased by 3.5 times. Guided walks (Health walks) were found to be a sustainable form of exercise,[280] but it was noted that planning and promotion activities should take into account the seasons and varying needs of walkers (grades of difficulty, evening walks for workers, etc.) as well as emphasising the social benefits.

Lack of time, confidential space, training and cost issues were barriers to the involvement of pharmacy contractors, advisors and pharmacists[270,271,274–276] and well as concerns about 'interference'.[270,271] In addition, consumers do not tend to regard the pharmacy as a source of health promotion advice.[270,286]

11.4.2.3 Incentives

Two physical activity interventions providing incentives demonstrated a positive short-term effect. A UK-based RCT offering vouchers entitling free access to leisure facilities reported increased physical activity scores at 12 weeks and increased vigorous activity in the intervention participants.[252] However this increase was not maintained at 12 months. Jeffery[231] reported that exercise decreased less in the education and education plus incentives groups. However, statistical significance of this was unclear.

11.5 Sub questions

Evidence on implementation identified potential barriers to behaviour change – such as time and social support – which if addressed, could increase participants receptiveness/ability to change.

11.5.1 Variation by gender, age, ethnicity, religious practices or social group

Studies were undertaken with a range of ages and with both men and women. The findings did not appear to vary by gender, although females may be more receptive to health professional advice than males.[262]

Participants in the majority of studies were predominantly white, of higher social status and reasonably motivated. However, there is some evidence that interventions can be effective among lower social groups (for example, Steptoe et al.[260]).

Cost and availability were identified as practical barriers to change for physical activity and diet (for example, Wrieden et al.,[246] Anderson et al.,[263] Lloyd et

al.[264]). Indeed one study found that a significantly higher proportion of those who cited 'lack of money' as a barrier dropped out of a physical activity programme than those who did not cite it as a barrier (55.3% vs 44.7%, $p = 0.024$).[281]

A range of studies suggest that tailoring advice is key to the effectiveness of interventions and that this will obviously impact on issues related to gender, age, ethnicity, religious practices or social group.

11.5.2 Previous weight loss

No evidence was identified.

11.5.3 Source and mode of delivery

11.5.3.1 Source of delivery

Evidence from three RCTs of primary care based interventions to increase physical activity showed a trend to a more positive outcome was achieved when interventions were delivered by facilitators from more than one discipline (GP/practice nurse and exercise specialist;[240] physiotherapist and local health walks coordinator;[244] and exercise specialist only[245]).

A weak UK-based study reported that trained community nutrition assistants providing healthy eating advice and support increased coverage by fourfold, and that the majority of respondents preferred advice from a local person rather than a health professional, perceiving them to be more approachable and easier to access.[287]

One cross-sectional UK-based survey of mainly white patients suggests that significantly more respondents would have liked to have received advice from health professionals than did ($p < 0.001$).[262] Hardcastle and Taylor[267] demonstrated the importance of encouragement from GPs in promoting physical activity in addition to participant commitment and confidence. However, a cross-sectional survey on the effectiveness of walking packs found that the major barrier was lack of time (60%) rather than motivation by a GP or health

professional (14%).[277] A small qualitative study found that couples and GPs viewed general practice as a place for treatment of illness and disease rather than provision of dietary advice.[268] The GP's advice was affected by personal preference (younger, females doctors being more enthusiastic). GPs were concerned that dietary advice could damage their relationship with patients. These findings were supported by a qualitative study of exercise promotion.[273] Data from a suspended RCT found that barriers to recruiting patients to a GP-led programme included time, overly complicated questionnaires and lack of financial incentive for the health professionals.[284]

The studies bear out the findings of Biddle and coworkers[269] on physical activity promotion schemes in primary care, which concluded that success depends on the qualities of key personnel in contact with participants and establishing a programme depends on the enterprise of an energetic innovator. Certainly the negative responses of those surveyed by Hopper and Barker[272] – where by the primary healthcare workers surveyed felt that their practice population was not sufficiently motivated to follow dietary advice – are unhelpful. With the negative views expressed by GPs, it is unsurprising that Hopper and Barker[272] reported that practice nurses gave dietary advice more frequently than GPs.

11.5.3.2 Mode of delivery

The identified evidence did not appear to suggest that the health professional who provides advice and support was important (for example, GP compared with practice nurse). The key issue is whether the health professional is motivational[269] and the support of the health professional (along with social support) is maintained, for example, through motivational phone calls, mailed information. The importance of health professionals reassuring participants on the consistency of advice was highlighted by Fuller and coworkers.[268]

No evidence identified on how best to encourage partnerships.

11.5.4 Potential negative impacts

No evidence was identified.

11.6 Limitations of the review

RCTs often lacked (or failed to report) a description of the randomisation process, concealment allocation and/or an ITT analysis.

According to the agreed parameters paper (Appendix 2), RCTs without ITT but 80% or more follow-up were downgraded in quality assessment but not to CCTs. The lack of description of randomisation and/or concealment allocation also led to a downgrading but not automatic rejection. Where an RCT did not meet one or more of the NICE criteria, reasons are listed in the comments column of the evidence tables (Appendix 9).

Relevant studies with evidence of efficacy of community-based interventions for children were not found, and so a number of studies containing corroborative evidence about children were not included in the evidence tables.

12 Prevention evidence summary: broader community interventions ('Community 2')

The following is based on an evidence review produced by Cardiff University.

Detailed evidence tables and supporting information are in Appendix 10.

12.1 Evidence statements (Table 12.1)

Table 12.1 Evidence statements and grading

No.	Statement	Grade	Evidence
Weight outcomes			
1	There is no evidence on the effectiveness of broader environmental interventions on the maintenance of a healthy weight and prevention of obesity	N/A	N/A
2	There is little evidence of benefit from locally implementable multi-component city- and state-wide interventions to prevent cardiovascular disease on weight outcomes	2+	Three CBAs (all 2+) generally do not support: Shelley et al. 1995[288] suggests trend; O'Loughlin et al. 1999,[106] Baxter et al. 1997[289] do not support
	Diet and activity outcomes		
3	No interventions were identified which addressed both diet and activity	N/A	N/A
4	There is little evidence of benefit from locally implementable city- and state-wide interventions to prevent cardiovascular disease in relation to diet and/or physical activity outcomes.	2+	Four CBAs (all 2+) generally do not support. Baxter et al.1997[289] supports diet change in one area No support for dietary change from Huot 2004,[290] O'Loughlin et al. 1999,[106] Osler and Jespersen 1993[109] No support for physical activity change from O'Loughlin et al 1999,[106] Baxter et al. 1997,[289] Osler and Jespersen 1993[109]
5	Point of purchase schemes in shops, supermarkets, restaurants	2++	Body of evidence variable but generally supportive from four

No.	Statement	Grade	Evidence
	and cafes can be effective in improving dietary intakes at least in the short term, particularly if accompanied by supporting education, information and promotion. There is some evidence that longer-term, multi-component interventions may show greater effects		systematic reviews of non-randomised studies and three RCTs Systematic reviews support: Roe et al. 1997[291] (1++), Seymour et al. 2004[206] (2++), Matson-Koffman et al. 2005[292] (2+), Holdsworth and Haslam 1998[293] (2+) One RCT suggests trend: Kristal 1997 [294] (1+) One RCT suggests low-fat alternative acceptable: Stubenitsky et al. 2000[295] (1+) One RCT does not support: Steenhuis et al. 2004[296] (1+)
6	There is a body of evidence that creation of, or enhanced access to space for physical activity (such as walking or cycling routes), combined with supportive information/promotion, is effective in increasing physical activity levels	2++	Body of evidence generally supports. One systematic review and three additional studies (all 2++/2+) One systematic review (Kahn et al. 2002[297] [2++]) and one BA (Merom et al. 2003[105] [2+]) support One CBA (Brownson 2004[298] [2+]) shows trend. One BA (Evenson et al. 2005[299] [2+]) does not support
7	The general promotion of active travel (for example, publicity campaigns) does not appear to be effective in increasing physical activity levels	1++	Body of evidence from one systematic review supports: Ogilvie et al. 2004[300] (1++)
8	Targeted behavioural change programmes with tailored advice appear to change travel behaviour of motivated groups. Associated actions such as subsidies for commuters may also be effective	1++	Body of evidence from one systematic review supports: Ogilvie et al. 2004[300] (1++)
9	Point of decision prompts or educational materials such as posters and banners have a weak	2+	Body of evidence from two systematic reviews and two BA studies generally suggest weak

No.	Statement	Grade	Evidence
	positive effect on stair walking		positive and/or short-term effect Systematic reviews (Foster and Hillsdon 2004[301] [2+], Kahn et al. 2002[297] [2++]) and two BA studies (Marshall et al. 2002[302]) support One BA study (Adams and White 2002[303] [2+]) does not support
Generalisability			
10	Barriers may vary by age, gender and social status	3	Body of evidence from 10 observational studies supportive (all 3) *Age:* Whelan et al. 2002[304] (qualitative), Holdsworth et al. 1997[305] (cross-sectional), Watt and Sheiham 1996[306] (cross-sectional), Watt and Sheiham 1997[307] (qualitative), Mulvihill et al. 2000[308] (qualitative), Davis et al. 1996[309] (qualitative) *Gender:* Foster et al. 2004[310] (cross-sectional), Coakley et al. 1998[81] (qualitative), Mulvihill et al. 2000[308] (qualitative) *Social status:* Coakley et al. 1998[81] (qualitative), Watt and Sheiham 1996[306] (cross-sectional), Furey et al. 2001[311] (qualitative /quantitative), Caraher et al. 1998[312] (cross-sectional), Whelan et al. 2002[304] (qualitative)
Implementation			
11	Auditing the needs of all local users can help engage all potential local partners and establish local ownership	3	Three sets of case studies support (all grade 3): Sustrans 2004,[313] Department for Transport 2003,[314] Derek Halden Consultancy 1999[315]
12	Interventions may be ineffective unless fundamental issues are addressed, such as individual confidence to change behaviour,	3	Body of evidence from 14 corroborative studies support (majority 3) *Dietary change*: Wrigley et al.

No.	Statement	Grade	Evidence
	cost and availability; pre-existing concerns such as poorer taste of healthier foods and confusion over mixed messages; the perceived 'irrelevance' of healthier eating to young people; and the potential risks (including perception of risk) associated with walking and cycling		2003[316] (BA; 2+), Whelan et al. 2002[304] (qualitative), White et al. 2004[317] (cross-sectional), Knox et al. 2001[318] (qualitative), Dibsdall et al. 2002[319] (qualitative) *Physical activity:* Cole-Hamilton et al. 2002[320] (systematic review), Derek Halden Consultancy 1999,[315] Dixey 1999[321] and 1998[322] (survey/interviews), DiGuiseppi 1998[175] (cross-sectional), Coakley et al. 1998[81] (qualitative), Jones 2001[323] (BA/survey; 2+), Hillman 1993[324] (cross-sectional)
13	Addressing safety concerns in relation to walking and cycling may be particularly important for females and children and young people and their parents	3	Four corroborative studies support: Foster et al. 2004[310] (cross-sectional), Coakley et al. 1998[81] (qualitative), Mulvihill et al. 2002[308] (qualitative), Davis and Jones1996[309] (qualitative).
14	Interventions which incorporate novel educational and promotional methods, such as videos and computer programmes, may improve dietary intake	1++	Three RCTs support: Winett et al. 1988, Winett et al. 1991 (both cited in Roe et al. 1997[291] [1++]), Anderson et al. 2001[325] (1+)
15	Changes to city-wide transport, which make it easier and safer to walk, cycle and use public transport – such as the congestion charging scheme in the City of London and Safer Route to School schemes, have the potential to make active transport more appealing to local users	3	Four corroborative studies support: Transport for London 2005[326] (case study/audit 3); DETR 2000[327] (case studies 3), Parker and Seddon 2003[328] (BAs; 2+), Jones 2001[323] (BA/survey; 2+)

BA, before-and-after study; CBA, controlled before-and-after study; DETR, Department for Transport, Environment and the Regions; N/A, not applicable; RCT, randomised controlled trial.

See Appendix 10 for associated evidence tables.

12.2 Methodology for review

Database searches were carried out in April 2005 for papers published from 1990 onwards (1995 onwards for systematic review level evidence). A final update search was completed on 1 December 2005 on a reduced number of databases. From an initial 4320 hits, 524 papers were assessed in detail of which 61 papers (including 10 systematic reviews) met the critical appraisal criteria for inclusion in evidence tables.

The inclusion and exclusion criteria for the review adhered to the standard public health review parameters. However, specific criteria were also developed to make this topic manageable in the time available. The following were included:

- City-, county- and state-wide interventions with potential for local implementation. Although interventions without a control or comparison group are usually excluded within rapid reviews, for two topics in this review, stair climbing and multi-use trails, the only evidence available was from uncontrolled before-and-after studies and therefore these were included.
- Mass media interventions that include an intervention and are not just about raising awareness. A note was made in the evidence tables if individual studies were assessed by McDermott et al.[329] as meeting the Andreasen[330] benchmarks for a social marketing programme.
- Papers on perception of causation (environmental reasons people give for not exercising, etc.) and all other corroborative evidence relating to the topics of interest.

The Guidance Development Group (GDG) also considered a non-evidence-based, expert review paper prepared by one of the GDG members on the potential impact of the built environment on weight and obesity.

12.3 Weight outcomes

Three multi-component before-and-after studies aimed at reducing cardiovascular risk factors in adults included weight outcomes.[106,289,288] The studies employed a range of educational and behavioural strategies such as workshops, point of choice, educational and multimedia components. O'Loughlin and coworkers[106] and Baxter and coworkers[289] looked at lower-income populations. None of the studies noted a significant reduction in weight or body mass index (BMI) in the intervention compared to the control communities although Shelley and coworkers[288] recorded a trend towards weight reduction in the intervention group.

No studies in other settings were identified that reported weight outcomes.

12.4 Diet and activity outcomes

Seven systematic reviews, five randomised controlled trials (RCTs) and four before-and-after studies were identified which provided evidence of efficacy. UK studies were identified in the majority of areas and an additional 20 UK-based studies provided evidence for implementation.

Interventions to improve diet focused on supermarkets, restaurants/cafes and churches. Environmental action to improve physical activity levels focused on the promotion of active travel, point of decision prompts to stimulate stair climbing, and the creation of space and safer routes.

Long-term follow-up of interventions was rare. Although interventions did not appear to be skewed towards higher income, white populations, dietary studies focused more on women rather than men. The majority of studies were delivered by researchers, and, where appropriate, setting-based workers (for example, supermarket or community centre staff).

12.4.1 Diet

The results suggest that point of purchase schemes can be effective in improving dietary intakes, at least in the short term, particularly if accompanied by supporting information and local promotion. Incorporating novel methods, such as video and computer programmes, may be particularly effective. Promotions in restaurants and cafes may have a greater impact than those in supermarkets. Interventions based in religious or other community settings may also have a positive impact on dietary intake.

There was little evidence of effectiveness from the five city/state-wide multi-component interventions in terms of dietary outcomes.

12.4.1.1 Supermarkets

Two good quality systematic reviews with limited overlap[206,291] and three RCTs[296,325,294] considered supermarket based interventions. These primarily focused on point of purchase schemes. The majority of studies were US based. Both systematic reviews concluded that point of purchase strategies in supermarkets can increase the purchase of targeted ‘healthier foods’ (particularly if supported by informational brochures and local promotion[291]). The magnitude of the effect was around 1–2% of total market share of healthier food items.[291]

The conclusions of the two reviews were not entirely supported by two additional supermarket-based RCTs. A Dutch RCT[296] assessing education with or without shelf labelling found no decrease in total fat intake 6 months post intervention, and a US-based RCT[294] found no increase in fruit and vegetable consumption at 4 months after the intervention. Kristal did note an 8.4% increase in intervention shoppers in the action or maintenance stage of dietary change but this was not significant ($p < 0.07$). These findings may reflect the length of the interventions; Seymour and coworkers[206] noted that the longer, multi-component studies appeared to be more effective (although no data were provided).

The two RCTs of educational videos included in the systematic review by Roe et al.[291] (Winett et al. 1988 and 1991) showed a 4–5% decrease in the percentage of energy from fat of purchases during the intervention. Longer-term follow-up data were not available. An RCT to assess the impact of a self-administered, computer-based intervention on supermarket shoppers found that the treatment group was more likely than the control to attain 'goals' for fat at the end of the 16-week intervention ($p < 0.001$) and 6-month follow-up ($p < 0.05$).[325] There was also a non-significant trend ($p < 0.1$) towards goal attainment for fibre and fruit and vegetables after the intervention. However, some caution is needed on these findings as the initial low response rate and compliance may suggest that the participants were a motivated group.

12.4.1.2 Restaurants and cafes

Four systematic reviews with limited overlap and including 28 studies in total were identified. Two were good quality (Roe et al.[291] and Seymour et al.[206]) and two were much lower quality (Matson-Koffman et al.[292] and Holdsworth and Haslam[293]). All four reviews focused on 'point of purchase' interventions in restaurants and cafes.

All four reviews concluded that point of purchase strategies increased the consumption of targeted items. Roe et al.[291] concluded that point of choice promotions led to an increase in sales of promoted items of 2–12% total market share but the effect generally only lasted as long as the intervention was in place. Seymour stated that most of the restaurant studies reported some significant increased sales of targeted menu items (but no data were provided).[196] The two lower-quality reviews (Matson-Koffman et al.[292] and Holdsworth and Haslam[293]) concluded that point of purchase or choice strategies increased the consumption of 'healthier foods'. Some caution is required when considering these findings as 'unpicking' of the reviews revealed that none of the included studies met the rapid review inclusion criteria.

An additional small UK-based RCT found that the provision of menu information about a lower-fat option had no effect on total energy and fat intake and did not influence the subjects' choice. However, information was only provided on one menu item.[295]

12.4.1.3 Multi-component state- and city-wide interventions

Four multi-component controlled before-and-after studies (CBAs) aimed at reducing cardiovascular risk factors measured dietary outcomes.[106,109,289,290] Of these, three reported no difference in dietary outcomes between the intervention and control areas.[106,109,290] One UK-based study[289] observed that 8.7% more people in the intervention population drank lowfat milk compared with the control group ($p < 0.001$), which the authors attributed to the mailing of a leaflet promoting semi-skimmed milk to 11,000 households over a 2-year period.

12.4.2 Physical activity

The results suggest that although the general promotion of active travel does not appear to be effective, targeted behavioural change programmes appear to improve travel behaviour of motivated subgroups. Associated action, such as subsidies for commuters, may also be effective. Promotions which aim to motivate stair use, such as posters and banners, appear to have a weak, positive effect. The only RCT considering safer routes to schools, which looked at the effect of a school travel coordinator, was unable to assuage parental fears and alter children's travel patterns.[331]

No studies were identified which considered interventions linked to supermarkets and shops, restaurant and cafes, or religious organisations. There was little evidence of effectiveness from the five city/state-wide multi-component interventions in terms of physical activity outcomes. Identified interventions included a mixture of UK, US and Australian-based studies. The length of follow-up varied considerably.

12.4.2.1 Active travel versus car travel

One good quality systematic review (including nine UK studies) concluded that targeted behavioural change programmes with tailored advice can improve the travel behaviour of motivated subgroups (the largest study showing a 5% shift to active travel).[300] The authors also concluded that identified single studies of commuter subsidies and a new railway station also showed positive effects, but this was not the case for publicity campaigns, engineering measures and other interventions promoting active travel.

12.4.2.2 Point of decision prompts to stimulate stair climbing

Two systematic reviews, one good-quality[297] (including two UK studies) and one lower-quality[301] (including eight UK studies) review concluded that educational materials such as posters and stair riser banners have a weak positive effect on stimulating stair climbing. Kahn et al.[297] reported a range of effect sizes from a 5.5% to 128.6% net increase and noted that the effectiveness of interventions may be increased by customising signs to appeal to specific population groups. Foster[301] found that most studies saw a short-term effect for up to 3 months although one study observed a 29% increase at 6 months. Three additional short-term before-and-after studies were identified, two supporting the conclusions of the systematic reviews (references [302] and [332], a very weak study) and the third not.[303] Finally, a Swedish-based observational study found that over a 1-hour period 35% of commuters walked up the stairs when one escalator was in operation compared with only 18% when two were in operation.[333]

12.4.2.3 Creation of space for physical activity

One good-quality systematic review (all US-based studies of varying designs) found strong evidence that the creation of space or enhanced access to places for physical activity combined with informational outreach activities is effective in increasing physical activity levels.[297] Interventions increased frequency of activity between 21% and 84%. Interventions included access to fitness equipment, access to community centres and creation of walking trails.

An additional CBA of walking trails in the USA found no significant difference between intervention and control communities overall, although two intervention subgroups (lower education/income) showed positive trends in total walking rates.[298] Two additional, non-UK-based before-and-after studies considered the use of multipurpose trails. Evenson and coworkers[299] found that 2 months following the building of a multi-use trail, there was no increase in physical activity among adults living within 3.2 km (2 miles) of the trail. However, this intervention did not include an associated campaign/promotion. Conversely, Merom and coworkers[105] found that a promotional campaign for a local cycle trail increased the number of bikes in the area ($p < 0.001$) and influenced cyclists living within 1.5 km of the trail (increasing cycling time).

12.4.2.4 Safer routes to school

One UK-(inner city)-based RCT found that assistance from a school travel coordinator did not change primary school children's travel patterns, nor did it substantially affect parental fears about the safety of the journey to school.[331]

12.4.2.5 Multi-component city/state-wide interventions

Three multi-component CBAs aimed at reducing cardiovascular risk factors measured physical activity outcomes.[106,109,289] None of the studies detected a difference between control and intervention groups although two noted an increase in physical activity in both intervention and control populations.[106,109]

12.5 Sub questions

Corroborative evidence highlighted the importance of interventions addressing fundamental issues such as cost and availability and pre-existing concerns such as the poorer taste of healthier foods and the potential risks of walking and cycling.

12.5.1 Variation by gender, age, ethnicity, religious practices or social group

12.5.1.1 Age

UK-based studies of ‘food deserts’ suggest that younger women, especially those with low incomes, may be more concerned about the cost rather than the quality of the food whereas this situation may be reversed in older women who may be more enthusiastic about buying ‘healthier’ foods.[304] This reflects the findings of the Heartbeat Award that the availability of healthier food choices was more important to those aged 45 or over.[305]

In London, 14-year-olds considered ‘healthy foods’ to be largely irrelevant, unappealing, expensive and not readily available outside their own homes.[306,307] Fast foods were consumed largely for the opposite reasons, and were considered part of their independent lives. Parental disapproval of fast foods was also part of their appeal. The participants considered addressing these factors, along with will power, support from family and advice from doctors, as helpful in promoting future changes in eating habits.

A cross-sectional and focus group study of 9–11 and 13–14-year-olds found that children were aware of the health promotion messages about being active but felt considerable environmental constraints.[309] Many were not allowed to play outdoors, use local parks or cycle to school – nor they did not feel comfortable doing so. Girls especially were restricted in how late they were allowed out. In the children’s views, traffic danger, ‘stranger danger’ and social and cultural factors interact to create barriers to keeping healthy and active. A qualitative study of 5–11-year-olds also found that the main barriers were lack of time, cost, lack of transport in rural areas and parental concerns about lack of safety and the poor condition of local parks.[308] Children stressed the importance of the social aspects of physical activity.

12.5.1.2 Gender

A cross-sectional survey found that the perceived safety of walking during the day and lack of shops within walking distance were significant barriers to walking for women but not men.[310] Conversely, environmental perceptions were not related to the number of women walking for more than 150 minutes a week whereas having a park within walking distance was significantly associated with this measure in men.

A qualitative study of young people in London reported that young women mentioned parental constraints and the influence of boyfriends as affecting their leisure choices whereas young men tended to 'do what they wanted'.[81] Young women's decisions about sport participation reflected past experiences and were often associated with feelings of discomfort and embarrassment. Mulvihill and coworkers[308] also found that barriers for young women being active included feeling intimidated by young men, lack of time and lack of self-confidence.

12.5.1.3 Ethnicity

No specific issues were identified.

12.5.1.4 Social status

Financial constraints may have a significant impact on sport participation for young people of both sexes.[81] However, Watt and Sheiham[306] reported that young people from non-manual households were more likely to consider friends' support, information and the availability of healthy foods as being important in making healthier choices than their peers from manual households.

Cost rather than quality is the major issue for those in lower-income brackets when deciding where to shop,[304,311] and lack of transport may be a limiting factor for those on a low income.[311,312] A qualitative study of women on low incomes found that although they reported good food availability and control of budgets, buying 'more' foods such as more fruits and vegetables was beyond their budgetary control.[319]

Six studies addressed the specific issue of ‘food deserts’: a before-and-after study[316] and associated qualitative study[304] considered the effect of the opening of a supermarket in a deprived, poor-retail-access community in Leeds; and a cross-sectional study assessed relations between dietary intake and retail access in Newcastle upon Tyne.[317] The studies did not provide evidence of a ‘food desert’ effect on dietary intake although in the Leeds study, participants who switched to the new store increased their consumption by 0.23 portions of fruit and vegetables per day.[316] The findings suggest that fundamental issues around cost, availability and taste are key considerations for future interventions. In the Leeds study, 28% of those who did not switch to the new store were concerned about the expense. This was backed-up by qualitative work which found that although the stores improved physical access, this did not fundamentally alter economic access. In the Newcastle study knowledge (itself related to social status) and relative affluence were the key indicators of ‘healthy eating’ rather than retail availability.[317]

Other corroborative evidence suggests that supermarket-based interventions to improve dietary intake may also be hindered by a range of factors including confusion about product labelling (particularly among lower social groups), conflicting or confusing information, and concerns about taste.[318,319]

12.5.2 Influence of previous weight loss

No evidence was identified.

12.5.3 Source and mode of delivery

12.5.3.1 Source

The majority of studies were delivered by researchers, and, where relevant, appropriate setting-based workers (for example, supermarket or community centre staff).

Case studies suggest that involving the local community from the outset, establishing effective partnerships and including an evaluation of pedestrian

needs may improve the effectiveness of interventions promoting active travel.[313–315] The need for project sustainability, publicity and clear roles for project champions have also been highlighted.[315]

Parents are likely to have an important role in the success of interventions aimed at children and young people. A systematic review of 93 consultation studies in England found that barriers to play for school-age children are: fears for their own safety, in particular bullies; dirty unkempt play areas and parks; the lack of things to do; traffic; and lack of facilities for disabled children.[320] A weak report of cross-sectional surveys of English 7–11-year-olds between 1971 and 1990 (Hillman 1993)[285] noted large decreases in the number of children, particularly girls, allowed to cycle, cross roads or use the bus on their own. The primary concerns of parents were danger from traffic, and children's reliability and fear of molestation.

Cross-sectional and focus group surveys provide powerful evidence that children would like to walk, cycle or take the bus to school but perceived and actual dangers have led to increase vigilance by parents and reduced activity in children.[175,315,321–323] A safer route to school scheme that incorporated the views of children in its development found a considerable increase in walking and cycling to school 3 years after the intervention.[323] Encouragement from parents may be particularly important for children and young people but advocates and role models may be more important for those over 16.[81] Children using staffed provision like staff who listen; staff who are funny, friendly and fair; having a say in what they do; and staff who can deal with conflicts between children.

12.5.3.2 Source

A systematic review (including two UK studies) suggests that tailoring prompts to stimulate stair climbing, either by specifying the benefits of stair use or by customising the sign to appeal to specific population groups, may increase intervention effectiveness.[297]

Data from two sets of case studies[313,314] suggest a range of practical issues that may improve the effectiveness of interventions promoting active travel including (i) improving the walking and cycling environment (for example, traffic calming, crossings, signs and lighting); (ii) improving facilities (for example, cycle stores, traffic-free routes); and (iii) influencing behaviour (for example, guides, maps, walking schemes). Experience from Scotland suggests that a promotional campaign and helpline may encourage motivated individuals (callers to the helpline) to walk more but this study found no effect on the population as a whole.[100]

The findings of the Department for Transport case studies[314] – that addressing practical issues may impact on behaviour – are reflected in the findings of the impact of the City of London's congestion charging scheme.[326] Two years after implementation of the scheme it was estimated that 10–20% car journeys had transferred to cycling, walking, motorcycle, taxi or car share. Before and after street surveys found that comfort and quality of walking and public transport, and safety of cycling, was perceived to have improved.

There is good corroborative evidence from the UK that 'Safer routes to school' schemes can be effective (that is, at odds with one identified RCT).[331] A series of before and after studies found that, when both school travel plan and safer routes to school programmes were in place, there was a 3% increase in walking, a 4% reduction in single-occupancy car use and a 1.5% increase in car sharing. Bus and cycle use remained largely static.[328] Conversely, a selected series of case studies found an overall increase in cycle use and decrease in car travel whereas the effects on walking and bus travel were variable.[327] Another scheme also found a considerable increase in walking and cycling to and from school 3 years after the intervention.[323] The effectiveness of such interventions among younger children remains unclear; the 'Early bird' longitudinal study found that being driven to school did not affect the overall physical activity of 5-year-olds.[174]

Support and advice for food providers, for example, through an award scheme may aid, the implementation and sustainability of point of purchase and other schemes promoting 'healthy eating'. Premises participating in the Heartbeat Award Scheme self-reported greater provision and uptake of 'healthier' food choices.[334] Provision of a range of affordable healthier choices may be viewed favourably by customers, particularly women and be one of a number of factors influencing their choice of eating place.[305] Qualitative work of community cafes suggests that a strong lead, active involvement of trained and supported staff, competitive pricing and active promotion of healthier options may be important for effectiveness of such schemes.[335] A weak cross-sectional study reported that 42% of respondents were eating more fruit and vegetables after the implementation of the scheme with 45% of respondents listed convenience/ease of access as a benefit.[336]

No evidence was identified on how best to encourage partnerships.

12.5.4 Potential negative impact

The majority of studies considering this issue did not report such findings. One UK study found evidence that prompts to stimulate stair climbing could be guilt inducing[303] (see also workplace review).

12.6 Limitations of the review

In general there was little evidence from RCTs for relevant interventions and this consisted of uncontrolled studies only for some topics (stair climbing and multi-use trails). By contrast there were a number of good UK-based corroborative studies although these did not always tie in directly to the intervention evidence.

RCTs often lacked (or failed to report) a description of the randomisation process, concealment allocation and/or an intention to treat (ITT) analysis.

According to the agreed review parameters, RCTs without ITT but 80% or more follow-up were downgraded in quality assessment but not to non-randomised clinical controlled trials (CCTs). Studies with no ITT and less than 80% follow-up

were treated as CCTs. The lack of description of randomisation and/or concealment allocation also led to a downgrading but not automatic rejection. Where an RCT did not meet one or more of the NICE criteria, reasons are listed in the comments column of the evidence tables.

13 Prevention evidence summary: interventions aimed at black, minority ethnic groups, vulnerable groups and vulnerable life stages ('BMEGs')

The following is based on an evidence review produced by the University of Teesside. Detailed evidence tables and supporting information are in Appendix 11.

13.1 Evidence statements (Table 13.1)

Table 13.1 Evidence statements and grading

No.	Statement	Grade	Evidence
Weight outcomes			
BMEGs			
1	There is a dearth of evidence on the effectiveness of interventions among BMEGs in the UK. All identified RCTs were undertaken in the USA, the majority among African/black Americans	N/A	N/A
2	There is some evidence that interventions among African/black American women, which promote a low-fat diet and moderate activity, can result in modest decreases in BMI and waist circumference in the short to medium term	1+	Two RCTs: Yanek et al. 2001[337] (1+) and Hall et al. 2003[338] (1++)
3	The effectiveness of interventions among African/black American children remains unclear. The majority of identified studies were not adequately powered to identify differences in BMI	N/A	Five of eight RCTs lacked power to detect changes in BMI (Baranowski 2003[339] [1+] , Beech et al. 2003[340] [1+], Robinson 2003[341] [1+], Story et al. 2003[137] [1+], Wilson 2002[342] [1+]); another two probably lacked power (Stolley 1997[343] [1+],

No.	Statement	Grade	Evidence
			Baranowski et al.1990[344] [1–])
			Only Hip-Hop (Fitzgibbon et al. 2005[110–111] [1+]) was adequately powered and showed positive improvements in BMI in children
4	There is evidence that school-based intervention are effective in preventing excess weight gain among black American children	1+	Three RCTs showed positive results: Flores 1995[138] (1+) (girls only at 12 weeks Stephens and Wentz 1998[140] (1+); Hip-Hop (Fitzgibbon et al. 2005[110–111] [1+])
			One RCT (Healthy Start[115–116] [2++]) showed intervention more effective in white pre-school children compared with African American children
5	There is some evidence that ethnicity may be a risk factor for greater weight gain during childhood, pregnancy and smoking cessation	3	Three (body of evidence from cohort studies – see energy balance review)
			Ethnicity in childhood: Ambrosius et al. 2001[88]
			Ethnicity and pregnancy: Rosenberg et al. 2003,[23] CARDIA[20,53–54]
Vulnerable groups			
6	The effectiveness of interventions among lower-income and other vulnerable groups remains unclear	N/A	Only one study among Mexican American children identified: Trevino 2005[154] (1+); no difference between intervention and control following intervention
7	There is a dearth of evidence on the effectiveness of interventions among individuals with a disability.	N/A	Rimmer 2004[345] (1+); two additional studies were not adequately powered: Chapman et al. 2005[346] (2–) and Van den berg-Emons et

No.	Statement	Grade	Evidence
	There is limited short-term evidence to suggest that intervention may prevent excessive weight gain in overweight adults with Down's syndrome		al. 1998[347] (1+)
8	There is some evidence that interventions to prevent excess pregnancy weight gain may be effective among lower-income groups but the impact of baseline weight remains unclear	1+	One RCT: Polley et al. 2002[348] (1+); one CBA Olson et al. 2004[349] (2++)
Vulnerable life stages			
9	On balance, smoking cessation interventions incorporating weight management may increase continuous abstinence rates but the long-term impact on weight, and the impact on diet and physical activity levels, remains unclear	1+	Four support: Marcus 1999[173] (1+), Danielsson et al. 1999[350] (1++), Perkins et al. 2001[351] (1+), Hall et al. 1992[352] (1+) Three did not: Pirie et al. 1992[353] (1++), Spring et al. 2004[354] (1+), Jonsdottir and Jonsdottir 2001[355] (2++)
10	There is a body of evidence that exercise (walking, other aerobic training, resistance training, strength training with weights machines or combinations) can improve body composition and result in a small loss of body weight and fat in postmenopausal women. This effect seemed to be optimal when combined with a weight-reducing diet	1++	Systematic review (1++): Asikainen et al. 2004[226]
11	There is limited evidence that a weight management programme addressing diet and activity during the menopause can prevent excess weight gain in	1++	One RCT (1++): Simkin-Silverman et al. 2003[227]

No.	Statement	Grade	Evidence
	women during the menopause		
12	There is limited evidence to suggest that continuing a regular exercise regimen and following an appropriate, healthy diet throughout pregnancy can result in significantly less total weight gain and significantly less increases in the sum of skinfolds	2+	Clapp 1995[356]) (2–); Olson et al. 2004[349] (2+); Polley et al. 2002[348] (1+); Kramer and Kakuma 2003[357] (1+)
Diet and activity outcomes			
BMEGs			
13	There is a dearth of evidence on the effectiveness of interventions among BMEGs in the UK. All identified RCTs were undertaken in the US, the majority among African/black Americans	N/A	N/A
14	There is a body of evidence that culturally specific interventions among black American adults can significantly improve fruit and vegetable intake, reduce percentage energy from total and saturated fat and reduce energy intake up to 2 years	1+	Body of evidence (seven RCTs) (1+/1++) *Fruit and vegetables:* Resnicow 2001[358] (1++), Resnicow et al. 2004[359] (1++), Resnicow et al. 2005[360] (1+), Campbell et al. 1999[361] (1++) *Energy and fat intake*: Hall et al. 2003[338] (1++), Yanek et al. 2001[337] (1+), Stolley 1997[343] (1+)
15	The effectiveness of tailored physical activity interventions targeted at BMEGs, compared with a non-targeted intervention programme, remains unclear	N/A	Three RCTs (all 1+) providing inconsistent findings Supportive: Chen et al. 1998[362] (1+) No difference: Newton and

No.	Statement	Grade	Evidence
			Perri 2004[363] (1+) Supportive for diet but not activity: Reniscow et al. 2005[360] (1+)
16	The effectiveness of interventions among children remains unclear	N/A	Eight studies but five lacked power (Baranowski 2003[339] [1+], Beech et al. 2003[340] [1+], Robinson 2003[341] [1+], Story et al. 2003[137] [1+], Wilson 2002[342] [1+]); another two probably lacked power (Stolley 1997[343] [1+], Baranowski et al.1990[344] [1–]) Only Hip-Hop (Fitzgibbon et al. 2005[110–111] [1+]) was adequately powered
Vulnerable groups			
17	There is a paucity of evidence on the effectiveness of interventions to manage weight, improve dietary intake and or improve activity levels among vulnerable groups	N/A	N/A
18	The impact of interventions during pregnancy to lower income groups in relation to long-term diet and activity levels remains unclear	N/A	No evidence
Generalisability			
BMEGs			
19	The generalisability of specific interventions among black American populations to all UK BMEGs may be limited but general learning can be applied to the UK	4	Expert opinion of GDG
Implementation			

No.	Statement	Grade	Evidence
20	Community settings, such as churches, have been shown to be an effective setting for engaging black/African Americans	1++	Five RCTs in churches for BMEGs: Yanek et al. 2001[337] (1+), Resnicow 2001[358] (1++), Resnicow et al. 2004[359] (1++), Resnicow et al. 2005[360] (1+), Campbell et al. 1999[361] (1++).
21	Additional barriers for BMEGs and vulnerable groups include cost, child care, cultural codes of conduct, language, racism and religious discrimination	3+	3+ body of evidence from case studies and surveys. Bush 1998,[364] Carroll et al. 2002,[365] Health Education Authority 1999,[366] Rai and Finch 1997,[367] Asian Arts 1996,[368] Verma 1994,[369] Dibsdall 2003,[370] Kennedy 2001[371]

BMEGs, black and minority ethnic groups; BMI, body mass index; CARDIA, Coronary Artery Development in Young Adults Study; CBA, controlled before-and-after study; GDG, Guidance Development Group; N/A, not applicable; RCT, randomised controlled trial.

See Appendix 11 for associated evidence tables.

13.2 Methodology

All studies previously identified for other review areas were considered for inclusion if they provided salient information on black and minority ethnic group (BMEGs), vulnerable groups or vulnerable life stages. Additional database searches were carried out in June 2005 for papers published from 1990 onwards (1995 onwards for systematic review level evidence). A final update search was completed on 1 December 2005 on a reduced number of databases. After de-duplication, 120 papers from previous reviews and additional database searches were assessed in detail of which 35 papers (including two systematic reviews) met the critical appraisal criteria for inclusion in evidence tables.

The inclusion and exclusion criteria for the review adhered to the standard public health review parameters (see Appendix 2). However, specific criteria were also

developed to make this topic manageable in the time available. The following were included:

- BMEGs – minority population groups to consider based on UK census data[372] and the prevalence data of obesity among BMEGs.[373] However, studies that met the inclusion parameters for effectiveness were conducted solely in black American or African American populations. Mean body mass index (BMI) in these populations is higher than in Caucasian populations. Therefore, at odds with the standard review parameters, studies among these population groups were not excluded if the mean baseline BMI was above 30 kg/m^2 but the study was not specifically aimed at weight loss.

- Vulnerable groups – included standard terms used for all previous Health Development Agency work regarding inequality (for example income, socioeconomic status, education) along with children in care; children in special schools; people in institutions. Additional terms were included to identify studies on individuals with learning difficulties, special needs and developmental disorders.

- Vulnerable life stages – based on the findings of the 'Energy balance' review which identified that smoking cessation, pregnancy and menopause were life stages associated with weight gain. Search terms were not included for other life stages where the energy balance review had identified more limited evidence (such as marriage, divorce and shift working).

13.3 Weight outcomes

13.3.1 BMEGs

Two large US-based studies in postmenopausal women reported weight outcomes, one in which 28% of the population were black, 16% Hispanic and 56% white[338] and the other in which all the middle-aged women were of African American descent.[337] The BMI of women in both studies ranged from approximately 28 kg/m^2 to 33 kg/m^2.

Eight randomised controlled trials (RCTs) were identified which reported weight outcomes in children of which four were conducted as pilots for one trial (GEMS [Girls health Enrichment Multi-site Studies]) in African American/black American children. Two additional family-based studies[111;337;337;344] were also identified. The RCTs focusing on children all had a 12–14-week follow-up (with the exception of one 2-year study) whereas seven of the nine studies including adults had follow-up between 5 and 30 months duration. All RCTs involved the staff at the location where the intervention was provided, including school staff, summer camp staff and community centre staff.

None of the RCTs were conducted among BMEGs in the UK. The majority of studies were conducted in African American females and five studies were conducted in church settings. This limits generalisability of the study outcomes to UK population groups.

13.3.1.1 Adults

Two good-quality, large RCTs reported weight outcomes in middle-aged African American/black American adults.[337;337;338] Both studies showed modest but statistically significant decreases in BMI (–0.6 kg/m^2 to –1.1 kg/m^2) and waist circumference (–1.7 cm to –1.9 cm). The study by Hall and coworkers[338] – incorporating weekly and monthly sessions with a research nutritionist encouraging a reduction in total and saturated fat, and an increase in fruit, vegetables and whole grain foods – showed modest but statistically significant decreases in weight, BMI, and waist and hip circumference in black American women at 6 months. Yanek and coworkers[337] reported the findings of a church-based intervention including nutrition education classes for 20 weeks and promoting moderate activity and a low-fat diet rich in fruit and vegetables. The intervention resulted in a significant reduction in BMI and waist circumference at 1 year in African American females but not weight or per cent body fat.

13.3.1.2 Children

Only one study was adequately powered to detect changes in weight.[374] Therefore the results of the four GEMS pilot studies – that there was no change in BMI at 12 weeks – must be treated with caution.[137;339-341] The four pilot studies addressed dietary intake (promoting reduced consumption of high-fat foods, increased water consumption/reduced sweetened beverages, increased fruit and vegetable intake) and physical activity (increased moderate to vigorous activity including dance and decreased sedentary behaviours including television viewing). Mothers were actively involved in one of the GEMS pilot studies.[340]

The two RCTs including parents and children did not report weight outcome data at 12 weeks for the children but one of these studies reported 'no weight change' between intervention and control group mothers[343] and the other study reported 'no significant differences' between groups (that is, parents and children) for anthropometric measures.[344] The two studies were assessed as unlikely to have been adequately powered and so the results should be treated with caution.

The one study that definitely was adequately powered appeared to be effective. US-based ethnic minority children who received a 14-week diet and physical activity intervention (Hip-Hop to Health Jr.) had significantly smaller increases in BMI compared with control children at 1-year ($p = 0.01$) and 2-year ($p = 0.02$) follow-up with adjustment for baseline age and BMI. This study was adequately powered.

13.3.1.3 Relevant studies from interventions identified in previous reviews

There is a notable dearth of information from the workplace and community reviews. In the workplace review, none of the included workplace studies focused exclusively on BMEGs. The studies which included African/black Americans did not analyse results by ethnicity. In the two reviews of community interventions none of the studies identified, which included black, ethnic minority populations, reported subgroup analysis by race. There is some evidence from the schools review that interventions are effective in preventing excess weight gain among

black American Children. Among pre-school children, one study suggested that the intervention reduced weight gain among white participants but not African American or Hispanic participants.[115]

13.3.2 Vulnerable groups

Few RCTs on vulnerable groups reported weight outcomes. Six of the RCTs of black, minority ethnic populations were among low-income groups.[137;340;343;344;361;374] Two of the pregnancy studies were in low-income women.[349,348] None of the seven smoking studies or the study during menopause was in low-income populations. Three further studies were identified focusing on low income/literacy groups, two among adults[231;375;375] and one among children.[153;154] Three further studies were identified focusing on children with spastic cerebral palsy,[347] adults with learning difficulties[346] and adults with Down's syndrome.[345]

13.3.2.1 Adults

The low-intensity diet and exercise 'pound of prevention' intervention showed no significant difference in weight outcomes between treatment and control groups (education, education plus lottery incentive and control).[376] The authors suggest intervention may be having a greater impact on high- than low-income women. There was a non-significant trend for less weight gain among intervention participants versus control in men and high-income women, but more weight gain among low-income women in the intervention versus control groups.[376] A culturally specific low-fat diet intervention among low literacy/income Mexican American women included weight outcomes but it was unclear whether the study was adequately powered to detect changes in weight.[375] It is therefore difficult to draw conclusions on the finding that the study failed to increase the effect of a standard nutritional education course without maintenance period, and there was no weight change in either group at 18 weeks. A study among low-income pregnant women suggests that such interventions may be more effective in preventing excess pregnancy weight gain in normal-weight low-income women than overweight women.[348] Conversely, Olson and coworkers[349] reported that

low-income women, particularly those who were overweight, who received the intervention to prevent excessive weight gain during pregnancy had a significantly reduced risk of excessive gestational weight gain.

A 12-month intervention led by health practitioners to reduce obesity among adults with learning difficulties in Manchester showed that in the control group obesity levels deteriorated in 10.2%, remained the same in 81.6% and improved in 8.2%.[346] In the intervention group 10.5% deteriorated, 63.2% remained the same and 26.3% improved. Mean BMI did not appear to significantly differ from baseline or between the groups at 1 year. A 12-week cardiovascular and strength exercise programme in adults with Down's syndrome showed a significant difference between groups ($p < 0.01$) with a slight reduction in weight at 12 weeks whereas control group weight increased. BMI was not significantly different between the groups at 12 weeks.[345] It is important to note that in both these studies the majority of participants were obese (in line with population estimates that approximately 69% of all adults with Down's syndrome are obese).

13.3.2.2 Children

Mexican American children from economically disadvantaged households who received a diet and exercise intervention to prevent diabetes did not improve per cent body fat compared with controls at 1 year.[153;154]

A nine-month German-based aerobic exercise programme (45 minutes, four times per week) in 20 9-year-old children with spastic cerebral palsy reported 'no changes' in fat mass compared with an average 1.1 kg increase in the control group (small sample, not powered to detect significant changes).[347]

13.3.2.3 Findings from interventions identified in previous reviews

There is a dearth of evidence relating to vulnerable in all the reviews, although particularly in the schools and workplace reviews. Where lower income groups were included subgroup analysis was seldom presented. The community 1 review noted that studies tended to be among higher socioeconomic status populations.

13.3.3 Vulnerable life stages

In relation to the menopause, one systematic review) of 18 good-quality RCTs of at least 8 weeks' duration assessed the effect of exercise in healthy postmenopausal women (aged 50–65 years) was identified.[226] An additional US-based RCT followed predominantly white women of higher social status from premenopause for 54 months when 35% of the women had become postmenopausal.[227]

In relation to pregnancy, a systematic review of diet during pregnancy was identified[357] and included three trials (two UK based) involving 384 women. An additional three US-based studies (one RCT[348] and two controlled before-and-after studies [CBAs][349,356]) were also identified which aimed to prevent excessive weight gain during pregnancy.

In relation to smoking, seven studies (six RCTs and one CBA) were identified that aimed to prevent excessive weight gain during smoking cessation.[173,350–355] The majority of the studies were small, US based and included predominantly women in their late thirties to forties who smoked 19–32 cigarettes a day. Although three of these RCTs included dietary and physical activity interventions[173,352,353,355] none reported dietary or physical activity outcomes. Most of the interventions were provided by research plus hospital staff, counsellors/therapists and/or an exercise specialist.

13.3.3.1 Menopause

One high-quality systematic review found that body composition was improved in 9 of the 18 included RCTs and the majority of RCTs showed a small loss of body weight and fat.[226] The effect was optimal when exercise (walking, other aerobic training, resistance training and/or strength training) was combined with a weight-reducing diet, particularly for overweight participants. The mean weight loss ranged from 2 kg to 10 kg in 12 weeks to 1 year.

Evidence from one high-quality RCT suggests that a tailored programme with a behavioural element addressing both dietary intake (calories, fat, and fruit and vegetable intake) and physical activity (for example, through lifestyle activities) can prevent excess weight gain and attenuate increase in waist circumference and per cent body fat in women during the menopause.[227] There was a significant reduction in waist circumference and BMI ($p < 0.001$) and per cent body fat ($p < 0.01$) in intervention women compared with controls at 54 months. At 54 months' follow-up 55% of the intervention women were at or below their baseline weight compared with 26% of controls.

13.3.3.2 Pregnancy

A Cochrane systematic review of diet in pregnancy reports that the limited evidence available suggests that protein/energy restriction of pregnant women who are overweight or exhibit high weight gain is unlikely to be beneficial and may be harmful to the developing fetus.[357] Only three studies were included, two in Scotland (published prior to1990), of which one was in obese women and the other in women with high gestational weight gain between weeks 20 and 30. Both trials reported that energy/protein restriction was associated with a significant reduction in weekly maternal weight gain, although the magnitude of the reduction was much larger in the 1975 trial.

Conversely, evidence from one RCT and one CBA suggests that interventions can minimise retention of excess weight after pregnancy among low-income women,[348;349] but it remains unclear whether the effectiveness varies depending on whether the woman is overweight or not. The CBA[349] demonstrated that the diet and exercise intervention reduced the risk of excessive gestational weight gain in the low-income subgroup only. Low-income women who received the intervention had a significantly reduced risk of excessive gestational weight gain at 1 year postpartum.

The RCT of diet and exercise, using a stepped-care approach that increased the intervention in women who had excessive weight gain, reported that the

intervention was effective in reducing the frequency of excessive weight gain in normal-weight women, with the intervention having no significant effect among overweight women.[348]

One controlled clinical trial (CCT) demonstrates that continuing a regular exercise regimen throughout pregnancy can result in significantly less total weight gain and significantly less increases in the sum of skinfolds at 37 weeks compared with women who voluntarily stop their regular exercise regimen because of concern that it would have negative effects on pregnancy ($p < 0.001$).[356] The intervention did not influence the rate of early pregnancy weight gain or subcutaneous fat deposition but both decreased in late pregnancy. Overall pregnancy weight gain remained within the normal range.

13.3.3.3 Smoking

Six of the seven identified studies suggested that additional interventions to prevent weight gain did not undermine smoking cessation.[173;350;351;353-355] Indeed three of the seven RCTs significantly increased continuous abstinence rates compared with controls.[173;350;351;353-355]

One study reported lower abstinence at 12 months in the intervention group compared with control (continuous abstinence 21–22% compared with 35% in control),[352] in other words including a specific and non-specific diet and exercise programme significantly increased the risk of smoking (13–14%) compared with control. Although the authors reported no significant difference in weight gain between treatment groups, the control group was 2.75 kg heavier than the diet and exercise group. Another study reported no significant difference in abstinence rates between the groups.[355]

One study demonstrated that cognitive behaviour therapy for weight concerns (to promote acceptance of and reduce concerns about modest weight gain when stopping smoking) significantly attenuated weight gain (2.5 kg vs 7.7 kg) compared with standard smoking cessation counselling in weight concerned women.[351] The third arm of the intervention included a 500 kcal/day deficit but

there was no significant difference in weight change between this weight control arm and the standard intervention arm (5.4 kg vs 7.7 kg).

Four other studies targeting exercise,[355] diet[350;354] or diet and exercise[350;352] reported no significant differences between groups in relation to weight change. Observed weight gain was consistently higher in the control compared with the intervention groups, though caution is required in interpreting non-significant trends. Furthermore, two of the studies[350;354;355] were not adequately powered to detect differences in weight.

Two of the seven studies found greater (non-significant) increases in weight in the intervention group compared with control. Marcus and coworkers[173;350] reported that the intervention group gained 8.92 kg compared with 5.76 kg in the control group. Pirie and coworkers[350;353] reported that weight gain ranged from approximately 4.5 kg (10 lb) in control or nicotine only to 4.4 kg (9.8 lb) in weight control or 6.4 kg (14 lb) in nicotine plus weight control.

13.4 Diet and activity outcomes

13.4.1 BMEGs

The evidence identified on diet and activity was limited. This was particularly the case in children where studies were generally relatively small pilots including girls only. Of the 16 US-based RCTs reporting intermediate outcomes in black/African American populations, four interventions addressed diet alone (three studies specifically focusing on increasing fruit and vegetables and one study of a low-fat diet).[338;350;358;359;361] Two RCTs addressed physical activity alone.[362;363] Ten other interventions addressed diet and physical activity.[137;339-342;360;374,343] The length of intervention ranged from 8 weeks[362] to 18 months.[338] Five of the identified dietary studies in adults were based in religious organisations.[337;358-361] In addition to research staff interventions, the interventions aimed at adults were provided by a range of individuals including a research nutritionist,[338] pastors and lay leaders,,[337] trained counsellors or lay members.[358;361-363] All eight RCTs that included children involved the staff at the location where the intervention was

provided, including school, fitness centre, summer camp and community centre staff.

The results suggest that dietary interventions aimed at BMEGs can be effective in children and adults (particularly in relation to intake of fat and fruit and vegetables). Physical activity programmes aimed at adults may also be effective but the evidence is equivocal on the benefits of tailoring the intervention to be culturally specific. The benefit of physical activity programmes in children remains uncertain due to the limited evidence base.

13.4.1.1 Diet

Adults

All seven adult RCTs addressing dietary intake reported significant improvements in intake in the intervention group. All four studies focusing on fruit and vegetable intake among African American churchgoers[358;358;359;359;360;360;361] reported that intakes were significantly increased in the intervention church populations up to 2 years, and one study reported significant difference in per cent energy from fat.[359] A culturally tailored diet and physical activity intervention significantly increased fruit and vegetable intake at 1 year compared with controls who received education materials only, with motivational telephone counselling having an additive effect.[360] A low-fat dietary intervention produced significant (11%) decreases in per cent energy intake from fat and total energy intake at 6 months in postmenopausal black American women.[338] A diet and moderate aerobic activity intervention produced significant decreases in total energy intake and total fat intake but not per cent energy from fat) at 1 year.[337] Saturated fat intake and per cent energy from fat was significantly reduced (by 8%) at 12 weeks in African American mothers following a diet and physical activity intervention.[343] A cross-sectional survey conducted at baseline and 3 years later, of women who were participating in the pound of prevention study showed that frequency of fast food restaurant use was higher among women of non-white ethnicity.[377] Intake of

several other foods, including fruits and vegetables, did not differ by frequency of fast food restaurant use.

Children

The evidence among children is more limited but also suggests that dietary interventions may have positive effects. The four GEMS pilots failed to show significant difference between study groups with regard to dietary intake (promoting reduced consumption of high-fat foods, increased water consumption/reduced sweetened beverages, increased fruit and vegetable intake) at 12 weeks, and also none were powered to detect statistically significant effects for weight/diet or exercise outcomes. The Memphis pilot[340] found that parent and child intervention groups combined significantly reduced intake of sweetened drinks compared with non-active controls and the Minnesota pilot[137] and the study by Stolley[343] both showed significant reduction in per cent energy from fat in the intervention girls. Among African American adolescents, social cognitive theory and social cognitive theory plus motivational interviewing to increase fruit and vegetable intake, were equally effective compared with control at 12 weeks.[342] The Hip-Hop to Health Jr. study (which was adequately powered) demonstrated only one significant difference between intervention and control pre-school children regarding diet outcomes and this was a difference in per cent of calories from saturated fat at 1-year follow-up ($p = 0.002$).

13.4.1.2 Physical activity

Adults

There is evidence from two RCTS that interventions promoting walking and home-based physical activity can increase the activity levels of sedentary ethnic minority populations.[362;363] Brief education was just as effective as adding mail and telephone counselling[362] and a culturally tailored programme was no more effective than a standard programme.[363] It is unclear whether the study by Chen and coworkers[362] was adequately powered to detect significant differences in treatment effects and the study by Newton and Perri[363] was not powered to detect significant differences in walking outcomes between the treatment groups.

The results for programmes specifically tailored to black American families reported mixed results. A culturally tailored diet and physical activity intervention significantly increased physical activity at 1 year compared with controls who received education materials only, however motivational telephone counselling did not increase effectiveness of the culturally tailored diet and physical activity intervention (both active interventions increased physical activity compared with controls).[360]

Both a culturally specific low-fat diet and an aerobic exercise intervention in black American families significantly increased energy expenditure from baseline but did not produce significantly increased metabolic equivalents (METs) or kilocalorie expenditure at 14 weeks compared with control.[344] Newton and coworkers[363] reported that a culturally tailored programme was no more effective than the standard programme and an RCT addressing diet and moderate aerobic activity failed to show a significant difference in energy expenditure between intervention and control at 1 year.[337]

Children

All three of the four GEMS pilots failed to show significant difference between study groups with regard to physical activity (increased moderate to vigorous activity including dance and decreased sedentary behaviours including television viewing) at 12 weeks, and none were powered to detect statistically significant effects for weight/diet or exercise outcomes. There was one exception: the Stanford GEMS pilot showed significant reduction in television viewing in the intervention group.[341] The children of a family diet and exercise intervention actually decreased their activity (METs) compared with the control children who increased their activity (METs) and kilocalorie expenditure.[344] The Hip-Hop to Health Jr. study, which was adequately powered, did not demonstrate any significant difference between intervention and control in relation to physical activity outcomes.

Relevant evidence from previous reviews

At least four of the 10 identified studies in the review of interventions aimed at 2–5-year-olds and families included a significant proportion of black and minority ethnic children. In the majority of identified studies self-reported diet and physical activity outcomes improved in the intervention groups compared with controls. The church-based interventions in African American adults in this review demonstrated significant effect in increasing fruit and vegetable intake. This finding is in agreement with an RCT identified in the Community 2 review which did not focus on a particular ethnic minority group.

13.4.1.3 Corroborative evidence

Six population surveys, two reviews and two intervention studies of diet and physical activity in BMEG populations in Britain were identified for corroborative evidence. The majority focused on South Asian women and one focused on white Irish adults. Another two non-UK surveys including African Americans were also identified.

A review of health education promotion in ethnic minorities[378] confirms a dearth of relevant research on nutritional health promotion among minority ethnic groups in UK with few studies that can be directly applicable to UK. Most were experimental or demonstration studies, and many community-based projects to promote healthy eating in ethnic minorities in UK were identified in ‘grey’ literature, lacked formal evaluation and any sound evidence of effectiveness. British examples of case studies of dietary and physical activity programmes contain little formal evaluation of these programmes.[364;379]

13.4.2 Vulnerable groups

Four studies were identified which included dietary and/or physical activity outcomes, one which separately recruited low-income women and analysed results by income for the women only,[376] one in Mexican Americans, mainly women with low income and low literacy,[375] one study in Mexican American low-

income school children[153;154] and a study in children with spastic cerebral palsy.[347]

13.4.2.1 Adults

Two of the studies that included the BMEGs were in low income populations;[361;362] one in a church setting that significantly increased fruit and vegetable consumption[361] and one partially home-based study that showed brief education was just as effective as adding counselling to increase amount of walking.[362] An additional study among a low-literacy/income population also found that both interventions resulted in significantly reduced percentage of energy from fat.[362;375] These findings do not appear to be replicated in the 'the pound of prevention study' which reported that a low-intensity diet and exercise intervention showed no significant difference by treatment group (education, education plus lottery incentive and control) at 1-year regarding dietary intake or physical activity. The RCT to prevent excessive weight gain during pregnancy in low-income women[348;362] reported a lack of significant effect of the intervention on changes in intake of high-fat foods and changes in exercise level from recruitment (prior to 20 weeks' gestation) to 8 weeks' post pregnancy.

13.4.2.2 Children

The GEMS pilots included low-income groups and suggest that intervention may have positive effects. The parent and child intervention groups combined significantly reduced intake of sweetened drinks compared with non-active control in the Memphis GEMS study (Beech 2003, Chen 1998.[340;362] The GEMS Minnesota pilot[137;362] and the study by Stolley[343] both showed significant reduction in per cent energy from fat in the intervention girls. However, in a relatively old study, the children of a family diet and exercise intervention[339;362] actually decreased physical activity levels compared with the control children.

Among Mexican American children from economically disadvantaged households who received a diet and exercise intervention to prevent diabetes, dietary fat intake did not differ between groups ($p = 0.52$) but physical fitness score was

significantly improved in intervention compared with control children after adjusting for age and pre-intervention BMI ($p < 0.003$).[153;154;362]

In the study of children with cerebral palsy, the physical activity ratio did not differ between the intervention group and control group but in both groups it significantly increased from baseline.

13.4.2.3 Findings from previous reviews

The findings of the community 1 review suggest that interventions to increase fruit and vegetables in the UK can be effective among lower-income groups. Five of the 10 included studies in the review of 2–5-year-olds and families included children from lower-income households. The majority of these studies were found to be effective, although subgroup analysis was rarely presented.

13.4.2.4 Corroborative evidence

Evidence of corroboration was limited. The health practitioner intervention to reduce obesity in adults with learning difficulties was conducted in Manchester, UK, and so is directly relevant to this population in the UK (Chapman 2005)[285]. An additional two questionnaires[362;370;380] and two reviews[95;371] were identified of healthy eating in low-income populations in the UK and a further two surveys from the USA. The findings are presented in section 13.5.3. No corroborative evidence was identified regarding physical activity and low-income populations.

13.4.3 Vulnerable life stages

13.4.3.1 Menopause

The systematic review found significant improvements in calorie and fat intake and moderate physical activity level;[226] postmenopausal women in the intervention group were consistently more physically active and reported eating fewer calories and less fat than controls.

In the RCT, calorie intake was significantly reduced in the intervention group compared with the control group at 54 months ($p < 0.01$). The intervention group

reported eating significantly less dietary fat and cholesterol than the controls. There was a significant increase in the amount of energy expended through physical exercise (walking) in the intervention group compared with the control at 54 months ($p < 0.001$) but not sport or recreational activity (kilocalories).

13.4.3.2 Pregnancy

Polley and coworkers[348] reported a lack of significant effect of the intervention on changes in intake of high-fat foods, and changes in exercise level from recruitment (prior to 20 weeks' gestation) to 8 week' post pregnancy were not related to treatment condition or BMI. One UK-based CCT[381] identified for corroborative evidence, found that women who received information packs from hospital staff on nutrition at time of booking and at 26 weeks' gestation had significantly higher knowledge about nutrition although no significant differences were noted on attitude variables or nutrient intake (fat, energy).

13.4.3.3 Smoking

None of the studies identified reported diet or physical activity outcomes.

13.4.3.4 Previous reviews

No relevant data were identified from the workplace, 2–5 year olds and families or schools' review. Limited data on middle-aged/menopausal women were identified in the community 1 review. Pereira and coworkers[242] reported no weight differences at 10-year follow-up of US postmenopausal women encouraged to walk as part of the original trial but the women did continue to walk significantly more than the control group. The findings of the review were supported by two more recent RCTs among middle-aged women.[233;255]

13.5 Sub questions

13.5.1 Variation by gender, age, ethnicity, religious practices or social group

No evidence was identified for vulnerable life stages. For BMEGs, one study carried out in African American churches reported that the largest increases in

fruit and vegetable intake were observed among older adults, those with education beyond high school, and those who were widowed or divorced and/or attended church frequently. The least improvement occurred among younger adults and/or those who were single.[361] The community 2 review found that cost and availability are fundamental considerations for future interventions. Younger people in particular may be concerned about the cost of food and view cost as a barrier to healthier eating.

13.5.2 Influence of previous weight loss

It was not possible to answer this question from the evidence identified.

13.5.3 Source and mode of delivery

The community 1 and community 2 reviews highlighted that tailoring advice is key to the effectiveness of interventions and that this will obviously impact on issues related to gender, age, ethnicity, religious practices or social group. Corroborative evidence identified for the broader community review highlighted the importance of interventions addressing fundamental issues such as cost and availability and pre-existing concerns such as the perceived poorer taste of healthier foods and the potential risks of walking and cycling. These factors may be barriers to change.

In addition to the data identified in the community reviews, a survey among inner city GP practices found that food insecurity was negatively associated with household income[380]. Subjects who were food insecure were less likely to report eating fruit, vegetables or salad daily. Experiences of food insecurity may be common in households with incomes at or below the minimum wage in the UK. A survey of adults with low incomes living in housing association homes in the UK also found that access and affordability were only a small part of the ‘problem’ surrounding low fruit and vegetable consumption.[370]

A review of food and low-income initiatives in UK (Hastings 2003) found a ‘great deal of existing work to tackle food poverty by local sector health workers running

statutory initiatives focusing on individual behaviour change'.[95] However, only low numbers of projects are reporting actual changes in behaviour or attitudes. Structural factors are not being addressed. Consultation with the community is not being done. Other agencies as well as health sector need to get involved.

A review of healthy eating and low income in the UK, based on the work of the SUPER (European Food and Shopping Research Project) health promotion programme in Liverpool, found that local food initiatives such as 'cook and taste' are labour intensive and are unable to reach a sufficiently large proportion of those in need to be cost effective.[371] Research consistently demonstrates that low-income households find it difficult to adopt healthy eating guidance because of economic and circumstantial barriers, such as lack of income, access to shops, or inadequate storage and cooking facilities, and not because of lack of nutrition knowledge. A major strength, and possibly the most important outcome, of the project in Liverpool was the process of reorientation experienced by participating health professionals and organisations. Experience demonstrated, however, that community involvement or community participation was much more difficult to achieve in practice. Local people were involved in the data collection process but because they were excluded from planning what questions to ask, were provided with no real sense of ownership. It is essential that communities share responsibility for the rapid appraisal of and help to identify local needs in order to develop a sustainable programme of activities.

Interventions may need to address specific issues around adherence among BMEGs. One survey conducted at baseline and year 5 among women who were participating in the Women's Health Initiative showed that one of the factors associated with poorer adherence was being African American (compared with white).[382]

Similar to rest of UK, South Asians have reported low motivation and priority to being physically active and reported barriers are also similar to the general population – with lack of time, burden of domestic duties and family

responsibilities cited as main barriers to participation.[367] Barriers also reported in general population surveys included issues around consciousness about body size or shape, high costs, personal safety, transport, opening hours, childcare facilities. However, other barriers appear to be more culturally specific to this group. Those questioned by Rai and Finch[367] viewed activity as part of normal everyday life and the concept of paying for it as strange. Participants were also concerned about lack of privacy, dress codes, separate sex provision, actual or potential experiences of racism, all of which acted as barriers to exercise, including 'not fitting in'.[367] These concerns are reflected in views of South Asian women interviewed by Verma.[369] Although all South Asian who wanted to exercise reported barriers, it appeared that Pakistani and Bangladeshi women in particular experienced additional barriers to exercise related to culture and custom (expected approval of other members of community, including religious teachers, parents, siblings and friends). Religion powerfully reinforced the authority and behaviour patterns which appeared to reduce participation; racism acted as constraint.[369]

A 14-week diet and exercise intervention in Asian women in Manchester[383] showed that formal methods of recruiting had little impact; verbal recommendation of the group by link worker and participants was more effective; the intervention fulfilled social and weight loss functions and both functions were interrelated and affected weight; difficulty getting to venue and needs of family coming first were cited as reasons for none attendance; and women who said they would definitely re-attend were generally those with a higher BMI. Carroll and coworkers[365] found that South Asian Muslim women were very positive about exercise on prescription schemes (indeed demand for the service was greater than could be met) and women were willing to pay if they had to, but only if classes remained local. Many significant barriers were reported including access, cost, childcare, cultural codes of conduct, language, racism and religious discrimination.

In relation to vulnerable life stages, although weight concern is a serious obstacle to quitting smoking, particularly for women, it is not clear how best to address these concerns in the context of smoking cessation. Perkins and coworkers[384]) have proposed that a logical approach may be to assist weight concerned smoker in attitudes to weight in relation to health risks of continuing smoking. The author of this review is the author of the only RCT identified demonstrating that cognitive behaviour therapy for weight concerns significantly attenuated weight gain during smoking cessation. Adding brief exercise counselling to a UK-based smoking cessation programme did not increase smoking abstinence or reduce gains in weight or body fat significantly, although exercise levels were raised and there were some beneficial effects on psychological symptoms.[385]

13.5.4 Potential negative impact

No evidence was identified for BMEG or vulnerable groups. For vulnerable life stages, one smoking cessation study[350] reported significantly more headaches among participants in the diet group compared with the control group. One of the seven smoking cessation studies reported that the weight intervention group had increased risk of smoking compared with standard smoking cessation treatment.[352]

13.6 Limitations of the review

There were extremely limited UK-based data on evidence of effectiveness for all the groups considered in this review, although particularly for children in all groups, people with disabilities, and children and adults from BMEGs. For the latter, the evidence identified (predominantly on black/African Americans) may not be directly applicable to the target groups in the UK. This is compounded by the limited UK-based corroborative data.

In the included BMEG studies, average baseline BMI was higher compared with average BMI in Caucasian populations. For all groups considered, the studies commonly included predominantly women and the studies in children were of short duration.

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Section 4: Management of obesity 1

14 Management of obesity in non-clinical settings

The following is based on an evidence review produced by the Centre for Reviews and Dissemination, University of York. Detailed evidence tables and supporting information are in Appendix 12.

14.1 Evidence statements (Table 14.1)

Table 14.1 Evidence statements and grading

No.	Statement	Grade	Evidence
Weight outcomes			
1	In both children and adults, there is a paucity of good-quality evidence on the effectiveness of interventions in non-clinical settings	N/A	N/A
Adults			
2	There is limited evidence on the effectiveness of interventions based in non-clinical settings to manage obesity in adults (particularly men)	N/A	N/A
3	There is moderate evidence that a multi-component commercial group programme may be more effective than a standard self-help programme. It remains unclear whether the branded commercial group programme for which there is evidence of effectiveness (WeightWatchers) is more or less effective than other branded commercial programmes	1++	Two RCTs (one good quality 1++ [Heshka et al. 2003[1]] and one poorer quality 1– [Rippe et al. 1998[2]])
4	There is no strong evidence to support the use of meal replacement products over a standard low-calorie diet	N/A	Two studies (one CBA 2– [Rothacker 2000[3]] and one RCT 1– [Ahrens et al. 2003[4]])
5	There is limited evidence that interventions to manage obesity based in workplace settings can be effective, though weight loss may be small in the long term	1–	Body of evidence: six RCTs of which one 1+ (Pritchard et al. 2002[5]), five 1– (Dennis 1999,[6] Peterson et al. 1985,[7] Follick et al. 1984,[8] Leslie et

No.	Statement	Grade	Evidence
			al. 2002,[9] Muto and Yamauchi 2001[10]) and one CBA 2– (Furuki et al. 1999[11])
6	There is some evidence that computer/email/internet-based programmes accompanied by greater ongoing support – in person, by post or email – may be more effective than those without	1+	Body of evidence: six RCTs of which four 1+ (Tate et al. 2001,[12] Tate et al. 2003,[13] Agras et al. 1990,[14] Womble et al. 2004[15]), two grade 1– (Taylor et al.1991,[16] Jones and Burkett 2002[17]) and one CBA 2– (Dennison et al. 1996[18])
7	The effectiveness of commercial and computer-based weight loss programmes in men remains unclear	N/A	N/A
8	There is limited evidence that a diverse range of novel, multi-component community-based interventions may be effective in the management of obesity, including a peer-led programme and a group-based and individual-based weight loss programme in a religious-based setting, a home-based exercise programme (accompanied by regular group sessions) and programme providing information through interactive television	1+	Five studies: four RCTs of which two 1+ (Perri et al. 1997[19] and McNabb et al. 1997[20]), two 2– (Jason et al. 1991[21] and Kennedy et al. 2005[22] and one CBA 2– (Harvey-Berino 1998[23])
Children			
9	There is a paucity of evidence on the effectiveness of interventions to manage obesity in children based in non-clinical settings; the evidence that was identified was generally for children aged 8–12 years of age and at the extreme end of obesity	N/A	N/A
10	There is no UK-based evidence available on the effectiveness of interventions to manage obesity in children and young people in non-clinical settings	N/A	N/A

No.	Statement	Grade	Evidence
11	There is limited evidence that interventions provided by school staff can aid the management of obesity in children and young people, at least in the short term, but this may be less effective than a more intensive intervention delivered in a clinical setting	2–	Two CBAs 2– (Donnelly et al. 1996[24] and Nuutinen 1991[25])
12	There is insufficient evidence to compare the effectiveness of interventions with or without family involvement in non-clinical settings	N/A	With family involvement: four studies – two RCTs 1+ (Figueroa-Colon et al. 1996[26], Grey et al. 2004[27]), one RCT 1– (Lansky and Vance 1983[28]) and one CBA 2+ (Graf 2005[29]) Versus without family involvement: one RCT 1– (Carrel et al. 2005[30]) and two CBAs 2– (Donnelly et al.1996[24] and Nuutinen 1991[25])
13	There is some evidence that home-based interventions may be more effective when accompanied by behaviour modification material and ongoing support. However, the replicability of this intervention on a wider scale remains unclear	1+	Three RCTs of which two 1+ (White et al. 2002[31] and Williamson et al. 2005[32] and one 1– (Jiang et al. 2005[33])
14	No evidence was identified which considered the effectiveness of exercise referral programmes to manage overweight or obesity in children and young people	N/A	N/A
Diet and activity outcomes			
15	Among both children and adults, interventions in non-clinical settings that are shown to be effective in terms of weight management, are likely to demonstrate significant improvements in participants' dietary intakes (most commonly fat and calorie intake) or physical activity	1+	Body of evidence: *In adults*: 12 studies of which six RCTs 1+ (Pritchard et al. 1997,[5] Tate et al. 2001,[12] Tate et al. 2003,[13] Womble et al. 2004,[15] McNabb et al. 1997,[20] Perri et al. 1997[19]), three RCTs 1– (Jason et al.

No.	Statement	Grade	Evidence
	levels		1991,[21] Taylor et al. 1991,[16] Rippe et al. 1998[2]) and three CBAs 2– (Harvey-Berino 1998,[23] Furuki et al. 1999,[11] Dennison et al. 1996[18]) *In children*: two studies – one RCT 1+ (Grey et al. 2004[27] and one CBA 2– (Nuutinen 1991[25])
Other outcomes			
16	No negative outcomes were reported in the identified studies for children or adults	N/A	N/ A
Generalisability			
17	The majority of studies identified were undertaken in the USA but many of the principles may be generalisable to the UK	N/A	1 RCT 1– (Leslie et al. 2002[9])
18	It remains unclear whether the effectiveness of programmes in children or adults varies by age, gender, ethnicity or social status	N/A	N/A
19	It remains unclear whether the effectiveness of programmes varies by whether participants have previously attempted to lose or maintain their weight	N/A	N/A
20	The impact of participant joining fees and participant costs on the long-term effectiveness in 'real life' commercial programmes remains unclear	N/A	N/A
Implementation			
21	There is insufficient evidence to identify strategies in non-clinical settings that are associated with the long-term maintenance of weight and continuation of improved behaviours among overweight and obese adults and children	N/A	N/A

No.	Statement	Grade	Evidence
22	It remains unclear whether the source of delivery (both the main intervention and ongoing support) had an influence on effectiveness	N/A	N/A
23	There is insufficient evidence to assess the importance of the source of delivery (for example, health professional versus volunteer worker) on the effectiveness of programmes for children or adults	N/A	N/A
24	None of the identified studies considered inter-agency or inter-professional partnerships	N/A	N/A

CBA, controlled before-and-after study; N/A, not applicable; RCT, randomised controlled trial.

Associated evidence tables for review are in Appendix 12.

14.2 Methodology

Database searches were carried out in July 2005 for papers published from 1990 onwards (1995 onwards for systematic review level evidence). A final update search was completed on 1 December 2005 on a reduced number of databases. Interventions of interest included:

- commercial and practice-based slimming groups
- exercise referral (for example, walking groups, access to sports facilities; to explicitly consider interventions among children as well as those for adults)
- community- and setting-based (for example schools, workplace) programmes for overweight and obese adults and children
- weight management/weight loss camps for children
- programmes for self-help/management for example, internet-based programmes.

Studies of children (age 2 years and over) and adults classified as overweight or obese (as measured by body mass index [BMI], waist, etc.) were included. Studies which included participants with any pre-existing medical condition such as diabetes, hypertension and eating disorders were excluded. Where studies included overweight and normal weight participants, the study was included only if outcome data were reported separately for overweight/obese participants. All other inclusion and exclusion criteria for public health reviews were applied.

From an initial 13,432 hits, 454 papers were assessed in detail of which 36 papers (35 individual studies) met the critical appraisal criteria for inclusion in evidence tables.

14.3 Weight outcomes

14.3.1 Adults

Although 23 primary studies were identified (19 randomised controlled trials [RCTs] and 4 controlled before-and-after studies [CBAs]), the studies tended to be small and with methodological limitations, providing little information on intervention setting and evaluating a fairly restricted range of interventions. In most RCTs, the methods of randomisation, allocation to treatment group and blinding of outcome assessors were inadequate or not possible to assess due to poor reporting. Most interventions were multi-component using the internet or a more traditional mode of delivery such as face-to-face group sessions, following participants from 3 months to 4 years. The participants in these studies were mainly middle-aged, white women from the USA (only one UK study was identified). Socioeconomic data were seldom reported. Several of the studies offered incentives to attend follow-up assessment, therefore if the intervention was implemented in a real-life setting without incentives, dropout may increase.

14.3.1.1 Commercial weight loss programmes

One systematic review of US-based commercial weight loss programmes was identified.[34] The review included two relevant studies of the WeightWatchers programme (both funded by WeightWatchers International).[1,2] The RCTs

included mainly female participants and the mean baseline BMI was greater than 30 kg/m^2.

The findings suggest that the WeightWatchers programme was more effective than a self-help programme. The larger, better quality RCT [1] reported that WeightWatchers participants lost a mean of 4.6% (4.3 kg) of their initial weight after 1 year with a mean loss of 3.1% (2.9 kg) of initial weight at 2 years. The mean weight loss in the self-help comparison group was 0% at 2 years. Non-completers were included in this analysis. After 2 years, 35% of the WeightWatchers participants and 21% of the self-help group participants had lost more than 5% of their baseline weight. However, this particular analysis included only participants who completed the programme and is likely therefore to be an overestimate. Participants attended the WeightWatchers programme free of charge; therefore the level of dropout (25% for self-help and 29% for WeightWatchers) may be lower than would be expected in a real-life situation. The second RCT, which had methodological limitations, reported a mean weight loss of 7.5% (6.1 kg) in the WeightWatchers group compared with 1.6% (1.3 kg) in the usual care group at 12 weeks.[2] Only participants who completed the programme were included in the analyses therefore the extent of weight loss is likely to be an overestimate. Loss to follow-up was considerably less in the WeightWatchers group than the usual care group though a quarter of participants did not complete the former programme.

Two US-based studies (funded by Slim-Fast Foods),[3,4] both with methodological limitations, including predominantly women, evaluated meal replacement shakes. (One study, an RCT, carried out in a pharmacy, reported similar weight loss and reduction in waist circumference at 12 and 22 weeks when a diet using liquid meal replacement shakes (Slim-Fast) was compared with a reduced-calorie diet.[4] The pharmacist was the point of contact for a fortnightly 15-minute review, with diet plans reviewed by a dietitian. The mean weight loss was just under 5 kg in both groups at 12 weeks with a further small loss of less than 1 kg at 22 weeks. The CBA compared a liquid meal replacement shake diet with a no intervention

control.[3] There was a weekly weigh-in at the local village centre during the first 12 weeks and then twice a year weigh-in for what appears to be 5 years. The BMI decreased in the meal replacement group (1.8 kg/m^2 for women and 1.6 kg/m^2 for men) whereas there was a weight gain in the control group. Participants were provided with free meal replacement shakes in both these studies therefore adherence may be more difficult outside the research context. Only participants who completed the programme were included in the analysis, therefore the extent of weight loss is likely to be an overestimate.

14.3.1.2 Computer-based interventions

Seven studies, based in the USA, used a computer in a non-clinical setting, as part of a weight loss programme. Although the setting was non-clinical, in some of these studies the setting was not the focus of the research question. On balance, the findings suggest there is some evidence that the internet was an effective mode of delivery for weight loss interventions. Weak evidence suggests that the intensity of support provided over the internet was important: an education-focused website was more effective when delivered with ongoing support by a therapist via email.

In two RCTs, the effect of varying levels of support or intensity of one-to-one contact over the internet was assessed.[12,13] Both studies investigated a primarily education-based website with and without weekly support via email from a therapist, including personalised feedback on progress. In one study the intervention was implemented in a large hospital group where website access was via the hospital intranet. In the other, participants were required to have their own computer access. Both studies included non-completers in the analysis and were of reasonable quality. Participants were predominantly women, white and well educated.

In both studies, weight loss was observed at 6 months[12] and 1 year[13] although this was statistically significantly greater in the group that received weekly support via email. The six-month mean weight loss in the group receiving

additional support was 2.9 kg compared with 1.3 kg in the education website only group.[12] In this study 35% of participants receiving additional support and 18% of participants in the education website only group achieved a weight loss of at least 5% of baseline weight (it was unclear whether this analysis included all participants). The 1-year weight loss in the group receiving additional support was 4.4 kg compared with 2 kg in the education website only group (per cent loss not available).[13]

One small RCT compared computer-assisted therapy (CAT) with or without an initial 3.6–4.5 kg (8–10 lb) weight loss through a 1200 calorie diet.[16] At 12 weeks, the authors reported less weight loss in the CAT only group compared with the diet and CAT group. By 38 weeks the weight loss was 0.9 kg and 3.8 kg, respectively, and the difference between the groups was statistically significant. However, this is likely to be an overestimate as only participants who completed the programme were included in the analysis.

The remaining four studies compared an internet- or computer-based intervention with an alternative mode of programme delivery.

Two small RCTs among female participants found similar levels of weight loss using different modes of delivery.[14,17] After 12 weeks there was no statistically significant difference in weight loss between a classroom-based, computer-based and self-help-manual-based programme. Although there was a statistically significant weight decrease over time for all the groups combined, the actual changes were very small.[17] A guided 1200 calorie weight loss programme provided through a hand-held computer (with regular exercise) led to a similar level of weight loss as a hand-held computer plus group sessions and behaviour therapy after 1 year. The mean weight loss was 0.3 kg, 1.9 kg and 1.0 kg, respectively.[14]

One internet-based intervention was found to be less effective than a self-help manual.[15] The small RCT compared a 1-year commercial internet-based programme with a self-help manual in women.[15] Participants in both groups also

had review meetings with a psychologist. After 1 year the internet group had lost less than 1 kg compared with a mean weight loss of 4 kg in the comparison group. Over a third of participants dropped out from both groups. Participants were given free 1-year membership of the commercial internet programme; therefore the level of dropout may be lower than would be expected in a real-life situation.

One small CBA among predominantly white male factory workers compared an 8-week computer-based and a group class (primarily education) programme.[18] However, three-quarters of the participants dropped out and so the weight loss data are not meaningful.

14.3.1.3 Work-based setting

Seven studies were identified that addressed weight control in a work-based setting. Only one was UK based and participants were predominantly male. The findings suggest that interventions in a work setting can be effective but the evidence was weak and the actual weight loss relatively small.

The UK-based RCT was conducted among men at a large petrochemical worksite in Scotland.[9] After 12 weeks an energy-deficit diet and a generalised low-calorie diet led to similar levels of weight loss (4.6 kg and 5.6 kg, respectively) whereas the control group gained 0.5 kg. At 24 weeks there was some weight re-gain in the two intervention groups, but weight was still lower than at baseline in both groups. Although all participants were included in the analysis at 12 weeks, only completers were included in the analysis of the later follow-up. In another men-only group in a small RCT there was greater weight loss with a diet and exercise intervention compared with no intervention at 12 months.[5] The mean BMI reduction was 8.2% in the group instructed to follow a personalised low-fat diet together with a weight loss manual and 4.5% in the group instructed to follow an aerobic exercise regimen in their leisure time compared to a 1% gain in the control group. Two further Japanese-based studies of mainly male participants reported a significantly greater reduction in BMI in the

intervention group. However, the mean change in BMI was fairly small: in the RCT, the mean BMI decreased by 0.6 kg/m^2 at 18 months in the intervention group,[10] and in CBA study, by 0.25 kg/m^2 at 4 years.[11] The intervention was directed at all staff or staff with cardiovascular heart disease risk factors, with outcome reported for an overweight subgroup. An intervention on a US navy ship, found similar weight loss in the intervention and no intervention groups.[6] None of these studies included non-completers in their statistical analysis, therefore any weight losses are likely to be overestimates.

One small RCT, carried out among mainly female participants in a US factory reported a similar level of weight loss at 8 months among participants of a 16-week professionally led weight loss programme and a volunteer-led programme.[7] In the former, participants lost a mean of 10.8 kg from a baseline of 82.9 kg; the latter lost 7.6 kg from a baseline of 81.6 kg. A structured weight loss programme was used with regular meetings and provision of workbooks. Volunteers were elected following the first two meetings which were led by health professionals. Dropout was greater in the professionally led group although all participants were included in the analysis. A further, very small RCT, including mainly women working in a US general hospital, found that using a financial incentive led to fewer participants dropping out of a programme involving 14, 30-minute behavioural weight loss sessions than no financial incentive.[8] However, even in the incentive group, 40% of participants did not complete the programme. In addition, although both groups lost weight following the intervention, there were no statistically significant differences between the groups in weight loss.

14.3.1.4 Other non-clinical settings

Five further studies, including predominantly women in a diverse range of non-clinical settings, were identified.

A small RCT of mainly white participants found that delivery of a 3-week weight loss intervention through a television programme and self-help book, with and without assistance in finding an appropriate self-help group, led to a self-reported

weight loss of 5.4 kg and 4.2 kg, respectively at 3 months.[21] Only completers were included in the analysis therefore the extent of weight loss is likely to be an overestimate.

One CBA reported similar weight loss with a 12-week behavioural therapy programme delivered through interactive television and face to face by a trained behavioural therapist.[23] The participants were predominantly white women and the mean baseline BMI was 34.5 kg/m^2 and 35.4 kg/m^2, respectively, for the two groups. The mean weight loss was almost 8 kg in both groups. However, this is likely to be an overestimate as only participants who completed the programme were included in the analysis.

One small RCT found that a home-based exercise programme led to significantly greater weight loss than a group clinic-based exercise programme after 15 months.[19] Both groups received similar exercise prescriptions of walking 30-minutes per day, 5 days a week with a target maximal heart rate of 60–70%. They also both received a behavioural intervention of 2 hours, weekly group sessions for 6 months followed by fortnightly sessions for 6 months. After the first 6 months both groups had similar weight loss but after 15 months the home-based group had lost more weight (11.7 kg) than the clinic-based group (7 kg). There were more dropouts from the group intervention, although non-completers were included in the analysis.

Two very small RCTs were based in African American churches. One was conducted in three urban churches with women who were educated beyond high school.[20] After 15 weeks, the BMI was reduced by 1.4 kg/m^2 in those who received the intervention of weekly 1.5-hour sessions led by trained lay facilitators compared with an increase in BMI in the no intervention control group. The other compared low-intensity group-based and individual-based weight loss programme over 6 months.[22] However, it was not possible to fully assess quality due to poor reporting of the methods of randomisation, allocation to treatment group and blinding of outcome assessors.

No controlled studies of exercise prescription were identified.

14.3.2 Children

Little evidence was available on interventions to manage overweight and obesity in children in a non-clinical setting. The majority of studies identified were conducted in schools. In particular, there was a paucity of evidence on management of overweight children as most of the studies were of very obese children and on management of young school-age children and children in their late teens. Ten studies (all non-UK based), including seven RCTs, involving pre-teen to early teen children were identified. The range of settings used was limited. The interventions were diverse, although generally multi-component, with methodological limitations, short duration (length of follow-up ranging from 6 months to 2 years) and small. No controlled studies were identified that addressed exercise referral in children.

14.3.2.1 School-based interventions with family involvement

Four studies considered school-based interventions with family involvement, of which two diverse interventions reported some evidence for effectiveness. In one, a protein-sparing modified fast diet followed by a hypocaloric diet, together with weekly multi-component sessions resulted in greater weight loss than in a no intervention control group.[26] After 6 months, BMI in the intervention group had decreased by 3.8 kg/m^2 from a baseline of 30.9 kg/m^2. Weight in the control group remained static. The intervention was intensive and involved a paediatrician, a psychologist, a nutritionist, a physical education (PE) instructor and a nurse. The intervention in the second study was delivered by a PE teacher and incorporated 12 weekly meetings of 45 minutes involving aerobic exercise, education and self-monitoring and four group meetings for parents.[28] Weight was recorded every 3 weeks and children received a lottery ticket (for prizes such as bowling) for each 0.23 kg lost. The mean percentage overweight (which took into account height and age) decreased by almost 6% in the intervention group compared with an increase of over 2% in the no intervention control group after 12 weeks.

Two of the interventions did not appear to be effective. One small RCT of 12-year-olds from mixed ethnic groups with a mean BMI above 35 kg/m^2 investigated a nutrition and physical activity programme with and without a culturally sensitive programme.[27] After 12 months the BMI in both groups remained fairly static and the culturally sensitive training did not lead to greater weight loss. None of the participants dropped out of the programme. Following a multi-component intervention involving 8-year-olds with a mean BMI above 21 kg/m^2, there was only marginally less gain in BMI compared with a usual care comparison at 9 months.[29]

14.3.2.2 School-based interventions without specified family involvement

Three diverse studies considered school-based interventions without family involvement.

One small CBA of children aged 8 and 11 years assessed a multi-component intervention incorporating nutrition education, modified school lunches and increased physical activity. The intervention was targeted at all the children in the specified age range, with outcomes reported for an overweight subgroup.[24] The control schools continued with usual lunches and PE programmes. After 2 years, the intervention was not found to be more effective than the control at reducing BMI.

In a small CBA of obese children, incorporating regular visits with the school nurse was less effective than a more intensive intervention in a clinical setting, although there was weight loss in both groups. The relative weight loss was 16% for the latter and 7% for the former after 2 years.[25]

A small RCT, with methodological limitations, compared 9 months of lifestyle-focused PE classes (of no more than 14 children) with standard PE classes (of 35–40 students), among 12-year-olds in a US school.[30] Both groups had five, 45-minute classes every 2 weeks. The intervention emphasised lifestyle activities such as walking and cycling but not competitive games. Children did not change their clothes for the class to maximise the amount of exercise time and the

emphasis was on keeping moving rather than watching. The typical amount of movement time in the intervention group was 42 minutes compared with 25 minutes in the standard class. The mean BMI at baseline was 32 kg/m^2 and 30 kg/m^2, respectively. BMI remained fairly static over the 9 months in both groups (33 kg/m^2 and 30 kg/m^2 for the intervention and control groups, respectively). Although there was no statistically significant difference between groups in change in BMI, there was a greater decrease in body fat in the intervention group compared with the control group (4.1% and 1.9%, respectively) which was statistically significant.

14.3.2.3 Home setting

In one small RCT of African American 13-year-old girls who had a baseline BMI of above 35 kg/m^2 and at least one obese parent, participants were provided with a personal computer for the home and free internet access.[31] An educational website specifically for teenagers was compared with and without support involving behaviour modification material, regular contact with a case manager via email and access to a chat room. At 6 months the group receiving the more intensive intervention lost 0.24 kg/m^2 whereas the comparison group gained 0.71 kg/m^2. Non-completers were included in the analysis. The obese parents of the children receiving the more intensive intervention also had a greater reduction in BMI than the comparison group parents although there was no difference on other weight measures.

One small RCT, with methodological limitations, of 12–14-year-old African American girls compared interactive behaviour therapy plus nutrition education via the internet to education only.[32] Both groups also received four sessions of face-to-face therapy over a 12-week period. The baseline BMI was 35.3 kg/m^2 and 37.3 kg/m^2, respectively, with one obese parent also participating in the study. There was a statistically significant difference in weight loss between the groups: the intervention group had a small decrease in BMI (0.19 kg/m^2) compared with an increase in the control group of 0.65 kg/m^2. There was a similar finding for per cent body fat. Among the parents, the intervention group

lost more weight than the control group and this was statistically significant, though the extent of weight loss was very small (1.03 kg/m^2 and 0.06 kg/m^2, respectively). Participants had to be willing to pay US$300 towards the purchase of a computer, although US$700 was contributed from the researchers.

One small RCT, with methodological limitations, compared an intensive 2-year family-based behavioural intervention to a usual family/school life control group in China.[33] The children were 13-year-olds with a baseline BMI of 26 kg/m^2. The intervention involved targeting specific dietary and activity patterns for each child based on individualised assessments. A detailed diet plan was developed for each family and daily food intake for each of the children was recorded. Paediatricians visited the families on a monthly basis over the 2 years. After two years there was a similar increase in height in both groups. Mean weight in the intervention group remained fairly static (decrease of 0.3 kg) whereas it increased in the control group (5.5 kg) and this difference was statistically significant. The mean change in BMI was 2.6 kg/m^2 and 0.1 kg/m^2, respectively.

14.4 Dietary and activity outcomes

Although studies that only reported diet and physical activity outcomes were eligible for inclusion in this review, no additional studies were identified. Ten studies reported diet or physical outcomes (using mainly self-reported measures) in addition to weight outcomes. Where diet and activity outcomes were reported they did not contradict the findings from the weight outcomes.

14.4.1 Adults

14.4.1.1 Commercial weight loss programmes

Along with weight loss, one of the WeightWatchers studies reported exercise and diet outcomes.[2] In addition to the WeightWatchers group achieving greater weight loss than a usual care group, they also reported a greater level of physical activity and greater reduction in calorie intake at 12-week follow-up.

14.4.1.2 Interventions using computers

Five studies reported diet and activity outcomes in addition to weight loss.[12,13, 15, 16, 18] Although the group that received e-counselling in addition to a website intervention lost more weight, there was a statistically significant reduction in calorie intake at 1 year in both groups with no statistically significant change in energy expenditure in either group.[13] A six-month follow-up of the same intervention reported a statistically significant improvement in both groups for diet and physical activity outcomes,[12;15] but no between-group differences were found in self-reported eating restraint, disinhibition and hunger, following an internet and self-help manual weight loss intervention. Following a comparison of computer-assisted therapy with or without a diet using pre-packaged meals first, Taylor and coworkers[16] reported that the latter group exercised more than the former following the intervention, as well as having greater weight loss. Baseline levels of exercise were not reported for the two groups therefore it is unclear how meaningful these data are. Three-quarters of the participants dropped out of the fifth study.[18] Therefore, the diet outcomes are not meaningful.

14.4.1.3 Work-based setting

Two studies reported diet and physical activity outcomes in addition to weight loss.[5,11] In one there were no between-group differences on these measures. Perhaps unsurprisingly Pritchard and coworkers[5] found that the diet intervention group consumed fewer calories than an exercise group and a no intervention control group; the exercise group took more exercise than the other two groups.

14.4.1.4 Other non-clinical settings

Four studies reported diet and physical activity outcomes in addition to weight loss. In the church-based intervention, besides weight loss in the intervention group, there was a reduction in consumption of high fat food and an increase in positive eating behaviours. But there was no change in the amount of exercise compared with a no intervention control group.[20] Perri and coworkers[19] reported a greater amount of exercise in a home-based exercise intervention compared with a clinic-based exercise group as well as a greater reduction in consumption

of high-fat foods. Jason and coworkers[21] reported more frequent exercise and lower calorie consumption in the group that had greater weight loss following the intervention. As well as reporting that there was no difference in weight loss following an interactive television and face-to-face intervention, Harvey-Berino[23] reported no between-group differences in calorie and fat intake or calories expended through activity, though there were improvements in both groups on these measures following the intervention.

14.4.2 Children

No controlled studies were identified that addressed exercise referral in children. Two studies reported diet and physical outcomes in addition to weight measures. For one study that reported no improvement in weight outcomes, there was also no improvement in diet or physical activity outcomes.[27] In a study that reported greater weight loss with a more intensive intervention in a clinical setting than a school-based intervention, there was also greater improvement on dietary measures in the former.[25]

14.5 Maintenance of weight loss

No studies were identified that addressed weight maintenance in children. Among adults, some of the identified interventions with weight outcomes included strategies to maintain weight loss as part of a multi-component programme. However, there was insufficient evidence from these studies to identify strategies associated with maintenance of weight loss or continuation of improved behaviours. Only two RCTs were identified that compared the effectiveness of a multi-component weight maintenance programme accessed over the internet, with frequent in-person and minimal in-person support following a 6-month behavioural weight control programme.[35,36] (Although these are reported as entirely separate studies the later study might have included the participants reported in the earlier data as the study was conducted from 2000 to 2002.) Participants were predominantly college-educated women, who had their own internet access. Although the earlier study found that internet support was less

effective than the other two forms of support, the more recent, larger study found that participants in the internet maintenance group achieved similar weight loss compared with the two levels of in-person support.

Weight loss from baseline to the end of the maintenance period (18 months in total) was 4.7 kg for the internet support group compared with 3.9 kg and 4.2 kg for frequent and minimal in-person support, respectively.[36] Non completers were included in this analysis. The proportion of participants achieving at least a 5% weight loss was 62%, 46% and 49% for each of the groups, respectively. However, this particular analysis included only those participants who completed the programme. Therefore is likely to be an overestimate. The earlier study also reported the acceptability of treatment group assignment following randomisation. At 6 months a similar proportion of participants in the internet and frequent in-person support groups agreed or strongly agreed that they would prefer to be in the other group (35% and 36%, respectively). After 1 year 70% of the internet support participants said they would prefer to be in the frequent in-person support group whereas 40% of the latter group said they would prefer to be in the internet support group. However, in the absence of any further data, it is difficult to reach a firm conclusion about the meaning of this information.

14.6 Sub questions

14.6.1 Variation by gender, age, ethnicity, religious practices or social group

Among children, no studies were identified that compared outcomes for participants with different socio-demographic characteristics. No studies were identified targeting young children or older teenagers. Apart from two studies involving different ethnic groups, little information was available on the social or ethnic backgrounds of the children who participated in the studies.

Among adults, no data were identified which allowed consideration of effectiveness by age, social status or ethnicity. The majority of participants in studies were white and the mean age of participants in most of the studies was

between 40 and 50 years. One study of liquid meal replacement shakes reported outcomes separately for men and women and the weight loss trends were similar in both groups.[3] The commercial weight loss programmes and interventions based on the use of a computer were mainly assessed in women therefore it is not possible assess the effectiveness of these interventions in men. One study comparing WeightWatchers and a self-help programme reported that weight loss was similar in men and women. However, this appeared to be for both intervention groups combined and only a fifth of participants were men.[1]

14.6.2 Influence of previous weight loss

No evidence was identified.

14.6.3 Source and mode of delivery

There was considerable variation between interventions in children in terms of the intervention and the comparator which means it is not possible to assess the role of the source of delivery or mode of delivery.

There was also insufficient evidence available for adults to assess the importance of source of delivery. A volunteer-led weight loss programme was as effective as a professional-led programme in one study.[7] In another study there was evidence that successful weight management can be achieved with the community pharmacist as the point of contact for participants.[4] However, comparison was not made with other possible sources of delivery.

The importance of mode of delivery for interventions aimed at adults remains unclear. There was some evidence that the delivery medium was not important. Weight loss was similar across groups in two studies comparing an internet-based intervention with a face-to-face intervention.[14,17] However, in one of the studies the intensity and nature of the intervention varied as well as the medium. A maintenance study reported similar levels of weight loss at 18 months with internet support, intensive in-person support and minimal in-person support,[36] as well as a study comparing interactive television with standard

therapy.[23] A further study found that a self-help manual was more effective than a programme delivered across the internet.[15] However, there appeared to be differences between the two interventions other than the mode of delivery.

The data identified did not allow an assessment of what strategies are effective in engaging a broad range of organisations and encouraging partnerships. The studies did not address inter-agency or inter-professional partnerships.

14.6.4 Potential negative impact

It is unknown whether the interventions identified had any negative effects. While no evidence was identified that reported a negative impact of interventions aimed at children or adults the studies did not explicitly attempt to address the question of negative impact. One study in adults comparing a diet-only to an exercise intervention reported a greater lean mass loss in the diet group compared with the exercise group. However, this is likely to be related to using a single component intervention rather than the non-clinical setting per se.

14.7 Review limitations

In applying the criteria for setting, it became apparent that there was some overlap with the other reviews. Some studies had a comparator in a clinical setting or had a treatment phase in a clinical setting and a maintenance phase in a non-clinical setting. Although all the studies had at least one intervention conducted in a non-clinical setting, the actual setting was not the focus of the research in some studies. Although every attempt has been made to resolve the overlap in a consistent and systematic manner, there may still be some overlap.

The details provided about the participants included in some of the studies were often limited, so it is possible that some participants may have had other medical conditions.

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Section 5: Management of obesity 2

15

Sibutramine (Reductil): marketing authorisation suspended
On 21 January 2010, the MHRA announced the suspension of the marketing authorisation for the obesity drug sibutramine (Reductil). This follows a review by the European Medicines Agency which found that the cardiovascular risks of sibutramine outweigh its benefits. Emerging evidence suggests that there is an increased risk of non-fatal heart attacks and strokes with this medicine.

The MHRA advises that:

- Prescribers should not issue any new prescriptions for sibutramine (Reductil) and should review the treatment of patients taking the drug.
- Pharmacists should stop dispensing Reductil and should advise patients to make an appointment to see their doctor at the next convenient time.
- People who are currently taking Reductil should make a routine appointment with their doctor to discuss alternative measures to lose weight, including use of diet and exercise regimens. Patients may stop treatment before their appointment if they wish.

NICE clinical guideline 43 recommended sibutramine for the treatment of obesity in certain circumstances. These recommendations have now been withdrawn and healthcare professionals should follow the MHRA advice.

Management of obesity in clinical settings

15.1 General introduction to clinical management

This section presents the reviews used by the Guidance Development Group (GDG) to inform recommendations. The reviews were conducted to address the identified key clinical questions (see Appendix 2 for details).

We have presented the reviews for children and adults separately. Each review consists of a narrative summary (with a quantitative summary of appropriate information) with the associated evidence statements. Evidence tables and excluded studies can be found in Appendices 13 and 14 for children and Appendices 15 and 16 for adults, respectively.

15.2 Children

See also the adult reviews (section 15.3) for details of evidence on clinical settings, brief interventions, barriers and attitudes to management.

15.2.1 Factors to be considered in the clinical assessment of children and adolescents who are overweight or obese

[The aim of an initial assessment is to identify individuals who are at increased risk and who would benefit from intervention. This initial assessment should follow the classification of the degree of overweight or obesity as recommended by the GDG based on the earlier evidence reviews.

Therefore, the factors to be assessed at the initial presentation should be based on two evidence bases: one on the common comorbidities, and one on the effectiveness of weight loss in people with comorbidities and their expected health gain.

Further assessment(s) should aim to determine any determinants of energy imbalance.]

15.2.1.1 Evidence statements (Table 15.1)

Table 15.1 Evidence statements and grading

No.	Evidence statement	Grade
1	Initial assessment should aim to identify children and adolescents at highest risk who have the potential to gain health benefits with weight loss	4
2	In children who are overweight or obese, individuals at highest risk and with the greatest potential to gain health benefits include those with current significant weight-related co-morbidities, high risk of developing significant co-morbidities in the future, or children with a significant level of psychosocial distress	2++
3	In children, contributors for energy imbalance can be as follows: ▪ Underlying causes of obesity (genetic, single-gene defects and obesity syndromes, artificial infant feeding, early adiposity rebound, medications, parental weight issues, in timing or rate of growth, endocrine disease, central nervous system pathology, acute lymphatic leukaemia therapy) ▪ Co-morbidities ▪ Lifestyle, environmental, social and family (television viewing, energy expenditure, dietary fat, dietary carbohydrate and eating patterns, social factors and other behavioural or psychological factors)	1++, 2++, 3

15.2.1.2 Evidence review on factors to be assessed in children and adolescents

In September 2005, the National Guideline Clearinghouse synthesised the recommendations on the assessment and treatment of obesity and overweight in children from six published guidelines.[1]

The different scopes, target populations, intended users, and practices covered can be seen in Appendices 13 and 14 (evidence tables and excluded studies, respectively).

The authors of the synthesis identified areas of agreement between the included guidelines surrounding assessment. They concluded that:

> 'In addition to BMI, AAP, RNAO, SIGN, and Singapore MOH advise health care providers to evaluate other risk factors for obesity. Parental obesity is identified by these 4 groups as being a strong predictor that an obese child will become an obese adult. The evidence for other risk factors, with the exception of certain childhood syndromes (e.g., Praeder-Willi syndrome) or diseases (e.g., hypothyroidism) is less clear. In addition, these 4 groups cite physical inactivity and increased television viewing as probable risk factors for overweight and obesity. AHA, while not identifying specific risk factors to look for, notes that the identification of risk for overweight before adolescence is encouraged so that health habits can be improved at a stage of increased parental influence and control. USPSTF does not provide recommendations regarding other risk factors.[1]

The individual guideline recommendations on assessment are given in Table 15.2.

Table 15.2 Recommendations on assessment

Assessment and classification of overweight/obesity*	
AHA (2005) New	Primary care providers should assess diet and activity habits at annual well-child visits; this should be routinely integrated into the overall care plan
RNAO (2005)	Nurses assess physical growth and development of children and adolescents, which includes: ▪ discussing and documenting basic dietary patterns (level IV) ▪ discussing and documenting physical activity patterns including sedentary activity (for example, television and computer time) (level IV) ▪ identifying individual and family risk factors for childhood obesity ▪ monitoring changes in BMI, dietary and physical activity patterns over time and noting important variations (level IV)
Assessment of other risk factors	
AAP (2003)	▪ Genetic, environmental, or combinations of risk factors predisposing children to obesity can and should be identified ▪ Identify and track patients at risk by virtue of family history,

* Recommendations on classification deleted as not relevant to this review.

	birth weight, or socioeconomic, ethnic, cultural, or environmental factors It has long been recognised that obesity 'runs in families' – high birth weight, maternal diabetes and obesity in family members all are factors – but there are likely to be multiple genes and a strong interaction between genetics and environment that influence the degree of adiposity. For young children, if one parent is obese, the odds ratio is approximately 3 for obesity in adulthood, but if both parents are obese, the odds ratio increases to more than 10. Before 3 years of age, parental obesity is a stronger predictor of obesity in adulthood than the child's weight status
AHA (2005) New	Identification of risk for overweight before adolescence is encouraged so that health habits can be improved at a stage of increased parental influence and control
RNAO (2005)	▪ Identify individual and family risk factors for childhood obesity (level IV) The nurse's assessment should include questions and observations related to individual or familial obesity risk factors. Studies have shown that children who have a genetic propensity for weight gain are more likely to become obese if they grow up in an environment that promotes overeating and inactivity. Numerous studies confirm that when parents are obese, the risk of persistent obesity in their children increases threefold. Monogenic (single gene) causes of obesity are being described with increasing frequency; this familial link to obesity, however, continues to represent only a minority of children with obesity. From a prevention perspective, it is more important to note that lifestyle patterns relating to nutrition and physical activity develop within the context of the family. Dietary energy and fat intake and physical activity profiles in children closely reflect those of their parents. Physical activity in pre-school children can be related to parental BMI. Reduced physical activity and increased sedentary behaviours in childhood are associated with higher levels of overweight and obesity Rates of overweight and obesity also vary by family income. The importance of a number of additional risk factors including gestational diabetes and maternal smoking during pregnancy, reduced fetal growth, and bottle-feeding during infancy on the development of overweight in childhood remains to be fully elucidated
SIGN (2003)	▪ Parental obesity should be recognised as a risk factor for childhood obesity to persist into adulthood (recommendation grade: C)

	In the UK, the prevalence of obesity increases with age through childhood and adolescence, and there is no evidence of any marked difference in prevalence between boys and girls. Limited survey data suggest that the prevalence of obesity rises with increasing socioeconomic deprivation. No study has appropriately examined specific environmental factors, such as low habitual physical activity and inappropriately high habitual energy intake, which are believed to have causal roles in the current epidemic of childhood obesity
Singapore MOH (2004)	Overweight in a child under 3 years of age does not predict future obesity, unless at least one parent is also obese. After 3 years, the likelihood that obesity persists increases with advancing age of the child, and is higher in children with severe obesity in all age groups. The presence of obesity in at least one parent increases the risk of persistence in children at every age In clinical evaluation of patients, practitioners should consider and exclude predisposing factors for, and secondary causes of, obesity (good practice point)
USPSTF (2005) New	No recommendations offered

AAP, American Academy of Pediatrics; AHA, American Heart Association; BMI, body mass index; MOH, Ministry of Health; RNAO, Registered Nurses Association of Ontario; SIGN, Scottish Intercollegiate Guidelines Network; USPSTF, United States Preventive Services Task Force.

Based on evidence for the common comorbidities, the National Health and Medical Research Council (Australia) (NHMRC)[2] recommended that an initial assessment in a child should include measurement of the waist circumference (although no cut-offs are defined) and blood pressure. However, the guideline stressed that these tests need to be performed and results interpreted in the context of greater degree of obesity, increasing age, history of comorbidities and a family history of metabolic disease related to obesity.

These and other assessments should be made as follows:

- **Waist circumference:** Waist circumference appears to be associated with cardiovascular risk profile. However, cut-points for children and adolescents have not yet been established.
- **Blood pressure:** Use an appropriate size cuff. The child may be hypertensive if systolic or diastolic blood pressure is greater than or equal to the 95th percentile for age, sex and height. The child is normotensive if blood pressure is below the 90th percentile.
- **Psychosocial distress:** Clinicians should determine whether the child is being teased and bullied about their weight. If distress and low self-esteem cannot be managed by simple interventions, consider referral for expert counselling.
- **Fasting lipid profile:** Should be considered in obese children and adolescents, particularly those who have a family history of cardiovascular risk factors.
- **Fasting insulin and glucose:** Should be considered in obese children or adolescents, particularly those with a family history of type 2 diabetes, those with acanthosis nigricans, and those from certain ethnic backgrounds.
- **Liver function tests:** May be necessary in greater degrees of obesity, followed by hepatic ultrasound if transaminases are elevated.
- **Endocrinology tests:** Are not required unless there is other evidence of endocrine disease or short stature. Many overweight children and adolescents have cutaneous striae – do not investigate for Cushing's disease unless the patient is hypertensive with growth delay, and obesity is of recent onset.

15.2.2 Energy imbalance in children and adolescents

The NHMRC guidelines[2] identified a number of risk factors associated with the development of obesity in children. These were:

- **Genes**: There is a significant genetic predisposition to obesity. Parental obesity is a risk factor for future, if not present, obesity.

- **Television viewing**: The (mainly American) data on television viewing indicate a positive correlation between hours of viewing and overweight. The correlation is stronger in older children and adolescents and clearer at low or high (less than 2 or greater than 5) hours of viewing per day. Studies on other forms of small-screen entertainment are awaited.

- **Energy expenditure**: (i) Just as measurement of obesity in children is limited by the lack of immediate morbidity and mortality data, so is the ability to develop physical activity – management guidelines that are based on evidence related to positive health outcomes. (ii) Measuring physical activity in the clinical setting is difficult. Until cheap, small and robust motion monitors become available, it will depend largely on self-reporting. (iii) Reduced physical activity energy expenditure may play a role in weight gain over time.

- **Artificial infant feeding**: The majority of cohort studies support the finding that breastfeeding plays a small protective role against subsequent overweight.

- **Dietary fat, dietary carbohydrate and eating patterns**: (i) The evidence that dietary fat intake is a significant risk for obesity in children and adolescents is minimal. (ii) There is no clear evidence that any particular dietary composition influences overweight or obesity in children or adolescents. (iii) There is minimal evidence that carbohydrate intake influences body weight in children and adolescents. (iv) Parents influence food choices and other eating behaviours in their children. Disordered eating in a parent may be associated with excess body weight in the child.

- **Single-gene defects and obesity syndromes**: (i) There are a number of single-gene abnormalities in which obesity is the predominant feature. (iii)

There are a number of rare congenital syndromes that have obesity as a component and in which intellectual impairment is a common feature.

- **Ethnicity**: International and local data suggest that certain ethnic backgrounds entail a higher predisposition to obesity.
- **Early adiposity rebound**: (i) There is evidence from population studies that early adiposity rebound is associated with higher adolescent and adult body mass index (BMI). (ii) No matter how overweight is defined in the individual study, there is a significant association between higher birth weight and higher weights in childhood. (iii) Additional risk is conferred by an average, rather than tall, birth length and by parental overweight. (iv) Small-for-gestational-age babies who exhibit catch-up growth are at risk of obesity in childhood.
- **Single-child, single-parent, rural versus urban, and socio-economic status**: Evidence statements related specifically to Australia only.
- **Endocrine disease**: Clinical observation confirms an association between obesity and a number of endocrine disorders. Height–growth failure is the feature that should alert the clinician.
- **Central nervous system pathology**: Hypothalamic damage can result in a severe form of obesity in children and adolescents.
- **Acute lymphatic leukaemia therapy**: There is general agreement that, at the end of therapy for acute lymphatic leukaemia, there is a higher prevalence of obesity among participants than at the commencement of therapy and that obesity persists.
- **Medications**: The role of pharmacological agents in causing weight gain in children and adolescents has not been extensively studied.

Recommendations about what to assess included:

- weight history of the child and first-degree relatives
- medical history
- family, school, and social environments (Australia data only)
- ethnicity (Australia data only)
- eating and physical activity behaviour of child and parents.

A recent cohort study[3] aimed to identify risk factors in early life (up to 3 years of age) for obesity in children in the UK. Participants were 8234 children in a cohort aged 7 years and a sub-sample of 909 children with data on additional early growth-related risk factors. Data from 5493 children were available for the multivariate analysis. Risk factors in entire cohort were as follows: intrauterine and perinatal factors, infant feeding and weaning practice, family characteristics and demographics, lifestyle in early childhood, sedentary behaviour, and dietary patterns. From these, birth weight, parental obesity, sleep duration, and television viewing remained independently connected with the risk of obesity in the final model. Also, a further four factors were significant in the children in focus subsample: size in early life, weight gain in infancy, catch-up growth, and early adiposity or BMI rebound.[3]

15.2.3 Lifestyle interventions in weight management and other outcomes in children and adolescents

15.2.3.1 Evidence statements (Table 15.3)

Table 15.3 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss		
1	The main requirement of a dietary approach to weight control is a reduction in total energy intake, with caloric expenditure exceeding caloric intake Energy balance is critical to weight loss. Energy expenditure must	GPP

No.	Evidence statement	Grade
	exceed energy intake	
2	In specialist weight management programmes, physical activity and diet combined are more effective in weight management in children aged 4–16 years, than diet alone	1++
3	There is no evidence on the effectiveness of physical activity alone in the treatment of childhood obesity in a clinical setting	
4	There is no clear evidence on which dietary intervention is the most effective in weight reduction and management in children and adolescents	
5	Any recommended diet should be consistent with other healthy eating advice Strict diets are not appropriate for children and adolescents except in rare occasions where combined with specialist supervision and intensive follow-up	GPP
6	As part of a specialist weight management programme in the USA, targeting sedentary behaviour[†] was shown to be as effective as promoting physical activity in managing weight in obese children aged 8–12 years.	1+
7	As part of a specialist weight management programme in the USA, lifestyle[‡] exercise was shown to be more effective than aerobic and calisthenics exercise in maintaining weight loss in obese children aged 8–12 years.	1+
8	In specialist weight management programmes, behavioural treatment combined with physical activity and/or diet is effective in the treatment of obese children and adolescents aged 3–18 years	1++
9	In specialist weight management programmes behavioural treatment can be more effective if parents, rather than children (aged 6 to 16 years), are given the main responsibility for behaviour change.	1++
10	There is no evidence on which components of behavioural treatment are the most effective for childhood and adolescent obesity	
Outcomes other than weight loss (from trials that reported weight loss)		

[†] Watching television, playing computer games, imaginative play, talking on the phone, and playing board games.

[‡] Lifestyle exercise relates to integrating exercise into the person's lifestyle without the focus on exercise intensity. It can be walking or cycling to school, walking up and down stairs or walking at lunch.

No.	Evidence statement	Grade
11	As part of specialist weight management programmes, physical activity can improve levels of fitness in obese children aged 8–12 years	1+
12	There is conflicting evidence on whether weight management programmes improve HDL and LDL cholesterol, and triglyceride levels in obese children	1++
13	There is conflicting evidence on whether weight management programmes improve diastolic and systolic blood pressure in obese children	1–
14	Specialist weight management programmes including diet and physical activity can improve the eating behaviour of 8–12-year-old obese children	1++
15	In specialist weight management programmes, behavioural treatment can have a positive effect on dietary quality	1++
16	In a specialist weight management programme targeting black adolescent girls aged 12-16 years, behavioural treatment improved self-esteem and feelings of depression	1+
17	In specialist weight management programmes, behavioural treatment can improve self-control in regard to weight-related behaviours in children aged 5–13 years	1+
18	In specialist weight control programmes, decrease in weight loss was associated with a decrease in consumption of 'red foods' in obese children aged 6–12 years	1+
19	Inpatient weight management programmes, with cognitive behaviour therapy can improve quality of life over time in obese children and adolescents aged 9–19 years	1+
Harms (from trials that reported weight loss)		
20	Both a protein-sparing modified diet and a hypocaloric balanced diet delivered in a school and outpatient programme setting can produce mild to moderate side effects such as: fatigue, weakness, muscle cramps, bad breath, headaches and abdominal pain in obese children aged 7–16 years	2+

GPP, good practice point ; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

15.2.3.2 Evidence review on lifestyle interventions

There is scarce evidence on which are the required components or treatment phases for childhood obesity. However, throughout the literature it appears that a

multidisciplinary approach is most commonly advocated. Programmes normally include one or several of the following components:

- nutritional and physical activity advice
- behavioural treatment components
- decreasing sedentary activities, and increasing lifestyle activities
- social and/or psychological support.

This review is partially based on the Cochrane review published in 2003.[4] The aim of the Cochrane review was to systematically review the effects of a range of lifestyle interventions designed to treat obesity in childhood. The Cochrane review included interventions such as: diet, physical activity, and/or behaviour therapy with or without the participation of family members.

This section reviews evidence on the assessment of the effectiveness of lifestyle interventions such as dietary change, physical activity, behaviour therapy, or some combination of these components.

The inclusion criteria for this evidence review initially followed the steps of the Cochrane review, although in light of the scarcity of randomised evidence in regard to the treatment of obesity in adolescents and children, a revised inclusion criteria was defined which encompasses the following designs of studies.

Types of study

- Randomized randomised controlled trials (RCTs)
- Controlled clinical trials
- Controlled before-and-after studies

Only studies with a minimum duration of 6 months or above (including follow-up) and published after 1985 were included, and also RCTs with a primary aim other

than the treatment of childhood obesity. Studies based in a setting other than clinical were not included in this review.

Update searches have been undertaken, however no studies were included as none added further details or contradicted any of the recommendations.

Types of participant

- Participants aged under 18 years at the start of the study, and exceptionally studies where the age cut-off was above 18 years and where the majority of the participants were below 18 years or presented age stratification.

Types of outcome

- Primary outcomes to be measured (not self-reported) estimates of overweight in per cent, BMI, weight in kilograms, per cent weight loss, percentage of ideal body weight, BMI z-score and others.

- Secondary outcomes to be behaviour change, participants' views, measures of self-esteem, health status, well-being and quality of life.

Finally several other studies were retrieved by cross-referencing with the review of systematic reviews,[5] the Australian Clinical Practice Guidelines for the Management of Overweight and Obesity in Children and Adolescents (NHMRC),[2] The Scottish Intercollegiate Guidelines Network (SIGN),[6] and other reviews.[7–17]

We considered the following as a working definition of what is behavioural treatment[§] when reviewing and assessing the interventions described in the published papers.

- Behavioural treatment draws on the principles of learning theory (stimulus–behaviour contingencies or behaviour–reward contingencies)

[§] Conceptual input from Professor Jane Wardle.

- Assessment consists of identifying and specifying problem behaviours and the circumstances in which they are elicited (both antecedents and consequences).
- Treatment starts with setting specific, measurable and modest goals that are continually revised as progress is achieved.
- Target behaviours are monitored – usually by the child and/or parent – to obtain a record of behaviour change.
- Behaviour change processes include stimulus control, graded exposure, extinction and reward.
- The perspective is educational: teaching behaviour change skills to the client. The term problem-solving skills may be used, but this does not necessarily mean that the treatment contains the other elements of conventional behavioural treatment.
- The term cognitive (as in 'cognitive behaviour' or CBT) may imply the inclusion of strategies designed to modify cognitions (thoughts) which can be identified as important stimuli for behaviour.

A treatment is behavioural if the published paper:

- uses the terms behavioural treatment, cognitive behavioural treatment, behaviour therapy or CBT
- mentions learning theory
- refers to the use of the common components of behavioural treatment (self-monitoring, goal-setting, stimulus control).

Terms that do not, in themselves, denote behavioural treatment are:

- motivational interviewing

- counselling
- learning
- psychological
- psychotherapy
- problem solving
- cognitive.

Settings

From 42 studies that were included in this review the majority consisted of specialist outpatient weight reduction programmes in university obesity research clinics in the USA.[18–23,25,27–31,38,40,43–47,51,53,59–61] The other studies were as following:

- outpatient research clinic in Hong Kong[33]
- inpatient child obesity treatment programme in a medical centre in France[35]
- outpatient paediatric clinic at the University of Leuven (Belgium) [34]
- outpatient child obesity treatment programme at Tel Aviv University[24]
- outpatient child obesity research clinic at the University of Graz (Austria) [32]
- outpatient service at a paediatric hospital in Cuba[36]
- family paediatrician office (Primary Care) in Italy[37]
- referral from school after screening in Sweden[26]
- university outpatient research clinic in Australia[39]
- US outpatient paediatric primary care clinic[41]

- university outpatient research clinic in Isreal[49]
- appears to be a research clinic in Australia[54]
- inpatient rehabilitation hospital in Germany[55]
- outpatient and inpatient research programmes in Belgium.[56–58]

Dropout rates

Overall, the retrieved studies are of poor methodological quality, and the high dropout rates have an even greater impact on the robustness of the evidence for the treatment of obesity in obese/overweight adolescents and children, as seen in Table 15.4.

Table 15.4 Dropout rates in studies on treatment of obesity

Epstein et al. 1995[19]	10%
Epstein et al. 1985[21]	17%
Epstein et al. 2000[20]	15%
Epstein et al. 1985[40]	5.%
Schwingshandl et al. 1999[32]	33%
Woo et al. 2004[33]	Unclear
Rolland-Cachera et al. 2004[35]	40%
Reybrouck et al. 1990[34]	48%
Amador et al. 1990[36]	17%
Nova et al. 2001[37]	30%
Spieth et al. 2000[38]	56%
Figueroa-Colon et al.1993[22]	No dropouts
Epstein et al. 1984 and 1989[23]	20%
Eliakim et al. 2002[24]	13%
Sothern et al. 2000[25]	21% for treatment group 65% for controls
Epstein et al. 2004[59]	17%
Epstein et al. 1994[60]	11%

Epstein et al. 1987[61]	Unclear
Flodmark et al. 1993[26]	21% conventional treatment group 37% for the family therapy group No details for control group.
Israel et al. 1990[28]	Helper group 14% Weight loss group 8%
Epstein et al. 1986[29] and 1987[30]	20 %
Mellin et al. 1987[27]	16%
Graves et al. 1988[53]	23%
Epstein et al. 2000[31]	7.5%
Epstein et al.1985[18]	15%
Senediak and Spence 1985[39]	31%
Golan and Crow1998[48] and Golan et al. 2004[49]	17%
Israel et al.1985[45]	39%
Wadden et al. 1990[43]	22% in paper, although equals 34% through calculation
Israel et al.1994[44]	41%
Epstein et al. 1981[47] and 1987[46]	Unclear
Wrotniak et al. 2004[51]	Not applicable
Duffy and Spence 1993[54]	37%
Warschburger et al. 2001[55]	No details given
Braet et al.1997[56] and Braet and Van Winckel 2000[57]	20%
Braet et al. 2003[58]	Seven children left the programme during the study. At 6 months, data for 3 children could not be collected, and at 14 months one additional child could not be traced

Guidelines summary

In September 2005, the National Guideline Clearinghouse synthesised the recommendations on the assessment and treatment of obesity and overweight in children from six published guidelines (Table 15.5).

Table 15.5 Summary of recommendations on the assessment and treatment of obesity in children

Management of overweight and obesity	
AAP (2003)	No recommendations offered.
AHA (2005)	The principal strategies for the treatment of overweight in children are similar to those for adults (dietary modification and increased physical activity), with treatment goals based on age, severity of obesity and the results of risk factor assessment Five guiding principles are important for the treatment of overweight. These guiding principles can be summarised as follows: 1. Establish individual treatment goals and approaches based on the child's age, degree of overweight, and presence of comorbidities. 2. Involve the family or major caregivers in the treatment 3. Provide assessment and monitoring frequently 4. Consider behavioural, psychological and social correlates of weight gain in the treatment plan 5. Provide recommendations for dietary changes and increases in physical activity that can be implemented within the family environment and that foster optimal health, growth and development. Treatment of overweight should rarely be instituted before 2 years of age because of the rapid growth and development that occurs during these early years and lower correlation with overweight in later years. Family involvement is critical in the treatment of childhood overweight. If treatment is initiated when a family is not ready to support the programme, then success is unlikely. The treatment planned should also take into consideration long-term management with the continued assessment of the child for adequate growth and development because overweight is a long-term problem *Dietary management*

	Age-specific dietary modification is the cornerstone of treatment. The major goals in dietary management are to provide appropriate calorie intake, provide optimum nutrition for the maintenance of health and normal growth, and to help the child develop and sustain healthful eating habits Estimated energy requirements vary throughout childhood and reflect large increments with a range of 570–3152 kcal/day for boys and 520–2368 kcal for girls from age 3 months to 16 years. In addition, caloric needs may vary widely even for children of the same age because of normal differences in size. Thus, individualising the calorie intake recommendation and monitoring weight change are essential. Healthcare professionals must help parents or caregivers recognise and prevent overeating Because it is difficult for parents to judge calorie intake and energy expenditure on a regular basis, it is necessary to help parents guide the diet and physical activity patterns of their children. Counselling and recommendations must be made and socioeconomic status. Involving children in meal planning, shopping, gardening, and preparation of food has been promoted, along with including all caregivers (including grandparents) in helping the child to adhere to recommended consumption patterns and healthier food choices *Physical activity* Regular physical activity is critical for the prevention of abnormal weight gain and weight maintenance. The current recommendation for the amount of physical activity is 30– 60 minutes of daily regular physical activity. 'Working up a sweat' during the activity suggests adequate effort expended. These recommendations apply to children of normal weight as well as to children who are overweight Recommended activities must be enjoyable and congruent with the child's and family's lifestyle and be rewarding independent of the health benefit A complementary approach is to restrict sedentary free-time activities to < 2 hours/day
RNAO (2005)	No recommendations offered.
SIGN (2003)	*Weight maintenance* ▪ In most obese children (BMI > 98th centile) weight maintenance is an acceptable goal (recommendation grade: D) ▪ Weight maintenance and/or weight loss can only be achieved by sustained behavioural changes, for example:

	Healthier eating, increasing habitual physical activity (for example, brisk walking) to a minimum of 30 minutes per day. In healthy children, 60 minutes of moderate vigorous physical activity/day has been recommended Reducing physical inactivity (for example, watching television and playing computer games) to < 2 hours/day on average or the equivalent of 14 hours/week (recommendation grade: D) In overweight children (BMI > 91st centile) weight maintenance is an acceptable goal. Annual monitoring of BMI percentile may be appropriate to help reinforce weight maintenance and reduce the risk of children becoming obese
Singapore MOH (2004)	*Dietary changes* In children, less restrictive diets should be used, rather than diets consisting of drastically altered portions of various nutrients, very-low-calorie diets, or protein-sparing modified fast regimens (grade B, level III) *Physical activity* Appropriately increased physical activity is recommended. Younger children generally need age-appropriate creative activities with generous periods of free play. Weight-bearing activities are recommended for overweight children, non-weight bearing activities for obese children, and preferably supervised activities for severely obese children. In the older obese pre-adolescent and adolescent, decreased time on sedentary pursuits and increased activity such as a moderate intensity, progressive physical activity programme with increasing levels of obesity are recommended (Grade B, level III) *Behaviour modification* Behaviour treatment programmes have shown consistent success in weight loss (Grade B, level IIa) *Family involvement* Interventions for obesity in children should be directed at both the parents and the child, rather than the child alone. (Grade B, level III)

USPSTF (2005)	Insufficient evidence is available on the effectiveness of interventions for overweight children and adolescents that can be conducted in primary care settings or to which primary care clinicians can make referrals. No specific recommendations are given concerning management of overweight and obesity.

AAP, American Academy of Pediatrics; AHA, American Heart Association; BMI, body mass index; MOH, Ministry of Health; RNAO, Registered Nurses Association of Ontario; SIGN, Scottish Intercollegiate Guidelines Network; USPSTF, United States Preventive Services Task Force.

Interventions emphasising a combination of diet and/or physical activity and behavioural modification component

Weight loss

According to the results from one study by Epstein and coworkers based on a specialist weight management programme, it appears that lifestyle exercise[**] can be more effective than aerobic exercise and calisthenics in maintaining weight loss.[18] Children in the lifestyle group maintained their weight change, whereas children in the aerobic exercise group gained significant amounts of weight. After 24 months the lifestyle exercise group had significantly lower per cent overweight than the aerobic group. After 24 months the difference in per cent overweight between the lifestyle exercise group (large reduction in sedentary behaviours) and the calisthenics group was significant. At 24 months, the lifestyle group had maintained relative weight changes whereas the calisthenics group had returned to baseline levels.[18]

Two studies looked at the effect of decreasing sedentary behaviours on weight reduction. In one of these studies, Epstein and coworkers compared reinforcing decreased sedentary activity to reinforcing increased physical activity, and reinforcing decreased sedentary activity and increased physical activity.[19] The results suggest that the decreased sedentary behaviours group (reduced time spent on watching television, playing computer games, imaginative play, talking on the phone and playing board games) had a more significant reduction in

[**] Lifestyle exercise relates to integrating exercise into the person's/children's lifestyle without the focus on exercise intensity. It can be walking or cycling to school, walking up and down stairs or walking at lunch.

percentage overweight than the combined and exercise groups at year 1.[19] In another study, Epstein and coworkers compared decreased sedentary behaviours with increased physical activity; high against low doses of increased physical activity; and high against low doses of reducing sedentary behaviours.[20] Both the reduction of sedentary behaviours and increase of physical activity ranged from 10 to 20 hours per week. Results show a reduction in percentage overweight greater at 6 months than at 24 months for all groups, having a slightly higher reduction in both the high dose decreased sedentary behaviour and high dose increased physical activity groups. The results indeed suggest that targeting inactivity can be as useful as targeting increased physical activity. However, the results were only statistically significant for the first study.[19]

In one Epstein et al. study that included girls aged 8–12 years, percentage overweight in the diet plus exercise group showed greater decreases from baseline to 6 and 12 months, than in the diet-only group.[21] Nevertheless, results were only statistically significant for the 6 months follow-up. One clinical controlled trial[22] compared a protein-sparing modified fast diet (PSMF) (50% protein, 40% fat, 10% carbohydrate) with a hypocaloric balanced (HCB) (20% protein, 30% fat, and 50% carbohydrate) in children ranging from 7.5 to 16.9 years, associated with 20 minutes of daily aerobic activity and behavioural modification components. Results suggest that on a short-term basis (10 weeks), PSMF achieved a greater weight loss (statistically significant) than the HCB diet. At 6 and 14.5 months the results were not significant. However, percentage overweight significantly decreased in the PSMF compared with the HCB at 6 and 14.5 months.[22]

Epstein and coworkers[23] also assessed the effects of weight change on serum lipids in overweight children aged 8–12 years old. This study compared participants who were on diet only to participants with diet plus lifestyle change exercise programme and a control group, although the two treatment groups (which appear to have been given behavioural intervention as described in the evidence table) were then combined as no difference was found between them.

Up to 6 months, significant improvements in weight and percentage overweight were reported, although such changes were not maintained at 5 years follow-up.[23]

Eliakim and coworkers compared the effects of a weight management programme on body weight in obese children and adolescents aged 6 –16 years against a control group that was referred every 3 months to an outpatient nutritional consultation. Participants were prescribed a hypocaloric diet, a twice-weekly training programme (1 hour) and encouraged to reduce inactivity. The treatment group had a statistically significant decrease in body weight and BMI at 3 and 6 months compared with the controls.[24]

Sothern and coworkers[25] evaluated the safety, feasibility and efficacy of a resistance-training programme in obese children aged 7–12 years, with a PSMF diet, a moderate-intensity progressive exercise programme and behaviour modification. Total body weight significantly decreased at 10 weeks ($p < 0.0003$) and 1 year ($p < 0.0003$), and BMI also significantly decreased at 10 weeks ($p < 0.0001$) and 1 year ($p < 0.0001$). However, the difference in BMI between the 10 week and 1 year follow-up was not significant.[25]

Flodmark and coworkers[26] evaluated the effect of family therapy on 44 obese children aged 10–11, by studying two treatment groups: one whereby children were given family therapy, and a second group that was given conventional treatment (for further detail on each treatment see evidence table [Appendix 13]). The results suggest that the increase of BMI was higher in the control group and conventional treatment group ($p = 0.04$ and $p = 0.02$, respectively), than in the family therapy group.[26]

In the SHAPEDOWN programme study,[27] a range of cognitive, behavioural, affective, and interactional techniques was adapted to the needs of adolescents, encouraging adolescents to make continuous, sustainable, small modifications in diet, exercise, relationships, lifestyle, communications and attitudes. Relative weight decreased significantly during the first 3 months. For the subsequent 3

months, both groups decreased their relative weights in comparison with baseline values ($p < 0.001$), although by month 15 both groups' relative weight had diverged significantly ($p < 0.01$).[27]

Israel and coworkers[28] assessed two levels of parental involvement roles in the treatment of childhood obesity, and findings suggest that the group in which parents focused their efforts on the child (helper condition) was slightly superior than the group in which the parents also engaged in their own weight loss (weight loss condition), although there was no difference in the overall child's weight status at 1-year follow-up.

Parent weight as predictor of child weight

Epstein and co-workers also examined, in two studies belonging to the same trial,[29,30], the effect of parent weight on the weight loss of obese pre-adolescent children – beyond the effect of parent control versus child self-control. At year 1, children of non-obese parents were significantly lighter ($p < 0.01$) than baseline (% = –16.3) and lighter ($p < 0.01$) than children of obese parents (% = –7.7). Nevertheless these changes were not significant at 5 years. Thus, parent weight can be related to weight loss, but not weight maintenance in obese children.

Other outcomes

In one study, physical work capacity improved significantly, with increases of 33% from baseline to 6 months, and 55% from 6 to 24 months. Per cent time of being active also increased from baseline to 2 years, and targeted sedentary behaviours showed significant decrease from baseline at 6 and 24 months.[31] Epstein and coworkers[18] reported that only children in the aerobic exercise group maintained significant improvements in fitness at 1 years, whereas in the lifestyle exercise group, significant improvements were observed up to 6 months, although they returned to baseline levels of fitness at 1 year. No changes in fitness were observed for the calisthenics group. In another Epstein et al. study, child fitness improved significantly over time, with no differential changes by

group.[19] Physical fitness was also improved in the family therapy group after 1 year follow-up ($p = 0.047$).[26]

Epstein and coworkers[18] also reported that eating behaviour in children improved significantly across all groups. The relative weight changes between parents and children increased across time, with $p < 0.01$ from 0 to 6 months, $p < 0.01$ from 6 to 12 months and $p < 0.01$ from 12 to 36 months.[18]

In one study, biochemical factors remained within normal values in every child throughout the duration of the study. Changes in both blood pressure and serum cholesterol and triglyceride levels were not significant. However, when the two groups were combined the initial mean serum cholesterol values decreased significantly at 10 weeks.[22]

Epstein and coworkers reported that high-density lipoprotein (HDL)-cholesterol levels significantly increased over the 6 months of the study. Serum cholesterol ($p = 0.03$) and serum triglycerides levels decreased ($p = 0.01$) significantly over 6 months. Moreover, fitness also improved significantly.[23]

In one clinical controlled trial, endurance time was significantly greater in the treatment group.[24]

Participants of the SHAPEDOWN trial showed significant improvements in weight-related behaviour, depression, self-esteem and knowledge of weight management concepts at post treatment and at 12 months follow-up compared with the control group.[27]

Children with non-obese parents were more compliant towards calorie limit ($p = 0.01$), exercise goal ($p = 0.02$), and self-monitoring ($p = 0.01$) components of treatment and showed better results in eating behaviour ($p < 0.01$), than those with obese parents.[29,30]

Reported harms

Almost half the children in two dietary groups reported decreased appetite. Hunger, fatigue, weakness, and muscle cramps were more common in the hypocaloric group. Of the children in the PSMF group, 11% reported bad breath, and 19% of the children in the HCB group reported headaches and abdominal pain.[22]

Other factors

No additional analysis was conducted on the effect of age, ethnicity, socioeconomic status, previous treatment for obesity, motivation, gender, degree of overweight/obesity, current medical conditions and setting and/or healthcare professional.

Methodological and context notes

It must be noted that in the study by Figueroa-Colon,[22] both dietary groups were placed on a hypocaloric diet after 3 months. However, this study was very small. The authors contend that both PSMF and HCB diets should not be used without close medical supervision.[22]

Interventions emphasising diet and physical activity

Weight loss

The results from three studies[32–34] suggest that combining physical activity with dietary interventions is more effective than diet alone. In one case, Schwingshandl and coworkers[32] reported that after 12 weeks the children given physical training and dietary advice (mean age 11.0) had significantly greater mean change in fat-free mass than the children given dietary advice alone (mean age 12.2).

An additional primary study, which was published after the Cochrane review, reported that at 1 year, there were significant changes in body fat content from baseline in the combined group but not in the diet-only group. No change in

weight was reported, although BMI showed no significant changes in either group.[33]

Reybrouck and coworkers[34] compared a low-calorie diet (800–1000 kcal) combined with physical activity against diet only in children aged 3.9–16.4 years. The results also suggest that the mean decrease in overweight at 4 months was significantly greater for the children in the combined group than in those treated with diet only. At 8 months the mean decrease was much smaller and similar between the two groups.

Rolland-Cachera and coworkers[35] compared two different diets in an inpatient setting in France: one composed of 15% protein and 54% carbohydrates (prot –), and the other composed of 19% protein and 50% carbohydrate (prot +) in children aged 11–16 years, with no statistically significant differences being reported between the two groups. Both groups showed a mean BMI decrease of 12.5 (statistically significant). Results suggest that the prot+ content did not induce any additional effectiveness in the treatment of childhood obesity, although weight loss was achieved with the combination of a moderately energy-restricted diet and normal fat content and physical activity (7 hours per week of vigorous sports and 7 hours per week of outdoor activities).

Amador and coworkers[36] compared a non-restricted diet with a restricted one (up to 30% of energy requirements) combined with a physical activity programme. Results suggest that a non-restricted diet delivered a greater weight decrease (statistically significant) than the restricted diet at 6 and 12 months, although greater at 6 months. Nova and coworkers[37] assessed the effect of having a greater level of involvement of the family paediatrician and family in the long-term management of obese children aged 3–12 years. The results suggest that a greater involvement from the family paediatrician and commitment from the family have a significantly greater reduction in percentage overweight at 6 and 12 months.

Other outcomes

In one trial, a significant decrease was seen in total cholesterol in both groups with low-density lipoprotein (LDL)-cholesterol decreasing only in the exercise group. Fasting glucose ($p < 0.002$) reduced slightly in the exercise group only. Between the first and second year, in both groups the energy intake increased by 171 kcal, physical activity decreased and time watching television increased .[35]

Other factors

No additional analysis was conducted on the effect of age, ethnicity, socioeconomic status, previous treatment for obesity, motivation, gender, degree of overweight/obesity, current medical conditions and setting and/or healthcare professional.

Methodological and context notes

Again, there is lack of robust evidence on this specific topic, thus, the validity and generalisability of the conclusions remain unconfident. Nevertheless, it is worth noting that due to the other health benefits, a healthy diet and physical activity are recommended for everyone regardless of their weight. In this sense, a healthy diet and the increase of the levels of physical activity in children should be promoted, regardless of their effect on weight reduction.

Interventions emphasising diet only

Weight loss

Few studies have examined the effects of dietary interventions alone on weight reduction in obese children, and to date we have not found any randomised clinical trial that assesses such interventions per se. Nevertheless, one retrospective cohort study[38] has suggested that a low glycaemic index (GI) diet can be effective in the management of childhood obesity with a mean age of 10.6 years. The results indicate that the low-GI diet (with no restriction of total energy or specific macronutrient consumption) had a statistically significant BMI

reduction of –1.47 kg/m^2 whereas the standard reduced-fat diet had a reduction of –0.20 kg/m^2 (statistically significant).[38]

Other outcomes

No other outcomes have been reported.

Other factors

The statistically significant difference (–1.15 kg/m^2 for the low-GI diet vs –0.03 kg/m^2 for the reduced-fat diet) remained the same after adjusting for age, sex, ethnicity, length of follow-up, baseline BMI and behaviour therapy referral.[38] No further analysis was conducted on socioeconomic status, previous treatment for obesity, motivation, degree of overweight/obesity, current medical conditions and setting and/or healthcare professional.

Methodological and context notes

It must pointed out that the data concerning dietary interventions were based on a retrospective cohort study, with a significant dropout rate and possible biases.[38]

Interventions where the main focus was behavioural treatment in comparison with no treatment or usual care

Weight loss

Part of the evidence suggests that behaviour therapy can be more effective than conventional care, as three studies reported better results for behaviour therapy compared to usual care[††] and/or controls.[39–41] Senediak and Spence[39] examined the effects of rapid (eight sessions in 4 weeks) or gradual (eight sessions over 15 weeks) behaviour therapy versus a non-specific control condition and a wait-list control group in obese children aged 6–13 years. Percentage overweight in the rapid behaviour group significantly decreased from baseline to 6 months, and in the gradual behaviour group, percentage overweight significantly decreased from

[††] For further details, see evidence tables for each study.

baseline to 6 months. In the non-specific control group, mean percentage overweight significantly decreased from baseline to 6 months. No significant differences were found between the rapid and gradual groups over 6 months.[39] In one of Epstein and coworkers' trials, which assessed a family-based behaviour therapy on obese children aged 5–8 years, BMI significantly decreased from baseline to 12 months in the behaviour group compared with the control group (prescribed with the traffic light diet[‡‡] and physical activity six times per week, but no behavioural intervention).[40] Post-hoc analyses showed significant differences between groups for per cent overweight and BMI at 8 and 12 months. In Saelens and coworkers[41] evaluation of a behavioural weight control programme for obese children aged 12–16 years, the results suggest that the BMI for the experimental group (healthy habits [HH] – multi-component behavioural weight control intervention) decreased (not significant) from baseline to follow-up. For the usual care group (typical care [TC] – single session of physician weight counselling), BMI significantly increased after the 4-month treatment and 3-month follow-up.[41]

Other outcomes

In one study, results suggest that treated children had improved eating habits compared with the control group, and a main effect of improved self-control was observed over time in children, although no changes in parent self-control were reported.[40] According to Saelens and coworkers,[41] the HH adolescents reported higher rates of total and eating specific behavioural skills use than the TC adolescents ($p < 0.03$). Parents of the HH adolescents also reported that their

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[‡‡] The majority of the studies from Epstein and coworkers (which are extensively used as evidence throughout interventions to treat childhood obesity) are based on the traffic light diet. This is a calorie-based food-exchange system. Foods are divided into five groups (fruits and vegetables, grains, proteins, dairy and other foods) and the foods in each group are colour coded according to nutrient density: green for 'go', yellow for 'eat with care'; and red for 'stop'. Green foods are foods containing fewer than 20 calories per serving, yellow foods are the staple of the diet and provide most of the basic nutrition, and red foods are those foods high in fat and simple carbohydrates. All sweets and sugared beverages are classified as red foods. Families are then instructed to count calories and cannot have more than four red foods a week.

adolescents used more overall and specifically eating-related behavioural skills than did parents of TC adolescents ($p < 0.04$). HH adolescents continued to report higher overall and eating-related behaviour skills use at follow-up assessment compared with the TC adolescents ($p < 0.01$).

Other factors

No additional analysis was carried out on the effect of age, gender, ethnicity, socioeconomic status, previous treatment for obesity, degree of overweight/obesity, motivation, frequency or length of the intervention and current medical conditions.

Interventions comparing behavioural treatment at varying degrees of family involvement

Weight loss

Several pieces of research on obesity treatment in children and adolescents have assessed the influence of including family members in the therapy process.

There seems to be substantial evidence that behavioural treatment is more effective in children and adolescents aged 6–16 years if the parent(s) are given the main responsibility for the behaviour change.[42–47] Golan and Crow[48] published a 7-year follow-up of previous studies,[42,49] and results demonstrated that the mean reduction in per cent overweight was superior in children of the parent-only group compared with those in the children-only group ($p < 0.005$). These results suggest that involving parents in the therapy process can be also more effective on a long-term weight loss and maintenance basis in obese children, as also seen in the next study. A 10-year follow-up study published by Epstein and coworkers[50] with children aged 6–12 years aimed to compare three groups: child and parent target (group 1), child target (group 2), and non-specific target (group 3). At both 5 and 10 years, significant per cent overweight differences ($p < 0.05$) were shown between children in groups 1 and 3 with children in group 2 midway between the other groups.

Parent weight as predictor of child weight

One study which consisted of a secondary data analysis based on three RCTs[51] (already included in this review), aimed to assess whether parent-standardised BMI (z-BMI) change influences child z-BMI (in children aged 8–12 years). Results suggested that parent z-BMI change can be a predictor of obese child z-BMI change in family-based treatment. Children of the parents in the greatest z-BMI change quartile had greater reductions in z-BMI changes over time ($p = 0.01$) than children of parents in the other three groups, who had smaller reductions or gains in z-BMI.[51] Nevertheless, it seems that the results are also connected with the participation of the parents in the treatment process, and not solely due to their weight loss.

Other outcomes

Wadden and coworkers[43] reported that total cholesterol concentration and HDL-cholesterol decreased significantly during treatment ($p< 0.01$ and $p < 0.06$, respectively). Furthermore, scores on the Pier–Harris scale[§§] increased significantly ($p < 0.05$) during treatment, indicating possible improvement in self-esteem, and the child depression inventory decreased significantly ($p < 0.01$), which shows reductions in feelings of depression.[43] Even before treatment, participants scored well within normal limits on both measures.[43] Neither the participants mean initial risk of cardiovascular disease, nor mean triglyceride level or blood pressure registered any significant changes.[43]

Golan and coworkers[42] pointed out that significant increase in the children asking permission to take or buy sweets was noted only in the experimental group – ($p < 0.001$) for taking and ($p < 0.01$) for buying – at termination of the programme. An overall reduction in the prevalence of poor eating habits was significantly greater in the experimental group. Moreover, a significant positive

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[§§] Piers EV. *Piers–Harris children's self-concept scale revised manual*. Los Angeles, CA: Western Psychological Services, 1984.

correlation was reported between the children's reduction in overweight and the following: presence of food stimuli in the house, eating while standing, eating while doing another activity, eating following stress situations, eating between meals, place of eating and activity level.[42] At the 7-year follow-up, Golan and coworkers reported that 6.6% of the girls from the child-only group reported eating disorder symptoms (binging and purging).[48]

Israel and coworkers[44] reported that the analysis of the Eating and Activity Self-Control Scale (EASC) indicated an increase in children's self-control and parental control regarding weight-related behaviours ($p < 0.001$ and $p < 0.05$), respectively). Parental opinion from the self-control rating scale also indicated significantly more self-controlled behaviours at week 26 than at week 1. Moreover, higher EASC self-control scores were significantly correlated with decreases in percentage overweight during treatment ($p < 0.05$).

Epstein and coworkers[47] indicated that there was an overall decrease in food intake from pre to post treatment (8 months), and that there was a strong relation between changes in red food intake and weight loss ($p < 0.02$).

Other factors

No additional analysis was carried out on the effect of age, gender, ethnicity, socioeconomic status, previous treatment for obesity, degree of overweight/obesity, motivation, frequency or length of the intervention and current medical conditions.

Methodological and context notes

Another study examined the feasibility and generalisability of a family-based behavioural treatment for childhood obesity in a clinical setting in Britain, and assessed whether the results were comparable with the original studies in the USA. Although this study was excluded from our review, it is important to mention, considering the proportion of studies from the USA that are included in

this study. The results support the applicability of the family-based behavioural treatment in a clinical setting in Britain.[52]

Interventions comparing problem solving, in addition to behaviour therapy with usual care or behaviour therapy

Weight loss

Based on the analysis of the results from two studies, there seems to be some contradictory evidence regarding the comparison of problem solving with behaviour therapy. Graves and coworkers[53] aimed to examine the effects of incorporating parental problem solving training in a behavioural weight reduction programme in obese children aged 6–12 years. Results suggest that combining problem solving with behaviour therapy may be more effective than behaviour therapy alone, as percentage overweight in the problem solving group had a greater decrease ($p < 0.01$) from baseline to 6 months than in the behaviour treatment only group .[53] Epstein and coworkers[31] also compared including parent and child problem solving to a behavioural weight control programme, only child problem solving and standard treatment (behavioural intervention only) in obese children aged 8–12 years. Nevertheless, the results suggest that problem solving did not provide any additional benefits in terms of weight loss.[31]

Other outcomes

Improvements in problem solving for both parents and children was reported in one study for the problem solving group vs problem solving with family.[31] In another study, parents in the problem solving group increased their problem solving ability from pre to post treatment, whereas behavioural and instruction-only parents did not.[53]

Children in both the problem solving and behavioural groups increased their consumption of green food and decreased their consumption of red foods significantly more than instruction-only children.[53] Moreover, a positive correlation was found between pre-and post-treatment weight change, and change in the consumption of red foods ($p < 0.05$) and green foods ($p < 0.01$).

Other factors

No additional analysis was carried out on the effect of age, gender, ethnicity, socioeconomic status, previous treatment for obesity, degree of overweight/obesity, motivation, frequency or length of the intervention and current medical conditions.

Interventions focusing on CBT

Weight loss

Duffy and Spence[54] did not find any additional effectiveness of cognitive therapy techniques such as targeting monitoring of negative thoughts, restructuring of maladaptive thoughts, problem solving, and self-reinforcement as adjuncts to behaviour therapy for 7–10-year-old and 10–13-year-old children. According to the results, percentage overweight significantly decreased ($p < 0.001$) in the relaxation control group from pre-treatment to the 6-month follow-up. In the CBT group percentage overweight also significantly decreased ($p < 0.001$) from pre-treatment to the 6-month follow-up. No significant differences were observed between groups.[54] Similar results were reported in another study by Warschburger and coworkers,[55] in which 6 months after intervention, 14.8% of the children and adolescents in the experimental group could be classified as non-obese, against 9.7% in the control group. However, these differences were not statistically significant.[55]

Braet and coworkers[56,57***]examined adding a healthy eating lifestyle programme rather than a strict diet, combined with CBT, delivered through different therapeutic forms to children aged 7–16 years. Significant loss of weight was reported in all therapeutic groups, as early as 3 months up to 1-year follow-up, and the results suggest that group rather than individual approaches result in significantly better outcomes. No significant results were found when comparing the 1-year follow-up with the 4.6 year follow-up.

*** Both Braet and coworkers[57,58] other outcomes are in section 15.2.8.

Braet and coworkers[58†††] also-assessed a 10-month inpatient cognitive behavioural weight loss programme, where the participants' median age and BMI was 14 years and 33 kg/m^2, respectively. During treatment, the children in the study group showed a decrease in the median adjusted BMI of –48% (range –4% to –102%). At 14-month follow-up, 13/27 children showed an increase in their overweight of less than 10% or continued to lose weight, compared with their post-treatment weight and 14/27 children had an increase of more than 10% overweight (up to +41%).

Other outcomes

Duffy and Spence[54] reported a significant reduction in the consumption per day of red foods from pre-treatment to post-treatment in both groups ($p < 0.001$), with no significant differences between groups.

Warschburger and coworkers[55] reported that both groups showed improvements in their quality of life over time ($p < 0.01$), and improvements in self-reported eating behaviours for the experimental group compared with the control group ($p < 0.05$).

Other factors

No additional analysis was carried out on the effect of age, gender, ethnicity, socioeconomic status, previous treatment for obesity, degree of overweight/obesity, motivation, frequency or length of the intervention and current medical conditions.

Interventions focusing on reinforcement and/or stimulus control of sedentary behaviours

Weight loss

From the analysis of the results of one study, there appears to be no significant improvement in applying mastery criteria and contingent reinforcement, as the

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[†††] Both Braet and coworkers[57,58] other outcomes are in section 15.2.8.

experimental group decreased from 60.6 % (SD 25.3) at baseline to 30.5% at 6 months and 34.1% at 1 year, and in the control group mean per cent overweight decreased from 58.8% (SD 19.6) at baseline to 38.8% at 6 months and then increased to 42.1 % at 1 year.[59]

Based on one study, results suggest that stimulus control and reinforcing reduced sedentary behaviours are equally useful to reduce sedentary behaviours and consequently in reducing standardised BMI (z-BMI) figures. z-BMI values (kg/m^2) for the stimulus control group were 3.3 ± 1.0, 2.3 ± 1.0 and 2.4 ± 1.0, at 0, 6 and 12 months, respectively, whereas the values for the reinforced reduction group at the same time were 3.2 ± 1.0, 2.2 ± 1.1 and 2.6 ± 1.0, respectively.[60]

Epstein and coworkers[61] assessed how preferences for food used to reinforce behaviour change in young children can be applied to modify food preferences of older, obese children. Two groups were assigned: one treatment group where novel low-calorie foods were given contingent upon the behaviour changes established for weight loss; and a control group where low-calorie foods were provided for a daily snack and not contingent upon behaviour change. There was also no difference in the rate of change in percentage overweight between the two groups, although both had a significant decrease ($p < 0.01$) from 2 to 6 months (25.1%). The findings of this study do not back-up the hypothesis that by using unfamiliar foods as reinforcers, one can change the preference of children for those unfamiliar foods.

Other outcomes

Significant changes regarding consumption of red foods per week ($p < 0.05$) and days within the caloric range ($p< 0.025$) were reported. Moreover, parents showed a significant improvement in knowledge of behavioural principles across time ($p < 0.001$). Epstein and coworkers[60] also reported significant reductions in the consumption of high-energy-density foods, and increases in physical activity and consumption fruits and vegetables were observed in both groups.

Other factors

There were differences between children who substituted physically active for sedentary behaviours and those who did not. There were a higher percentage of boys substituting physically active for sedentary behaviours than girls.[60]

No additional analysis was carried out on the effect of age, ethnicity, socioeconomic status, previous treatment for obesity, degree of overweight/obesity, motivation, frequency or length of the intervention and current medical conditions.

15.2.4 Pharmacological Interventions

Orlistat in weight loss and other outcomes in children and adolescents

15.2.4.1 Evidence statements (Table 15.6)

Table 15.6 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss		
1	In children (aged 7–12 years) orlistat (120 mg three times a day) in combination with advice on reducing fat is effective in producing weight loss at 12 weeks (decrease in BMI of approximately 2 kg/m^2)	3
2	In adolescents (aged 12–16 years), orlistat (120 mg three times a day) in combination with a hypocaloric diet is equally effective for weight loss as diet and activity at three weeks (approximately 7 to 8% of initial body weight)	1–
3	In adolescents (aged 10–16 years), orlistat (120 mg three times a day) in combination with a hypocaloric diet and increased activity is more effective for weight loss than diet and activity at 10–11 months (decrease in BMI of approximately 4 kg/m^2)	1–
4	In adolescents (aged 12–16 years) orlistat (120 mg three times a day) in combination with a hypocaloric diet, increased	1+

No.	Evidence statement	Grade
	activity, and behaviour modification is more effective for weight loss than placebo (with diet, activity and behaviour modification) at 12 months (decrease in BMI of approximately 0.5 kg/m^2)	
Outcomes other than weight loss (from trials that reported weight loss)		
5	In children (aged 7–12 years) orlistat (120 mg three times a day) in combination with advice on reducing fat did not result in any significant changes in levels of plasma cholesterol or triglycerides. Some U-shaped variation was seen in levels of vitamins A and E, compared with a slight decrease in vitamin D	3
6	In the one study that reported outcomes related to psychological health, no negative effect of the use of orlistat and dietary advice was seen. Increased avoidance of fattening foods, and increased oral control were reported, as was a trend towards improved body image and increased motivation (although this was not significant)	3
7	In adolescents (aged 12–16 years) orlistat (120 mg three times a day) in combination with a hypocaloric diet, increased activity and behaviour modification is more effective in improving diastolic blood pressure (approximately –0.5 mm Hg) than placebo (with diet, activity and behaviour modification) at 12 months. No significant improvements were seen for systolic blood pressure, or levels of lipids, triglycerides, or fasting plasma glucose	1+
8	Rates of growth (height and stages of sexual maturation) were not significantly different for adolescents taking orlistat compared to placebo	1+
9	Levels of vitamins and minerals were not significantly different for adolescents taking orlistat compared with placebo	1+, 1–
Harms (from trials that reported weight loss)		
10	Orlistat treatment is associated with increased rates of gastrointestinal events. However, these are frequently mild and transient	3
11	Only one serious reported event (symptomatic cholelithiasis leading to cholecystectomy) was assessed as being possibly related to orlistat treatment	1+
Generalisability (from trials that reported weight loss)		
12	None of the included studies were conducted in the UK	3
13	All included studies were conducted in specialist centres, with	3

No.	Evidence statement	Grade
	specialist healthcare professionals (dietitians, behavioural psychologist, paediatricians, paediatric endocrinologists and paediatric nurses)	
14	One study was conducted in an inpatient unit, but the aim of this study was not to assess weight loss, but mineral balance	1–
15	Where reported, studies recruited mainly through referrals to the specialist centres, with some advertising only in one study	3
16	From the included studies not conducted in an inpatient setting, the follow-up rate varied from weekly telephone contact to every 2 months. Two studies used an approach of decreased contact over time. However, most studies were of a very short duration. In the two studies lasting longer than 3 months, participants were contacted every 2 weeks for first 4 months then every 2 months in one study, and participants maintained contact with dietitian monthly with an appointment at the outpatient clinic every two months in the other study	3

BMI, body mass index.

15.2.4.2 Orlistat (120 mg three times daily) versus placebo

Weight loss

Two placebo controlled randomised trials were identified.[62,63] One trial[62] compared the use of orlistat in combination with a nutritionally balanced hypocaloric diet (designed to produce an initial weight loss of 0.5–1.0 kg per week), an exercise plan and a programme of behaviour modification (see evidence table for details [Appendix 13]). The study participants (n = 533) were adolescents aged 12–16 years who were overweight and obese (BMI ≥ 2 units above the 95th centile, excluded if BMI ≥ 44 kg/m^2 or weighed over 130 kg). Both groups lost weight during the first 4 weeks of the intervention, with weight loss remaining stable in the placebo group from weeks 4 to 12 compared with continued weight loss in the orlistat group until week 12. Weight increased in both groups from week 12 onwards. At 12 months, the group assigned to orlistat gained less weight than the group assigned to placebo (+0.53 kg vs +3.14 kg,

p < 0.001) with decrease in BMI compared with an increase in the placebo group (–0.55 vs +0.31, p = 0.001). Significantly more participants lost 5% or more and 10% or more of initial BMI in the orlistat group at 12 months. Overall, the trial was assessed as being of good quality.[62] It is important to note that some of the children would have completed linear growth, although some would have been still growing during the study.[62]

Another RCT[63] compared the effect of orlistat with placebo alone, without any additional dietary or activity component. This trial was assessed as of poorer quality than Chanoine's 2005 study,[62] and was considerably smaller. Participants (n = 32) were aged between 12 and 16 years, and were overweight or obese (BMI ≥ 85th centile adjusted for age and gender). At three weeks, participants in both groups had lost weight (7.0% orlistat vs 7.8% placebo of initial body weight), but the difference did not appear to be significant (no p value was reported). This trial, however, was not designed to measure weight loss, but the effects of orlistat on mineral balance.[63]

A quasi-randomised controlled study[64] investigated the effect of orlistat in combination with diet (20% reduction in kcal per day) and activity (at least 30 minutes moderate daily physical activity). Participants (n = 42) were aged 10–16 years, and were obese (> 140% weight for height index). A significant weight change was seen in the orlistat-treated group compared with placebo (–6.27 kg vs +4.16 kg, p < 0.001) at approximately 10–11 months (follow-up varied). Similarly, the orlistat group showed a decrease in BMI compared with an increase in the control group, and weight loss (percentage of initial weight) compared to a weight increase in the control group. However, the participants in the orlistat group had a higher mean initial BMI than the placebo group (32.5 vs 31.2, p = 0.018). Again, this study[64] was small and was assessed as of poorer quality than Chanoine's study above.[62]

Two before-and-after studies investigated the effect of orlistat in children[65] and adolescents.[66] Norgren and colleagues[65] conducted a pilot study of orlistat and

dietary advice (sources of fat and recommended daily fat intake) in children (n = 11) aged 7–12 years (pre-pubertal) and who were overweight or obese (BMI >4 SD above normal). In the 12 weeks preceding treatment (no intervention), children tended to gain weight. However, at 12 weeks after initiation of orlistat treatment, the median weight change was –4.0 kg (range –12.7 kg to +2.5 kg, p = 0.016), with an corresponding decrease in BMI.[65]

Another study[66–68] assessed the effect of orlistat as an adjunct to both a comprehensive behavioural programme and periods of inpatient evaluation (see details below). Participants (n = 20) were aged 12–17 years and were obese (BMI ≥ 95th centile for age, sex, race). Significant weight loss was seen at both 4 and 6 months (–4.4 kg and –5.4 kg, respectively), with a corresponding decrease in BMI. At 6 months, 30% of participants has lost 5% or more of initial weight and 15% had lost 10% or more.[66–68]

Both of these before-and-after studies were small, and due to the design used had increased potential for bias compared with studies using a controlled study design.

Other outcomes

A large good-quality RCT showed significant decreases in diastolic blood pressure (DBP), but not in other outcomes such as lipids, glucose levels, triglycerides or systolic blood pressure (SBP) at 12 months.[62]

The remainder of the studies reported a variety of different outcomes at different times.

Other factors

Age

Most studies included adolescents only (range 10–17 years), but one study[65] included pre-pubertal children aged 7–12 years.

Current medical conditions

McDuffie and coworkers[66] included adolescents with one of several obesity associated comorbidities (hypertension, type 2 diabetes or glucose intolerance, hyperinsulinaemia, hyperlipidaemia, hepatic steatosis, sleep apnoea). All other studies included otherwise healthy participants.

Degree of obesity

Most studies included children or adolescents who were overweight or obese, but Chanoine[62] included only adolescents who were overweight (and excluded those who were very obese) and Ozkan and coworkers[64] included only obese adolescents.

Setting

All studies were based in specialised treatment or research centres. Two studies included either partial[66] or total[63] inpatient treatment.

Country

No studies were based in the UK.

Methodological and context notes

Due to the inclusive searches and criteria, studies of varied design are included.

Sibutramine in weight loss and other outcomes in adolescents and children

15.2.4.3 Evidence statements (Table 15.7)

Table 15.7 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss		
1	In specialist settings, a combination of sibutramine (ranging from 5 mg to 15 mg/day) with behaviour therapy, 1200–1500 kcal/day diet, and 120 minute/week aerobic exercise can result in a weight change of –7.8 kg at 6 months in obese adolescents aged 13–17 years compared with controls (–3.2 kg change)	1+
2	In specialist settings, a combination of 10 mg/day sibutramine, diet, 30 minute/day physical activity can achieve a weight and BMI change of –10.3 kg and –3.6 kg/m^2, respectively at 24 weeks in obese adolescents (with completed linear growth) aged 14–17 years compared with controls (–2.4 kg and –0.9 kg/m^2, respectively)	1+
Outcomes other than weight loss (from trials that reported weight loss		
3	In specialist settings, a combination of sibutramine, behaviour therapy, 1200–1500 kcal/day diet, and 120 minute/week aerobic exercise can increase HDL-cholesterol levels and reduce serum insulin levels in obese adolescents	1+
4	In specialist settings, a combination of diet, 30 minute/day physical activity and 10 mg/day sibutramine can decrease triglycerides and LDL-cholesterol levels in obese adolescents	1+
Harms (from trials that reported weight loss)		
5	In specialist settings, a combination of behavioural therapy and sibutramine can elevate blood pressure in obese adolescents aged 13–17 years	1+
6	In specialist settings, a combination of sibutramine diet and physical activity can cause constipation in obese adolescents aged 14–17 years	1+

The marketing authorisation for sibutramine has been suspended. See front cover for details.

No.	Evidence statement	Grade
Generalisability (from trials that reported weight loss)		
7	There is no evidence on the efficacy and safety of sibutramine in non-specialist setting and in non-volunteer populations	N/A
8	The two studies were conducted in Brazil and the USA and were based in university research centres. Recruitment was either not clear or not reported. Follow-up rate varied from every month (n = 1), to a combined approach that went from every week to biweekly sessions (phase 1) and biweekly and monthly (phase 2) (n = 1)	N/A

BMI, body mass index; HDL, high-density lipoprotein; LDL, low-density lipoprotein; N/A, not applicable.

15.2.4.4 Evidence review

This section reviews the evidence on the effectiveness of pharmacological interventions (sibutramine) combined with behaviour therapy and/or dietary interventions and physical activity in obese adolescents.

Types of study

- RCTS
- Controlled clinical trials
- Controlled before-and-after studies
- Cohort studies with a control group

Only studies with a minimum duration of 6 months or above (including follow-up) and published after 1985 were included, and also RCTs with a primary aim other than the treatment of childhood obesity. Studies based in a setting other than clinical and delivered by non-health-care professionals (for example, school teacher) were not included in this review.

We did not retrieve any studies in the update searches that would potentially add further details or contradict any of the recommendations.

Types of participant

- Participants aged under 18 years at the start of the study, and exceptionally studies where the age cut-off was above 18 years and where the majority of the participants were below 18 years or presented age stratification.

Types of outcome

- Primary outcomes to be measured (not self-reported) estimates of overweight in per cent and BMI.

- Secondary outcomes to be behaviour change, participants' views, measures of self-esteem, health status, well-being and quality of life.

Again, there is limited evidence in this field. The American Heart Association (AHA) pointed out that sibutramine has been studied in an RCT. It stated that sibutramine had been shown to be efficacious compared with behaviour therapy alone, but it may be associated with side effects including increases in heart rate and blood pressure.[1] The NHMRC guidelines[2] stated that there is no evidence that sibutramine has a role in the management of adolescent obesity. Similarly, the Singapore Ministry of Health guidelines referred to the non-existence of data on the long-term efficacy and safety of medication in childhood and adolescent obesity (grade C, level).[1]

Only two RCTs[70,71] were retrieved from searches. One study consisted of 82 participants[71] whilst the other trial included 60[70]. One of the studies was a 6-month placebo controlled trial,[70] in which participants were given 10 mg/day. This 6-month period was preceded by a 4-week single-blind period where all participants were given a placebo capsule. Participants were also advised to achieve an energy deficit of 500 kcal/day and to undertake at least 30 minutes of moderate aerobic exercises per day, and to reproduce a 'regular' clinical setting, no behavioural counselling was given. Routine clinical advice to increase

physical activity was given by the medical practitioners in the form of a leaflet and only one appointment was made with the dietitian. At 6 months the sibutramine group had a statistically greater reduction in weight and BMI ($p < 0.001$) compared to the placebo group.

The other study consisted of a 12-month trial,[71] which comprised two phases: one placebo controlled period for 6 months and an open label extension for another 6 months. Participants were given a family-based behavioural weight loss programme including a 1200–1500 kcal diet and 120 minute/week of physical activity. At 6 months the placebo group had a significantly smaller reduction of weight and BMI than the sibutramine group ($p = 0.001$). The group that was randomised to sibutramine for the first 6 months and then continued on the medication for another 6 months gained weight during the second 6 months and ended up not significantly different from the placebo group. There was no statistically significant difference at month 12 between the two groups as the placebo group were able to switch to sibutramine in the open-label phase at 6 months to 12 months.

In one of the studies,[70] there was a significant decrease ($p < 0.05$) in triglycerides and very-low-density lipoprotein at week 24 in the sibutramine group. In the other hand, in the other study,[71] a significant increase in HDL-cholesterol ($p = 0.001$) and significant reductions in serum insulin ($p < 0.001$) were reported.

One of the studies[70] reported statistically significant adverse events – constipation ($p = 0.039$) in the sibutramine group. The other study[71] reported that during the 12-month study period, sibutramine was reduced to 10 mg in 16 participants and to 5 mg in 7 participants (42 participants in the sibutramine group). Ten participants discontinued treatment due to increases in blood pressure.

15.2.5 Surgery for weight loss and other outcomes in adolescents and children

15.2.5.1 Evidence statements (Table 15.8)

Table 15.8 Evidence statements and grading

No.	Evidence statement	Grade
Intervention		
1	Evidence suggests that bariatric surgery should only be undertaken by highly specialised surgeons	4
2	Evidence suggests that bariatric surgery should only be performed in adolescents who are aware of the risks and benefits of surgery and who have a supportive family environment	3
3	Vitamin supplements should be given postoperatively and patients should be closely followed up to avoid deficiencies	3
4	There is no sufficient evidence on the use of surgery in obese adolescents due to obesity causes, e.g. Prader–Willi syndrome	
Weight loss		
5	There is no evidence on which surgical procedure is the most effective in achieving weight loss in adolescents	
6	Evidence suggests that bariatric surgery should only be performed in obese adolescents who have systematically failed to manage weight for 6 months or more as determined by primary care provider	3
7	Evidence appears to suggest that an approximate change in BMI of –20 kg/m^2 (after approximately 2 years) can occur in obese adolescents who underwent bariatric surgery	3
8	Evidence appears to suggest a varying median excess weight loss ranging from 15.9% at 6 months to 69% at 24 months for laparoscopic adjustable gastric banding, and from 62% at 12 months to 87% at 2 years in adolescents who underwent gastric bypass	3
Outcomes other than weight loss (from trials that reported weight loss)		
9	Evidence suggests that bariatric surgery can have an impact on psychosocial adjustment of severely obese adolescents	3
10	Some evidence suggests that bariatric surgery can reduce significant comorbidities in severely obese adolescents	3

No.	Evidence statement	Grade
Intervention		
1	Evidence suggests that bariatric surgery should only be undertaken by highly specialised surgeons	4
2	Evidence suggests that bariatric surgery should only be performed in adolescents who are aware of the risks and benefits of surgery and who have a supportive family environment	3
3	Vitamin supplements should be given postoperatively and patients should be closely followed up to avoid deficiencies	3
4	There is no sufficient evidence on the use of surgery in obese adolescents due to obesity causes, e.g. Prader–Willi syndrome	
Harms (from trials that reported weight loss)		
11	Evidence suggests that severely obese children and adolescents who undergo bariatric surgery may develop micronutrient deficiencies and other postoperative complications	3
12	Adolescents and children who undergo bariatric surgery (more common in gastric bypass) may require revisional surgery, or may develop other late postoperative complications such as cholecystitis or hernias	3
13	Some older studies have reported deaths due to perioperative and postoperative complications. There are no reports of deaths in recent studies	3
14	One recent study reported band slippage, port infection and replacement of a leaking port in adolescents who underwent laparoscopic adjustable gastric banding	3
Generalisability (from trials that reported weight loss)		
15	Generalisability of the findings remains unclear, as no study was conducted in the UK, and all of the studies were based in university surgery departments	
16	Generalisability of the findings is all hindered by the limited quality of the retrieved studies	

15.2.5.2 Evidence review on surgery

This section reviews evidence on the assessment of the effectiveness of bariatric surgery in obese adolescents. Due to the absence of methodologically strong studies among the existing literature, more expanded inclusion criteria were adopted for this particular review. Thus, the following were included:

Types of study

- RCTs
- Controlled clinical trials
- Controlled before-and-after studies
- Cohort studies with a control group
- Non-comparative studies (case series and case studies)

Only studies with a minimum duration of 6 months or above (including follow-up) were included.

Update searches have been undertaken, however no further studies were identified.

Types of participant

- Participants aged under 18 years at the start of the study, and exceptionally studies where the age cut-off was above 18 years but where the majority of the participants were below 18 years and results were stratified by age.

Types of outcome

- Primary outcome of measured (not self-reported) estimates of weight change in per cent and BMI.
- Secondary outcomes of behaviour change, participants' views, measures of self-esteem, health status, well-being and quality of life.

The National Institutes of Health (NIH) Bariatric Consensus Development Conference in 1991[72] set out the basis for the increase in adult bariatric surgery undertaken in the previous 6 years. This conference concluded that insufficient data existed to make recommendations for patients younger than 18 years of age. Fourteen years later, outcome data remain limited for adolescents, with no controlled assessment of bariatric surgery in this group.

Guidelines for surgical intervention

Only three guidelines have issued recommendations with regard to bariatric surgery in adolescents: NHMRC Australian guidelines for the management of overweight and obese children and adolescents,[2] the Singapore Ministry of Health clinical guidelines,[73] and the Institute for Clinical Systems Improvement (ICSI).[74] The Scottish Intercollegiate Guidelines Network (SIGN)[6] did not propose any recommendations.

The NHMRC Australian guidelines[2] recommended (grade C) that bariatric surgery might be considered as a last resource in severely obese adolescents with obesity-related comorbidity. The surgery should be carried out only in an experienced surgical centre after meticulous consultation, education of the patient and family, and a full psychological assessment. Furthermore, postoperative care should be ensured in an experienced weight-management centre. The Singapore Ministry of Health guidelines[73] stated that bariatric surgery cannot be recommended (grade B) for most adolescents, although with exceptions for those at the highest risk of mortality from obesity, and with both patient and parental understanding of the consequences of surgery. Finally, the ICSI[74] recommended that bariatric surgery should be undertaken in carefully selected patients, those with a BMI greater than or equal to 40 kg/m^2, or with a BMI of 35–39.9 kg/m^2, and those who are at a very high absolute risk for increased morbidity or premature mortality. Patients should be motivated, well-informed in disease management, psychologically stable and accepting of operative risks.

Finally, the AHA guidelines stated that:

- ‘surgical approaches to treat severe adolescent obesity are being undertaken by several centres. Indications used include a BMI > 40 kg/m^2 and severe associated co-morbidities, such as obstructive sleep apnoea, type 2 diabetes mellitus, and pseudotumor cerebri

- ‘more severe elevation of BMI (> 50 kg/m^2) may be an indication for survival treatment in the presence of less severe co-morbidities such as hypertension and dyslipidemia, particularly if the degree of overweight hinders performing the activities of daily living

- ‘an experienced team approach including comprehensive medical and psychological evaluation is critical both for selection of appropriate candidates and for postoperative care that is sophisticated and often intense

- ‘weight loss goals and reduction of morbidity are often achieved with gastric bypass surgery. The rates of short-term mortality appear to be low but significant complications can occur. Intermediate and long-term outcomes, including information on malabsorption of critical nutrients, are unknown.

- ‘overall, surgical therapy should be reserved for full-grown adolescents with the severest obesity-related morbidity, offered only by experienced multidisciplinary teams, and presented to families with appropriate informed consent procedures.’

Views and insights from surgical societies and associations and expert opinion

Inge and coworkers[75–77] have thoroughly reviewed the role of surgery in the treatment of severe childhood and adolescent obesity. These authors contended that adolescents being considered for bariatric surgery should:

- have been unsuccessful at managing weight for ≥ 6 months, as determined by the primary care provider

- have achieved or nearly achieved physiological maturity

- have a BMI ≥ 40 kg/m^2 with serious obesity-related comorbidities or have a BMI of ≥ 50 kg/m^2 with less severe comorbidities

- be able to show adherence to comprehensive medical and psychological evaluations both before and after surgery

- agree to avoid pregnancy for at least 1 year postoperatively
- demonstrate responsibility in committing to nutritional guidelines postoperatively
- provide informed assent to surgical treatment
- possess decisional ability
- be surrounded by a supportive family environment (ensure that both patients and families understand that bariatric surgery is not a cure for obesity but an effective weight loss tool if used in compliance with specific dietary and physical activity regimens; and to understand the known risks and possible side effects of bariatric surgery).

The authors asserted that the above suggested criteria could not be applied strictly to each patient but should be tailored to the individual's needs, taking into account the level of maturity and severity of comorbid conditions. Strong emphasis was also placed on the requirement of having highly trained and skilled bariatric surgeons to perform safe and effective procedures, undertaken at appropriately equipped facilities capable of adolescent bariatric surgery. Furthermore, a multidisciplinary team with expertise in adolescent weight management and bariatric surgery is required to carefully manage all the aspects of the procedure for each individual.

Overall, the American Society for Bariatric Surgery[78] agreed with the criteria proposed by Inge and co-workers, although they added:

- A qualifier of a BMI of ≥ 35 kg/m^2 in the presence of significant comorbidities.
- A bariatric surgeon should have successfully performed at least 100 bariatric procedures or have completed a year-long bariatric surgery fellowship.

- The preoperative presence of comorbidities as an indicator for surgery is not appropriate, as bariatric surgery can play an important role in preventing such comorbidities.
- There is no real evidence that supports the argument that given any age and with a balanced nutrition, bariatric surgery will lead to impaired growth or early osteoporosis.
- Recommendations for procedures should not be limited to the Roux gastric bypass and laparoscopic adjustable gastric banding (LAGB).
- There is a need to discuss possible complications of gastric distension and possible rupture in the presence of a bowel obstruction when recommending the Roux gastric bypass; and an LAGB needs to encompass discussion of oesophageal dilation and the possible advent of functional and histological oesophageal problems in the future, alongside long-term risks of band erosion into stomach or balloon malfunction.

Primary studies synthesis[‡‡‡]

No RCTs or clinical controlled trials were retrieved from the searches. The bulk of the evidence consisted of case studies, case series and retrospective reviews that addressed bariatric surgery procedures as follows: LAGB, vertical banded gastroplasty (VBG),[§§§] Roux-en-Y gastric bypass, jejunoileal bypass, biliopancreatic diversion and duodenal switch. All these come under the broader categories of restrictive, restrictive/malabsorptive, malabsorptive/restrictive surgical procedures.

- Restrictive: the gold standard is LAGB. VBG was a forerunner to laparoscopic gastric banding, but had high rates of complications/failure. Both operations

[‡‡‡] We have excluded studies based solely on VGB, although included those which combine VGB with other surgery techniques, or have one group that was given VGB.

[§§§] We have excluded studies based solely on VGB, although included those which combine VGB with other surgery techniques, or have one group that was given VGB.

have similar, expected clinical outcomes. Laparoscopic gastric banding restricts intake (volume) of solid food. Older operations are VBG, horizontal gastroplasty, open adjustable banding.

- Restrictive/malabsorptive: gold standard is gastric bypass (Roux-en-Y). Gastric bypass mainly restricts intake but also reduces absorption of nutrients.

- Malabsorptive/restrictive: these are more similar to the older operations. The gold standard is duodenal switch (DS) and biliopancreatic diversion (BPD). Jejunoileal switch was the forerunner to the DS, but was abandoned in 1982. These reduce calorie absorption, with limited restriction.

Restrictive surgical techniques

LAGB

Three of the studies consisted of prospective case series [79–82] Abu-Abeid and coworkers[79] looked at adolescents aged 12–19 years (who had been under the care of a dietitian for at least 1 year, and had failed to reduce weight with a 800 kcal/day diet) who underwent LAGB. Widhalm and coworkers[82] followed eight patients with a mean age of 16.0 ± 1.3 years who underwent adjustable laparoscopic banding surgery. Dolan and coworkers[80,81] also studied adolescents aged 12–19 years who underwent LAGB.

In one case study, an inpatient physical activity programme and dietary restriction to 800 kcal per day was given to a 12-year-old girl for 6 weeks. Since severe obesity persisted, she underwent LAGB. After the surgery, a daily caloric intake was still restricted to 1200 kcal per day and physical activity at least twice a week.[83] Horgan and co-workers[84] addressed patients aged 19 or younger who underwent LAGB between 2001 and 2003. Angrisani and coworkers[85] also conducted a retrospective multicentre study in patients who underwent LAGB, aged 19 and younger.

Weight loss

In one study, BMI fell from 46.6 kg/m^2 preoperatively to 32.1 kg/m^2 at 23 months follow-up.[79] In two studies belonging to the same trial that compared weight and BMI reduction in adolescents and adults, the median BMI of the adolescents decreased from 42.2 kg/m^2 (preoperatively) to 32.4 kg/m^2 at 12 months and further to 30.2 kg/m^2 at 24 months.[80,81] No differences were observed in weight reduction between adults and adolescents.[80,81] Widhalm and coworkers[82] reported that in all their eight patients there were no major problems after surgery, and the mean weight change after a mean follow-up period of 10.5 ± 6 months was – 25.0 ± 3.8 kg. In one case study, weight loss in a 13-year-old girl was 14 kg at 3 months post-operation.[83]

Angrisani and coworkers[85] reported a mean percentage excess weight loss (%EWL) at 1, 3, 5 and 7 years follow-up of 45.6 ± 29.6; 39.7 ± 29.8; 43.7 ± 38.1; and 55.6 ± 29.2, respectively. Five of 25 (20%) patients had ≤ 25% EWL at 5 years' follow-up, whereas none of the 10 patients subject to follow-up at 7 years had ≤ 25% EWL.

Other outcomes

Abu-Abeid and coworkers[79] stated that all adolescents reported improved well-being; they were more physically active, more socially involved with their peers and reported feeling happier than before surgery.

Reported harms

Dolan and coworkers[80,81] reported that two patients had complications: one had slippage of the band, and another patient required port replacement. Horgan and coworkers[84] reported one patient who developed cholecystitis.

Angrisani and coworkers[85] reported the following cases:

> 'Laparoscopic conversion was necessary in 1 patient with gastric perforation on the anterior wall during perigastric band positioning. The overall postoperative complication rate was 6/58 (10.3%): Band slippage was observed in 1 patient and was treated by laparoscopic

> repositioning after 4 days, gastric pouch dilatation was observed in 2 patients and was treated by band repositioning, and intragastric migration was observed in 3 patients and was treated with band removal. The band also was removed in 2 patients for psychologic intolerance, and 1 patient was converted 2 years after surgery to laparotomic gastric bypass. The overall band removal rate was 6/58 (10.3%). Biliopancreatic diversion with gastric preservation and band left in situ was performed in 2 patients (3.4%).'

Regardless of the type of procedure, the authors stated that the postoperative course in the eight adolescents who underwent reoperation was uneventful.[85]

Older surgical techniques such as VBG, horizontal gastroplasty, open adjustable banding[****]

Capella and coworkers[86] studied a form of gastric bypass which combined the VBG with a Roux-en-Y gastric bypass in adolescents aged 13–17 years of age. These adolescents had attempted several weight reducing regimens, such as medically supervised diets, physical activity, behaviour modification, commercial diets, psychological interventions and pharmacological agents. Postoperatively, patients were given advice from a dietitian on the benefits of a balanced diet and regular physical activity, and no attempts were made to refer them for another diet or behavioural modification programme.

Mason and coworkers[87] retrospectively studied 47 severely obese individuals who were under 21 when they underwent VBG.

Weight loss

The mean BMI decreased from 49 kg/m^2 preoperatively to 28 kg/m^2 at 5.5 years post-operation.[86]

Mean BMI decreased from a mean 48.1 ± 7.01 kg/m^2 at operation to 36.2 ± 5.99 kg/m^2 at 5 years, and decreased from a mean 49.6 ± 7.73 kg/m^2 at

[****] These studies do not include evidence tables, as they are older procedures, and are not used in the NHS.

operation to 39.2 ± 7.15 kg/m^2 at 10 years assessment. Average weight decreased from 138 kg at operation to 103.6 kg at 5 years, and from 135.8 kg at operation to 107.6 kg at 10 years.[87]

Other outcomes

In one study all serious comorbidities disappeared early in the weight loss process.[86]

Reported harms

No operation-related deaths among the 47 patients who underwent VBG were reported. No leaks, instances of peritonitis, wound infections or cases of pneumonia were reported. Three revisions were performed in female patients, two at 5 years, and the third at 12 years post-operation.[87]

Restrictive/malabsortive

Gastric bypass

The first studies on bariatric surgery date from the mid-1970s. In 1975, Soper and coworkers[88] reported 18 severely obese adolescents younger than 20 years of age who underwent either gastric bypass or gastroplasty. Anderson and coworkers[89] published a follow-up report on both procedures with 30 adolescents. In this study, careful dietetic counselling was provided to each patient and family. Both studies were case series.

Strauss[90] reviewed records of adolescents aged 17 years or younger who underwent gastric bypass surgery, and who had made serious attempts at weight loss in diet and behaviour modification programmes; Stanford and coworkers[91] also reviewed medical records of patients less than 20 years of age who underwent laparoscopic Roux-en-Y gastric bypass (RYGB). Breaux[92] reviewed 22 patients (11 with sleep apnoea and 11 without sleep apnoea), whose ages ranged from 8 to 18 years, and who had undergone VBG, RYGB or BPD. BPD was only performed in super-obese patients with sleep apnoea.

One study consisted of interviews with patients who had undergone bariatric surgery;[93] 34 patients were interviewed an average of 6 years after the surgery and ranged from 11 to 19 years of age at the time of the surgery. Patients underwent RYGB or VGB.

Weight loss

The mean weight loss from two studies dating from 1975 and 1980 was approximately 40 kg at 3 years and 26 kg at 5 years post-operation.[88,89]

Strauss[90] stated that maximum weight loss occurred by 12–15 months after the operation; 9 of 10 adolescents had weight loss in excess of 30 kg. The mean weight loss was 53.6 ± 25.6 kg for the nine adolescents who had persistent weight loss. Stanford and co-workers[91] reported a BMI decrease from 55 kg/m^2 (preoperatively) to 35 kg/m^2 at 20 months' follow-up. Rand and Macgregor[93] reported that preoperatively, patients had an average BMI of 47 kg/m^2, and at 6 years follow-up the average BMI had dropped to 32 kg/m^2. The patients' average excess body weight loss was 66%. Breaux[92] pointed out that in the group without sleep apnoea BMI improved from a mean 56.4 kg/m^2 to a mean 35.5 kg/m^2 post-operation. In the group with sleep apnoea, mean BMI dropped from 70.3 kg/m^2 to a mean BMI of 46.5 kg/m^2 post-operation.

Other outcomes

Rand and Macgregor[93] found that at follow-up, 82% of the patients considered themselves attractive, compared with a figure of 94% of those who felt unattractive before surgery.

Reported harms

Both Soper and coworkers[88] and Andersen and coworkers[89] reported postoperative complications. Soper reported: 3 wound infections; 3 patients with respiratory difficulty; 1 patient with thrombophlebitis; 1 patient with upper gastrointestinal bleeding; 1 patients with urinary tract infection; and 1 patient with

protracted vomiting. Andersen reported: 3 patients with wound infections; 2 patients 'slow to open' due to stomal obstruction; 3 patients developed atelectasis; 2 developed pneumonia; and 1 developed a subphrenic abscess. Strauss [90] reported a serious complication in one patient with a distal gastric bypass who had protein-calorie malnutrition and micronutrient deficiency approximately 1 year after gastric bypass. Two other adolescents had symptomatic cholelithiasis requiring laparoscopic cholecystectomy. Small bowel obstructions occurred approximately 10 years after gastric bypass surgery in one patient.

Towbin and coworkers[††††] found three cases of beriberi (thiamine or vitamin B-1 deficiency) in adolescents who underwent gastric bypass. Breaux[92] reported nine complications including vitamin A and D deficiencies, folic acid deficiency, protein deficiency, gallstone development, kidney stone, postoperative laryngeal oedema and incisional hernia.

Malabsortive/restrictive

Duodenal switch and biliopancreatic diversion

Breaux[92] reviewed 22 patients (11 with sleep apnoea and 11 without sleep apnoea), whose ages ranged from 8 to 18 years, and who had undergone VBG, RYGB or biliopancreatic diversion (BPD). BPD was only performed in super-obese patients with sleep apnoea.

Weight loss

Breaux[92] found that in the group without sleep apnoea, BMI improved from a mean 56.4 kg/m^2 to a mean 35.5 kg/m^2 post-operation. In the group with sleep apnoea, mean BMI dropped from 70.3 kg/m^2 to a mean BMI of 46.5 kg/m^2 post-operation. Nevertheless, no figures were provided for the children who underwent BPD, as results for the three surgical procedures were all grouped together.

[††††] Towbin A, Inge TH, Garcia VF et al. Beriberi after gastric bypass surgery in adolescence. *Journal of Pediatrics* 2004;145:263–7.

Other outcomes

All patients had resolution of sleep apnoea on the long-term follow-up.

Older surgical procedures such as jejunoileal bypass

Two retrospective reviews were retrieved that examined the long-term effects of jejunoileal bypass in obese adolescents. Organ and coworkers[95] did a retrospective review on 16 patients aged 15–20 years at the time of the surgery (1970–1975). Silber and coworkers[96] reviewed 11 patients (who had made repeated failures of medical-dietary treatments) aged between 11 and 22 years at the time of the surgery (between 1972 and 1974). Another study which consisted of a case series of four patients aged 11–16 years who had failed dietary treatment of at least 1 year was also retrieved.[97]

Weight loss

With regard to the two studies that addressed jejunoileal bypass, in one study the mean weight dropped from 121.99 kg (pre-operative) to 77.07 kg ($p < 0.001$) after a mean follow-up of 8.2 years.[96] Mean BMI dropped from 43.21 kg/m^2 to 27.26 kg/m^2 ($p < 0.001$).[95] Randolph and coworkers[97] reported a mean percentage weight loss of 32.75% at 12 months.

Other outcomes

Organ and coworkers[95] discovered a significant change in attitude which reflected a greater sense of pride in the patient's own body. This also led to changes in their eating habits with greater psychosocial adjustment. Patients' involvement in social activities increased and many found themselves more employable. Randolph and coworkers[97] reported a gradual decrease in appetite, and that patients appeared brighter, more alert and more outgoing.

Reported harms

Randolph and coworkers[97] reported significant effects on levels of absorption, evidenced by flattening of the glucose and xylose tolerance tests, an increase in

faecal losses of fat and nitrogen, and lower levels of serum triglycerides and cholesterol.

Other factors

Current medical conditions

One or several comorbidities were present including dyslipidaemia, sleep apnoea, pulmonary hypertension, low back pain and severe arthalgias, hypertension, liver steatosis, hypertriglyceridaemia, hypercholesterolaemia, peptic oesophagitis, cholelithiasis, degenerative joint disease (DJD), bronchial asthma, type 2 diabetes mellitus, urinary urgency and stress incontinence, dependent oedema, and gastro-oesophageal reflux disease.[84,86,90,91] Rand and coworkers also reported anaemia and thyroid problems in seven patients. Breaux also reported sleep apnoea and brain-stem tumour.

In one case study,[83] a 12-year-old girl had arterial hypertension, uremic odour, end-stage renal failure, renal anaemia, hypercalcaemia, metabolic acidosis, preserved diuresis with isosthenuria and renal osteopathy.

Organ and coworkers[95] reported that no patients with the Prader–Willi or Laurence–Moon–-Biedl syndromes or other endocrinopathies were included. Any existing metabolic defect was stabilised prior to surgical intervention. Silber and coworkers[96] reported three patients who died within a year of procedure (one with known incipient heart failure, one with established diabetes mellitus, who died of perinephric abscess and sepsis, and the third with hepatic disease). Two of these had Prader–Willi syndrome. Patients with Prader–Willi syndrome were also present in Randolph et al.'s case series,[97] and Widhalm et al.'s study.[82]

Setting

All the retrieved studies were undertaken in university surgery departments.

Country

The vast majority of the studies were from the USA, with the exception of: Australia,[80,81] Israel,[79] Germany[83] and Austria.[82]

Methodological and context notes

All the retrieved studies were of poor quality, with no RCTs or other types of controlled study. Moreover, levels of statistical significance were either not applicable or not provided. Therefore the reliability and validity of the results remain uncertain, and robustness of the evidence statements and recommendations on the use of bariatric surgery in adolescents is extremely weak.

15.2.6 Referral to specialist care for children and adolescents

In September 2005, the National Guideline Clearinghouse synthesised the recommendations on the assessment and treatment of obesity and overweight in children from six published guidelines.[1]

Only the guidelines from SIGN[6] made detailed recommendations on the process of referral. These can be seen in Table 15.9. However, the authors noted that 'formal trials of the impact of different referral criteria are not easily carried out', and the subsequent recommendations were based on an expert committee statement.

The NHMRC guidelines recommended that:

- if a child presents with obesity in association with intellectual disability and multiple physical abnormalities, the child should be assessed by a paediatrician, an endocrinologist and/or a geneticist (level C)
- an obese child or adolescent with height–growth failure should be referred to a paediatrician or an endocrinologist or both (level B)

- conditions that cause hypothalamic obesity are rare and should be managed in a tertiary institution (level B).

Other recommendations were made around the use of very-low-energy diets, drugs and surgery **only** in specialist settings.

Table 15.9 Referral recommendations from the Scottish Intercollegiate Guidelines Network[6]

The following groups should be referred to hospital or community paediatric consultants before treatment is considered [in primary care]:

- Children who may have serious obesity-related morbidity that requires weight loss (for example, benign intracranial hypertension, sleep apnoea, obesity hypoventilation syndrome, orthopaedic problems and psychological morbidity)
- Children with a suspected underlying medical (for example, endocrine) cause of obesity including all children under 24 months of age who are severely obese (BMI > 99.6th centile)
- All children with BMI > 99.6th centile (who are at higher risk of obesity-related morbidity)

The primary purposes of referral are to exclude underlying medical causes of obesity and to treat comorbidity. Most patients will not have an underlying medical cause and should be discharged back to management in the community

In patients with no underlying medical causes but with serious obesity-related comorbidity, treatment of the comorbidity may be indicated. In many cases (for example, type 2 diabetes), such treatment will be enhanced by weight management. In secondary care, treatment should follow the principles outlined above, but weight loss, rather than weight maintenance may be the appropriate aim

Where medical causes of obesity (or related) comorbidities exist, weight loss is indicated, and specialist referral may be appropriate

Where there is no underlying medical cause of obesity, patients should be referred back to primary care with the maintenance/prevention message reinforced

Obese children showing signs of distress and their families should be considered for referral for psychological assessment and treatment

15.2.7 Harms arising in children and adolescents who undergo weight management/maintenance programmes

15.2.7.1 Evidence statements (Table 15.10)

Table 15.10 Evidence statements and grading

No.	Evidence statement	Grade
Harms (from trials that reported weight loss)		
1	There is no evidence to suggest that professionally administered weight management programmes for children and adolescents increase the likelihood of developing eating disorders or cause psychological harm	2+
2	There is no evidence to suggest that professionally administered weight management programmes for children and adolescents have a negative impact on growth or lean mass loss	2–
3	There is no evidence to suggest that professionally administered weight management programmes for children and adolescents have a negative impact on psychosocial well-being	2+
Generalisability (from trials that reported weight loss)		
4	Generalisability of the findings remains unclear, as no study was conducted in the UK and majority of the studies were based in highly specialised research settings	N/A
5	Generalisability of the findings is hindered by the methodological limitations of the retrieved studies	N/A

N/A, not applicable.

15.2.7.2 Evidence review on harms

Types of study

We only included studies that specifically assessed the effects on eating behaviours and child/adolescent growth of professionally prescribed weight loss programmes, with the following designs:

- RCTs
- controlled clinical trials

- before-and-after studies
- cohort studies
- non-comparative studies (case series and case studies).

Again, we decided to adopt more expanded inclusion criteria due to the nature of the existing evidence. Studies that examined the effects of unsupervised dieting were not included in this review.

Update searches have been undertaken, however no studies were identified.

Types of participant

Obese and/or overweight children and adolescents.

Types of outcome

- Primary outcomes to be (not self-reported) reports of eating disorders and growth variations.

Reports of harm in other guidelines

According to the National Guideline Clearinghouse Guideline synthesis,[1] none of the included guidelines reported any harm that may arise if children or adolescents undergo professionally delivered weight management/maintenance programmes. Only the United Stated Preventive Services Task Force (USPSTF)[98] tackled the topic of eating disorders, reporting one good-quality RCT in a primary care setting, where no problematic eating was detected in adolescents participating in a behavioural intervention treatment. The NHMRC[2] recommended that 'abnormal eating behaviours in childhood and adolescent obesity should be addressed both before and during weight-management programs'.

Effects of professionally prescribed weight loss programmes on eating behaviour

We found one recent systematic review[99] that examined the effect of dieting on eating behaviour and psychosocial status. The findings of the five studies that

looked at the effects of dieting on eating behaviours, suggested that professionally delivered weight loss interventions did not contribute to the development of eating disorders in overweight children and adolescents.

Braet and coworkers[58] assessed a 10-month inpatient cognitive behaviour weight loss programme, where the participants' median age and BMI was 14 years and 33 kg/m^2, respectively. At post-treatment, scores on the Drive for Thinness subscale of the Eating Disorder Inventory (EDI) decreased significantly, and the number of participants scoring at least one standard deviation above the norm on the subscale (showing an increased risk for developing an eating disorder) decreased from 7 to 2 during the treatment. On the Dutch Eating Behaviour Questionnaire (DEBQ), scores on the external eating subscale decreased, and no significant changes were found on the Emotional Eating or Restrained Eating scales.[58]

Levine and coworkers[100] assessed a family-based behaviour change programme in children with a mean age of 10.2 years and weight of 79.7 kg. Symptoms of eating disorders were measured at pre-treatment and follow-up by the Children's Eating Attitudes Test (ChEAT), which showed a statistically significant decreasing trend at follow-up, suggesting that concerns with dieting, unhealthy dieting behaviours and concerns regarding being overweight tended to decrease.[100]

Epstein and coworkers[101] examined an intervention in which all participants were given the traffic light diet, and some also received training in problem solving techniques. Participants had a mean age of 10.3 years and a weight of 59.5 kg. The Kids' Eating Disorder Survey (KEDS) which assesses weight dissatisfaction, purging/restricting and total symptoms of disordered eating did not show any significant changes.[101]

Braet and Van Winckel[57] evaluated a cognitive behaviour change programme that delivered self-regulation, problem solving techniques and promotion of lifestyle change to children with a mean age of 11 years and weight of 62 kg. This

programme was delivered either in a group or to individuals or as summer camp component. The DEBQ assessment showed that external eating decreased and restrained eating increased during the 4.6 years. On the other hand, emotional eating did not change. At follow-up, 9% of the participants scored more than one standard deviation above the norm on the bulimia subscale of the EDI.[57]

Another study of Epstein and coworkers[102] consisted of a 10-year follow-up of an earlier trial where all interventions were family based and included the traffic light diet. Participants had a mean age of 10.4 years and a weight of 55.3 kg. On a medical history form, 4% of the participants reported that they had been treated for bulimia nervosa during the 10 year follow-up, and none reported treatment for anorexia nervosa.[102] However, the authors pointed out that this prevalence of bulimia was not high, as self-reported studies have shown an average prevalence for eating disorders of 9% in girls.

Effects of professionally prescribed weight loss programmes on child/adolescent growth

No recommendations were found in the National Guideline Clearinghouse Guideline synthesis or the NHMRC guidelines regarding the effects of professionally prescribed weight loss programmes on child or adolescent growth.

One study[103] examined whether a multidisciplinary weight loss programme in adolescents with severe obesity allowed adequate growth and avoided lean mass loss. Participants were aged 9 to 17 years and had a mean BMI of 38.4 ± 8.0 kg/m^2 for girls and 34.5 ± 3.2 kg/m^2 in boys. Total lean mass (LM) did not vary and was positively correlated to pubertal development in both sexes before and after weight loss.[103]

Another study[104] examined height velocities prior to and during weight reduction in 14 girls and 5 boys with a mean ± SD age of 8.5 ± 2.7, achieved by restricting caloric intake in all cases to two-thirds of the usual daily intake. Protein intake was maintained at 1.5–2.0 g/kg of initial body weight per day. A significant correlation between the change in z-scores of height velocity prior to and during

weight reduction and the change in weight was observed. However, it should be noted that this was a poor-quality study, and biases may have occurred, leading to some misinterpretation of results.[104]

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Section 5: Management of obesity 2 (continued)

Sibutramine (Reductil): marketing authorisation suspended
On 21 January 2010, the MHRA announced the suspension of the marketing authorisation for the obesity drug sibutramine (Reductil). This follows a review by the European Medicines Agency which found that the cardiovascular risks of sibutramine outweigh its benefits. Emerging evidence suggests that there is an increased risk of non-fatal heart attacks and strokes with this medicine.

The MHRA advises that:

- Prescribers should not issue any new prescriptions for sibutramine (Reductil) and should review the treatment of patients taking the drug.
- Pharmacists should stop dispensing Reductil and should advise patients to make an appointment to see their doctor at the next convenient time.
- People who are currently taking Reductil should make a routine appointment with their doctor to discuss alternative measures to lose weight, including use of diet and exercise regimens. Patients may stop treatment before their appointment if they wish.

NICE clinical guideline 43 recommended sibutramine for the treatment of obesity in certain circumstances. These recommendations have now been withdrawn and healthcare professionals should follow the MHRA advice.

15 Clinical management of obesity (contd).

15.3 Adults

15.3.1 Factors to be considered in the clinical assessment of adults who are overweight or obese

[The aim of an initial assessment is to identify individuals who are at increased risk and who would benefit from intervention. This initial assessment should follow the classification of the degree of overweight or obesity as recommended by the GDG based on the earlier evidence reviews.

Therefore, the factors to be assessed at the initial presentation should be based on two evidence bases: one on the common comorbidities, and one on the effectiveness of weight loss in people with comorbidities and their expected health gain.

Further assessment(s) should aim to determine any determinants of energy imbalance.]

15.3.1.1 Evidence statements (Table 15.11)

Table 15.11 Evidence statements and grading

No.	Evidence statement	Grade
1	Initial assessment should aim to identify individuals at highest risk who have the potential to gain health benefits with weight loss, and maintenance of that weight loss	4
2	In adults who are overweight and obese, individuals at highest risk and with the potential to gain health benefits include those with current significant comorbidities, or those at high risk of developing significant comorbidities in the future	2++
3	In adults, reasons for energy imbalance are environment, genes, stress and psychological factors, current medication, life stage (early childhood and adolescence, pregnancy and childbirth, menopause) and life events (quitting smoking, marriage, giving up sport, holidays)	1++, 2++

15.3.1.2 Evidence review on factors to be assessed in adults and mature adolescents

In February 2005, the National Guideline Clearinghouse synthesised the recommendations on the assessment and treatment of obesity and overweight in adults from six published guidelines.[1] The different scopes, target populations, intended users, and practices covered can be seen in Appendix 15 (evidence tables of included studies). The authors of the synthesis identified areas of agreement between the included guidelines surrounding assessment. They concluded that:

> ‘AGA, BWH, and Singapore MOH recommend screening for comorbid conditions, particularly obesity-related health risks, as part of the medical evaluation. The presence or absence of such conditions is helpful in determining the intensity of therapy. ACP refers to the assessment of comorbid conditions as part of an algorithm that is provided for the suggested management of obesity. AGA and Singapore MOH also recommend screening for psychiatric disorders, such as depression and binge eating, which may affect the success of therapy. BWH points to the presence of depression, disinhibition, and

binge eating at baseline as factors that increase the likelihood of weight regain after an initial weight loss.'[1]

No area of disagreement was noted for assessment.

The individual guideline recommendations on assessment are given in Table 15.12.

Table 15.12 Existing recommendations on assessment for obesity

AGA (2002)	A medical evaluation is needed to identify patients who either have, or are at risk for, obesity-related medical complications. This assessment should include a careful history, physical examination (including determination of BMI) and laboratory tests to identify eating and activity behaviours, weight history and previous weight loss attempts, obesity-related health risks, and current obesity-related medical illnesses.
ACP (2005)	No specific recommendations offered However, the assessment of comorbid conditions is indicated in an algorithm contained in the original guideline for the suggested management of obesity. Obesity-related comorbid conditions such as hypertension, impaired glucose tolerance, diabetes mellitus, hyperlipidaemia, and obstructive sleep apnoea are noted in the original guideline
ACPM (2001)	No recommendations offered
AGA (2002)	The medical evaluation should include an assessment of obesity-related health risks and current obesity-related medical illnesses. Obesity-related health risks, the presence of other disease risk factors, and coexisting obesity complications should be used to help determine the need for obesity therapy and the aggressiveness of the treatment approach. The presence of psychiatric illnesses (for example, severe depression, substance abuse, or binge-eating disorders) should also be assessed, as all of these disorders can derail weight loss efforts.
BWH (2003)	Clinicians should consider risk factors when deciding upon treatment Health risks associated with obesity include high blood pressure, type 2 diabetes, coronary heart disease,

	dyslipidaemia, stroke, osteoarthritis, sleep apnoea, cancer and mortality. These risks increase with increasing degrees of overweight and obesity. Specific factors, such as race, ethnicity, age, general and social conditions, may also increase or decrease an individual's health risks at different stages of overweight or obesity.
SINGAPORE MOH (2004)	In clinical evaluation of patients, practitioners should consider and exclude predisposing factors for, and secondary causes of, obesity (GPP) Overweight and obese adults should be screened for comorbid conditions and should be stratified according to their health risks, in particular for cardiovascular disease, prior to the commencement of treatment (grade C, level IV) The presence of depression and binge eating disorders in obese patients must be evaluated for, with appropriate referral for psychiatric treatment (grade B, level IIa)
USPSTF (2003)	No recommendations offered

ACP, American College of Physicians; ACPM, American College of Prevention Medicine; AGA, American Gastroenterological Association; BMI, body mass index; BWH, Brigham and Women's Hospital; MOH, Ministry of Health; USPSTF, United States Preventive Services Task Force.

The National Health and Medical Research Council (Australia) (NHMRC) guidelines[2] on the management of overweight and obesity in adults recommended that after discussing weight with the individual and whether measurements should be taken, the next steps were to assess and treat associated comorbidities (specifically to measure blood pressure, plasma cholesterol, lipids and glucose) and to determine the individual's need to lose weight. The decisions on which factors to assess were made on the identified common comorbidities (see Section 1 Chapter 3 section 3.1) and also on the evidence for the benefit of weight loss in individuals with these conditions. Diseases and conditions associated with obesity (see Table 15.13) were listed and further categorised into two groups: those with indirect links (as a result of metabolic consequences) and those with direct links (as a result of the excess weight).

Table 15.13 Diseases and conditions associated with obesity[2]

Relative risk (RR)	Associated with metabolic consequences	Associated with excess weight
Greatly increased RR > 3	Type 2 diabetes	Sleep apnoea
	Gall bladder disease	Breathlessness
	Hypertension	Asthma
	Dyslipidaemia	Social isolation and depression
	Insulin resistance	Daytime sleepiness and fatigue
	Non-alcoholic fatty liver	
Moderately increased RR 2 –3	Coronary heart disease	Osteoarthritis
	Stroke	Respiratory disease
	Gout/hyperuricaemia	Hernia
		Psychological problems
Slightly increased RR 1– 2	Cancer[a]	Varicose veins
	Reproductive abnormalities/impaired fertility	Musculoskeletal problems
	Polycystic ovaries	Bad back
	Skin complications	Stress incontinence
	Cataract	Oedema/cellulitis

[a] Breast, endometrial, colon and others.

The Agency for Healthcare Research and Quality (AHRQ) report on obesity in the elderly[3] concluded that:

> 'Those at risk for obesity-associated health problems stand to benefit most from intervention, if such intervention alters their weight-related risk. The strongest evidence for obesity intervention is for those with cardiovascular risk. Cardiovascular risk factors – including family history, diabetes, tobacco use, or dyslipidemia – can help identify this group.'[3]

Although no recommendations were made on this evidence, it seems logical that an initial assessment should focus on identifying those who have most to gain.

15.3.2 Energy imbalance in adults and mature adolescents

The NHMRC guidelines[2] considered that the reasons (how and why) for energy imbalance should be assessed. The mechanism for energy imbalance is the imbalance between food intake (total energy and the energy per unit weight of food) and the energy expenditure, but the evidence suggested that food intake and levels of physical activity could only be estimated approximately in a clinical (or non-specialist) setting.

Reasons for why this imbalance should occur were categorised into six key areas: environment, genes, stress and psychological factors, current medication, life stage (early childhood and adolescence, pregnancy and childbirth, menopause) and life events (quitting smoking, marriage, giving up sport, holidays). The authors made evidence statements as follows:

- The modern environment is a potent stimulus for obesity.
- Some rare cases of single-gene mutations cause severe obesity disorders, which usually manifest early in life.
- In general, cases of severe obesity are more likely to have a specific genetic basis than cases of overweight, which may result from environmental influences alone.
- Psychological stress can have variable effects on a person's body weight.
- Several prescription medications can cause weight gain.
- Obesity in childhood and adolescence is a risk factor for obesity later in life.
- The tracking of childhood obesity into adult obesity is stronger for older children than for younger ones.

- Pregnancy and menopause are critical periods for weight gain in women.
- It appears that a change in weight at menopause can be prevented by lifestyle change.
- Hormone replacement therapy after menopause can result in reduced body-fat gain (particularly on the upper body) when compared with a placebo.
- Certain life events – for example, marriage, holidays, and giving up sport – can have an influence on body fatness.
- Quitting smoking can cause significant weight gain – on average 5–6 kg in the first year.
- Lack of motivation and a history of failed attempts to lose weight may make it more difficult to maintain a low body weight.
- Psychological factors – including early life experiences – can play an important part in the development of overweight or obesity.[2]

15.3.3 Lifestyle interventions (diet, behaviour therapy and physical activity) for weight loss and other outcomes in adults

All summary statistics, other than those presented in the figures, can be found in Appendix 17. Please note that all summary statistics have been checked by a consultant statistician.

15.3.3.1 Evidence statements – diet (Table 15.14)

Table 15.14 Evidence statements and grading

No.	Evidence statement	Grade
1	Energy balance is critical to weight loss. Caloric expenditure must exceed caloric intake	2++ (see review on energy imbalance)
Weight loss		
2	Overall, a 600 kcal deficit diet or low-fat diet is effective for weight loss: a change of approximately –5 kg (95% CI -5.86kg to -4.75kg, range –0.40 kg to –7.80 kg) compared with usual care at 12 months Median weight change across all studies was approximately –4.6 kg (range –0.60 kg to –7.20 kg) for a 600 kcal deficit diet or low-fat diet and +0.60 kg (range +2.40 kg to –1.30kg) for usual care (n = 12 comparisons)	1++
3	Overall, a low-calorie diet (1000–1600 kcal/day) is effective for weight loss: a change of approximately –6 kg (95% CI -9.05kg to -3.24kg, range –5.30 kg to –7.00 kg) compared with usual care at 12 months Two studies showed an absolute weight change of –5.50 kg and –5.90 kg for the low-calorie diet compared with weight change of +1.50 kg and –0.60 kg for usual care (n = 2 comparisons)	1+
4	One study showed that a VLCD (420kcal per day) for a limited period of 8 weeks, resulted in a significant weight change of -13.40 kg (95% CI -18.43kg to -8.37kg) compared with usual care at 12 months. Absolute weight changes were –11.10 kg for the VLCD compared with +2.30 kg for usual care (n = 1 comparison)	1+

No.	Evidence statement	Grade
5	Overall, a low-calorie diet is as effective for weight loss as a 600 kcal deficit diet or low-fat diet: a change of approximately +1 kg (95% CI -1.06kg to 2.63kg, range +1.63 kg to +0.20 kg) compared with usual care at 12 months Two studies showed an absolute weight change of –0.82 kg and –3.00 kg for the low-calorie diet compared with weight change of –2.45 kg and –3.20 kg for the 600 kcal deficit diet or low-fat diet (n = 2 comparisons)	1+
6	One study showed that a VLCD (420kcal per day), for a limited period of 12 weeks, resulted in a (non-significant) weight change of –4.70 kg (95% CI -11.79kg to 2.39kg) compared with a 600 kcal deficit diet or low-fat diet at 24 months. Absolute weight changes were –6.70 kg for the VLCD compared with 2.00 kg for a 600 kcal deficit diet or low-fat diet (n = 1 comparison)	1+
7	Overall, a 800kcal/day VLCD (used for 4 days a week, in conjunction with a 1200kcal/day low-calorie diet) is as effective for weight loss as a continuous low-calorie diet: a change of approximately 0 kg (range +3.52 kg to –3.56 kg) compared with a low-calorie diet at 12 months (n = 1 comparisons) Overall, a 750kcal/day maximum VLCD (used for 2 days a week, in conjunction with a individualised low-calorie diet of weight in lbsx12-1000kcal) is as effective for weight loss as a continuous low-calorie diet: a change of approximately 0 kg (range +2.11 kg to –2.33 kg) compared with a low-calorie diet at 12 months (n = 2 comparisons from 1 study) Overall, a VLCD (800kcal/day for 8 weeks) is as effective for weight loss as a continuous low-calorie diet for 8 weeks: a change of approximately 1.13 kg (range +3.06 kg to –5.32 kg) compared with a low-calorie diet at 18 months (n = 2 comparisons from 1 study)	1++

No.	Evidence statement	Grade
8	Overall, a low-fat diet is as effective for weight loss as other diets (with the same calorie content): a change of approximately 0.5 kg (95% CI -1.14kg to 2.11kg, range +5.70 kg to –4.24 kg) compared with other diets at 12 months Median weight change across all studies was approximately –3.00 kg (range –1.60 kg to –5.20 kg) for a low-fat diet and –3.50 kg (range –0.96 kg to –8.70 kg) for other diets with the same calorie content (n = 5 comparisons)	1++
9	Overall, a PSMF (food-based, with a calorie content in the range of 1400–1900 kcal/day) is as effective for weight loss as a 600 kcal deficit diet or low-fat diet: a change of approximately –0.5 kg (95% CI -2.17kg to 1.04kg, range +1.10 kg to –1.88 kg) compared with a 600 kcal deficit diet or low-fat diet at 12 months Median weight change across all studies was approximately –4.34 kg (range –2.10 kg to –5.10 kg) for a PSMF and –3.10 kg (range –2.46 kg to –3.20 kg) for a 600 kcal deficit diet or low-fat diet (n = 3 comparisons)	1++
10	Overall, a PSMF (based on food or VLCD) is as effective for weight loss as low-calorie diet: a change of approximately –0.6 kg (95% CI -2.35kg to 1.11kg, range +0.90 kg to –4.00 kg) compared with low-calorie diet at 12 months. Median weight change across studies with a calorie content of approximately 400 kcal/day (food VLCD, alternating with a low-calorie diet) was approximately –14.20 kg (range –10.60 kg to –17.33 kg) for a PSMF and –10.50 kg (range –6.60 kg to -14.43 kg) for a low-calorie diet. One study showed that a PSMF (low carb, no details of calories), resulted in a (non-significant) weight change of +0.90 kg (95% CI -1.23kg to 3.03kg) compared with a low-calorie diet at 12 months. Absolute weight changes were –2.10 kg for the PSMF compared with –3.00 kg for a low-calorie diet (n = 4 comparisons)	1++

No.	Evidence statement	Grade
11	Overall, an 8-week PSMF (based on food with a calorie content of 1000 kcal/day) is as effective for weight loss as an 8-week VLCD (420kcal/day) PSMF: a change of approximately +1.5 kg (95% CI -1.57kg to 4.69kg, range +3.76 kg to –0.20 kg) compared with low-calorie diet at 18 months Median weight change across studies with a calorie content of approximately 1000 kcal/day (food based) was approximately -4.9kg (range -1.13kg to -8.64kg) for a protein sparing modified fast and –6.6kg (range -0.93kg to -12.40kg) for a very low calorie PSMF diet (meal replacements) (n = 4 comparisons from 1 study)	1++
12	One study showed that a low-calorie diet, resulted in a (non-significant) weight change of +0.30 kg (95% CI -2.42 to 3.02) compared with a very-low-fat diet at 12 months. Absolute weight changes were –3.00 kg for the low-calorie diet compared to –3.30 kg for a very-low-fat diet.	1+
13	One study showed that a protein sparing modified fast (based on food, calorie content 1700–1800 kcal/day), resulted in a weight change of +1.20 kg compared with a very-low-fat diet at 12 months. Absolute weight changes were –2.10 kg for the (food based) PSMF compared with –3.30 kg for a very-low-fat diet	1+
14	One study showed that a high-protein diet (25% of energy from protein, low glycaemic index), resulted in a (non-significant) weight change of –1.90 kg compared with a standard/medium-protein diet (12% of energy from protein, high glycaemic index) at 12 months. Absolute weight changes were –6.20 kg for the high-protein diet compared with –4.30 kg for a standard/medium-protein diet	1+
15	There is not enough evidence to compare the use of diets in populations with specific comorbidities	N/A
16	The effectiveness of all diets appears to change over time, with a trend for greater weight loss in the short term (up to 12 months), with a reduction in overall weight loss in the longer term (up to 60 months)	1++

No.	Evidence statement	Grade
Outcomes other than weight loss (from trials that reported weight loss)		
17	Overall, a 600 kcal deficit diet or low-fat diet is more effective in lowering total cholesterol levels than usual care: a change of approximately –0.21 mmol/l (95% CI -.34 to -0.08, range –0.34 mmol/l to –0.08 mmol/l) at 12 months Median change across studies was approximately –0.37 mmol/l (range –0.23 mmol/l to –0.42 mmol/l) for a 600 kcal deficit diet or low-fat diet and –0.15 mmol/l (range –0.03 mmol/l to –0.23mmo/l) for usual care A 600 kcal deficit diet or low-fat diet is also more effective in lowering levels of LDL-cholesterol (–0.13 mmol/l, 95% CI -0.26 to 0.00), HDL-cholesterol (+0.06 mmol/l, 95% CI 0.03 to 0.09), triglycerides (–0.19 mmol/l, 95% CI -0.31 to -0.06), systolic blood pressure (–3.78 mmHg, 95% CI -5.53 to -2.03), and diastolic blood pressure (–3.44mmHg, 95%CI -4.86 to -2.01) than usual care at 12 months (n = 4 comparisons)	1++
18	Overall, a 600 kcal deficit diet or low-fat diet is more effective in lowering total cholesterol levels than a PSMF (food-based, with a calorie content in the range of 1400–1900 kcal/day): a change of approximately –0.18 mmol/l (95% CI -0.35 to -0.02, range –0.15 mmol/l to –0.37 mmol/l) at 12 months Median change across studies was approximately –0.21 mmol/l (range –0.14 mmol/l to –0.26 mmol/l) for a 600 kcal deficit diet or low-fat diet and +0.01 mmol/l (range +0.16 mmol/l to –0.11mmo/l) for a PSMF (food-based, with a calorie content in the range of 1400–1900 kcal/day). But the PSMF appears to be more effective in improving HDL-cholesterol levels (+0.08 mmol/l, 95% CI 0.03 to 0.18), and triglyceride levels (–0.28 mmol/l, 95% CI -0.48 to -0.09) than a 600 kcal deficit diet or low-fat diet at 12 months (n = 3 comparisons)	1++
19	In people with insulin resistance, one study showed that a 600 kcal deficit diet or low-fat diet resulted in a lowering of fasting plasma glucose of –0.28 mmol/l (95% CI -0.47 to -0.09) compared to usual care at 12 months. Absolute changes were –0.21 mmol/l for the 600 kcal deficit diet or low-fat diet compared with +0.07 mmol/l for usual care (n = 1 comparison)	1+

No.	Evidence statement	Grade
20	In people with a family history of diabetes, one study showed that a low-fat diet resulted in lowering of total cholesterol levels of –0.42 mmol/l (95% CI -0.75 to -0.09) compared with a low-calorie diet at 12 months. Absolute changes were –0.18 mmol/l for the low-fat diet compared with +0.24 mmol/l for the low-calorie diet (n = 1 comparison)	1+
21	In people with type 2 diabetes, one study showed significant lowering of fasting plasma glucose (–4.50 mmol/l, 95% CI -7.07 to -1.93) and %HbA1c (–2.60%, 95% CI -4.36 to -0.84) at 18 months after use of a protein sparing modified VLCD (meal replacements or food based, 400 kcal/day) alternating with a low-calorie diet compared with continuous use of a low-calorie diet (n = 1 comparison)	1+
22	One study showed that a low-calorie diet, resulted in an increase in HDL-cholesterol levels of +0.10 mmol/l (95% CI 0.01 to 0.19) compared with a very-low-fat diet at 12 months. Absolute changes were +0.09 mmol/l for the low-calorie diet compared with –0.01 mmol/l for a very-low-fat diet (n = 1 comparison)	1+
23	One study showed that a PSMF (based on food, calorie content 1700–1800 kcal/day), resulted in an increase in HDL-cholesterol of +0.10 mmol/l (95% CI 0.02 to 0.18) compared with a very-low-fat diet at 12 months. Absolute changes were +0.09 mml/l for the PSMF compared to –0.01 mmol/l for a very-low-fat diet (n = 1 comparison)	1+
24	No significant differences were seen between diets for other outcomes at 12 months	1++
Harms		
25	No evidence statements can be made as reporting of harms and adverse events was rare and ad hoc	N/A

No.	Evidence statement	Grade
Generalisability		
26	Only two studies were conducted solely in the UK, with the majority of studies done in the USA (n = 29) Many of the studies (15 of the 34 unique studies) were based in secondary care or specialist outpatient or university clinics (although it was often difficult to assess exactly what setting), with only two based in primary care. Five workplace studies were included as the aim of the study was to evaluate the effectiveness of the diet and not the effect of the setting. However, the resulting effect may have been different if the intervention was delivered in a clinical setting Where reported, participants were recruited as volunteers (that is, through advertising) in 19 studies and through selection (that is, some element of referral or from waiting lists) in five studies It is difficult therefore to know how generalisable the results of the included studies are to the UK population, particularly in primary care	1++
27	From the included studies, the duration of intervention varied considerably (range 8 weeks to 48 months) and the rate of follow-up varied; for example, one study made contact every week for 18 months. However, most studies used either a one visit every month approach or an approach of decreased contact over time (for example, every 2 weeks, then every month, then every 2 months)	1++
28	Dietary advice and support were provided most often by a dietitian. Other personnel who delivered interventions were physicians, research nurses, health educators, graduate students, diet group leaders, experts in nutritional counselling and behavioural therapists	1++
29	One assumption could be that the effect size achieved in the included studies may be smaller in practice; in a less motivated, non-volunteer population and less intensive follow-up delivered by generalists	N/A

HDL, high-density lipoprotein; LDL, low-density lipoprotein; N/A, not applicable; PSMF, protein-sparing modified fast; VLCD, very-low-calorie diet.

15.3.3.2 Evidence review on dietary interventions

This review is primarily based on a health technology appraisal (HTA) published in 2004.[4] The aim of the HTA was to review systematically obesity treatments in adults to identify therapies that impact by achieving weight reduction, risk factor modification or improved clinical outcomes. All randomised controlled trials (RCTs) of dietary interventions in adults with a body mass index (BMI) of 28 or more were included. The duration of the trials had to be for 52 weeks or more. The main outcome was weight change in kilograms at 12 months' follow-up.

The diets were classified as follows:

- healthy eating advice
- 600 kcal/day deficit or low-fat diet
- low-calorie diet (1000–1600 kcal/day)
- very-low-calorie diet (VLCD) (< 1000 kcal/day)
- protein-sparing modified fast (PSMF) (carbohydrate content of 40 g or less)
- low-carbohydrate, high-monounsaturated-fat diet
- salt restriction.

Due to reporting issues, healthy eating advice and 600 kcal/day deficit or low-fat diets were classified together, along with diets where the fat or calorie restriction was not stated or could not be estimated.

We used the definitions as above when classifying diets. Because of some concerns about the definitions, we have tried to be explicit (that is, include as much detail as possible about the dietary content) in both the evidence tables and the evidence statements.

Other outcomes included longer-term weight loss and blood pressure, lipids and fasting blood glucose. However, these outcomes were reported in only some of the included trials so the results are based on more limited evidence (often only the results of one trial) than that of weight change at 12 months so caution should be exercised when interpreting these.

Another review is cited which addressed the diagnosis and treatment of obesity in older people (defined as aged 60 years or more), a technology assessment published in 2003 by the US Agency for Healthcare Research.[3]

The aim of the review was to reassess the evidence for the diagnosis and treatment of obesity in older people. The key clinical question relevant to this evidence review is 'Are there dietary or behavioural therapies that improve net health outcomes in obese older people?' The defined inclusion criteria for dietary interventions were:

- RCT of fair or good quality
- weight loss or reduction in BMI, waist circumference, waist-to-hip ratio as a reported outcome
- BMI of 25 kg/m^2 or more
- minimum 12-month follow-up
- population generalisable to a typical US primary care population
- sample mean age of 60 years or more.

Only one trial was reported as evaluating the effectiveness of a dietary intervention only (that is, not combined with any other intervention such as behavioural treatment) and satisfied the criteria above. However, when we examined this trial in detail, the intervention was not diet alone. See excluded studies (Appendix 16). No additional studies were identified from the Update searches.

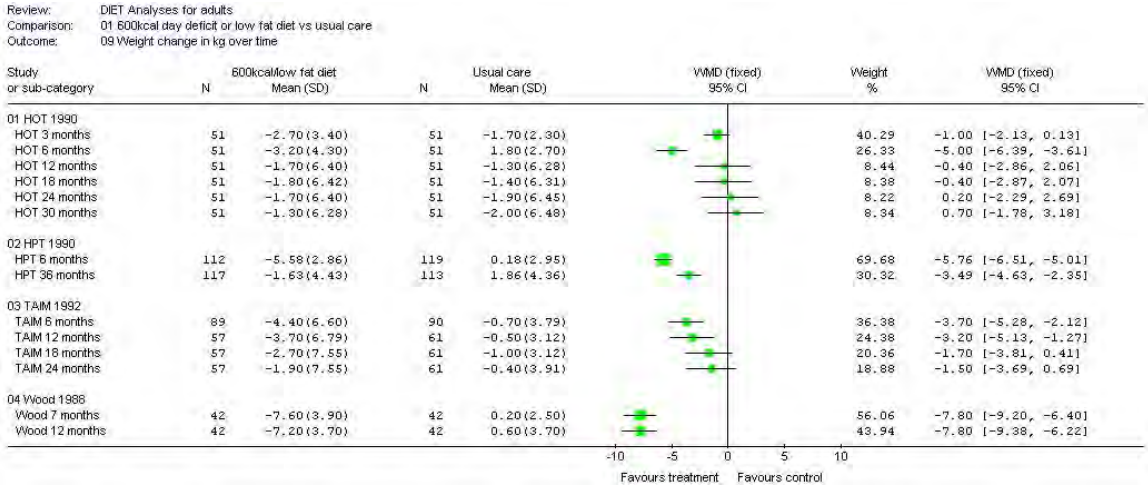
600 kcal/day deficit or low-fat diet* compared with usual care

A total of 13 RCTs were included in the Avenell HTA.[4] No additional studies were identified for this comparison. One study[5] was conducted in a workplace setting, but was included as the setting was not the focus of the study. One HTA included study was excluded[6-8] in this review because not all participants were overweight.

Weight loss

Overall, there was an significant weight change of –5.32 kg at 12 months in this group (weighted mean difference [WMD] 95% confidence interval (CI) –5.88 to -4.75)† when compared with a control group, and although there was statistical heterogeneity ($p \leq 0.00001$, $I^2 = 76.7\%$) between the 12 included studies the direction of effect was consistent.[4] (Figure 15.1). One cluster randomised controlled trial (C-RCT) reported a mean ± SD weight change at 12 months of -0.88 ± 4.0 kg for the diet group and 1.3 ± 3.0 kg for the control group (not statistically significant).

Figure 15.1 Maintenance of weight loss over time for all adults on a low-fat or 600 kcal/day deficit diet compared with usual care



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* Due to lack of reporting, healthy eating advice and diets where the fat or calorie restriction was not estimable are included in this category.

† Recalculated with sample size halved for control group in Pritchard 1999[18]

Other outcomes

At 12 months, there were significant improvements in blood pressure (change in diastolic blood pressure [DBP] –3.44 mm Hg, WMD 95% CI –4.86 to –2.01 based on four trial results; change in systolic blood pressure [SPB] –3.78 mm Hg, WMD 95% CI –5.53 to –2.03 based on four trial results), lipids (change in total cholesterol –0.21, WMD 95% CI –0.34 to –0.08 based on four trial results), and fasting plasma glucose (change in fasting plasma glucose –0.28 mmol/l, WMD 95% CI –0.47 to –0.09 based on one trial) compared with usual care. But these were not maintained over time, even in obese populations with hypertension or type 2 diabetes. In an obese population with hypertension, changes in SBP and DBP in the diet group compared with the control group were not significant at 18 months (one study only). The data suggested that a low-fat diet or 600 kcal/day deficit diet prevented the development of diabetes and improved blood pressure control.[4]

Other factors

No additional analysis was carried out on the effect of age, ethnicity, socioeconomic status, previous treatment for obesity, motivation, frequency or length of the intervention in the HTA.[4]

Gender

Three studies recruited men only,[5;9;10] and a further four studies[11-14] had mainly male participants. No studies recruited women only.

The Dietary Intervention Study of Hypertension trial (DISH) showed no difference between men and women for weight loss (–11.0 kg vs –9.7 kg respectively, 45.8% and 46.8% lost 5% or more of initial body weight, respectively) at 56 weeks. Similarly, gender was not significantly associated with weight loss at 6 months in the Trial of Antihypertensive Interventions and Management (TAIM) study.[14]

Age

The age range of participants varied (overall, range 20 years minimum to 80 years maximum, where reported). Some studies recruited younger adults (for example, aged 25–49 years), whereas others recruited older people (for example, aged 50–80 years).

DISH showed no difference between people aged under 60 years and those aged 60 years or over for weight loss (–11.0 kg vs –8.5 kg, respectively, 46.7% and 45.4% lost 5% or more of initial body weight, respectively) at 56 weeks.

Other groups, including black and minority ethnic groups

Although the results of the DISH trial were analysed for groups of black and white participants, we have not reported the results here as the study was based in the USA. Therefore it may be less applicable to the UK population.

Current medical conditions

Of the included studies, four studies recruited only people with hypertension,[14-17] one trial included people with 'high normal' blood pressure,[12] one trial recruited people with glucose intolerance including some with diabetes, one trial recruited people with insulin resistance,[13] one trial recruited people with one or more risk factor,[5] and one trial recruited people who had had myocardial infarction (who also received exercise).[11] The remainder recruited otherwise healthy participants.

Setting and/or healthcare professional

One study reported that there was no difference between the effect of diet counselling delivered by the doctor and the dietitian compared with the dietitian alone. The cost of 1 kg weight loss was less for the dietitian-alone group (Aus$7.30 vs Aus$9.76).[18]

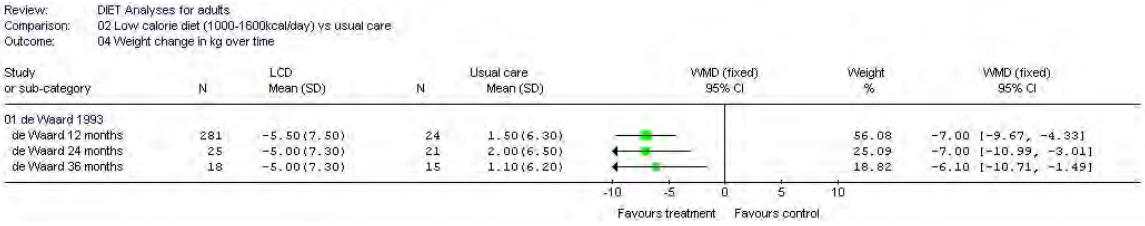
Low-calorie diet (1000–1600 kcal/day) compared with usual care

Only one study was included for this comparison in the HTA review.[19] No additional studies were identified.

Weight loss

One study (two trials based in Poland and the Netherlands) reported a weight change at 12 months of –6.25 kg (WMD 95% CI –9.05 to –3.45) compared with control. This weight loss was maintained over 36 months of follow-up.[19]

Figure 15.2 Maintenance of weight loss over time for women with breast cancer on a low-calorie diet (LCD) compared with usual care (results for Netherlands only)



Other outcomes

No other data on change in risk factors were reported.

Other factors

This trial was a single feasibility study of 107 women who were obese (BMI of 27 kg/m^2 or more), postmenopausal and who had undergone primary treatment for breast cancer with no signs of distant metastases.[19]

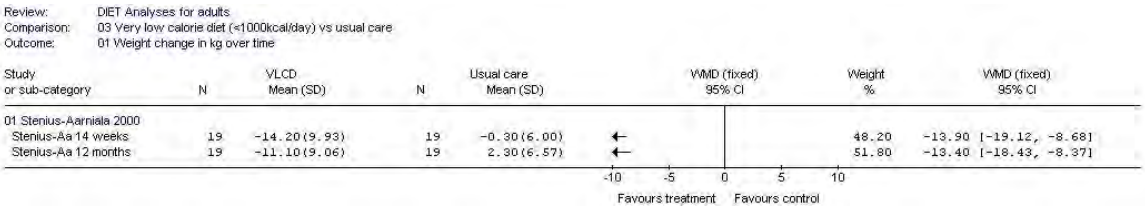
VLCD (< 1000 kcal/day) compared with usual care

Only one study was included for this comparison in the HTA review.[20] No additional studies were identified.

Weight loss

This trial reported results of a VLCD in obese participants with asthma. At 12 months, the weight change was –13.40 kg (WMD 95% CI –18.43 to –8.37) compared with control.[20]

Figure 15.3 Maintenance of weight loss over time for people with asthma on a very-low-calorie diet (VLCD) compared with usual care



Other outcomes

Two of the participants found the liquid diet intolerable and followed an alternative low-energy diet. No other outcomes (other than those associated with asthma – see below) were reported.

Other factors

Current medical conditions

The trial reported improvements in forced expiratory volume, forced vital capacity, exacerbations of asthma, the use of rescue medications and steroids.[20]

Low-calorie diet compared with 600 kcal/day deficit or low-fat diet

Only one study was included for this comparison in the HTA review.[21;22] One additional study was identified.[23]

Weight loss

At 12 months, the low-calorie diet was associated with a summary estimate of weight change of 0.78 kg (WMD 95% CI –1.06 to 2.63, based on two trials).

Other outcomes and factors

None were reported in Shah and coworkers' trial.[21] Mean metabolic cardiac risk factor levels and blood pressure measurements improved from baseline in the low-calorie diet group (significant changes were seen for triglycerides, low-density lipoprotein [LDL], high-density lipoprotein [HDL] levels, $p \leq 0.05$), but the changes were not statistically significant at 12 months compared with the low-fat group.[23]

Age and gender

Shah and coworkers[21] recruited only women aged 25–45 years, who were otherwise healthy. Dansinger and coworkers[23] recruited both men and women of any age, who had at least one identified risk factor.

VLCD compared with 600 kcal/day deficit or low-fat diet

Only one study was included for this comparison.[24] No additional studies were identified.

Weight loss

No data were reported for weight change at 12 months.

Simonen and coworkers[24] compared a VLCD (PSMF VLCD) to a low-fat diet in people with type 2 diabetes. At 24 months, the VLCD produced a weight change of –4.70 kg compared with the low-fat diet (WMD 95% CI –11.79 to 2.39).

Other outcomes and factors

Although this trial was undertaken in a population of people with type 2 diabetes and other clinical outcomes were reported, the authors of the review did not present these results due to concern over significant baseline differences between the groups in rates of treatment of diabetes and HbA1c levels.

VLCD compared with low-calorie diet

Three studies were included for this comparison in the HTA review.[25-27] No additional studies were identified. One study[27] was conducted in a workplace setting, but was included as the setting was not the focus of the study.

Also, two trials[25;26] compared the use of a VLCD for a short period of time, in conjunction with a low-calorie diet, to continuous use of a low-calorie diet.

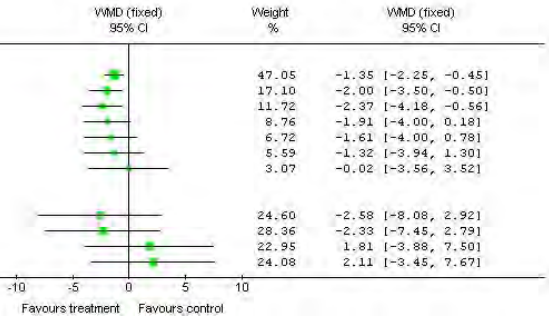
Weight loss

At 12 months, based on three trials, VLCD was associated with a weight change of –0.15 kg compared with the low-calorie diet (WMD 95%CI –2.73 to 2.43). No significant effect was seen at 18 months (change of –1.13 kg, 95% CI –5.32 to 3.06, based on results from one trial only).[27]

Figure 15.4 Maintenance of weight loss over time for people on a very low-calorie diet (VCLD) compared with a low-calorie diet (LCD)

Review: DIET Analyses for adults
Comparison: 06 Very low calorie diet (<1000kcal/day) vs LCD
Outcome: 09 Weight change in kg over time

Study or sub-category	N	VLCD Mean (SD)	N	LCD Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Viegener 1990							
Viegener 1 month	31	-3.72(1.65)	32	-2.37(2.00)		47.05	-1.35 [-2.25, -0.45]
Viegener 2 months	31	-5.91(2.88)	32	-3.91(3.19)		17.10	-2.00 [-3.50, -0.50]
Viegener 3 months	31	-7.88(3.17)	32	-5.51(4.12)		11.72	-2.37 [-4.18, -0.56]
Viegener 4 months	31	-8.89(3.78)	32	-6.98(4.67)		8.76	-1.91 [-4.00, 0.18]
Viegener 5 months	31	-9.63(4.44)	32	-8.02(5.23)		6.72	-1.61 [-4.00, 0.78]
Viegener 6 months	31	-10.19(5.06)	32	-8.87(5.56)		5.59	-1.32 [-3.94, 1.30]
Viegener 12 months	30	-8.97(6.72)	30	-8.95(7.26)		3.07	-0.02 [-3.56, 3.52]
02 Wing 1984							
Wing 6 months conc	11	-4.05(7.06)	12	-1.47(6.33)		24.60	-2.58 [-8.08, 2.92]
Wing 12 months conc	11	-1.95(6.47)	12	0.38(6.02)		28.36	-2.33 [-7.45, 2.79]
Wing 6 months space	12	-1.31(6.29)	9	-3.12(6.80)		22.95	1.81 [-3.88, 7.50]
Wing 12 months space	12	-0.58(6.08)	9	-2.69(6.68)		24.08	2.11 [-3.45, 7.67]



Other outcomes

No other outcomes were reported.

Other factors

No additional analysis was carried out on the effect of age, ethnicity, socioeconomic status, degree of obesity, current medical conditions, previous treatment for obesity, motivation or the setting or delivery of care.

Gender

One study recruited men (aged 26–52 years) only[27] and one recruited women (aged 21–59 years) only.[25]

Low-fat diet compared with another weight reducing diet

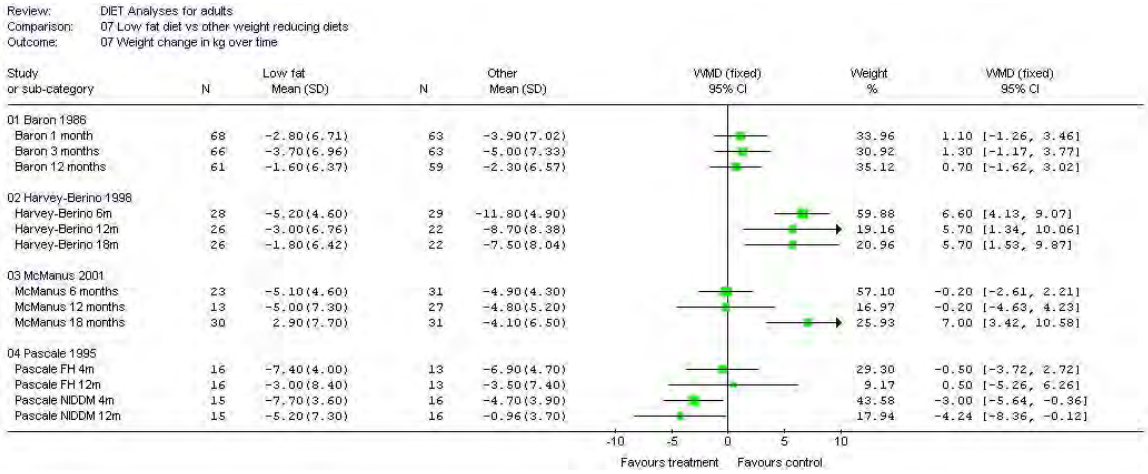
The HTA did not examine the comparisons of low-fat and low-calorie diets, where the aim of the trials was to evaluate the different types of diet using the same calorie value. The authors cited a Cochrane review[28] published in 2002. The results of trials which met our defined inclusion criteria are presented below). No additional studies were identified.

One study[29] was conducted in diet clubs and workplaces, but was included as the setting was not the focus of the study.

Weight loss

At 12 months, the overall weight change was 0.49 kg (WMD 95% CI –1.14 to 2.11 based on five trial results), again with significant heterogeneity (p = 0.03, I^2 = 62.6%).

Figure 15.5 Maintenance of weight loss over time for people on a low-fat diet compared with another weight reducing diet



Other outcomes

Only one trial[30] showed any significant effect on total cholesterol for women with a family history of diabetes. The other trials showing no significant differences on serum lipids, blood pressure or fasting blood glucose.[29;31;32]

Other factors

Gender and current medical conditions

One trial recruited women with a family history of diabetes or a diagnosis of non-insulin-dependent diabetes mellitus (NIDDM);[30] the remaining trials recruited mainly women, but who were otherwise healthy.[29;31;32]

A subgroup analysis found that a low-carbohydrate/low-fibre diet tended to be more successful for weight loss among women than a higher-carbohydrate/higher-fibre diet.[29]

Age

A subgroup analysis found that a low-carbohydrate/low-fibre diet tended to be more successful for weight loss among younger people (aged 40 years or less) than a higher-carbohydrate/higher-fibre diet.[29]

Social class

A subgroup analysis found that a low-carbohydrate/low-fibre diet tended to be more successful for weight loss among people in a lower social class (classes III–IV) than a higher-carbohydrate/higher-fibre diet.[29]

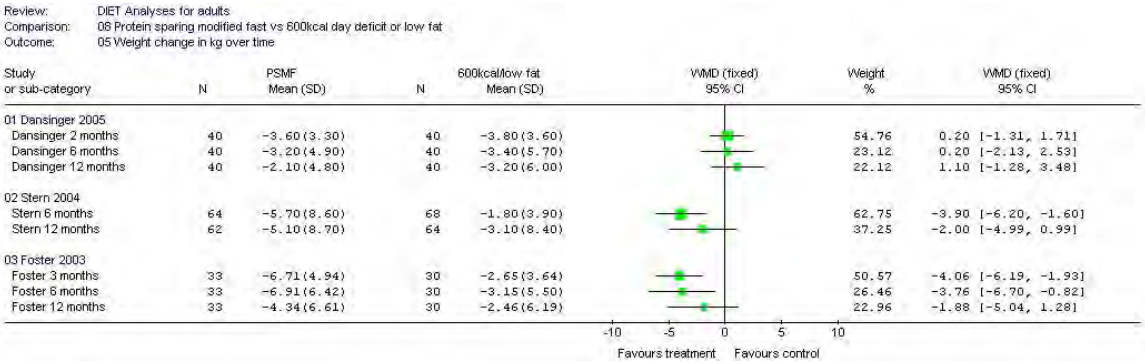
PSFM[‡] compared with 600 kcal/deficit or low-fat diet

Three trials have been published since the HTA[4] that evaluated the use of PSMF (caloried content approx 1400-1900kcal/day, food based)compared with a 600 kcal/deficit or low-fat diet in people who were overweight.[23;33-35]

Weight loss

At 12 months, the overall summary estimate of weight change was –0.56 kg (WMD 95% CI –2.17 to 1.04 based on three trial results) for the PSMF (**not** a VLCD) diet compared with a low-fat diet.

Figure 15.6 Maintenance of weight loss over time for people on a protein-sparing modified fast (PSMF) compared with a 600 kcal/deficit or low-fat diet



Other outcomes

Summary estimates at 12 months showed no significant difference between a PSMF diet and low-fat diet, apart from a significant increase in HDL levels (0.08 mmol/l, p = 0.001) on the PSMF. However, lower levels of adherence to the low-carbohydrate diet suggested that a low-fat diet may be more sustainable in the long term.[23]

Fasting plasma glucose was reported in both the Dansinger[23] and Stern studies.[33] The Stern paper did not report results overall but split into people who

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[‡] Defined as a diet with 40 g or less of carbohydrate, irrespective of calorie content.

had diabetes and those who did not. Therefore, we were not able to estimate a summary effect, but results from the Dansinger trial[23] and subgroups of people with or without diabetes in the Stern trial[33] suggested that there was no significant difference between the diets.

Other factors

No additional analysis was done.

PSMF[§] compared with low-calorie diet

Seven RCTs were included in the Avenell HTA.[4] One additional study was identified for this comparison.[23]

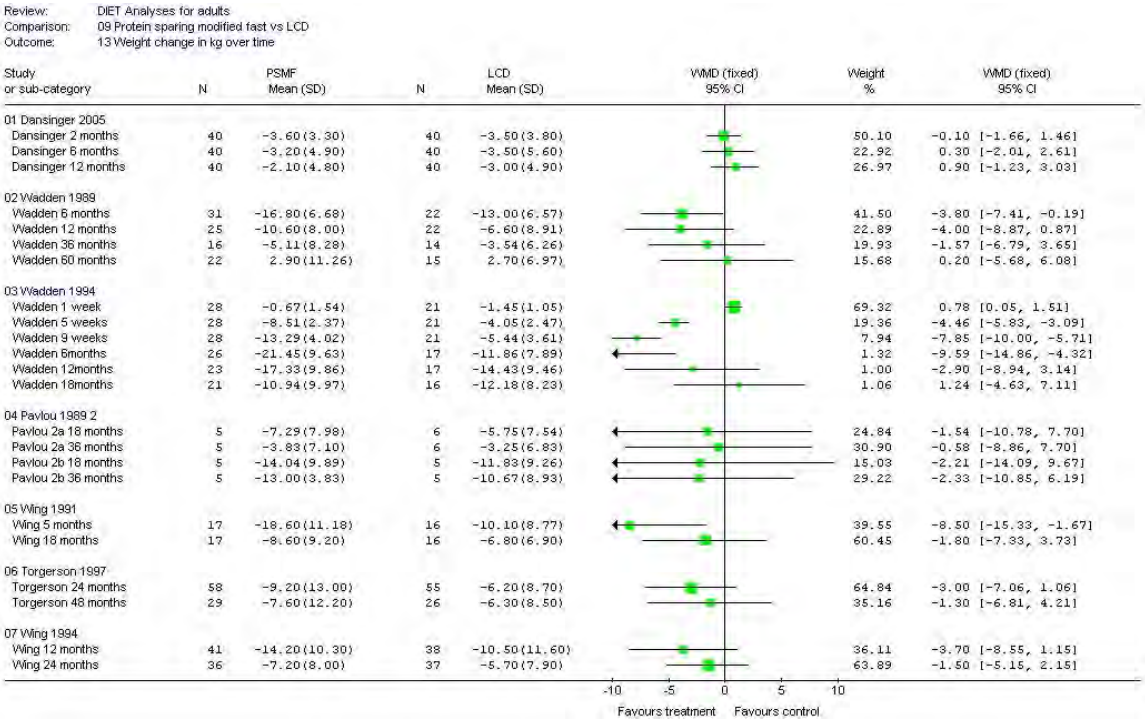
Weight loss

The overall weight change associated with a PSMF compared with a low-calorie diet at 12 months was –0.62 kg (WMD 95% CI –2.35 to 1.11 based on four trial results). No further significant effect was seen at 18[**], 24, 36 and 60 months. However, there was considerable range in the calorie content of each of the diets; three studies used approx 400-500kcal/day,[36-38] compared with one assumed to be much higher.[23]

[§] Defined as a diet with 40g or less of carbohydrate, irrespective of calorie content

[**] Problems with HTA analysis, but recalculated figures were still non-significant.

Figure 15.7 Maintenance of weight loss over time for people on a protein-sparing modified fast (PSMF) compared with a low-calorie diet (LCD)



Other outcomes

Dansinger and coworkers[23] showed no significant differences between PSMF and a low-calorie diet for changes in cholesterol, LDL or HDL levels, triglycerides, or blood pressure measurements at 12 months.

Other factors

Gender

Of the included trials, two recruited men only[27;39] and one recruited women only.[36] One trial recruited men, but then excluded them from the analysis due to small numbers.[37]

Torgerson and coworkers[40;41] did an intention to treat (ITT) analysis of results by men and women. At 24 months, the mean weight change in men was –13.0 ± 15.6 kg) in the PSMF group and –5.8 ± 9.7 kg in the low-calorie diet group (p = 0.1, non-significant). At 24 months, the mean weight change in

women was –6.8 ± 10.6 kg) in the PSMF group and –6.4 ± 8.4 kg) in the low-calorie diet group (non-significant). Similarly at 48 months, there was no statistically significant difference between the weight change in men and women who completed the study.

Wing and coworkers[38] found that women in the PSMF group lost significantly more weight at 12 months than did the low-calorie diet participants (14.1 kg vs 8.6 kg, $p < 0.023$). Men had comparable losses between the groups (15.4 kg and 15.5 kg). The percentage of women losing 15 kg or more or at least 5 BMI units was significantly greater in the PSMF group ($p < 0.01$ for both comparisons). The proportion of men achieving these two goals was similar in each group.

Current medical conditions

Most studies recruited otherwise healthy participants, but Dansinger and coworkers recruited people with at least one risk factor,[23] Wing and coworkerspeople with NIDDM,[38] and Wing and coworkers[39] people with type 2 diabetes.

PSMF[††] compared with VLCD

Both of the diets being compared in this study[27] could be classed as PSMF, but with different daily caloric values (420kcal/day vs 1000kcal/day).

Weight loss

No data for weight loss at 12 months were reported.

The summary estimate weight change at 18 months was 1.56 kg for the PSMF compared with a very-low-calorie diet (WMD 95% CI –1.57 to 4.69, based on results from one trial with multiple treatments).[27]

[††] Defined as a diet with 40 g or less of carbohydrate, irrespective of calorie content.

Other outcomes and factors

None were reported.

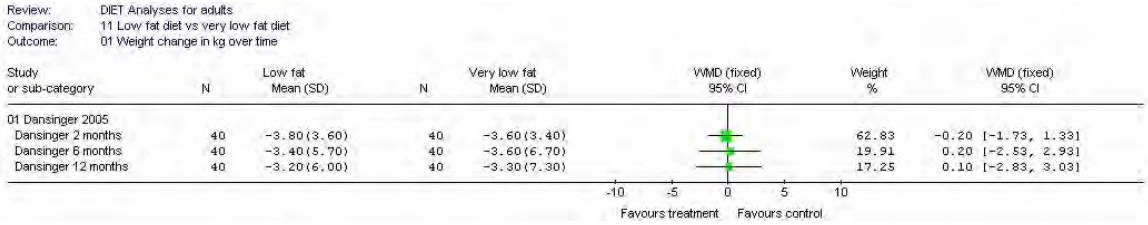
Low-fat diet compared with very-low-fat diet

One study was identified that compared a low-fat diet (Zone) and a very-low-fat diet (Ornish).[23]

Weight loss

There was an overall weight change at 12 months of 0.10 kg in the low-fat group compared with the very-low-fat group (95% CI –2.83 to 3.03).[23]

Figure 15.8 Maintenance of weight loss over time for people on a low-fat diet compared with a very-low-fat diet



Other outcomes and factors

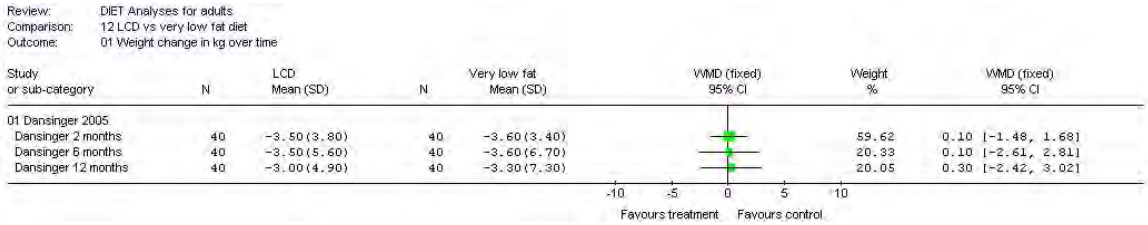
There were no significant changes in lipids and blood pressure between the groups. Although HDL levels increased in the low-fat group and decreased in the very-low-fat group (0.08 mmol/l vs –0.01 mmol/l), and DBP decreased in the lowfat group compared with an increase in the very-low-fat group (–1.20 mm Hg vs 0.20 mm Hg), these changes were not significantly different between the groups (p = 0.07 and p = 0.40, respectively).

Low-calorie diet compared with very-low-fat diet

Weight loss

One study published since the HTA found an overall weight change at 12 months of 0.30 kg in the low-calorie diet group compared with very-low-fat group (95% CI –2.42 to 3.02).[23]

Figure 15.9 Maintenance of weight loss over time for people on a low-calorie diet compared with a very-low-fat diet



Other outcomes and factors

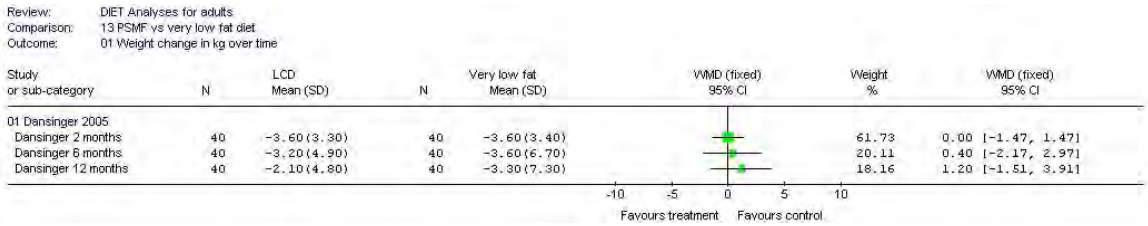
Changes in lipids and blood pressure were not significantly different between the groups, other than HDL levels which increased in the low-calorie diet group and decreased in the very-low-fat group (0.09 mmol/l vs –0.01 mmol/l, p = 0.04).

PSMF[‡‡] compared with very-low-fat diet

Weight loss

One study published since the HTA found an overall weight change at 12 months of –1.20 kg in the PSMF (food based, low carb) group compared with the very-low-fat group (95% CI –1.51 to 3.91).[23]

Figure 15.10 Maintenance of weight loss over time for people on a protein-sparing modified fast (PSMF) compared with a very-low-fat diet



Other outcomes and factors

Changes in lipids and blood pressure were not significantly different between the groups, other than HDL levels which increased in the PSMF group and decreased in the very-low-fat group (0.09 mmol/l vs –0.01 mmol/l, p = 0.01).

[‡‡] Defined as a diet with 40 g or less of carbohydrate, irrespective of calorie content.

Low glycaemic index (high-protein) diet compared with high glycaemic index (standard-protein) diet

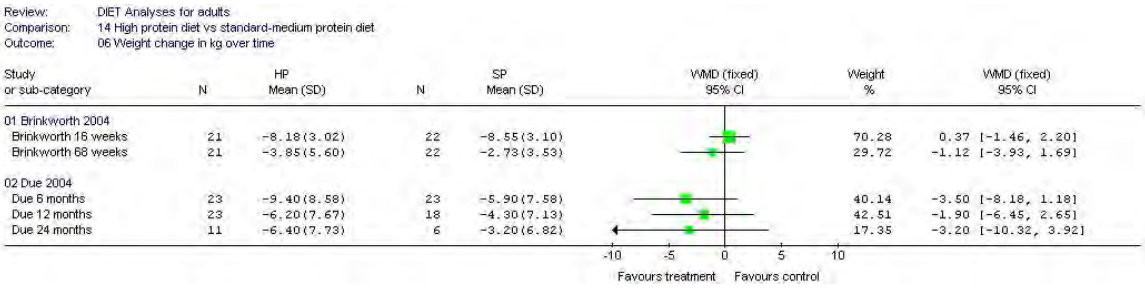
One Cochrane review was identified that evaluated the effect of low glycaemic diets on coronary heart disease and other risk factors (including weight). It was not clear whether participants in the included trials were overweight, so the review was excluded.[42]

Two trials were found that compared the effectiveness of a diet high in protein compared with a diet high in carbohydrate and lower in protein.[43;44]

Weight loss

The summary estimate weight change at 12 months was –1.90 kg for the high-protein (low glycaemic [GI]) diet compared with a standard/medium-protein (high GI) diet (WMD 95% CI –6.45 to 2.65, based on results from one trial).[44]

Figure 15.11 Maintenance of weight loss over time for people on a high-protein (HP) diet compared with a standard/medium-protein (S-MP) diet



Other outcomes and factors

None were reported.

Brinkworth and coworkers[43;45] recruited mainly women aged 20–65 years with hyperinsulinaemia. Due and coworkers[44] again recruited mainly women, but those who were otherwise healthy and aged 18–56 years of age.

15.3.3.3 Evidence statements – behaviour therapy (with or with diet) (Table 15.15)

Table 15.15 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss		
1	Overall, a combination of active support for diet (VLCD or low-calorie diet) and behaviour therapy (problem solving, relapse prevention, stimulus control, dealing with problem situations, assertion, behaviour chain analysis) is effective for weight loss: a change of approximately –4 kg (95% CI -5.77 to -1.70, range -1.40 kg to –5.20 kg) compared with a passive approach (advice or self-help) at 12 months Median weight change across all studies was approximately -3.86 kg (range –2.10 kg to –5.50 kg) for active support and -0.50 kg (range –0.30 kg to –0.70 kg) for passive intervention (n = 3 comparisons)	1++
2	One study showed a combination of active support for a VLCD diet and behaviour therapy resulted in weight change of –5.20 kg (95% CI -8.07 to -2.33) compared with a passive approach (advice or self-help) at 12 months Absolute weight changes were –5.50 kg for the VLCD compared with –0.30 kg for usual care (n = 1 comparison)	1+
3	One study showed a combination of diet and behaviour therapy (self-monitoring, goal setting, cognitive restructuring, problem solving, and environmental management) resulted in weight change of –3.51 kg (95% CI -5.60 to -1.42) compared to a healthy lifestyle information at 18 months Absolute weight changes were –4.61 kg for the diet and behaviour therapy compared with –1.10 kg for information (n = 1 comparison)	1+

No.	Evidence statement	Grade
4	Overall, a combination of diet (low-calorie diet and PSMF 400-500kcal/day food based) and behaviour therapy (cue avoidance, self-monitoring, stimulus control, slowing rate of eating, social support, planning, problem solving, assertiveness, cognitive restructuring, modifying thoughts, reinforcement of changes, relapse prevention, strategies for dealing with weight gain) is effective for weight loss: a change of approximately –7.6 kg (95% CI -11.96 to -3.36, range –6.80 kg to –8.19 kg) compared with diet alone at 12 months. Median weight change across all studies was –7.70 kg low-calorie diet and behaviour therapy and –12.89 for PSMF and behaviour therapy compared with –0.90 kg for low-calorie diet alone and –4.70 kg for PSMF alone (n = 2 comparisons)	1+
5	One study showed a combination of a PSMF diet (400–500 kcal/day based on food) and behaviour therapy resulted in weight change of –8.19 kg (95% CI -13.64 to -2.74) compared with diet alone at 12 months Absolute weight changes were –12.89 kg for the VLCD compared with –4.70 kg for usual care (n = 1 comparison)	1+
6	One study showed a combination of intensive behaviour therapy and VLCD (combination of 200 or 800kcal.day and 600kcal/day deficit) resulted in weight change of –1.18 kg (95% CI -4.16 to 1.80) compared with a less intensive approach at 12 months. Absolute weight changes were –7.58 kg for the intensive programme compared with –6.40 kg for the less intensive programme Contacts were every 2 weeks for 12 months, then six meetings in the next 12 months for the intensive group compared with meetings every 3 months in the less intensive group. Both groups met twice a week during the VLCD period (n = 1 comparison)	1+

No.	Evidence statement	Grade
7	One study showed a combination of 20 weeks' behaviour therapy (self-monitoring, goal setting, stimulus control) with a low-calorie diet and physical activity followed by 12 months of relapse prevention training was less effective for (+ 4.97 kg, 95% CI 0.46 to 9.48) compared with a combination of the 20 weeks' programme followed by 12 months of group problem solving. Absolute weight changes were –5.85 kg for the relapse prevention compared with –10.82 kg for problem solving (n = 1 comparison)	1+
8	Involving family members (usually spouses) in behavioural treatment programmes can be more effective for weight loss than targeting the overweight individual only. Overall, involving family members (in the same sessions as the individual) is effective for weight loss: a change of approximately –2.96 kg (95% CI -3.04 to 0.87) range –6.09 kg to 0.38 kg) compared with the individual alone at 12 months Median weight change across all studies was –7.04 kg family (range –3.80 kg to –8.75 kg) and –3.18 kg (range –2.10 kg to –7.42 kg) for the individual (n = 7 comparisons)	1++
9	Group behavioural programmes do not result in a greater weight loss than behavioural programmes aimed at individuals at 12 months At 24 months, one study showed that group intervention resulted in a significant weight difference of +8.10 kg (95% CI 2.19 to 14.01) compared to the individual alone Absolute weight changes were –4.20 kg for the group compared with –12.30 kg for individual intervention. This difference was not maintained at 60 months (n = 4 comparisons overall)	1++
10	The effectiveness of all interventions appears to change over time, with a trend for greater weight loss in the short term (up to 12 months), with a reduction in overall weight loss in the longer term (up to 60 months)	1++
Outcomes other than weight loss (from trials that reported weight loss)		
11	Few studies reported outcomes other than weight loss. Where these were reported, no significant effects of any intervention were seen at 12 months	1+

No.	Evidence statement	Grade
Harms (from trials that reported weight loss)		
12	No evidence statements can be made as reporting of harms and adverse events was rare and ad hoc	N/A
Generalisability (from trials that reported weight loss)		
13	Only two studies were conducted solely in the UK, with the majority of studies done in the US (n = 11) Many of the studies (11 of the 17 unique studies) were not explicit about their setting, with only one based in primary care. Where reported, participants were recruited as volunteers (that is, through advertising) in 10 studies and through selection (that is, some element of referral or from waiting lists) in five studies Therefore, it is difficult to know how generalisable the results of the included studies are to the UK population, particularly in primary care	1++
14	From the included studies, the duration of intervention varied considerably (range 10 weeks to 248 months) and the rate of follow-up varied; for example, one study made contact every week, then every 2 weeks for 17 months. However, most studies used an approach of decreased contact over time (for example, weekly, then every month, then every 2 months)	1++
15	Behaviour therapy and additional support was provided most often by dietitian and/or people with behavioural treatment or psychological expertise. Other personnel who delivered interventions were physicians, physiotherapists, health educators, graduate students, occupational therapist, and specially trained GPs	1++
16	One assumption could be that the effect size achieved in the included studies may be smaller in practice; in a less motivated, non-volunteer population and less intensive follow-up, delivered by generalists	N/A

GP, general practitioner; N/A, not applicable; PSMF, protein-sparing modified fast; VLCD, very-low-calorie diet.

15.3.3.4 Evidence review on behaviour therapy (with or without diet)

This review was primarily based on four key reviews.[4;46-48] A comparison of the reviews can be seen in Table 15.16. Additional searching was also done to identify any other RCTs published since these key reviews were published. Reference lists of other reviews were also cross-referenced.[49-51]

For this evidence review, only RCTs with a duration (including follow-up) of 12 months or more were included. Also, mean BMI of participants had to be 28 or over.

On the advice of our co-opted expert, we only included specific techniques as being behavioural treatment. Such techniques were defined as:

- drawing on the principles of learning theory: stimulus–behaviour contingencies or behaviour–reward contingencies
- assessment consisting of identifying and specifying problem behaviours and the circumstances in which they are elicited (both antecedents and consequences)
- treatment starting with setting specific, measurable and modest goals that are continually revised as progress is achieved
- target behaviours being monitored – usually by self-monitoring – to obtain a record of behaviour change
- behaviour change processes including stimulus control, graded exposure, extinction and reward
- having a perspective of educational: teaching behaviour change skills to the client. The term problem solving skills may be used, but this does not necessarily mean that the treatment contains the other elements of conventional behavioural treatment
- the use of the term cognitive (as in ‘cognitive behaviour’ therapy or CBT) may imply the inclusion of strategies designed to modify cognitions (thoughts) which can be identified as important stimuli for behaviour.

We identified a treatment as being behavioural if the study paper:

- used the terms behavioural treatment, cognitive behavioural treatment or behaviour therapy, CBT
- mentioned learning theory
- referred to the use of the common components of behavioural treatment (self-monitoring, goal-setting, stimulus control).

Study reports that used the following terms alone were excluded as not meeting our criteria for behavioural treatment

- motivational interviewing
- counselling
- learning
- psychological
- psychotherapy
- problem solving
- cognitive.

Table 15.16 Comparison of systematic reviews on behaviour therapy for weight loss in adults

ID	Avenell HTA[4]	Shaw CR[46]	Smith ICSI[47]	McTigue AHRQ[48]

ID	Avenell HTA[4]	Shaw CR[46]	Smith ICSI[47]	McTigue AHRQ[48]
Title	Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement	Psychological interventions for overweight or obesity	Behaviour therapy programmes for weight loss in adults	Diagnosis and treatment of obesity in the elderly
Published	2004	2005	2005	2003
Aim	To review systematically treatments for the prevention and management of obesity in adults	To assess the effects of psychological interventions for overweight or obesity as a means of achieving sustained weight loss	To evaluate the safety and efficacy of behaviour therapy programmes for weight loss in adults	To examine the data for the effectiveness of obesity diagnosis and treatment in older people
Included study designs	RCTs only	RCTs and quasi-RCTs only	RCTs, CCTs (not explicitly defined)	RCTs
Excluded study designs	–	–	–	–
Included participants	Adults aged 18 years and older	Adults aged 18 years or older defined as overweight or obese by any criteria (BMI, weight, WHR, WC)	Adults who are overweight or obese (not explicitly defined)	Adults aged 60 years or older (mean baseline). Population generalisable to USA. BMI ≥ 25

ID	Avenell HTA[4]	Shaw CR[46]	Smith ICSI[47]	McTigue AHRQ[48]
Excluded participants	People with bulimia nervosa, pregnant women. Studies where average BMI < 28 kg/m^2 for all groups combined	None reported	–	–
Interventions	Behavioural interventions (cognitive behaviour therapy, others including motivational interviewing)	Psychological interventions that could be identified as such	Behaviour therapy programmes (no further details)	Behaviour therapy (no further details)
Key outcomes	Weight change in kilograms	Weight or other indicator of body mass	Weight change (not defined explicitly)	Weight or other indicator of body mass
Duration	52 weeks or more	3 months (12 weeks) or more	Not reported	52 weeks
Databases searched	13 databases; handsearching; reference lists; abstracts and NRR; trialists and biomedical companies; experts	Five databases; ongoing trials; reference lists; experts (not done)	One database (Medline and PREMedline); reference lists; group members	Two databases; reference lists
Period searched	Inception to April 2001 (e-databases)	Inception to June 2003	Not reported, but 2003 studies included	1980 to February 2003
Language restrictions	None (reports only?)	None	Not reported	English language only

BMI, body mass index; CCT, controlled clinical trial; NRR, National Research Register; RCT randomised controlled trial; WHR, waist-to-hip ratio; WC waist circumference.

Diet and behaviour therapy versus usual care

One trial included in the HTA was excluded in this evidence review because there was no requirement that participants in the study were overweight or obese.[52] Hakalaand Karvetti[53] and Karvetti and Hakala[54] were also excluded as although the participants received counselling or lectures from a psychologist, no details of the behavioural techniques used were reported. Wing and coworkers[55] compared an active intervention on diet and behaviour therapy with passive information on diet and behaviour therapy, so was moved to the appropriate section.

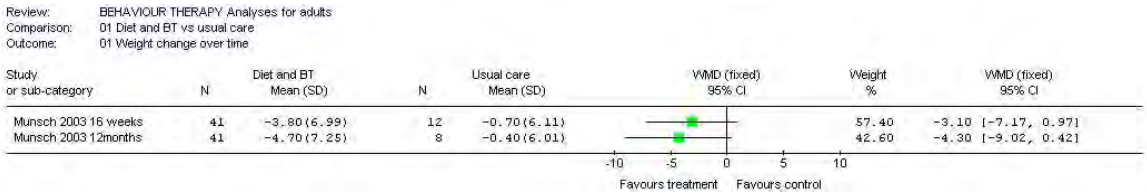
One additional RCT was found comparing diet and defined (or named) behaviour therapy with usual care.[56]

Update searches identified one relevant study,[57] comparing diet and a cognitive behavioural programme with a waiting list control. The long term results (18 months after completion of the programme) support the evidence already reviewed in detail.

Weight loss

At 12 months, a combination of diet (no specific details other than 'balanced, fat-reduced nutrition') and behaviour therapy (self-monitoring, strategies to control eating behaviour, problem analysis and self-observation, alteration of cognitive patterns, social competence, relapse prevention) was associated with a summary estimate of weight change of –3.10 kg (WMD 95% CI –7.17 to 0.97, based on one comparison) compared with usual care.

Figure 15.12 Maintenance of weight loss over time for diet and behaviour therapy (BT) compared with usual care



Other outcomes

No outcomes (such as lipids or blood pressure) were reported. But improvements in psychological outcomes (such as control and attractiveness) were seen in the diet and behaviour therapy group compared with the control group.

Other factors

Gender and setting

Both men and women (mainly women) were recruited from referrals and from adverts. The trial was conducted in a primary care setting, by general practitioners (GPs) and tutors who had undergone specific training to deliver the programme of diet and behaviour therapy.

Diet and behaviour therapy versus information

One RCT was found comparing diet and defined (or named) behaviour therapy with a healthy lifestyle intervention.[58]

Weight loss

At 12 months, a combination of diet (classified as calorie deficit) and behaviour therapy (self-monitoring, goal setting, cognitive restructuring, problem solving, and environmental management) was associated with a summary estimate of weight change of –3.51 kg (WMD 95% CI –5.60 to-1.42, based on one comparison) compared with information.

Other outcomes

No outcomes (such as lipids or blood pressure) were reported. No physiological outcomes (related to arthritis) were found to be significantly different between the groups.

Other factors

Participants and current medical conditions

Both older men and women (mainly women) with ostearthritis were recruited from adverts and publicity.

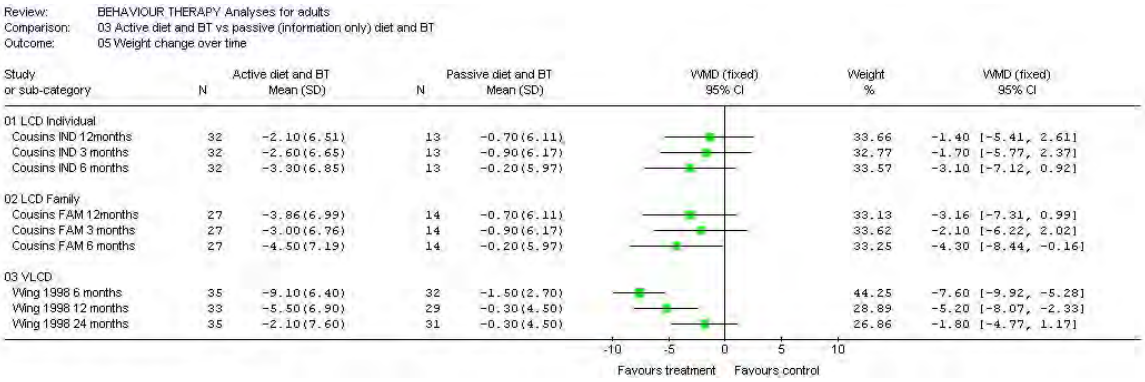
Active diet, and behaviour therapy versus passive (information based) diet and behaviour therapy

Two trials were included in this comparison.[55;59] Cousins and coworkers[58] compared the use of behaviour therapy and a low-calorie diet with information on diet and behaviour, and Wing and coworkers[55] used an VLCD in conjunction with behavioural techniques compared to self-help (diet and behaviour therapy).

Weight loss

At 12 months, the active diet and behaviour therapy (problem solving, relapse prevention, stimulus control, dealing with problem situations, assertion, behaviour chain analysis) was associated with a summary estimate of weight change of -3.73 kg (WMD 95% CI –5.77 to –1.70, based on three comparisons) compared with passive information. However, if the different diets were considered separately, only the VLCD (800-1000kcal/day) remained significantly more effective (weight change of –5.20 kg, 95% CI WMD 95% CI –8.07 to –2.33).

Figure 15.13 Maintenance of weight loss over time for active diet and behaviour therapy (BT) compared with passive diet and BT



Other outcomes

Only Wing and coworkers reported any outcomes other than weight. No significant changes were seen in any of the reported outcomes (lipids, blood pressure, triglycerides, fasting plasma glucose, %HbA1C) at 12 or 24 months, other than for total cholesterol (a change of –0.30 mmol/l WMD 95% CI –0.58 to –0.02) at 24 months (one trial).[55]

Other factors

Cousins and coworkers recruited women participants aged 18–45 years only,[59] and Wing and coworkers recruited mainly older women (inclusion criteria 40–55 years).[55]

Context and methodological notes

The Cousins study was included in the diet, activity, and behaviour therapy versus control section of the HTA. No details of the physical activity were reported (other than 'group exercise'), and the control group received a manual of diet and behaviour therapy strategies, so this study has been reclassified. Wing and coworkers[55] compared an active diet and behaviour therapy intervention with passive information on diet and behaviour therapy, so was moved to the appropriate section.

Family versus individual treatment

Seven trials were included in this comparison.[59-65]

Weight loss

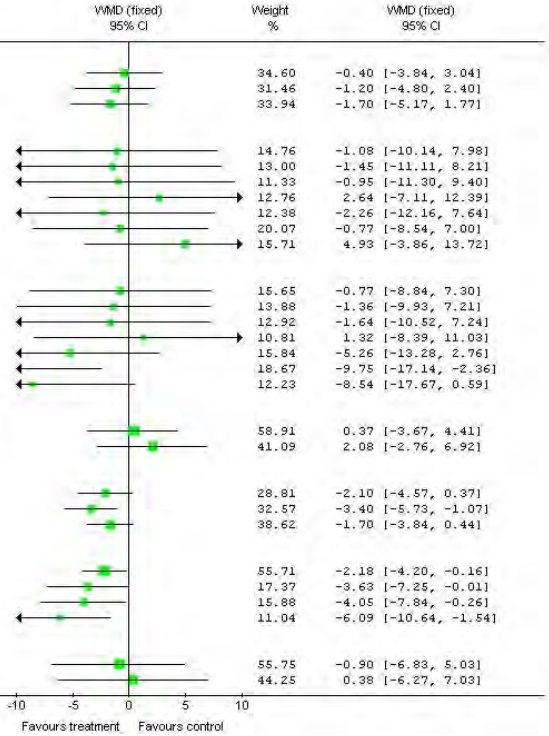
At 12 months, the family-based intervention was associated with a summary estimate of weight change of –2.96 kg (WMD 95% CI –5.32 to –0.60, based on five comparisons) compared with individual intervention. However, if the different interventions were considered separately, only the intervention involving spouses (with low-calorie diet, behaviour therapy and physical activity if no weight loss)

remained significantly more effective (weight change of –6.09 kg, 95% CI WMD 95% CI –10.64 to –1.54).

Figure 15.14 Maintenance of weight loss over time for family compared with individual intervention

Review: BEHAVIOUR THERAPY Analyses for adults
Comparison: 04 Family vs individual
Outcome: 15 Weight change over time

Study or sub-category	N	Family Mean (SD)	N	Individual Mean (SD)	Weight %	WMD (fixed) 95% CI
01 LCD, BT, and PA Cousins						
Cousins 1992 12weeks	27	-3.00(6.76)	32	-2.60(6.65)	34.60	-0.40 [-3.84, 3.04]
Cousins 1992 26weeks	27	-4.50(7.19)	32	-3.30(6.85)	31.46	-1.20 [-4.80, 2.40]
Cousins 1992 12month	27	-3.80(6.99)	32	-2.10(6.51)	33.94	-1.70 [-5.17, 1.77]
02 LCD, BT, and PA Murphy 1991 a						
Murphy a 10 weeks	5	-8.16(8.23)	8	-7.08(7.92)	14.76	-1.08 [-10.14, 7.98]
Murphy a 15 weeks	5	-9.43(8.59)	7	-7.98(8.17)	13.00	-1.45 [-11.11, 8.21]
Murphy a 22 weeks	5	-10.34(8.84)	6	-9.39(8.57)	11.33	-0.95 [-11.30, 9.40]
Murphy a 36 weeks	5	-6.89(7.87)	6	-9.53(8.61)	12.76	2.64 [-7.11, 12.39]
Murphy a 12 months	4	-5.44(7.46)	4	-3.18(6.81)	12.38	-2.26 [-12.16, 7.64]
Murphy a 24 months	5	-3.36(6.86)	7	-2.59(6.65)	20.07	-0.77 [-8.54, 7.00]
Murphy a 48 months	5	0.73(6.12)	4	-4.20(7.10)	15.71	4.93 [-3.86, 13.72]
03 LCD, BT, and PA Murphy 1991 b						
Murphy b 10 weeks	8	-7.62(8.07)	7	-6.85(7.85)	15.65	-0.77 [-8.84, 7.30]
Murphy b 15 weeks	8	-9.66(8.65)	7	-8.30(8.26)	13.88	-1.36 [-9.93, 7.21]
Murphy b 22 weeks	8	-10.89(9.00)	7	-9.25(8.53)	12.92	-1.64 [-10.52, 7.24]
Murphy b 36 weeks	7	-8.21(8.24)	5	-9.53(8.61)	10.81	1.32 [-8.39, 11.03]
Murphy b 12 months	8	-8.75(8.39)	6	-3.49(6.90)	15.84	-5.26 [-13.28, 2.76]
Murphy b 24 months	8	-7.21(7.96)	7	2.54(6.63)	18.67	-9.75 [-17.14, -2.36]
Murphy b 48 months	6	-2.87(6.73)	4	5.67(7.52)	12.23	-8.54 [-17.67, 0.59]
04 LCD, BT, and PA Wing 1991 b						
Wing 1991 b 20 weeks	20	-8.66(5.08)	23	-9.03(8.26)	58.91	0.37 [-3.67, 4.41]
Wing 1991 b 18months	20	-3.18(5.31)	23	-5.26(10.39)	41.09	2.08 [-2.76, 6.92]
05 LCD, BT, and PA Wing 1999						
Wing 1999 16 weeks	80	-8.80(8.41)	86	-6.70(7.81)	28.81	-2.10 [-4.57, 0.37]
Wing 1999 40 weeks	80	-7.70(8.09)	86	-4.30(7.13)	32.57	-3.40 [-5.73, -1.07]
Wing 1999 18 months	80	-4.70(7.25)	86	-3.00(6.76)	38.62	-1.70 [-3.84, 0.44]
06 LCD, BT, and PA if no weight loss						
Pearce 1981 10 weeks	14	-6.50(2.91)	13	-4.32(2.45)	55.71	-2.18 [-4.20, -0.16]
Pearce 1981 22 weeks	12	-8.18(4.74)	12	-4.55(4.31)	17.37	-3.63 [-7.25, -0.01]
Pearce 1981 36 weeks	12	-7.47(5.08)	12	-3.42(4.37)	15.88	-4.05 [-7.84, -0.26]
Pearce 1981 12months	12	-8.25(5.38)	12	-2.16(5.97)	11.04	-6.09 [-10.64, -1.54]
07 Behavioural contracts						
Black 1984 10 weeks	11	-4.61(7.22)	11	-3.71(6.96)	55.75	-0.90 [-6.83, 5.03]
Black 1984 12 months	11	-7.04(7.91)	11	-7.42(8.01)	44.25	0.38 [-6.27, 7.03]



Other outcomes

Only Wing and coworkers[64] reported clinical outcomes other than weight. No changes were significant between interventions at any time points.

Other factors

Gender

Four of the trials recruited women only,[59;60;62;63] and overall the majority of participants were women.

Delivery

One of the trials recruited support from people other than family.[64] However, no details of the members and relationships of the support group were reported. All interventions were delivered to family and individual in the same sessions.[59-65]

One trial[64] noted a significant interaction of gender and treatment, such that women did better when treated with a spouse and men did better when treated individually.

Methodological and context notes

Slightly different figures from the HTA have been used for Black and Lantz[59] due to conversion/calculations rounding.

Also, there were some differences between 12 month follow-up. For example, Cousins and coworkers[58] assessed at 12 months from beginning of intervention, Black and Lantz[59] and Murphy and coworkers[60] assessed at 12 months after the end of the intervention which lasted 10 weeks. Also Wing and Jeffery[64] used 18 months' figures.

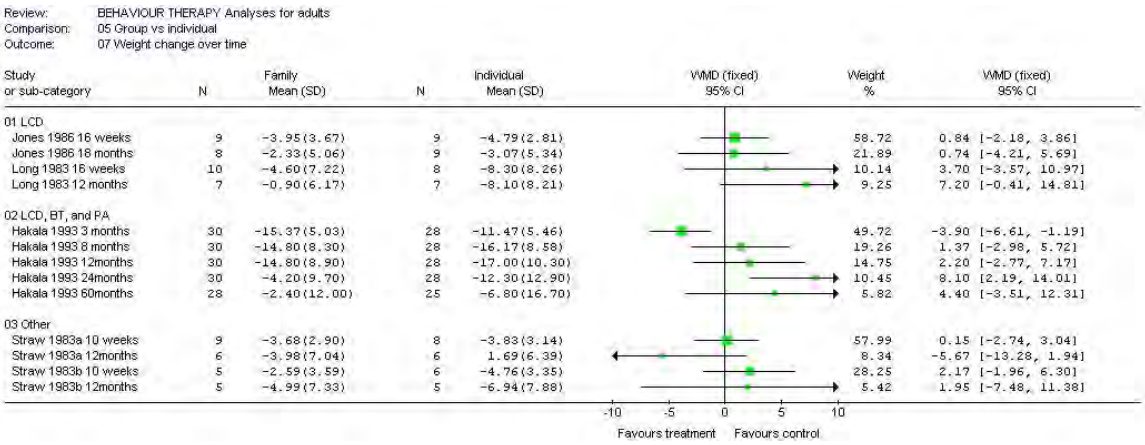
Group versus individual treatment

Four trials were included in this comparison.[66-69]

Weight loss

At 12 months, the group-based intervention was associated with a summary estimate of weight change of 1.59 kg (WMD 95% CI –1.81 to 5.00, based on four comparisons) compared to individual intervention. However, at 24 months, one trial[66] showed a significantly greater weight loss in the individual group compared with the group intervention.

Figure 15.15 Maintenance of weight loss over time for group compared with individual intervention



Other outcomes

No clinical outcomes were reported. One study[66] reported higher attendance rates in the individual groups than in the group sessions.

Other factors

Gender

Three of the four trials recruited women only.[67-69] Again, the majority of participants were women.

Degree of obesity

Hakala and coworkers recruited men and women who were severely overweight (at least 50% overweight).[66] The other trials recruited women who were overweight (different criteria used) but not severely obese specifically.

Setting

Two of the studies were set in the NHS.[66,67] None of the results were significant.

Diet and behaviour therapy versus diet

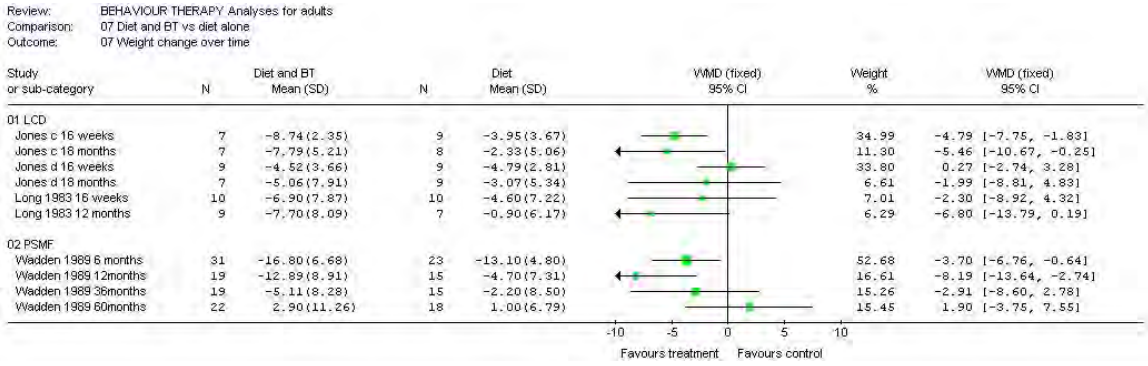
Phenix[70] was excluded from this review, as this was a PhD thesis and no subsequent published papers were identified.

Three trials were included in this comparison.[36;67;68] All compared the use of diets (low-calorie diet,[66,67] PSMF[37]) in conjunction with behaviour therapy compared to the use of the diet alone.

Weight loss

At 12 months, a combination of diet and behaviour therapy (cue avoidance, self-monitoring, stimulus control, slowing rate of eating, social support, planning, problem solving, assertiveness, cognitive restructuring, modifying thoughts, reinforcement of changes, relapse prevention, strategies for dealing with weight gain) was associated with a summary estimate of weight change of –7.66 kg (WMD 95% CI –11.96 to –3.36, based on two comparisons) compared with diet alone. However, if the different diets were considered separately, only the PSMF (food based 400–500 kcal/day) remained significantly more effective (weight change of –8.19 kg, 95% CI WMD 95% CI –13.64 to –2.74).

Figure 15.16 Maintenance of weight loss over time for diet and behaviour therapy (BT) compared with diet alone



Other outcomes

No other outcomes were reported.

Other factors

Gender

All trials in this section recruited women only.

Setting

Jones and coworkers[67] and Long and coworkers[68] were conducted in the NHS. Mixed results were seen, but a combination of group behaviour therapy and diet seemed to work better than individual behaviour therapy and diet at 6 months, although this was not statistically significant.

Different levels of intensity of behaviour therapy and diet

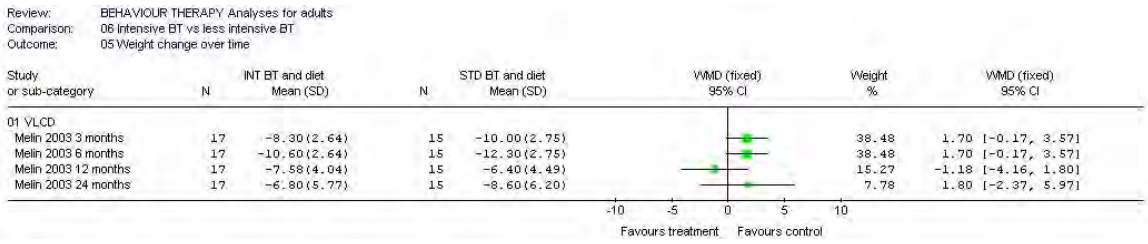
One study was identified that compared different levels of intensity of the same behavioural treatment programme in conjunction with periods of a VLCD.

Update searches identified a further study, showing that weight loss could be achieved even with relatively minimal follow-up contact (twice a year).[71]

Weight loss

At 12 months, a combination of VLCD and intensive behaviour therapy (self-monitoring, relapse situations, eating behaviour) was associated with a summary estimate of weight change of –1.18 kg (WMD 95% CI –4.16 to 1.80, based on one comparison) compared to a combination of VLCD and less intensive behaviour therapy.

Figure 15.17 Maintenance of weight loss over time for diet and intensive behaviour therapy (BT) compared with diet and less intensive BT



Other outcomes

Only significant differences were seen for blood pressure (both SBP and DBP) at 24 months, with the more intensive programme appearing to be more effective.

Other factors

Gender and setting

Both men and women (mainly women) were recruited from referrals to a secondary care obesity clinic.

Comparison of different behavioural treatments

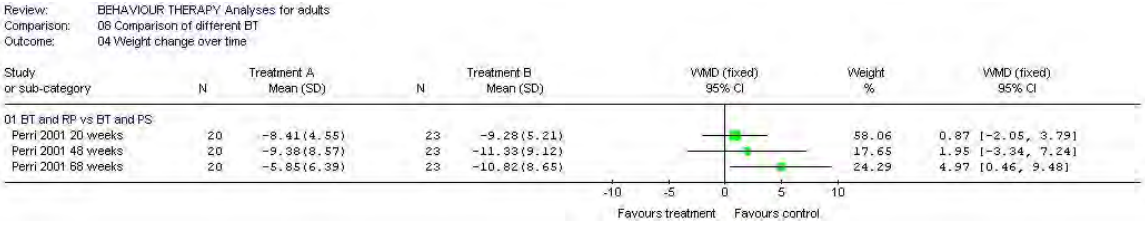
One study was identified that compared different types of behaviour therapy.[72]

Update searches identified one pilot study comparing different approaches to behavioural treatments.[73] Weight changes were similar, and therefore would not change either evidence statements or recommendations.

Weight loss

At 17 months, a combination of 20 weeks' behaviour therapy (self-monitoring, goal setting, stimulus control) with a low-calorie diet and physical activity followed by 12 months of relapse prevention training was associated with a summary estimate of weight change of +4.97 kg (WMD 95% CI 0.46 to 9.48, based on one comparison) compared with a combination of the 20 weeks' programme followed by 12 months of group problem solving. However, both groups did lose weight from baseline.

Figure 15.18 Maintenance of weight loss over time for behaviour therapy and relapse prevention maintenance compared with behaviour therapy and problem solving



Other outcomes

No other outcomes were significant.

Other factors

Gender and setting

In both trials, men and women (mainly women) were recruited from adverts. The setting was unclear.

15.3.3.5 Evidence statements – physical activity (alone or in combination with diet or behaviour therapy) (Table 15.17)

Table 15.17 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss		
1	Overall, physical activity (minimum of 30 minutes three times a week) is effective for weight loss: a change of approximately –3 kg (95% CI _4.00 to -2.18, range –2.00 kg to –4.60 kg) compared to no treatment at 12 months Median weight change across all studies was approximately -2.60 kg (range –0.90 kg to –4.00 kg) for physical activity and 0.60 kg (range 0.30 kg to 1.10 kg) for no treatment (n = 3 comparisons)	I++
2	One study showed physical activity (60 minutes of three times a week) resulted in a weight change of –2.36 kg (95% CI -4.41 to -0.31) compared with information at 18 months Absolute weight changes were –3.46 kg for activity compared with –1.10 kg for information (n = 1 comparison)	1+
3	Overall, physical activity alone (minimum of 30 minutes three times a week) was less effective for weight loss than diet alone at 12 months: a change of +3 kg (95% CI 2.28 to 4.35, range 3.10 kg to 3.80 kg). Median weight change across all studies was approximately –2.60 kg (range –0.90 kg to –4.00 kg) for physical activity and –6.40 kg (range-4.00 kg to –7.20 kg) for diet alone. (n = 3 comparisons)	1++

No.	Evidence statement	Grade
4	Overall, physical activity (minimum of 45 minutes three times a week) and diet (600 kcal/deficit or low fat) is effective for weight loss: a change of approximately –7 kg (95% CI -7.88 to -5.87, range –1.70 kg to –10.40 kg) compared with no treatment at 12 months Median weight change across all studies was approximately –5.10 kg (range 0.70 kg to –8.70 kg) for physical activity and diet and 1.30 kg (range 2.40 kg to –0.60 kg) for no treatment (n = 5 comparisons)	1++
5	One study showed a combination of physical activity (30 minutes of moderate exercise daily plus supervised resistance training twice a week) and diet (classified as calorie deficit) resulted in weight change of –3.50 kg (95% CI -4.27 to -2.73) compared with information at 12 months. Absolute weight changes were –4.50 kg for the activity and diet compared with –1.00 kg for information (n = 1 comparison)	1+
6	Overall, physical activity (minimum of 45 minutes three times a week) and diet (600 kcal/deficit or low fat) is effective for weight loss: a change of approximately –1.95 kg (95% CI -3.22 to -0.68) range –1.00 kg to –3.60 kg) compared o diet alone at 12 months Median weight change across all studies was approximately -5.60 kg (range –5.10 kg to –8.70 kg) for physical activity and diet and –4.10 kg (range –4.00 kg to –5.10 kg) for diet alone (n = 5 comparisons)	1++

No.	Evidence statement	Grade
7	Overall, a combination of physical activity (varying in level from three four sessions over 12 months to 30–45 minutes four to five times week), behaviour therapy (situational control, including cue avoidance, self-monitoring of calorie intake, eating behaviours and pulse rate, management of eating behaviours, relapse prevention, goal setting, cognitive reframing and coping imagery, stimulus control, social assertion, reinforcement techniques for enhancing motivation, cognitive strategies for replacing negative thinking with more positive statements and constructive self-statements), and diet (either calorie deficit or a low-calorie diet) is effective for weight loss: a change of –4.22 kg (95% CI -4.80 to -3.64, range –2.20 kg to –4.88 kg) compared with control (no treatment) at 12 months Median weight change across all studies was approximately –4.60 kg (range –3.33 kg to –5.87 kg) for the combined intervention and –0.48 kg (range 0.53 kg to –2.40 kg) for diet alone (n = 5 comparisons)	1++
8	Overall, a combination of physical activity (minimum 150 minutes per week), behaviour therapy (behaviour change goals and problem solving, goal setting, menu planning, self-efficacy, consideration of body image, social support, social eating, removing road blocks, positive thinking, dealing with high-risk situations and slips, cue elimination, stress management and relapse prevention, self-monitoring, problem solving, managing cues, stimulus control, positive assertion, positive thinking, holiday eating, social support, motivation, role playing, modelling food tasting and grocery store tours) and diet (either calorie deficit or a VLCD) is effective for weight loss: a change of –3.82 kg (95% CI -4.63 to -3.02, range 1.70 to –8.85) compared with information alone Median weight change across all studies was approximately –3.90 kg (range 2.50 kg to –8.00 kg) for the combined intervention and 0.15 kg (range 0.85 kg to –0.50 kg) for information (n = 6 comparisons)	1++

No.	Evidence statement	Grade
9	One study showed a combination of physical activity (individualised level), behaviour therapy (self-monitoring, stimulus control, reinforcement, cognitive change), and diet (calorie deficit) was associated with a summary estimate of weight change of –5.80 kg (WMD 95% CI –8.91 to –2.69, based on one comparison) compared with behaviour therapy (enhancing body acceptance, disentangling self-worth from weight, barriers transformation, increased support and assertion, self-monitoring) alone Absolute weight changes were –5.90 kg for the combined group compared with –0.10 kg for behaviour therapy. (n = 1 comparison)	1+
10	One study showed a combination of physical activity (approximately 45 minutes five times a week maximum), behaviour therapy (stimulus control, problem solving,; reducing barriers, exercising in different weather conditions), and diet (VLCD 800-1000kcal/day and 1200-1500kcal for maintenance) was associated with a summary estimate of weight change of –7.00 kg (WMD 95% CI –10.90 to –3.10, based on one comparison) compared with physical activity and behaviour therapy Absolute weight changes were –7.4 kg for the combined approach compared with –0.40 kg for activity and behaviour therapy (n = 1 comparison)	1+
11	Other benefits of physical activity (alone or in combination) include: ▪ delay of onset of diabetes in people with impaired glucose tolerance ▪ increased motility in older people with arthritis ▪ reduction in the risk of developing hypertension and other cardiovascular events ▪ reduction in medication use for comorbidities ▪ improved quality of life	1++
Comparison of different programmes		
12	No statement could be made on the effectiveness of different levels of intensity.	…
Outcomes other than weight loss (from trials that reported weight loss)		
13	Physical activity, either alone or in combination, improves other clinical outcomes, such as lipids and blood pressure. However, any improvements may not be maintained in the longer term (up to 36 months)	1+

No.	Evidence statement	Grade
14	No effect on cardiovascular fitness was observed based upon exercise intensity or duration	1+
Harms (from trials that reported weight loss)		
15	No evidence statements can be made as reporting of harms and adverse events was rare and ad hoc	N/A
Generalisability (from trials that reported weight loss)		
16	No studies were conducted in the UK, and 26 of the 33 unique studies were based in the USA Many of the studies did not report the setting, and only two studies were based in primary care. Three workplace studies were included as the aim of the study was to evaluate the effectiveness of the intervention and not the effect of the setting. However, the resulting effect may have been different if the intervention was delivered in a clinical setting Where reported, participants were recruited as volunteers (that is, through advertising) in 12 studies and through selection (that is, some element of referral or from screening programmes) in 10 studies Therefore, it is difficult to know how generalisable the results of the included studies are to the UK population, particularly in primary care	1++
18	From the included studies, the duration of intervention varied considerably (range 8 weeks to 36 months, including a 1 month inpatient programme) and the rate of follow-up varied; for example, one study made contact every week for 12 months. However, most studies used an approach of decreased contact over time (for example, weekly, then every 2 weeks, then monthly)	1++
19	A wide variety of personnel delivered the different components of the interventions; this included physicians, researchers, health educators, graduate students, exercise coaches, trained interventionists, dietitians, commercial services (physical activity), and psychologists	1++
20	One assumption could be that the effect size achieved in the included studies may be smaller in practice; in a less motivated, non-volunteer population and less intensive follow-up, delivered by generalists	N/A
21	The intensity and duration of exercise required to impact on long-term weight loss may be much higher than recommended in most behavioural treatment programmes	1++

N/A, not applicable; VLCD, very-low-calorie diet.

15.3.3.6 Evidence review on physical activity (alone or in combination with diet or behaviour therapy)

This review was primarily based on three key reviews.[4;48;74] A comparison of the reviews can be seen in Table 15.16. Although the AHRQ report did not specifically evaluate physical activity, some of the included RCTs included a physical activity component. Additional searching was also done to identify any other RCTs published since these key reviews were published. Reference lists of other reviews were also cross-referenced.

For this evidence review, only trials with a duration (including follow-up) of 12 months or more were included. Also, mean BMI of participants had to be 28 kg/m^2 or over.

Table 15.18 Comparison of systematic reviews on physical activity (alone or in combination with diet or behaviour therapy) for weight loss in adults

ID	Avenell HTA	Shaw CR	McTigue AHRQ
Title	Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement	Exercise for obesity	Diagnosis and treatment of obesity in the elderly
Published	2004	Unpublished	2003

ID	Avenell HTA	Shaw CR	McTigue AHRQ
Aim	To review systematically treatments for the prevention and management of obesity in adults	To assess regular exercise as a means of achieving sustained weight loss, using randomised controlled clinical trials. This review focused on participants who were overweight or obese and who were exercising for any purpose	To examine the data for the effectiveness of obesity diagnosis and treatment in older people
Included study designs	RCTs only	RCTs and quasi-RCTs only	RCTs
Excluded study designs	–	–	–
Included participants	Adults aged 18 years and older	Adults aged 18 years or older defined as overweight or obese by any criteria (BMI, weight, WHR, WC) Note: Also stated that BMI > 25 kg/m^2?	Adults aged 60 years or older (mean baseline); population generalisable to USA; BMI ≥ 25 kg/m^2
Excluded participants	People with bulimia nervosa, pregnant women; studies where average BMI < 28 for all groups combined	None reported	–

ID	Avenell HTA	Shaw CR	McTigue AHRQ
Interventions	Physical activity (including endurance exercise, and resistance training)	Exercise was defined as any form of physical activity performed on a repeated basis for a defined period of time (exercise training). Studies stating that they simply recommended increasing physical activity were not included in the analysis unless it was possible to quantify the exercise stimulus Studies that combined exercise and medication as an intervention were not included in the analysis, unless the study design allowed the effects of these two components to be separated	Did not specifically evaluate physical activity, but some of the included trials had a physical activity component
Key outcomes	Weight change in kilograms	Weight or other indicator of body mass	Weight or other indicator of body mass
Duration	52 weeks or more	3 months (12 weeks) or more	52 weeks
Databases searched	13 databases; handsearching; reference lists; abstracts and NRR; trialists and biomedical companies; experts	Four databases. ongoing trials; reference lists; experts (not done)	Two databases; reference lists

ID	Avenell HTA	Shaw CR	McTigue AHRQ
Period searched	Inception to April 2001 (e-databases)	Inception to 2003	1980 to February 2003
Language restrictions	None (reports only?)	None	English language only.

BMI, body mass index; CCT, controlled clinical trial; NRR, National Research Register; RCT randomised controlled trial; WHR, waist-to-hip ratio; WC waist circumference.

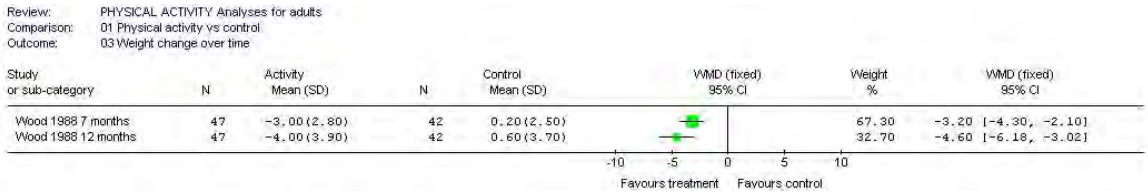
Physical activity versus control (no treatment)

Three trials were included in this comparison.[5;10;13]

Weight loss

At 12 months, physical activity (minimum of 30 minutes three times a week) was associated with a summary estimate of weight change of –3.09 kg (WMD 95% CI –4.00 to –2.18, based on three comparisons) compared with no treatment.

Figure 15.19 Maintenance of weight loss over time for physical activity compared with no treatment



Other outcomes

One trial[10] showed significant decreases in levels of triglycerides at 12 months (–0.30 mmol/l, WMD 95% CI –0.49 to –0.10) in the activity group, but other clinical outcomes were not significantly different between the groups.

Other factors

Gender

Two of the three included trials recruited men only.[5;10;75;76]

Current medical conditions

The Oslo Diet and Exercise Study (ODES) study recruited men and women who had athero-thrombogenic syndrome (or insulin resistance).

Age

All included studies recruited middle-aged people (age range 30–59 years).

Setting and delivery

Of the three trials, one was community based, one workplace based, and one based in a university clinic. None were based in the UK.

The physical activity was supervised in two studies[10;13] by 'highly qualified instructors' and 'training staff', respectively.

Context and methodological notes

The included studies in the Cochrane review were re-examined and either excluded (or were reassigned to alternative categories). The ODES study was also added.

Physical activity versus information

One trial was found that compared physical activity with information on a healthy lifestyle.[58;77]

Weight loss

At 18 months, mean ± SD weight change in kilograms was –3.46 ± 6.89 kg in the activity group, and –1.10 ± 6.23 kg in the information group. Mean weight change in the intervention group compared with behaviour therapy was –2.36 kg (95% CI –4.41 to –0.31).

Other outcomes

A significant improvement in the 6-minute walk distance ($p < 0.05$) was observed in the activity group.

Other factors

Current medical conditions

The included study recruited only participants with osteoarthritis of the knee.

Age

Messier[58] recruited older people only (aged 60 years or older).

Setting and delivery

The trial was based in an older people's independence centre in the USA. The physical activity could be done either in the centre or at home. Details of whether the facility-based training was supervised was not reported.

Physical activity versus diet

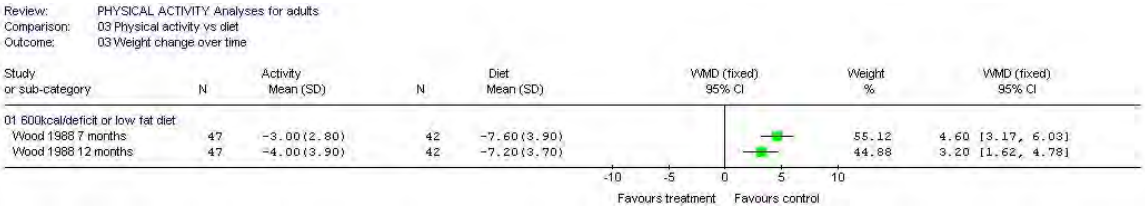
Three trials were included in this comparison.[5;10;13] All three diets were classified as 600 kcal/deficit or low-fat diets.

Weight loss

At 12 months, physical activity (minimum of 30 minutes three times a week) was associated with a summary estimate of weight change of +3.32 kg (WMD 95% CI

2.28 to 4.35, based on three comparisons) compared with a 600 kcal/deficit or low-fat diet.

Figure 15.20 Maintenance of weight loss over time for physical activity compared with diet



Other outcomes

No reported outcomes were significantly different overall at any time points.

Other factors

Gender

Two of the three included trials recruited men only.[5;10;75;76]

Current medical conditions

The ODES study recruited men and women who had athero-thrombogenic syndrome (or insulin resistance).

Age

All included studies recruited middle-aged people (age range 30–59 years).

Setting and delivery

Of the three trials, one was community based, one workplace based, and one based in a university clinic. None were based in the UK.

The physical activity was supervised in two studies[10;13] by ‘highly qualified instructors’ and ‘training staff’, respectively.

The dietary advice was delivered to individuals[5;10] or with the spouse initially.[13]

Context and methodological notes

The included studies in the Cochrane review were re-examined and either excluded (see Appendix 16) or were reassigned to alternative categories. The ODES study was also added.

Although the Wood[10] study did mention that behavioural strategies were used, no details were reported so the intervention was classed as diet only.

Physical activity versus diet and behaviour therapy

One trial was found that compared physical activity with diet and behaviour therapy.[58;77]

Weight loss

At 18 months, mean ± SD weight change in kilograms was –3.46 ± 6.89 kg in the activity group, and –4.61 ± 7.22 kg in the diet and behaviour therapy group. Mean weight change in the intervention group compared with behaviour therapy was 1.15 (95% CI –1.02 to 3.32).

Other outcomes

A significant improvement in the 6-minute walk distance ($p < 0.05$) was observed in the activity group.

Other factors

Current medical conditions

The included study recruited only participants with osteoarthritis of the knee.

Age

Messier[58] recruited older people only (aged 60 years or older).

Setting and delivery

The trial was based in an older people's independence centre in the USA. The physical activity could be done either in the centre or at home. Details of whether the facility-based training was supervised was not reported. No details of who delivered the behaviour therapy were reported, but the majority of sessions were group sessions.

Context and methodological notes

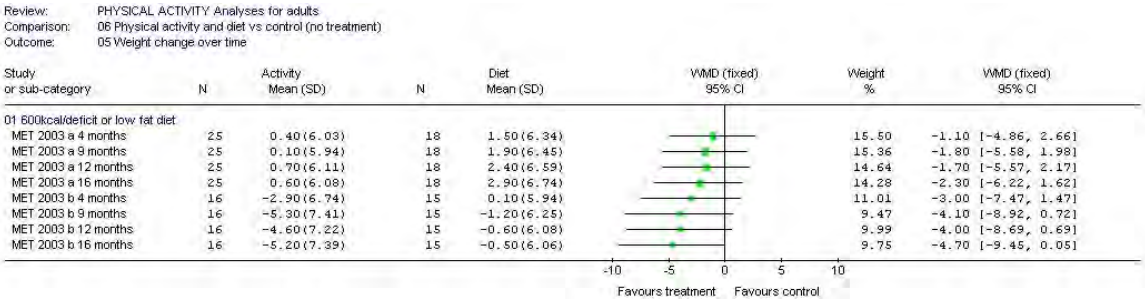
Two papers on the same study were identified which appeared to give different results. For this review, the Messier[58]paper was used, but Nicklas[77] was checked for apparent differences (possibly due to different populations used).

Physical activity and diet versus control (no treatment)
Three trials were included in this comparison.[13;78-87]

Weight loss

At 12 months, physical activity (minimum of 45 minutes three times a week) and diet (600 kcal/deficit or low fat) was associated with a summary estimate of weight change of –6.87 kg (WMD 95% CI –7.88 to –5.87, based on five comparisons) compared with a no treatment control.

Figure 15.21 Maintenance of weight loss over time for physical activity and diet compared with no treatment



Other outcomes

Overall, significant improvements in levels of total cholesterol (–0.27 mmol/l, WMD 95% CI –0.42 to –0.12, three comparisons), LDL-cholesterol (-0.20 mmol/l, WMD 95% CI –0.33 to –0.06, three comparisons), HDL-cholesterol (0.12 mmol/l, WMD 95% CI 0.09 to 0.16, three comparisons), triglycerides (–0.29 mmol/l, WMD 95% CI –0.41 to –0.17, three comparisons), fasting plasma glucose (-0.33 mmol/l, WMD 95% CI –0.54 to –0.12, three comparisons), DBP (-4.64 mm Hg, WMD 95% CI –6.04 to –3.25, three comparisons), and SBP (-4.60mm Hg, WMD 95% CI –6.61 to –2.58, three comparisons) at 12 months were seen in the activity and diet group, but other clinical outcomes were not significantly different between the groups.

Other factors

Gender

The authors of one trial[78] reported that 'exercise prevented weight gain in women and produced weight loss in men'.

Current medical conditions

The ODES study recruited men and women who had athero-thrombogenic syndrome (or insulin resistance).

Setting and delivery

Of the three trials, one was community based, and two were based in university clinics. None were based in the UK.

The physical activity was supervised in two studies (ODES and Midwest Exercise Trial) by 'highly qualified instructors'[13] and 'research assistants',[78] respectively.

The dietary advice was delivered to individuals (ODES[13]) or with the spouse initially (ODES[13]). In the Midwest Exercise trial, participants had to eat in the

university cafeteria, but no specific counselling was reported as being given (other than told to follow an ad-libitum diet of 30–35% fat, 45–55% carbohydrates, 10–25% protein).[78-80]

Context and methodological notes

The Finnish Diabetes Prevention Study (FDPS) (HTA) was moved to another section, as the control group did receive some specific dietary advice.

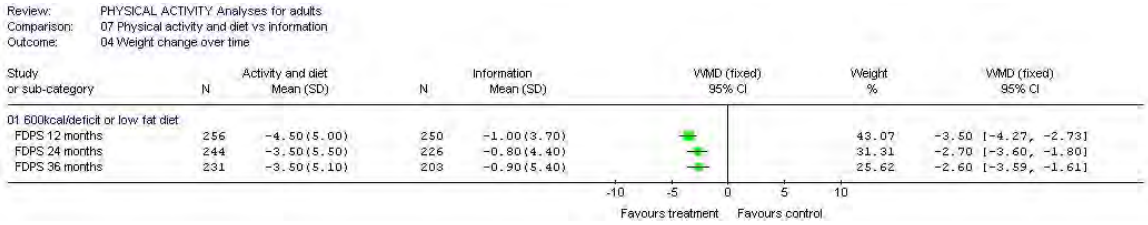
Physical activity and diet versus information

One RCT was found comparing physical activity and diet (600 kcal/deficit or low fat) with information.[88-90]

Weight loss

At 12 months, a combination of physical activity (30 minutes of moderate exercise daily plus supervised resistance training twice a week) and diet (classified as calorie deficit) was associated with a summary estimate of weight change of –3.50 kg (WMD 95% CI –4.27 to-2.73, based on one comparison) compared with information.

Figure 15.22 Maintenance of weight loss over time for physical activity and diet compared with information



Other outcomes

At 12 months, participants in the activity and diet group had greater improvements in HDL, triglyceride and fasting plasma glucose at 12 months than the information alone group. However, these were not maintained in the longer term (up to 36 months). In addition, participants in the activity and diet group were less likely to develop diabetes (p = 0.0001) during the study period.

Other factors

Participants and condition

People (majority women) were included if they had impaired glucose tolerance.

Delivery

A nutritionist gave individualised and group information on diet. The study physician and the nutritionist informed participants of general risk factors for diabetes. Physical activity was delivered either by an exercise instructor or physiotherapist if part of the study team, or if not, by commercial services (the delivery of the intervention varied across centres, depending on local availability of services and personnel).

Physical activity and diet versus diet alone

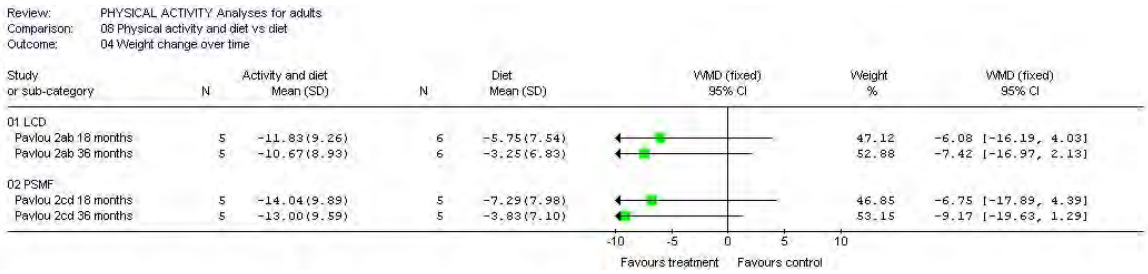
Three RCTs[13;27;81-87] and one pilot study[27] were included in this comparison.

Weight loss

At 12 months, a combination of physical activity (min 45 minutes three times a week) and diet (classified as 600 kcal/day deficit or low fat) was associated with a summary estimate of weight change of –1.95 kg (WMD 95% CI –3.22 to-0.68, based on three comparisons) compared to diet alone.

A significant difference was maintained at 18 months (–7.63 kg (WMD 95% CI -10.33 to-4.92, based on six comparisons), with dietary interventions including a low-calorie diet (1000 kcal/day) and PSMF (420 kcal/day).

Figure 15.23 Maintenance of weight loss over time for physical activity and diet compared with diet alone



Other outcomes

Overall, three comparisons from two trials[13;86] showed significant improvements in triglyceride levels at 12 months (–0.18 mmol/l, WMD 95%CI -0.31 to –0.06). Also blood pressure was improved (DBP –12.10 mm Hg, WMD 95%CI –15.20 to –9.00, and SBP –8.90 mm Hg, WMD 95%CI –13.65 to –4.15) at 18 months, but not at 12 months (one comparison).[27]

Other factors

Gender

Two studies (Pavlou 1989 1 and 1989 2) recruited men only.[27]

Current medical conditions

The ODES study recruited men and women who had athero-thrombogenic syndrome (or insulin resistance).

Setting and delivery

One study was community based,[13] two were workplace based,[27] and one was based in a university clinic.[86] None were based in the UK.

The physical activity was supervised in all studies. No details of who supervised the exercise were reported in three studies, but in one trial the exercise was supervised by 'highly qualified instructors'.[86]

Dietary interventions were delivered by nutritionists,[88] or by a registered dietitian.[86] There was a variety of methods of delivering the dietary advice: from counselling with the spouse[13] to weekly education sessions[27] (assumed to be group sessions).

Context and methodological notes

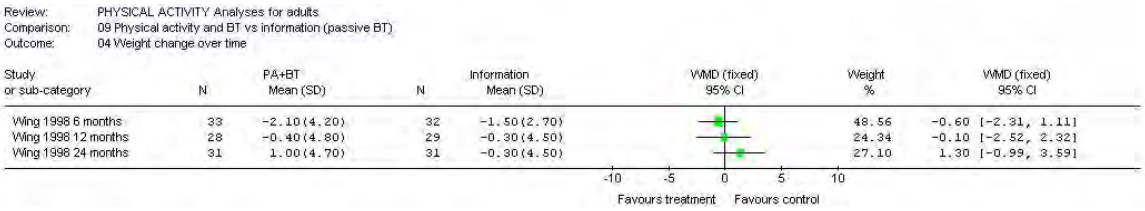
The included studies in the Cochrane review were re-examined and either excluded (see Appendix 16) or were reassigned to alternative categories. HTA studies were also included. However, the Phenix study[70] was excluded as was not a published paper, but a PhD thesis (no subsequent articles published, checked April 2005).

Physical activity and behaviour therapy versus passive (information or self-help) behaviour therapy

Weight loss

At 12 months, a combination of physical activity (approximately 45 minutes five times a week) and behaviour therapy (stimulus control, problem solving, reducing barriers, exercising in different weather conditions) was associated with a summary estimate of weight change of –0.10 kg (WMD 95% CI –2.52 to 2.32, based on one comparison) compared to passive (information, self-help) behaviour therapy (self-monitoring, goal setting, social support, relapse prevention, problem solving) alone.

Figure 15.24 Maintenance of weight loss over time for physical activity (PA) and behaviour therapy (BT) compared with information



Other outcomes

No other reported outcomes were significant.

Other factors

Age

Wing 1998 recruited people aged 40–55 years.[55]

Current medical conditions

Wing and coworkers recruited people who did **not** have diabetes, but who had one or both biological parents with diabetes.[55]

Setting and delivery

Wing and coworkers' study was assumed to be based in a university hospital in the USA.[55] Behavioural treatments and information on exercise were delivered in lectures given by a team led by a behaviour therapist and an exercise physiologist, who also supervised the exercise.

Physical activity, diet and behaviour therapy versus control (no treatment)
Six trials were included in this comparison.[91-102]

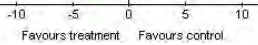
Weight loss

At 12 months, a combination of physical activity (varying in level from three sessions to 30–45 minutes 4 to 5 times week), behaviour therapy (situational control, including cue avoidance, self-monitoring of calorie intake, eating behaviours and pulse rate, management of eating behaviours, relapse prevention, goal setting, cognitive reframing and coping imagery, stimulus control, social assertion, reinforcement techniques for enhancing motivation, cognitive strategies for replacing negative thinking with more positive statements and constructive self-statements), and diet (either calorie deficit or a low-calorie diet) was associated with a summary estimate of weight change of –4.22 kg (WMD % CI –4.80 to –3.64, based on five comparisons) compared with control.

Figure 15.25 Maintenance of weight loss over time for physical activity, diet and behaviour therapy compared with control

Review: PHYSICAL ACTIVITY Analyses for adults
Comparison: 10 Physical activity, diet, and behaviour therapy vs control
Outcome: 08 Weight change over time

Study or sub-category	N	Combined Mean (SD)	N	Control Mean (SD)	WMD (fixed) 95% CI	Weight %	WMD (fixed) 95% CI
01 Ost 1976 - 600kcal/deficit or low fat							
Ost 1976 4 months	11	-9.35(4.47)	11	-3.51(4.04)		64.70	-5.84 [-9.40, -2.28]
Ost 1976 12 months	11	-4.60(6.20)	11	-2.40(5.30)		35.30	-2.20 [-7.02, 2.62]
02 TONE 1998 - 600kcal/deficit or low fat							
TONE 12 months	133	-5.36(4.56)	125	-0.48(3.24)		32.55	-4.88 [-5.84, -3.92]
TONE 18 months	131	-4.77(4.52)	122	-0.21(3.44)		30.93	-4.56 [-5.55, -3.57]
TONE 24 months	104	-4.58(4.55)	95	-0.09(3.53)		23.69	-4.49 [-5.62, -3.36]
TONE 30 months	60	-4.99(4.11)	53	-0.05(4.17)		12.83	-4.94 [-6.47, -3.41]
03 TOHP II 2001 - 600kcal/deficit or low fat							
TOHP II 6 months	565	-4.40(7.16)	561	0.10(5.94)		16.46	-4.50 [-5.27, -3.73]
TOHP II 12 months	545	-3.33(6.86)	551	0.53(6.06)		16.53	-3.86 [-4.63, -3.09]
TOHP II 18 months	545	-2.00(5.80)	551	0.70(4.20)		26.97	-2.70 [-3.30, -2.10]
TOHP II 24 months	545	-1.22(6.26)	551	1.17(6.25)		17.71	-2.39 [-3.13, -1.65]
TOHP II 36 months	557	-0.20(5.90)	554	1.80(5.30)		22.34	-2.00 [-2.66, -1.34]
04 Jeffery 1993 - LCD							
Jeffery 1993 12month	24	-5.87(7.58)	27	-1.51(6.34)		45.52	-4.36 [-8.22, -0.50]
Jeffery 1993 30month	24	-3.05(6.78)	27	0.25(5.99)		54.48	-3.30 [-6.83, 0.23]



Other outcomes

From the reported outcomes, no significant differences were seen other than for blood pressure. Both DBP and SBP were statistically significantly improved at all time points (other than DBP at 36 months) in populations with 'high normal' blood pressure or with diagnosed hypertension.

Other factors

Age

The included studies covered a wide range of ages (25–45 years,[102] 60–80 years TONE[92]).

Current medical conditions

Jalkanen's[99] and the TOHP studies[96-98] included participants with hypertension.

Gender

The TOHP I study[96] suggested although there were sex differences in the results for blood pressure, these were largely (but not exclusively) due to the differential weight loss for men and women.

Ethnicity

Subanalysis from the TONE study suggested that white participants lost more weight than black (African American) participants without, but not with, a concurrent focus on sodium reduction.[92-95]

Setting and delivery

One study was based in primary hypertension clinics,[99] three were based in university clinics or academic health centres,[92-98] and two gave no details of the setting. None of the studies were based in the UK.

Where reported, dietary components were delivered by professionals with expertise in nutrition.

Where reported, physical activity components were delivered by physiotherapists,[99] or exercise physiologists.[96] Activity was supervised in one study[99] (Jalkanen) and took place in the weekly sessions in the TOHP studies.[96-98]

Behaviour therapy was delivered by psychologists,[96;99] trained interventionists,[92;102] undergraduates with a thorough knowledge[91] or health educator.[97] The majority of studies used a group format. TONE[92] used a mixture of individual and group sessions, and the Ost study[91] was unclear but appeared to be individual sessions.

Context and methodological notes

Several studies[55;59;103;104]were moved to various other sections as the control group was considered to have received some intervention, even if the intervention was passive (for example, provision of a manual alone without additional support).

Physical activity, diet and behaviour therapy versus information

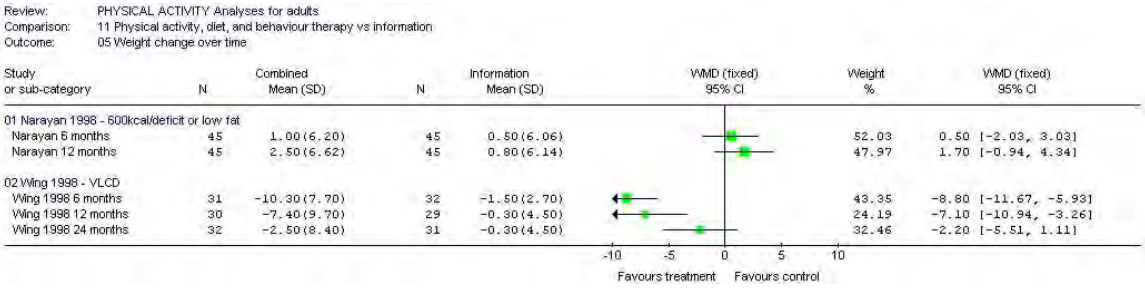
Seven trials were included in this comparison.[55;58;77;103-108]

Weight loss

At 12 months, a combination of physical activity (minimum 150 minutes per week), behaviour therapy (behaviour change goals and problem solving, goal setting, menu planning, self-efficacy, consideration of body image, social support, social eating, removing road blocks, positive thinking, dealing with high-risk situations and slips, cue elimination, stress management and relapse prevention, self-monitoring, problem solving, managing cues, stimulus control, positive assertion, positive thinking, holiday eating, social support, motivation, role playing, modelling food tasting and grocery store tours), and diet (either calorie deficit or a VLCD) was associated with a summary estimate of weight change of –3.82 kg (WMD 95% CI –4.63 to –3.02, based on six comparisons) compared with information alone.

Narayan and coworkers' study[104] which included only Pima Indians as the study population, appeared to be an outlier at 12 months.

Figure 15.26 Maintenance of weight loss over time for physical activity, diet and behaviour therapy compared with information



Other outcomes

The majority of clinical outcomes were not significantly different between groups and were not maintained over time (where reported). However, Wing and coworkers showed improved levels of triglycerides at 6 and 24 months (not at 12 months.[55]

Also both DBP and SBP were improved significantly at 12 months (DBP -1.74 mm Hg, WMD 95%CI –3.43 to –0.04, and SBP –3.59 mm Hg, WMD 95%CI

–6.31 to –0.86, based on three comparison) but this was not maintained at 24 months.

Wolf and coworkers[108] also reported that participants in the combined group lowered their use of medications, primarily diabetes medications, by 0.8 medications per day more than participants treated with usual care ($p = 0.03$). In seven of nine quality-of-life domains, the combined group improved compared with usual care ($p < 0.05$).

Other factors

Gender

Djuric and coworkers included women only, and the rest of the studies had a majority of women participating.[105]

Current medical conditions

Mayer-Davis and coworkers[107] included only people with diabetes, Lindhahl and coworkers[103] those with abnormal glucose tolerance, Messier[58] older people with arthritis, and Djuric and coworkers[105] survivors of breast cancer.

Setting and delivery

Studies were conducted in a variety of settings, including primary care. No studies were based in the UK.

Dietary components were delivered by dietitians[55;105] and nutritionists,[107] where reported. Physical activity components were delivered by exercise physiologists[55] and nutritionists.[107] Activity was supervised in two studies (during the inpatient stage[103] and walk with the therapist at weekly meetings[55]). Behaviour therapy was delivered by behaviour therapists and health educators.

Lindahl and coworkers delivered all interventions in a 1-month stay at a wellness centre, repeated in a 4-day stay at 12 months.[103]

Context and methodological notes

Some studies were excluded from this section for the following reasons: weight change in the control (education) group was not reported;[52] no requirement for participants to be overweight;[109] and because the intervention was not delivered in a clinical setting.[105,110]

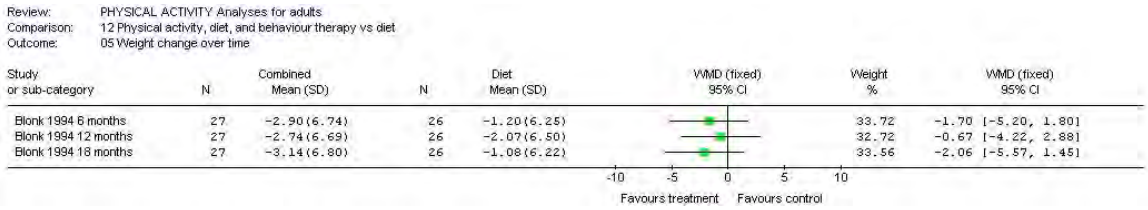
Physical activity, diet and behaviour therapy versus diet

Only one study compared physical activity, diet, and behaviour therapy with diet.[111]

Weight loss

At 12 months, a combination of physical activity (supervised training plus home-based activity), behaviour therapy (self-monitoring, stimulus control, self-reinforcement, cognitive restructuring and relapse prevention training), and diet (calorie deficit) was associated with a summary estimate of weight change of -0.67 kg (WMD 95% CI –4.22 to 2.88, based on one comparison) compared to diet alone.

Figure 15.27 Maintenance of weight loss over time for physical activity diet and behaviour therapy compared with diet



Other outcomes

No reported outcomes were significant.

Other factors

Current medical conditions

Blonk and coworkers recruited only people with type 2 diabetes.[111]

Setting and delivery

The study was conducted in the Netherlands, and no detail of setting was reported.

A dietitian provided dietary education. Group sessions on behaviour therapy were led by a psychologist experienced in eating disorders. Group exercise training was led by two physiotherapists, so assumed to be supervised.

Context and methodological notes

Phenix cluster RCT[70] (HTA study) excluded as no published papers could be identified (unpublished PhD thesis only).

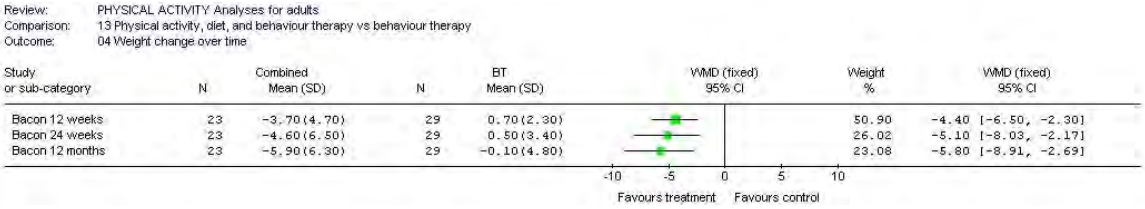
Physical activity, diet and behaviour therapy versus behaviour therapy

Only one study compared physical activity, diet and behaviour therapy with behaviour therapy.[112]

Weight loss

At 12 months, a combination of physical activity (individualised level), behaviour therapy (self-monitoring, stimulus control, reinforcement, cognitive change), and diet (calorie deficit) was associated with a summary estimate of weight change of –5.80 kg (WMD 95% CI –8.91 to –2.69, based on one comparison) compared with behaviour therapy (enhancing body acceptance, disentangling self-worth from weight, barriers transformation, increased support and assertion, self-monitoring) alone.

Figure 15.28 Maintenance of weight loss over time for physical activity, diet and behaviour therapy (BT) compared with BT



Other outcomes

No reported outcomes were significant.

Other factors

Age

Only women aged 30–45 years were recruited.

Gender

Bacon and coworkers[112] recruited women only. The participants also had to be 'chronic dieters' (defined as a Restraint score greater than 15).

Setting and delivery

Bacon's study was conducted in the USA and assumed to be based in university clinics.

The diet programme was taught by an experienced registered dietitian, based on the LEARN manual. The non-diet programme was facilitated by a counsellor with experience of using that approach previously. Both interventions were delivered in group formats. Activity was not supervised.

Physical activity, diet and behaviour therapy versus physical activity

One trial was found that compared physical activity, diet and behaviour therapy with physical activity.[58;77]

Weight loss

At 18 months, mean ± SD weight change in kilograms was –5.20 ± 6.89 kg in the combined group, and –3.46 ± 6.89 kg in the activity group. Mean weight change in the intervention group compared with activity was –1.74 (95% CI –3.98 to 0.50).

Other outcomes

At 18 months, no significant differences in improvement were seen for self-reported physical function, motility or pain between groups.

Other factors

Current medical conditions

The included study recruited only participants with osteoarthritis of the knee.[58]

Age

Messier and coworkers recruited older people only (aged 60 years or older).[58]

Setting and delivery

The trial was based in an older people's independence centre in the USA. The physical activity could be done either in the centre or at home. No details of whether the facility-based training was supervised were reported. No details of who delivered the behaviour therapy were reported, but the majority of sessions were group sessions.

Context and methodological notes

Two papers on the same study were identified and which appeared to give different results. For this review, the Messier paper was used[58], but Nicklas[77] was checked for apparent differences (possibly due to different populations used).

Physical activity, diet and behaviour therapy versus diet and behaviour therapy

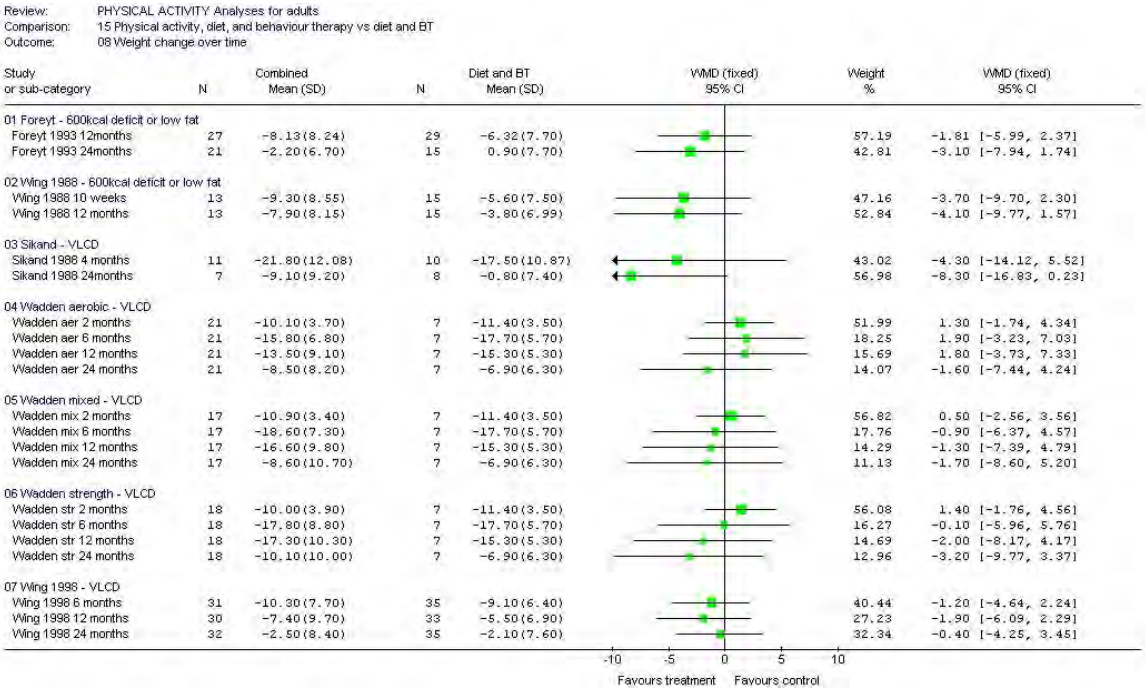
Six studies were included in this comparison.[55;58;77;113-117]

Weight loss

At 12 months, a combination of physical activity (min 45 minutes three times a week), behaviour therapy (contracts to reward behaviour change, stress management, stimulus control and goal setting, cognitive behaviour therapy, slowing down rate of eating, reducing eating signals in the home, social pressures, pre-planning and relapse prevention techniques, problem solving, reducing barriers, exercising in different weather conditions), and diet (calorie deficit or VLCD) was associated with a summary estimate of weight change of -1.59 kg (WMD 95% CI –3.67 to 0.49, based on six comparisons) compared with diet and behaviour therapy.

No significant difference was seen between the two approaches at any reported time point.

Figure 15.29 Maintenance of weight loss over time for physical activity, diet and behaviour therapy (BT) compared with diet and BT



Other outcomes

No reported outcomes were significant.

Other factors

Gender

Sikand and coworkers[115] and Wadden and coworkers[116] recruited women only.

Current medical conditions

Wing and coworkers[117] recruited people with type 2 diabetes. Wing and coworkers[55] recruited people who did **not** have diabetes, but who had one or both biological parents with diabetes. Messier and coworkers recruited older people with arthritis.[58]

Setting and delivery

All studies were based in the USA, and where reported, were conducted in university clinics.

Dietary components were delivered by dietitians where reported. Similarly, activity was delivered by exercise physiologists, where reported. The activity was supervised in two studies (initially),[113;117] but individuals were also encouraged to exercise on their own. Also supervised activity was undertaken in two studies (walk with the therapist at weekly meetings).[116;117] It was unclear in one study.111

Behaviour therapy was delivered by behaviour therapists,[58] dietitians with experience in behaviour modification,[113] and clinical psychologists.[116] All studies used a group format for delivery.

Context and methodological notes

The Phenix cluster RCT[70] (HTA study) was excluded as no published papers could be identified (unpublished PhD thesis only). Also the Kaplan[52] (HTA study) was excluded as all participants received the Exchange diet and an exercise prescription based on the results of the graded exercise test.

Wadden[116] was added to the meta-analysis as follows: 26 week results added to 6 months, 48 week results added to 12 months, and 100 weeks added to 24 months.

Wing[117] was moved to the section comparing physical activity, diet and behaviour therapy with physical activity and behaviour therapy.

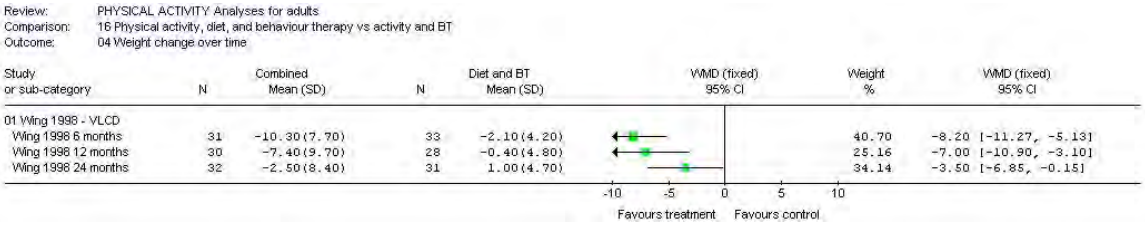
Physical activity, diet and behaviour therapy versus physical activity and behaviour therapy

One study compared a combined approach with physical activity and behaviour therapy.[55]

Weight loss

At 12 months, a combination of physical activity (approximately 45 minutes five times a week maximum), behaviour therapy (stimulus control, problem solving, reducing barriers, exercising in different weather conditions), and diet (VLCD) was associated with a summary estimate of weight change of –7.00 kg (WMD 95% CI –10.90 to –3.10, based on one comparison) compared with physical activity and behaviour therapy.

Figure 15.30 Maintenance of weight loss over time for physical activity, diet and behaviour therapy (BT) compared with activity and BT



Other outcomes

Some clinical outcomes (such as cholesterol, triglycerides, and SBP) improved in the short term (6 months), but the differences were not maintained beyond that time.

Other factors

Age

Wing and coworkers included only people aged 40–55 years.[117]

Current medical conditions

Wing recruited people who did **not** have diabetes, but who had one or both biological parents with diabetes.[117]

Setting and delivery

The study was based in the USA and assumed to be in a university hospital.

Group meetings were led by a multidisciplinary team, with primary therapists for activity being a behaviour therapist and an exercise physiologist, and for diet a behaviour therapist and a registered dietitian. The activity was supervised (walk with the therapist at weekly meetings).

Intensity of physical activity

This review was based upon six RCTs[118-123] which varied either exercise intensity (kilocalories expended per week) or duration (length of exercise time) or both. Weight loss was not the primary outcome measure in all of these studies but each trial did vary exercise prescriptions and report weight loss between groups. For this evidence review, only trials with a duration (including follow-up) of 12 months or more were included. Also, mean BMI of participants had to be 28 or over. Due to the nature of the studies (weight loss not being a primary outcome, heterogeneity of the interventions) no summary statistics were calculated.

Additional studies comparing exercise with stretching[124;125], walking vs resistance training[126], and intensive vs a control exercise programme[127] were identified in the Update searches. However, because the GDG considered that there was a lack convincing evidence overall, recommendations would be based on accepted national guidance,[128] so these have not been added to this review.

Weight loss

Between group weight losses were observed in only two of the seven studies reviewed. Jakicic and coworkers reported no significant difference between the long and short bout exercise groups but weight loss was significantly different between the short bout group which used exercise equipment (treadmill) and the short bout group which did not use a treadmill.[120] In Jeffery and coworkers' study the between-group weight loss in the high physical activity group (2500 kcal/week) and the standard behaviour group (1000 kcal/week) was significant at 18 months ($p = 0.04$).[123]

Other outcomes

There were no significant cardiovascular differences reported.

Other factors

Gender

Four of the included trials recruited women only.[118-121] Overall, the majority of participants were women.

Age

All included studies recruited middle-aged people (age range 25–58 years).

Setting and delivery

All studies were US based. Exercise settings varied between home and exercise centre and between supervised and unsupervised. Reporting of home-based, unsupervised exercise was by self-report.

15.3.4 Pharmacological interventions♣

15.3.4.1 Evidence statements – orlistat (Table 15.19)

Table 15.19 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss and maintenance		
1	Overall, people taking orlistat were 33% (95% CI 28% to 37%) more likely to achieve at least a 5% weight loss at 12 months (approximate mean of people who achieved 5% weight loss or more 54%, range 33–73%) than people taking placebo (approximate mean of people who achieved 5% weight loss or more 32%, range 13–50%) (n = 14 studies) For people with type 2 diabetes and for people with hypertension, a minimum 5% weight loss was also more likely (28%, 95% CI 20% to 35%, n = 3 studies, 39%, 95% CI 12% to 43%, n = 1 study respectively) However, the use of orlistat does not guarantee weight loss. In one trial, approximately 8% of the orlistat group and 18% of the control group did not lose any weight or actually put weight on	
2	Overall, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective for weight loss than placebo and diet: a change of approximately –3.3 kg (95% CI -3.55kg to -3.00kg, range –1.0 kg to –4.4 kg) at 12 months. Median weight change across studies was approximately –5.4 kg (range –3.3 kg to –10.6 kg) for orlistat and –2.7 kg (range –0.9 kg to –7.6 kg) for placebo (n = 15 studies)	1++

♣ Detailed information on previous technology appraisals are described in section 15.3.11.

No.	Evidence statement	Grade
3	In people who are otherwise healthy, or have one or more identified risk factors, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective for weight loss than placebo and diet: a change of approximately –3.6 kg (95% CI -3.96kg to -3.27kg, range –1.0 kg to –4.4 kg) at 12 months. Median weight change across studies was approximately –6.0 kg (range –3.3 kg to –10.6 kg) for orlistat and –3.0 kg (range –0.9 kg to –7.6 kg) for placebo (n = 11 studies)	1++
4	In people with type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective for weight loss than placebo and diet: a change of approximately –2.7 kg (95% CI -.3.18kg to -2.18kg, range -2.4 kg to –2.9 kg) at 12 months. Median weight change across studies was approximately –3.9 kg (range –3.8 kg to –4.7 kg) for orlistat and –1.3 kg (range –1.4 kg to –1.8 kg) for placebo (n = 3 studies)	1++
5	In people with hypertension, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective for weight loss than placebo and diet: a change of approximately -2.7 kg (95% CI -3.79kg to -1.61kg) at 12 months. Absolute weight change was approximately –5.4 kg for orlistat and –2.7 kg for placebo (n = 1 study)	1+
6	Overall, In people who are otherwise healthy, orlistat (120 mg three times a day) in combination with diet is more effective for weight loss than placebo and diet: a change of approximately -3.3 kg (95% CI -4.15kg to -2.37kg, range –2.9 kg to –3.6 kg) at 24 months. Median weight change across studies was approximately -4.2 kg (range –2.5 kg to –6.0 kg) for orlistat and -0.1 kg (range +1.0 kg to –3.0 kg) for placebo (n = 2 studies)	1++

No.	Evidence statement	Grade
7	Overall, in people who are otherwise healthy, orlistat (120 mg three times a day) in combination with diet is more effective for weight loss than placebo and diet: a change of approximately -2.8 kg (95% CI -3.29kg to -2.31kg) at 48 months Absolute weight change across studies was approximately -5.8 kg for orlistat and –3.0 kg for placebo (n = 1 study)	1++
8	Overall, in people who are otherwise healthy, the use of orlistat in combination with either a 1000 kcal deficit diet or a 500 kcal deficit diet resulted in a similar weight loss at 12 months: -9.5 kg compared with –8.6 kg. (n = 1 study)	
Weight regain		
9	Two studies showed the effect on weight change over the subsequent 12 months when orlistat was withdrawn after the initial 12 months treatment. People who continued on orlistat regained, on average, approximately half as much weight as those on placebo (+3.2 kg vs +5.6 kg, p < 0.001). (n = 2 studies)	1++
Outcomes other than weight loss (from trials that reported weight loss)		
10	Overall, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering total cholesterol levels than placebo and diet: a change of approximately –0.36 mmol/l (95% CI -0.40mmol/l to -0.31mmol/l, range –0.46 mmol/l to –0.23 mmol/l) at 12 months. Median change across studies was approximately –0.21 mmol/l (range –0.51 mmol/l to +0.03 mmol/l) for orlistat and +0.16 mmol/l (range –0.08 mmol/l to +0.41mmo/l) for placebo (n = 12 studies)	1++

No.	Evidence statement	Grade
11	In people who are otherwise healthy, or have one or more identified risk factors, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering total cholesterol levels than placebo and diet: a change of approximately –0.35 mmol/l (95% CI -0.35mmol/l to -0.28mmol/l, range –0.43 mmol/l to –0.23 mmol/l) at 12 months Median change across studies was approximately –0.08 mmol/l (range –0.51 mmol/l to +0.03 mmol/l) for orlistat and +0.20 mmol/l (range –0.08 mmol/l to +0.30mmo/l) for placebo (n = 8 studies)	1++
12	In people who have type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering total cholesterol levels than placebo and diet: a change of approximately –0.40 mmol/l (95% CI -0.50mmol/l to -0.30mmol/l, range –0.46 mmol/l to -0.33 mmol/l) at 12 months. Median change across studies was approximately -0.27 mmol/l (range –0.30 mmol/l to –0.05 mmol/l) for orlistat and +0.08 mmol/l (range +0.06 mmol/l to +0.41mmo/l) for placebo (n = 3 studies)	1++
13	In people who have hypertension, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering total cholesterol levels than placebo and diet: a change of approximately –0.32 mmol/l (95% CI -0.47mmol/l to -0.17mmol/l) at 12 months Mean absolute change was approximately –0.36 mmol/l for orlistat and –0.04 mmol/l for placebo (n = 1 studies)	1++
14	In people with type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering triglyceride levels than placebo and diet: a change of approximately –0.22 mmol/l at 12 months (95% CI -0.45mmol/l to -0.28mmol/l, range –0.28 mmol/l to -0.13 mmol/l) Median change across studies was approximately 0.02 mmol/l (range –0.25 mmol/l to +0.18 mmol/l) for orlistat and +0.28 mmol/l (range +0.03 mmol/l to +0.31 mmo/l) for placebo (n = 3 studies)	

No.	Evidence statement	Grade
15	Overall, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering %HbA1c levels than placebo and diet: a change of approximately –0.23 at 12 months (95% CI -0.28 to -0.17, range –0.47 to –0.11) Median change across studies was approximately –0.20 (range –0.75 to +0.08) for orlistat and +0.08 (range –0.41 to +0.32) for placebo (n = 6 studies)	
16	In people with type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering %HbA1c levels than placebo and diet: a change of approximately –0.36 at 12 months (95% CI -0.45 to -0.28, range –0.47 to –0.34) Median change across studies was approximately –0.62 (range –0.75 to –0.15) for orlistat and –0.27 (range –0.41 to +0.32) for placebo (n = 3 studies)	
17	Overall, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering fasting plasma glucose levels than placebo and diet: a change of approximately –0.24 mmol/l (95% CI -0.31mmol/l to -0.18mmol/l, range –1.30 mmol/l to –0.08 mmol/l) at 12 months Median change across studies was approximately -0.19 mmol/l (range –2.00 mmol/l to +0.10 mmol/l) for orlistat and +0.09 mmol/l (range –1.08 mmol/l to +0.70mmo/l) for placebo n = 10 studies)	1++
18	In people with type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering fasting plasma glucose levels than placebo and diet: a change of approximately –0.84 mmol/l (95% CI -1.04mmol/l to -0.64mmol/l, range –1.30 mmol/l to –0.55 mmol/l) at 12 months Median change across studies was approximately –1.63 mmol/l (range –2.00 mmol/l to +0.04 mmol/l) for orlistat and –0.70 mmol/l (range –1.08 mmol/l to +0.70mmo/l) for placebo (n = 3 studies)	1++

No.	Evidence statement	Grade
19	Overall, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering blood pressure than placebo and diet: a change of approximately -1.42 mm Hg DBP (95% CI -1.80 to -1.05, range –3.00 mm Hg to +0.40 mm Hg) at 12 months and –1.98 mm Hg SBP (95% CI -2.54 to -1.42, range –3.94 mm Hg to +0.40 mm Hg) at 12 months Median change across studies for DBP was approximately –2.20 mm Hg (range –11.40 mm Hg to –0.90 mm Hg) for orlistat and –1.30 mm Hg (range –9.20 mm Hg to +2.00 mm Hg) for placebo Median change across studies for SBP was approximately –2.10 mm Hg (range –13.30 mm Hg to +2.00 mm Hg) for orlistat and –0.90 mm Hg (range –11.00 mm Hg to +4.15 mm Hg) for placebo (n = 12 DBP, 13 SBP studies)	1++
20	In people who were otherwise healthy, or had one or more identified risk factors, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering blood pressure than placebo and diet: a change of approximately –1.38 mm Hg DBP (95% CI -1.79 to -0.97, range –2.40 mm Hg to +0.40 mm Hg) at 12 months and –2.04 mm Hg SBP (95% CI -2.67 to -1.41, range –3.70 mm Hg to +0.40 mm Hg) at 12 months Median change across studies for DBP was approximately –2.10 mm Hg (range –5.50 mm Hg to –0.90 mm Hg) for orlistat and –1.30 mm Hg (range –3.10 mm Hg to +2.00 mm Hg) for placebo Median change across studies for SBP was approximately –2.70 mm Hg (range –7.30 mm Hg to +2.00 mm Hg) for orlistat and –0.90 mm Hg (range –5.20 mm Hg to +3.00 mm Hg) for placebo (n = 9 studies)	1++

No.	Evidence statement	Grade
21	In people with type 2 diabetes, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering blood pressure than placebo and diet: a change of approximately –1.28 mm Hg DBP (95% CI -2.40 to -0.15, range –1.30 mm Hg to –1.24 mm Hg) at 12 months and –1.62 mm Hg SBP (95% CI -2.99 to -0.25, range -3.94 mm Hg to –0.30 mm Hg) at 12 months. Median change across studies for DBP was approximately -1.70 mm Hg (range –2.30 mm Hg to –1.01 mm Hg) for orlistat and –0.39 mm Hg (range –1.00 mm Hg to +0.23 mm Hg) for placebo. Median change across studies for SBP was approximately -1.20 mm Hg (range –2.10 mm Hg to +0.21 mm Hg) for orlistat and –0.30 mm Hg (range –0.90 mm Hg to +4.15 mm Hg) for placebo. (n = 2 DBP, 3 SBP studies)	1++
22	In people with hypertension, orlistat (120 mg three times a day) in combination with a weight reducing diet is more effective in lowering blood pressure than placebo and diet: a change of approximately –2.20 mm Hg (95% CI -3.62 to -0.78) DBP at 12 months and –2.30 mm Hg (95% CI -4.87 to 0.27) SBP at 12 months. Mean absolute change for DBP was –11.40 mm Hg for orlistat and –9.20 mm Hg for placebo Mean absolute change for SBP was –13.30 mm Hg for orlistat and –11.00 mm Hg for placebo (n = 1 study)	1++
23	Orlistat (120 mg three times a day) plus lifestyle changes significantly decreased the progression to type 2 diabetes compared with placebo plus lifestyle changes: a 37.3% decrease in the risk of developing diabetes at 4 years In people with impaired glucose tolerance at baseline, the decrease in the risk of developing diabetes was 45% at 4 years (n = 1 study)	1+

No.	Evidence statement	Grade
24	Only two studies reported outcomes relating to satisfaction or quality of life. Both reported significant improvements for selected outcomes in the orlistat group (greater satisfaction with weight loss medication, weight loss, weight loss programme, less weight related distress, increased vitality) compared with placebo. However, the same outcomes were not reported in both papers and therefore it is difficult to make any definitive statement about quality of life (n = 2 studies)	1++
25	Not all studies reported an analysis of which outcomes were statistically independent of weight loss. Of those studies that did report some associations, the most often reported outcomes independent of weight loss were total cholesterol levels and LDL cholesterol levels The association between weight loss and %HbA1c levels was less conclusive, with mixed results reported	1++
Harms (from trials that reported weight loss)		
26	Orlistat treatment is associated with increased rates of gastrointestinal events. However, these are frequently mild and transient	1++
Generalisability (from trials that reported weight loss)		
27	Of the 19 included trials, the majority included people with a BMI or 28 kg/m^2 or more (n = 10), or of 30 or more (n = 8) 13 studies had a maximum cut-off for BMI for participants; this ranged from 38 kg/m^2 (n = 1) to 50 kg/m^2 (n = 1), with most studies (n = 8) having a maximum BMI of 43 kg/m^2. Of those studies where a maximum was not defined, only one study reported the range for the participants, with the highest BMI being 59.3 kg/m^2 The evidence on the effectiveness of orlistat for people with a BMI of 50 kg/m^2 or more is therefore extremely limited	1++

No.	Evidence statement	Grade
28	Only three studies were conducted solely in the UK, with the majority of studies done in the USA (n = 8 studies) The majority of studies were based in secondary care (although it was often difficult to assess exactly what setting), with only two based in primary care and one in both secondary and primary care. One study was community based Where reported, participants were recruited as volunteers (that is, through advertising) and through selection (that is, referral or from waiting lists) in two studies It is difficult therefore to know how generalisable the results of the included studies are to the UK population, particularly in primary care	1++
29	From the included studies, the follow-up rate varied from every 2–4 weeks (n = 2), to every 3 months (n = 1). Most studies used either a schedule of contact every month for the duration of the study (n = 5), or an approach of decreased contact over time (every 2 weeks, then every month, then every 2 months) (n = 5)	1++
30	Dietary advice and support was provided most often by a dietitian (n = 8). However, in three studies, the aim was pragmatic and the intervention was delivered by general physicians with no additional training, or (for 80% of the participants) by generalists who would 'not be as experienced' as staff in specialist centres or by the practice nurse. Only one study reported using a expert in cognitive behavioural modification, but the aim of this study was to assess the effect of complete lifestyle intervention, not the effect of drug treatment specifically	1++
31	One assumption could be that the effect size achieved in the included studies may be smaller in practice, in a less motivated, non-volunteer population and less intensive follow-up, delivered by generalists. However, conversely those attending hospital/specialist clinics, or participating in trials may be more resistant than most patients seen in primary care	N/A
Combining drugs		
32	There is no evidence on the combining of orlistat and sibutramine. The actions of the drugs are not synergistic and the prescribing of a combination of these drugs is not recommended in the Summary of product characteristics	4

BMI, body mass index; DBP, diastolic blood pressure; N/A, not applicable; SBP, systolic blood pressure.

15.3.4.2 Evidence review on orlistat

This review was primarily based on two key reviews.[4;129] A comparison of the reviews can be seen in Table 15.16. Additional searching was also done to identify any other RCTs published since these key reviews were published. Reference lists of other relevant reviews were also cross-referenced. Update searches did not identify any additional relevant studies.

For this evidence review, only trials with a duration (including follow-up) of 12 months or more were included. Also, mean BMI of participants had to be 28 or over.

Table 15.20 Comparison of systematic reviews on orlistat for weight loss in adults

ID	Avenell HTA[4]	O'Meara HTA[120]
Title	Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement	A rapid and systematic review of the clinical effectiveness and cost effectiveness of orlistat in the management of obesity
Published	2004	2001 (and published review in 2004)
Aim	To review systematically treatments for the prevention and management of obesity in adults	To assess systematically the clinical effectiveness and cost effectiveness of orlistat in the management of obesity
Included study designs	RCTs only	RCTs
Excluded study designs	–	–
Included participants	Adults aged 18 years and over	Participants defined as overweight or obese or participants who wished to maintain weight loss, having previously been overweight or obese

ID	Avenell HTA[4]	O'Meara HTA[120]
Excluded participants	People with bulimia nervosa, pregnant women. Studies where average BMI < 28 kg/m^2 for all groups combined	None reported
Interventions	Orlistat (either alone or in combination)	Orlistat (either alone or in combination)
Key outcomes	Weight change in kilograms	Weight or other indicator of body mass
Duration	52 weeks or more	None, other than 12 months duration for company submissions
Databases searched	13 databases; handsearching; reference lists; abstracts and NRR; trialists and biomedical companies; experts	Not reported?
Period searched	Inception to April 2001 (e-databases)	Not reported?
Language restrictions	None (reports only?)	English, French, Dutch or German only

BMI, body mass index; NRR, National Research Register; RCT, randomised controlled trial.

Orlistat and diet versus placebo and diet

16 studies were included in this comparison.[130-152]

Weight loss

See summary statistics (Tables 15.21–15.23) for results for the individual studies.

Table 15.21 Orlistat and diet vs placebo and diet: weight loss (12 months)

Population	Weight loss compared with placebo (95% CI) at 12 months	No. of studies
All studies	–3.27 kg (–3.55 to –3.00)	15

Healthy or mixed	–3.61 kg (–3.96 to –3.27)	11
Type 2 diabetes	–2.68 kg (–3.18 to –2.07)	3
Hypertension	–2.70 kg (–3.79 to –1.61)	1

Table 15.22 Orlistat and diet vs placebo and diet: weight loss (24 months)

Population	Weight loss compared with placebo (95% CI) at 24 months	No. of studies
All studies (all healthy or mixed)	–3.26 kg (–4.15 to –2.37)	2

Table 15.23 Orlistat and diet vs placebo and diet: weight loss (48 months)

Population	Weight loss compared with placebo (95% CI) at 48 months	No. of studies
All studies (all healthy or mixed)	–2.80 kg (–3.29 to –2.31)	1

Weight maintenance

See summary statistics (Table 15.24 and Appendix 17).

Table 15.24 Orlistat and diet vs placebo and diet: weight maintenance

Population	Weight loss compared with placebo (95% CI) at 12 months	No. of studies
All studies	-0.19 kg (–0.97 to 0.58)	3

Other outcomes

See summary statistics (Tables 15.25–15.32 and Appendix 17).

Table 15.25 Orlistat and diet vs placebo and diet: total cholesterol

Population	Change in total cholesterol compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.36 mmol/l (–0.40 to –0.31)	12
Healthy or mixed	–0.35 mmol/l (–0.40 to –0.30)	8
Type 2 diabetes	–0.40 mmol/l (–0.50 to –0.30)	3
Hypertension	–0.32 mmol/l (–0.47 to –0.17)	1

Table 15.26 Orlistat and diet vs placebo and diet: LDL-cholesterol

Population	Change in LDL compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.30 mmol/l (–0.33 to –0.27)	12
Healthy or mixed	–0.31 mmol/l (–0.35 to –0.28)	8
Type 2 diabetes	–0.28 mmol/l (–0.35 to –0.20)	3
Hypertension	–0.20 mmol/l (–0.32 to –0.08)	1

Table 15.27 Orlistat and diet vs placebo and diet: HDL-cholesterol

Population	Change in HDL compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.04 mmol/l (–0.05 to –0.03)	10
Healthy or mixed	–0.05 mmol/l (–0.06 to –0.03)	7
Type 2 diabetes	–0.01 mmol/l (–0.04 to 0.02)	3
Hypertension	Not reported	–

Table 15.28 Orlistat and diet vs placebo and diet: triglycerides

Population	Change in triglycerides compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.01 mmol/l (–0.06 to +0.03)	10
Healthy or mixed	+0.04 mmol/l (–0.01 to +0.09)	7
Type 2 diabetes	–0.22 mmol/l (–0.32 to –0.12)	3
Hypertension	Not reported	–

Table 15.29 Orlistat and diet vs placebo and diet: %Hb1Ac

Population	Change in %Hb1Ac compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.23% (–0.28 to –0.17)	6
Healthy or mixed	–0.15% (–0.21 to –0.09)	3
Type 2 diabetes	–0.36% (–0.45 to –0.28)	3
Hypertension	Not reported	–

Table 15.30 Orlistat and diet vs placebo and diet: fasting plasma glucose

Population	Change in fasting plasma glucose compared with placebo (95% CI) at 12 months	No. of studies
All studies	–0.24 mmol/l (–0.31 to –0.18)	10
Healthy or mixed	–0.18 mmol/l (–0.24 to –0.11)	7
Type 2 diabetes	–0.84 mmol/l (–1.04 to –0.64)	3
Hypertension	Not reported	–

Table 15.31 Orlistat and diet vs placebo and diet: diastolic blood pressure

Population	Change in DBP compared with placebo (95% CI) at 12 months	No. of studies
All studies	–1.42mmHg (–1.80 to –1.05)	12
Healthy or mixed	–1.38mmHg (–1.79 to –0.97	9
Type 2 diabetes	–1.28mmHg (–2.40 to –0.5151)	2
Hypertension	–2.20mmHg (–3.62 to –0.78)	1

Table 15.32 Orlistat and diet vs placebo and diet: systolic blood pressure

Population	Change in SBP compared with placebo (95% CI) at 12 months	No. of studies
All studies	–1.98mmHg (–2.54 to –1.42)	13
Healthy or mixed	–2.04mmHg (–2.67 to –1.41)	9
Type 2 diabetes	–1.62mmHg (–2.99 to –0.25)	3
Hypertension	–2.30mmHg (–4.87 to 0.27)	1

Other factors

Age

Derosa and coworkers[133] included people aged over 40 years only, Kelley and coworkers[138] and Miles and coworkers[143] people aged 40–65 years, Swinburn and coworkers[150] people aged 40–70 years, and Torgerson and coworkers[151] people aged between 30 and 60 years.

Current medical conditions

Most studies included people who were otherwise healthy, or had one or more risk factors.[131,140,150,151] Hollander and coworkers,[137] Kelley and coworkers,[138] and Miles and coworkers[143] included people with type 2 diabetes only. Only people

with raised cholesterol levels were included by Broom and coworkers[131] and Derosa and coworkers.[133] Bakris and coworkers[130] included people with hypertension and who were taking antihypertensive medication.

Setting

Of those studies that reported details of the setting, most were university research clinics or outpatient clinics.

Two were based in primary care alone[135,140] and one was based in both primary and secondary care.[131]

Country

Two studies only were conducted in the UK.[131,134]

Recruitment

Recruitment was by referral or from clinical databases in Finer and coworkers' study (partially),[134] and in two other studies.[133,145] However, most studiesdid not report details of recruitment.

Methodological and context notes

The summary statistics were only calculated by subgroup (that is, weight reduction and weight maintenance) as comparing different outcomes, so we considered it was not appropriate to combine for an overall effect size.

The comparison of failures to achieve 5% or 10% weight loss was only done at 12 months, where the data were available.

Note that many studies calculated weight loss from after a trial run-in period. Therefore, the absolute weight loss may be an under-estimate. Details can be seen in the Evidence tables.

Orlistat and diet versus placebo and then orlistat and diet
One study was identified for this comparison.[153]

Weight loss

See summary statistics (Appendix 17).

Other outcomes

See summary statistics (Appendix 17).

Other factors

Participants had raised cholesterol.

Orlistat and lifestyle modification versus control (waiting list)
Only one study compared orlistat and lifestyle modification with a waiting list control.[154]

Weight loss

See summary statistics (Appendix 17).

Other outcomes

Women in the intervention group had significant improvements in total cholesterol and LDL-cholesterol. No other (usual) outcomes were significant.

Other factors

Age

Included women were aged 21–65 years.

Current medical conditions

Women with borderline hypertension or diabetes treated with oral medications were permitted to participate if their physician also consented.

Setting

The study was based in a community setting in the USA, and included only women of Mexican American descent.[154]

Orlistat and 1000 kcal/day deficit diet versus orlistat and 500 kcal/day deficit diet

One study was identified and participants only continued if they achieved a 5% or more weight loss from baseline at 3 and 6 months.[155]

Weight loss

See summary statistics (Appendix 17).

Other outcomes

See summary statistics (Appendix 17).

Other factors

No details reported (see Table 15.19 [Generalisability]).

15.3.4.3 Evidence statements – sibutramine (Table 15.33)

Table 15.33 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss		
1	Sibutramine (in combination with diet) is more effective for weight loss than placebo and diet alone: a change of approximately –4.7 kg (95% CI -5.38kg to -4.03kg, range –2.80 kg to –7.80 kg) at 12 months Median weight change across studies was approximately –5.25 kg (range –4.40 kg to –8.00 kg) for sibutramine and –0.45 kg (range 0.50 kg to –2.60 kg) for placebo at 12 months (n = 8 comparisons)	1++
2	Sibutramine (in combination with diet, activity and behaviour modification) is more effective for weight loss than placebo and diet, activity and behaviour modification: a reduction of approximately 3.5 kg (95% CI -4.45kg to -2.51kg) at 12 months (n = 2 comparisons)	1++
3	In people with type 2 diabetes, sibutramine in combination with diet is more effective for weight loss than placebo and diet (–5.70 kg, 95% CI -6.84kg to -4.54kg) Median weight change was approximately –7.10 kg (range –5.50 kg to –8.00 kg) for sibutramine compared with –0.20 kg (range –0.20 kg to –2.60 kg) for placebo at 12 months (n = 3 comparisons)	1++
4	In people with hypertension, sibutramine in combination with diet is more effective for weight loss than placebo and diet (–4.00 kg, 95% CO -5.30kg to -2.70kg). Median weight change was approximately –4.45 kg (range –4.40 kg to –4.50 kg) for sibutramine compared with –0.45 kg (range –0.40 kg to –0.50 kg) for placebo at 12 months. (n = 2 comparisons)	1++

No.	Evidence statement	Grade
Weight maintenance		
5	Sibutramine can be more effective than placebo in weight maintenance after 18 months, having 43% of participants maintaining 80% or more of their original 6 month weight loss compared with 16% in the placebo group (n = 1 study)	1+
6	Evidence from one trial suggests that sibutramine helped maintain at least 5% of weight loss in 69% of participants, and 10% weight loss in 46% of the participants after 18 months. However, participants who did not achieve 5% weight loss over 6 months of treatment were excluded from the maintenance phase. (n = 1 study)	1+
Weight regain		
7	There is evidence that suggests that 3 months after stopping treatment, weight gain was 4.3 (±3.1) kg in the sibutramine group, compared to 2.3 (±2.9) kg in the placebo group (n = 1 study)	1+
Outcomes other than weight loss (from trials that reported weight loss)		
9	Overall, sibutramine and diet had an effect in changing HDL levels by +0.10 mmol/l (95% CI +0.06 to +0.14, range +0.08 mmol/l to +0.11 mmol/l) compared with placebo and diet Median change was approximately +0.12 mmol/l (range +0.10 mmol/l to +0.34 mmol/l) for sibutramine compared with +0.03 mmol/l (range (0.00 mmol/l to +0.23 mmol/l) for placebo at 12 months (n=5 studies)	1++
10	Overall, sibutramine and diet had an effect in lowering triglyceride levels by –0.18 mmol/l (95% CI -0.28 to -0.08, range –0.05 mmol/l to –0.30 mmol/l) compared with placebo and diet Median change was approximately –0.20 mmol/l (range –0.05 mmol/l to –0.44 mmol/l) for sibutramine compared with –0.01 mmol/l (range –0.11 mmol/l to –0.21 mmol/l) for placebo at 12 months (n=6 comparisons)	1++

No.	Evidence statement	Grade
11	For people with type 2 diabetes, significant lowering of levels was seen in the sibutramine groups for levels of fasting plasma glucose (–0.40 mmol/l, 95% CI -0.81 to 0.00) and triglycerides (–0.30 mmol/l, 95% CI -0.59 to -0.01)) compared with placebo at 12 months (n = 2 studies)	1++
12	For people with hypertension, SBP did not differ significantly between groups, but at 12 months DBP increased in the treatment group compared to placebo (+3.20, 95% CI 1.53 to 4.87) (n = 2 studies)	1++
Harms (from trials that reported weight loss)		
13	Common side effects associated with sibutramine treatment were headaches, constipation and dry mouth	1++
Generalisability (from trials that reported weight loss)		
14	Of the 13 included trials, the majority included people with a BMI or 27 kg/m^2 or more (n = 7) Eight studies had a maximum cut-off for BMI for participants; this ranged from 40 kg/m^2 (n = 5) to 50 kg/m^2 (n = 1) The evidence on the effectiveness of sibutramine for people with a BMI of 50 kg/m^2 or more is therefore extremely limited	1++

No.	Evidence statement	Grade
15	One study was entirely conducted in the UK, whilst two others which consisted of multicentre trials, included people from the UK. The majority of the studies were conducted in the US The majority of the studies were based in university research clinics or outpatient clinics, with only three trials being based in a primary care setting. Two studies were multicentre trials, one with 21 primary and secondary care centres, and one with with eight European secondary care centres Recruitment was by referral from general practitioners and family doctor internists in one study. All other studies did not provide details of recruitment Follow-up rate varied from every month (n = 5), to every 3 monthly visit (n = 1). Most of the studies applied an approach of decreased contact over time, although differing slightly from study to study	

BMI, body mass index; DBP, diastolic blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure.

15.3.4.4 Evidence review on sibutramine

Sibutramine and diet versus placebo and diet

Seven studies were included in this comparison.[156-164]

Weight loss

See summary statistics for results for the individual studies (Table 15.34 and Appendix 17).

The marketing authorisation for sibutramine has been suspended. See front cover for details.

Table 15.34 Sibutramine and diet versus placebo and diet: weight loss

Population	Weight loss compared with placebo (95% CI) at 12 months	No. of comparisons
All studies	–4.71 kg (–5.38 to –4.03)	8
Healthy or mixed	–4.32 kg (–5.41 to –3.22)	3
Type 2 diabetes	–5.69 kg (–6.84 to –4.54)	3
Hypertension	–4.00 kg (–5.30 to –2.70)	2

Weight loss was maintained at 15 months (–3.70 kg, 95% CI –5.71 to –1.69) on a weight reduction programme, and also when used with a weight maintenance programme (–3.40 kg, 95% CI –4.45 to –2.35).

Other outcomes

No significant differences were seen for levels of total cholesterol, LDL-cholesterol, %HbA1c, fasting plasma glucose or SBP overall at 12 months. Levels of HDL-cholesterol (+0.10 mmol/l), and triglycerides (–0.18 mmol/l) improved at 12 months. DBP increased significantly at 12 months (+2.16 mm Hg, 95% CI 1.20 to 3.11) in the sibutramine group compared with placebo.

For people with type 2 diabetes, significant improvements were seen in the sibutramine groups for levels of fasting plasma glucose (–0.40 mmol/l) and triglycerides (–0.30 mmol/l) compared with placebo at 12 months.

For people with hypertension, SBP did not differ significantly between groups, but at 12 months DBP increased in the treatment group compared with placebo (+3.20, 95% CI 1.53 to 4.87).

Other factors

Age and gender

The ages of participants ranged overall from 17 to (maximum defined) 70 years of age. The majority of the participants were women.

Current medical conditions

Three trials included people who were otherwise healthy,[156;158;159] two studies people with type 2 diabetes,[162;164] and two studies people with well-controlled hypertension.[157;163]

Setting

One study[158] was based in a primary care setting and another study[164] included 21 primary and secondary care centres in several countries. The remaining studies were based in either university research clinics or outpatient clinics. The Sibutramine Trial of Obesity Reduction and Maintenance (STORM)[159] study was conducted in eight European health centres (appeared to be primary care).

Country

Only Smith and Goulder's study[158] was conducted exclusively in the UK. One Study[156] was conducted in France. McNulty and coworkers' study[164] was conducted in England, Canada, France, Belgium. STORM[159] was conducted in eight European countries, including the UK.

Recruitment

In Smith and Goulder's study[158] the participants were recruited by by general practitioners and family doctor internists. Apfelbaum and coworkers[156] recruited participants from 12 medical centres, although no details were given. In STORM,[159] participants were recruited from local health centres. All other studies did not provide details of recruitment.

Sibutramine and diet with activity versus placebo and diet with activity

One trial compared the use of sibutramine or placebo with diet (50% carbohydrates, 30% fats, 20% proteins) and activity (30 minutes of walking per day) in people with type 2 diabetes.[165]

Weight loss

No significant difference in weight loss was seen at 12 months, although both groups had lost weight (–4.10 kg sibutramine vs –1.40kg placebo).

Other outcomes

Significant improvements were seen in the sibutramine group at 12 months for levels of LDL-cholesterol (–0.37 mmol/l) and %HbA1c (–-0.70).

Other factors

Participants had type 2 diabetes, were taking glibenclamide, and were mainly women. The study was based in secondary care in Mexico.

Sibutramine and diet with activity and behaviour therapy versus placebo and diet with activity and behaviour therapy

Two trials compared the use of sibutramine or placebo with a combination lifestyle intervention.[166;167]

Weight loss

A significant difference in weight loss was seen at 12 months (–3.48 kg, 95% CI –4.45 to –2.51) between the two groups.

Other outcomes

No significant changes were seen at 12 months.

Other factors

Participants in both studies were otherwise healthy, and the majority were women.

Sibutramine and lifestyle versus lifestyle intervention alone then sibutramine and lifestyle for all participants

One trial compared the use of sibutramine and lifestyle with lifestyle intervention alone in people with type 2 diabetes.[168;169] After 12 months, the standard lifestyle group was prescribed sibutramine.

Weight loss

A significant difference in weight loss was seen at 12 months (–6.50 kg sibutramine compared to lifestyle alone), but at 24 months, the standard lifestyle (followed with 12 months sibutramine) group lost more weight than the sibutramine (continuous for 24 months) group (–8.10 kg vs –4.60 kg, respectively).

Other outcomes

No significant changes were seen at any time points.

Other factors

Participants had type 2 diabetes and were mainly women. The study was based in a research centre in the USA.

Sibutramine with a combination lifestyle intervention versus sibutramine, low-calorie diet and activity

One trial was included in this comparison.[170;171]

Update searches identified one additional study by the same authors, using a similar, but extended protocol.[172] This study concluded that the use of sibutramine in combination with lifestyle was more effective than either

sibutramine or lifestyle alone. Therefore, as the study supported the detailed evidence review, no further details are reported here.

Weight loss

A significant difference in weight loss was seen at 12 months (–10.61 kg, 95% CI –14.64 to –6.58).

Other outcomes

Authors reported significant reductions at 12 months in triglyceride and low-density lipoprotein cholesterol levels but systolic and diastolic blood pressure both increased significantly ($p<0.05$ for all).

Other factors

Participants were women who were otherwise healthy. The study was based in a research clinic in the USA.

Sibutramine and diet versus placebo and diet (for 4 months) then open label sibutramine for all participants

One trial was included in this comparison.[173]

Weight loss

A significant difference in weight loss was seen at 4 months (–4.10 kg, 95% CI -7.58 to –0.62), but this was not maintained at 12 months, although both groups did lose weight (–12.90 kg sibutramine for 12 months, –11.90 kg placebo then diet).

Other outcomes

No other outcomes were reported.

Other factors

Participants were women who were otherwise healthy. The study was based in an obesity management centre in the Czech Republic.

Sibutramine in combination with orlistat

Wadden and coworkers[171] (continuation trial of Wadden and coworkers[170]) evaluated whether adding orlistat to sibutramine would induce further weight loss in participants who previously had lost weight while taking sibutramine alone. The initial period of the trial (that is, sibutramine alone) lasted 12 months, with the period using both drugs lasting only 16 weeks. Because the period of evaluation of the combination was only 16 weeks, this trial did not meet our criteria of a 12 month follow-up (for the combination), so it was excluded from the review.

15.3.4.5 Summary of previous NICE Technology Appraisals - drugs

Orlistat

The Technological Appraisal Guidance- No.22: Guidance on the use of Orlistat for the treatment of obesity in adults (2004) stated that orlistat should be prescribed for people who have lost at least 2.5kg by dietary control and increased physical activity alone in the month prior to first prescription. This guideline recommends that pharmacological treatment should be initiated only after dietary, exercise and, additionally, behavioural approaches have been started (NICE 1.2.5.1, full guideline 1.7.5.1).

The Technological Appraisal Guidance- No.22: Guidance on the use of Orlistat for the treatment of obesity in adults (2004) did not recommend the continuation of therapy beyond 12 months. This guideline recommends that the decision to use drug therapy for greater than 12 months (usually for weight maintenance) should be made after discussing potential benefits and limitations with the patient (NICE 1.2.5.20, full guideline 1.7.5.20).

See also Section 6 for the detailed health economic modelling.

Sibutramine

The Technological Appraisal Guidance- No.31: Guidance on the use of Sibutramine for the treatment of obesity in adults (2001) recommended a starting dose of 10mg/day. This guideline does not recommend a starting dose but suggests that prescription should be in accordance to the drug's summary of product characteristics (NICE 1.2.5.4, full guideline 1.7.5.4).

See also Section 6 for the detailed health economic modelling.

15.3.5 Surgery and referral to specialist services♣

15.3.5.1 Evidence statements (Table 15.35)

Table 15.35 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss (surgery vs non-surgery)		
1	Evidence supports the use of surgery for weight loss in people for whom surgery is an appropriate option One RCT showed that at 12 months, the use of an exceptional diet, with intensive follow-up (approximately 30 contacts per year initially) and support (outpatient clinic visits and group meetings) can achieve similar results to surgery (–18.0 kg vs –22.0 kg) in people with at least 60% excess weight, but these results are not maintained at 24 months Surgery remains more effective than a non-surgical approach for people who are obese (BMI ≥ 38 kg/m^2 for women, ≥ 34 for men) in the longer term (measured up to 10 years after surgery)	1+, 2+
2	Percentage EWL was not reported by any of the included studies comparing surgery and non-surgical interventions	N/A
3	In one study reporting the effects of surgery on weight maintenance, weight loss from surgery can be maintained up to 10 years after surgery (approx 17% excess weight loss).	2+
4	There is a lack of evidence comparing surgical and non-surgical options in groups with a mean BMI ≥ 50 kg/m^2	N/A
Weight loss (by different procedures)		
5	Laparoscopic RYGB resulted in a significantly higher % EWL at all measured time points when compared with LAGB (n = 1)	2+
6	DS-BPD and RYGB show similar rates of % EWL at 12 (53% vs 54%) and 24 months (63% vs 67%)	3
7	From observational studies, % EWL was as follows: Procedure / 24 months Median (range) / 60 months Median (range)	2++

♣ Detailed information on previous technology appraisals are described in section 15.3.11

No.	Evidence statement			Grade
	LAGB	54.5% (38% to 87%) n = 16	54% (44% to 66%) n = 6	
	Laparoscopic GB	69% (67% to 83%) n = 5	82% n = 1	
	Open GB	65% (55% to 71%) n = 3	57% (56% to 58%) n = 2	
	DS-BPD	71.5% (67% to 78%) n = 4	69% (66% to 73%) n = 4	

From observational studies, mean change in BMI was as follows:

Procedure	24 months Median (range)	60 months Median (range)
LAGB	-11.9 (-19.2 to -8.9) n = 17	-11 (-12.8 to -8.9) n = 4
Laparoscopic GB	-16.8 (-20.86 to -16.8) n = 3	Not reported
Open GB	-18.5 (-19 to -18.4) n = 3	Not reported
DS-BPD	-23 n = 1	-20.3 (-21 to -17.1) n = 3

Outcomes other than weight loss (from trials that reported weight loss)

No.	Evidence statement	Grade
8	Surgery was associated with improvements in clinical outcomes (such as blood pressure, cholesterol levels, triglycerides and glucose) compared with non-surgical intervention (n = 1)	2+
9	People who underwent surgery were less likely to develop type 2 diabetes at both 2 and 8 years, or hypertension at 2 years, but not at 8 years, compared with those who had non-surgical intervention Recovery from other conditions (such as hyperinsulinaemia and hypertriglyceridaemia) was also more likely in people who had surgery (n = 1)	2+
10	Where reported, the majority of people experienced remission or improvement of associated comorbidities, including diabetes, hypertension, arthritis, sleep apnoea, after surgery	2+
11	Where reported, the majority of people experienced improvement in quality of life after surgery	2+
12	Both LAGB and LGBP resulted in lower rates of hypertension, diabetes up to 24 months after surgery, but LGBP was associated with a lower rate of dyslipidaemia compared with LAGB (n = 1)	2+
13	Laparoscopic GBP was associated with a shorter hospital stay than open GBP in two studies but a similar length of stay in two other studies	1+
14	Mean length of stay is higher for DS-BPD than for RYGB (8.7 vs 5.9 days)	3
Harms (from trials that reported weight loss)		
15	In trials comparing surgery with non-surgical interventions, mortality rates between groups were not compared	1+, 2+
16	In one comparative study, LAGB was associated with similar rates of early complications to LGBP (p = 0.36), but with higher levels of late complications (p = 0.001). Mortality was nil in both groups (n = 1)	2+
17	Reoperation rates were higher in the LAGB group compared with the LGBP group (26.2% vs 10.7% overall) (n = 1)	2+
18	Reoperation rates were similar in both laparoscopic and open GBP procedures, but late complications were more common in the open GBP group (24% vs 11%)	1+

No.	Evidence statement	Grade
19	In the four trials comparing laparoscopic and open GBP conversion rates from laparoscopic to open surgery ranged from 2.5% to 23% Complication rates (minor 7.6% vs 11.8% and major 7.6% vs 9.2%) were similar in both lap and open GBP procedures (Nguyen), and early complications were similar for both techniques, but complication rates after 30 days were lower in the laparoscopic group.	1+
20	Sick leave tended to be lower in the LGBP group than in the open GBP group, but this was not seen across all studies	1+
21	Quality of life (several scores such as physical functioning) tended to be higher in the LGBP group at 1 month, but there was no significant difference between groups from 3 to 6 months onwards	1+
22	Where reported, some patients experienced significant nutritional adverse effects after surgery, which required intervention	2+
23	No evidence was identified to support routine psychological assessment. Many studies did not report any details of the preoperative work-up	N/A
24	From observational studies, reoperation rates were as follows	2++

Procedure	Median (range)
LAGB	6.5% (0.5% to 24%) n = 16
Laparoscopic GB	1.8% (0.03% to 9.8%) n = 4
Open GB	5% (2.8% to 12%) n = 3
DS-BPD	3.9% (2.7% to 6.3%) n = 5

No.	Evidence statement	Grade
25	Revision rates varied across operations, and studies. From the observational studies, 2.3% of laparoscopic adjustable bands were removed, 0.06% of the LGBPs were reversed, and approximately 4.75% (median, range 3.8% to 6.8%, n = 4) of DS-BPDs were revised; the majority for lengthening of the common limb for nutritional problems	2+
26	From observational studies, mortality rates were as follows	2++

Procedure	Median (range)
LAGB	0.0% (0% to 0.6%) n = 16
Laparoscopic GB	0.4% (0% to 1.1%) n = 5
Open GB	0.5% (0% to 1.5%) n = 4
DS-BPD	0.5% (0% to 1.4%) n = 5

27	DS-BPD and RYGB have similar rates of wound infection (22% vs 20%), postoperative anastomotic leaks (6% vs 3%) and mortality (0.9% vs 0.8%)	3
28	Staged surgery is an appropriate surgical option for people with BMI > 50 kg/m^2, but the evidence on weight loss and other outcomes remains limited	2+
Generalisability (from trials that reported weight loss)		
29	Most of the studies were based in large, specialist centres with high levels of support. Results may change if the centre is small or the setting is non-specialist.	1+, 2+, 3
30	Higher hospital and surgeon volume is associated with lower rates of mortality and complications	2+
Competencies and training		

No.	Evidence statement	Grade
31	There are learning curves associated with bariatric surgery and the individual procedures. Appropriate training is associated with complication rates and mortality similar to those when the rate plateau has been reached	2+
Referral to specialist services		
32	No evidence on the referral criteria to specialist services was identified	N/A

DS-BPD, duodenal switch and biliopancreatic diversion; EWL, excess weight loss; GB, gastric banding; GBP, gastric bypass; LAGB, laparoscopic adjustable gastric banding; LGBP, laparoscopic gastric bypass; RCT, randomised controlled trial; RYGB, Roux-en-Y gastric bypass.

15.3.5.2 Evidence review on different surgical procedures

This review was primarily based on two key reviews.[174;175] Additional searching was also done to identify any other trials published since these key reviews were published. Reference lists of other reviews were also cross-referenced. [176;177]

On expert advice, we widened our inclusion criteria for study design, and included study designs as follows:

- RCTs
- controlled clinical trials
- controlled before-and-after studies
- case series.

The focus of the study had to be the effectiveness of the surgical procedure, with a key (required) outcome of weight loss. Other criteria for inclusion were a minimum period of follow-up (mean or median) of at least 12 months for RCTs, and (for studies other than RCTs) a minimum follow-up of 24 months and minimum number of 150 participants.

The evidence review only considered procedures that were currently being performed. These are of three types: restrictive, restrictive/malabsorptive, malabsorptive/restrictive.

- Restrictive: the gold standard is laparoscopic adjustable gastric banding (LAGB). Vertical gastric banding (VBG) was a forerunner to laparoscopic gastric banding, but had high rates of complications/failure. Both operations have similar, expected clinical outcomes. Laparoscopic gastric banding restricts intake (volume) of solid food. Older operations are VBG, horizontal gastroplasty, open adjustable banding.
- Restrictive/malabsorptive: gold standard is gastric bypass (Roux-en-Y), which mainly restricts dietary intake but also reduces absorption.
- Malabsorptive/restrictive: these are more similar to the older operations. The gold standard is duodenal switch (DS) and biliopancreatic diversion (BPD). These reduce calorie absorption, with limited restriction.

Gastric balloons are a short-term option, so were not considered as an appropriate surgical intervention for this review. Therefore, we did not review the evidence for this procedure.

The areas reviewed were as follows:

- Surgery versus non-surgical interventions
- LAGB versus gastric bypass (comparative studies)
- LAGB versus DS-BPD (comparative studies)
- DS-BPD versus gastric bypass (comparative studies)
- Laparoscopic gastric bypass versus open gastric bypass (comparative studies)
- Gastric bypass (open or laparoscopic) (single-arm studies)

- LAGB (single-arm studies)
- DS-BPD (single-arm studies)

Although we have reported details of complication rates associated with each procedure, caution should be used when interpreting these. Many of the series were undertaken over a long period of time, and initial rates of complications were often higher than would be anticipated for an established procedure or service (see Learning curve review below for further details). Also, concern was raised about the effect of different procedures on food intake (and therefore nutrient intake) and appetite. Where studies reported such outcomes, these have been reported, but it should be noted that this is an area of active research.

Also, because of the heterogeneous nature of the populations included in the series and the different levels of reporting, the rates differed considerably across studies.

An evidence review was also undertaken, using the same criteria as above, to evaluate the effectiveness of staged surgery for people with a BMI of 55 kg/m^2 or more.

Surgery versus non-surgical interventions

Some of the studies originally included in the HTA have been excluded as they considered the use of procedures no longer performed.[178] Also, two cohort studies included in the Cochrane review[174] were excluded as they did not have a minimum of 150 participants.[179;180] No additional studies were identified.

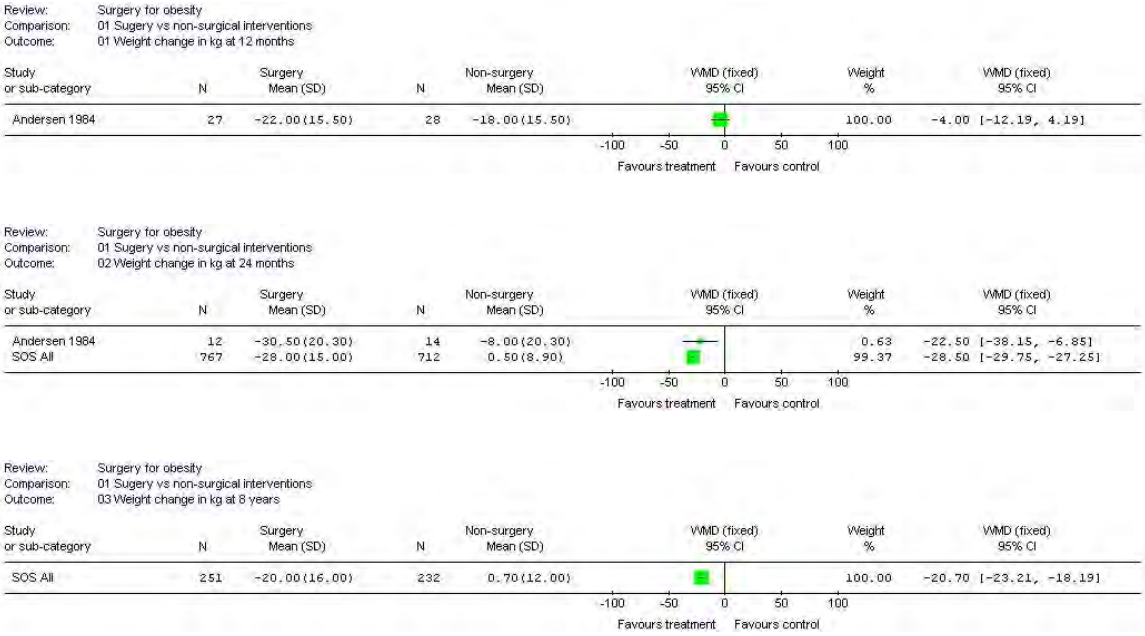
Three studies met our inclusion criteria,[181-183] and details can be seen in Appendix 15. Two of these were RCTs,[181;182] and one was a matched cohort study.[183-198]

No additional studies were identified in the Update searches (see Methods chapter for details).

Weight loss (Figure 15.31)

See evidence tables and statements (Table 15.35). No summary statistics were calculated due to differences in study design, and lack of data to include all relevant studies and time points.

Figure 15.31 Weight loss for surgery compared with non-surgical interventions



Other outcomes

See evidence tables (Appendix 15).

Restrictive surgery

This section was primarily based on the Technology Evaluation Centre (TEC) review of 2005[175] which evaluated laparoscopic gastric banding compared with various other procedures. Of the four included studies comparing the effectiveness of laparoscopic gastric banding with other procedures, two case–control studies met our inclusion criteria.[199;200] as Hell and coworkers study[201] had fewer than 150 participants, and Morino and coworkers[202] compared laparoscopic gastric banding with VBG, which is no longer performed.

Of the 46 single-arm studies (excluding 6 with fewer than 150 participants, a further 16 with a follow-up of less than 24 months, and 5 because no weight loss data were reported), 20 met our inclusion criteria (see Appendix 15 for details).[203-222] We also identified one additional paper[223] published since the TEC review.[175]

Update searches identified a further four relevant new or updated single-arm studies.[224-227] Three of these studies did not add any additional data to the evidence already reviewed in detail, with weight loss and revision rates being within the ranges reported in the evidence statements above. One study[224] however, examined the effectiveness of LAGB in people with a BMI less than, or equal to 35kg/m^2. This was a retrospective study using sub-group data from the Angrisani study[204] already included in the evidence review. Because of the retrospective nature of the study, and lack of other supporting evidence on this (the authors themselves noted in the Conclusions that surgical indications for BMI≤35 were questionable), we have not reported the data in this review.

Weight loss

See evidence tables Appendix 15

Other outcomes

See evidence tables Appendix 15 and evidence statements Table 15.35.

From those studies that reported revision rates, removal of the band occurred in approximately 2.3% (median) of participants (range 0.6%–15%). Approximately 6.5% (median) of patients were reoperated on (range 0.5–24%).

In addition:

- Dargent[213] reported that comorbidities improved in all people who lost 25% or more of excess weight (no further details).

- Favretti and colleagues[214] noted that 20% of patients who had excess weight loss greater than 30% lost compliance to dietetic, psychological and surgical advice.

- In the Frigg study,[215] the rate of remission and improvement in comorbiditites were: hypertension 58% and 42%, diabetes 75% and 8%, dyspnea 85% and 12%, arthralgia 52% and 24%, reflux 79% and 11%, self-esteem 45% and 39%, and general physical performance 58% and 33%. An improvement in stress incontinence, sleep apnoea, peripheral oedema, and regulation of menstruation was also reported. Greater weight loss was associated with greater reduction in dyspnoea, arthralgia, self-esteem, and physical performance. Hypertension, diabetes, reflux, and oedema improved independent of the amount of weight loss.

- US Food and Drug Administration (FDA) data[210] showed improvements in quality of life measures, such as depression, appearance, physical and emotional function, pain, general, mental, and physical health (no statistical significance reported).

- O'Brian and coworkers[219] reported improvements for people with diabetes (54% asymptomatic, 43% better control), asthma (Asthma Severity Score from 44.5 to 14.3, $p < 0.001$, 100% reduction in medication), dyslipidaemia (reduction from 34% to 9% of people with triglyceride levels > 2.0 mmol/l), hypertension (complete resolution in 55%, improvement in 31%), sleep apnoea (33% to 2%), gastro-oesophageal reflux disease (GORD) (76% complete resolution, 14% significantly improved), and quality of life (Beck Depression Index 18.0 to 7.8, $p < 0.001$, Medical Outcome Survey Short Form 36 subscales all returned to normal scores).

- Spivak and coworkers[220] reported improvements in hypertension (recovered 40%, improved 23%), diabetes (recovered 29%, improved 36%), hypercholesterolaemia (recovered 67%, improved 0%), sleep apnoea (recovered 38%, improved 13%), and GORD (recovered 82%, improved 5%).

- Weiner and coworkers[222] reported that 92% of people were satisfied with the general success, and this was associated with an improvement in quality of life. Improvements were also seen for people with hypertension (recovered 38%, improved 57%, diabetes (recovered 38%, improved 63%), and asthma (recovered 6%, improved 9%).

Restrictive/malabsorptive surgery

This section was primarily based on the TEC review of 2005[175] which evaluated gastric bypass compared with various other procedures. Eight of the nine included studies either compared the effectiveness of gastric bypass with procedures that are no longer performed (see other sections for comparisons with LAGB and DS-BPD) or did not meet the inclusion criteria for non-RCTs. In addition, Westling and Gustavsson[228] compared open versus laparoscopic GB, so was reviewed elsewhere.

Open gastric bypass

An additional search for single-arm studies of open GB found seven studies which met our inclusion criteria.[229-235] We focused the review on Roux-en-Y gastric bypass, as that is the commonest method performed in the UK. Details of the studies can be seen in Appendix 15. Any comparative studies comparing open gastric bypass with other included procedures were reviewed in the appropriate section.

Update searches identified one additional study.[236] Whilst the mean weight loss was within the range as reported above in the evidence statements, reoperation rates were considerably higher overall (27%). However, two techniques were used (silastic ring and, in the later cases, Fobi pouch) and the reoperation rates were 70% and 7% respectively. The reoperation rate for the newer technique is therefore within the range expected.

Weight loss

See evidence tables Appendix 15 and evidence statements Table 15.35.

Other outcomes

See evidence tables Appendix 15 and evidence statements Table 15.35.

Three studies reported details of reoperation rates:

- Reoperations were required because of suspicion of anastomotic leak in two patients (only one proved to have a leak), inadvertent removal of a gastrostomy tube (one patient) and small bowel obstruction (five patients).[230]
- Pories and coworkers[233] reported a reoperation rate of 2.8% (no details).
- Reoperation due to early and late complications was done in 12% of patients.[235]

In addition, Avinoah and coworkers[229] reported meat intolerance in over half of people and significant, but gradual, decreases in mean iron saturation, haemoglobin, and mean corpuscular volume. Mean vitamin B-12 levels declined significantly during the first four years but showed signs of improvement in the longer term. No significant change was seen in serum folic acid, and levels of serum albumin were normal throughout. People who took vitamin and mineral supplements had significantly higher mean values of vitamin B-12, folic acid and iron saturation than those who did not.

Balsiger and coworkers[230] reported a decrease in use of antihypertensive medication (36% to 16%), insulin (12% to < 1%), and anti-inflammatory medication (33% to 9%). Also, 93% of people were satisfied at 3 years after the gastric bypass, with early postprandial satiety in 84% of people and decreased appetite in 82%. Gastrointestinal events (such as constipation, heartburn, vomiting) were rare, but 22% of people reported diarrhoea at least once a week.

Csendes and coworkers[231] reported improvements in diabetes (resolved 100%), hyperlipidaemia (resolved 92.5%, improved 7.4%), hypertension (resolved 63.6%, improved 36.3%) and osteoarticular problems (resolved 73.3%, improved 26.6%). Quality of life was also much better with respect to self-esteem (81.6%),

work capacity (63.2%), sociability (52.9%), and physical capacity (83.9%), but for the majority, sexual activity remained as before the operation (42.5%). The final Bariatric Analysis and Reporting Outcome System (BAROS) index in 96.6% of people was very good or excellent.

Pories and coworkers[233] reported improvements in non-insulin-dependent diabetes mellitus or impaired glucose tolerance (IGT) (91% maintained normal fasting plasma glucose and HbA1c levels) and hypertension (58.1% to 14%). Also, improvements were almost always seen in cardiopulmonary function, sleep apnoea, snoring, asthma, peptic reflux, arthritis, fertility and mental health (including mood).

Schoepel and coworkers[234] reported improvements in diabetes (75%), hypertension (81%), GORD (86%), back pain (66%), arthritis (52%), sleeping problems (59%), skin rashes (67%), urinary incontinence (74%) and shortness of breath (92%). Over 90% of people showed an improvement in self-esteem, over 85% in physical activity and over 80% in social activity. Two-thirds of people increased their workload. Almost two-thirds reported an increase in sexual activity.

We were not able to get a complete full-text copy of the Torres paper,[235] so have reported only those outcomes as published in the TEC review[175].

Laparoscopic gastric bypass

An additional search for single-arm studies of laparoscopic gastric bypass found five studies which met our inclusion criteria.[237-241] We focused the review on Roux-en-Y gastric bypass, as that is the commonest method performed in the UK. Details of the studies can be seen in Appendix 15. Any comparative studies comparing laparoscopic gastric bypass with other included procedures are reviewed in the appropriate section.

No additional studies were identified in the Update searches.

Weight loss

See evidence tables (Appendix 15) and evidence statements (Table 15.35).

Other outcomes

See evidence tables (Appendix 15) and evidence statements (Table 15.35).

Reversal of the laparoscopic gastric bypass was reported in only one paper, and was done in only one patient (out of 1497 operations).[238] Revision for a leak at the jejunojejunostomy was also reported in one patient (out of 275).[239] Reoperation rates for indications including cholecystectomy and leaks also varied (median 1.8%, range 0.03–9.8%).

In addition, Schauer and coworkers[239] reported that 97% of people available to follow-up would choose laparoscopic gastric bypass again, if given the opportunity, and 95% of people reported an improvement in their quality of life. Also, improvements were seen in comorbidities such as diabetes (resolved 82%, improved 18%), hypercholesterolaemia (resolved 63%, improved 33%), osteoarthritis or degenerative joint disease (resolved 41%, improved 47%), GORD (resolved 72%, improved 24%), hypertension (resolved 70%, improved 18%), sleep apnoea (resolved 74%, improved 19%), hypertriglyceridaemia (resolved 57%, improved 29%), depression (resolved 8%, improved 47%), urinary incontinence (resolved 44%, improved 39%) and asthma (resolved 13%, improved 69%). Other conditions that either improved or resolved for the majority of people (although the numbers were small for some conditions) were peripheral oedema, migraine headaches, gout, coronary heart disease, chronic obstructive pulmonary disease, congestive heart failure and obesity hyperventilation syndrome. Venous insufficiency remained unchanged in 71% of people but improved in 29% of the seven people with this condition.

Schauer and coworkers[240] evaluated the effect of laparoscopic gastric bypass in people with impaired fasting glucose or type 2 diabetes. Improvements were seen in fasting plasma glucose and Hb1Ac (returned to normal levels 83%,

markedly improved 17%). Also, a significant reduction in use of oral antidiabetic agents (80%) and insulin (79%) was reported. People with the shortest duration of IGT or diabetes (< 5 years), the mildest form of type 2 diabetes (diet controlled), and the greatest weight loss after surgery were most likely to achieve complete resolution of their type 2 diabetes. Other improvements were seen in hypertension (resolved 36%, improved 53%), hypercholesterolaemia (resolved 37%, improved 41%), sleep apnoea (resolved 33%, improved 47%), symptoms of diabetic neuropathy (improved 50%) and erectile dysfunction (18%, although 82% were unchanged).

Wittgrove and Clark[241] reported improvements in GORD (resolved 98%), diabetes (resolved 98%, improved 2%) and hypertension (resolved 92%).

Laparoscopic versus open gastric bypass

This was primarily based on Colquitt and coworkers' Cochrane review.[174] Four RCTs were included.[228;242-244] Because there was a body of RCT evidence comparing these two procedures, we did not review lower level evidence, such as case series.

No additional studies were identified in the Update searches.

Weight loss

See evidence tables (Appendix 15) and evidence statements (Table 15.35)..

Other outcomes

See evidence tables (Appendix 15) and evidence statements (Table 15.35).

Malabsorptive/restrictive surgery

This review considered the evidence for the effectiveness of DS (with BPD) and was based primarily on the 2005 TEC review.[175]

One study comparing DS-BPD and Roux-en-Y gastric bypass was included[245] and seven single-arm studies (all included in the TEC review)[246-252]. One further

observational study has been published,[223] but did not meet the criterion of 150 participants: only 40 people underwent DS-BPD and 90 people Roux-en-Y gastric bypass.

No additional studies were identified in the Update searches.

Weight loss

See evidence tables (Appendix 15) and evidence statements (Table 15.35).

Other outcomes

See evidence tables (Appendix 15) and evidence statements (Table 15.35).

Revisions were reported in:

- 5.7% of patients to increase the length of the common channel.[246]
- 2.7% of patients to increase the length of the common limb due to malnutrition.[248]
- 3.8% of patients due to low protein and excess weight loss, excess diarrhoea, or poor weight loss. Also one reversal was reported due to patient demand.[249]
- 6.8% of patients for recurrent protein malnutrition.[250]

Overall reoperation rates also varied (median 3.9%, range 2.7–6.3%).

In addition, Anthone and coworkers[246] reported that no clinical sequelae occurred from hypocalcaemia or anaemia in patients who did not require revision of the length of the common channel. No evidence of hepatic dysfunction or liver failure was seen. No specific food intolerances were seen, and reported mean energy intake was 1600 calories (approximately 63% of preoperative intake).

Biron and coworkers[247] showed that, for people with an initial BMI less than 50 kg/m^2, a residual BMI of 35 kg/m^2 caused a significant drop in the degree of satisfaction from 90% to 40%. For super-obese people (BMI ≥ 50 kg/m^2), the

same critical point was found at a BMI of 40 kg/m^2 where satisfaction dropped from 91% to 57%.

Guedea and coworkers[248] reported that glycaemia, cholesterolaemia and triglyceridaemia resolved in 100% of people, and 82.4% stopped antihypertensive medication at 12 months. Sleep apnoea also resolved in 100% and osteoarthritis and difficulty in walking improved in 84%. Menstruation became regular in 100% of women. The results of the operation (using the BAROS classification) were assessed as either excellent or very good at 5 years by 66% of people.

Hess and Hess[249] reported normal blood sugar levels for 100% of people with diabetes prior to surgery. In a sample of 100, 9% required iron supplementation or surgery (for excessive uterine bleeding). Although alkaline phosphatase was elevated in a sample of 100 people, vitamin D levels were within the normal range although low. The authors stressed the need for adequate vitamin D and calcium supplementation.

Marinari and coworkers[250] reported that 3.5% of operations were classified as a failure, 11% were fair results, 22.8% good, 39.5% very good and 23.2% as excellent results using the BAROS classification.

Slater and coworkers[251] focused specifically on vitamin and calcium deficiencies following BPD. Generally, the incidence of deficiencies increased over time. By year 4, 48% of the participants were found to have low calcium levels (from 15% at year 1) and 63% had low levels of vitamin D (57% at year 1). Low vitamin A was found in 69% of participants at 4 years (52% at 1 year) and low vitamin K in 68% (51% at 1 year). However, the incidence of low levels of vitamin E or zinc did not increase over time (vitamin E 0% at 1 year, 4% at 4 years; zinc 51% at 1 year, 50% at 4 years). The authors recommended high levels of supplementation after such surgery, and highlighted the need for ‘long-term nutritional monitoring’.

Totte and coworkers[252] reported improvements in hypercholesterolaemia (resolved 100%), type 2 diabetes (resolved 100%), type 1 diabetes (improved 100%), hypertension (resolved 83.6%, improved 17.4%), hypertension and cardiomyopathy (improved 100%), Pickwickian syndrome (resolved 100%), respiratory insufficiency (resolved 82%, improved 18%), sleep apnoea (resolved 66.6%, improved 33.3%), severe arthritic pain (improved 100%) and depression (improved 85.6%).

Staged surgery

This review considered the evidence for the effectiveness of staged surgery in people with a BMI of 50 kg/m^2 or greater. Due to the limited evidence on this technique, no limitations on study duration or number of participants were imposed. Four relevant studies were identified.[253-256]

Arteaga and coworkers[253] examined the morbidity and mortality of a two-step approach to surgery (jejunoileal bypass, converted to a Roux-en-Y gastric bypass at 6–24 months). Regan and coworkers[256] described their experience of a two-stage gastric bypass (laparoscopic sleeve gastrectomy, followed by laparoscopic Roux-en-Y gastric bypass). Milone and coworkers[254] compared laparoscopic sleeve gastrectomy and intragastric gastric balloon as a first stage procedure, before conversion to DS-BPD. However, these authors only reported results for the initial stage, so this study is not considered further in this review. Similarly, although Nguyen and coworkers[255] described the use of a staged procedure (modified Roux-en-Y gastric bypass, followed by completion of the sleeve gastrectomy), no results were reported so the study was excluded.

No additional studies were identified in the Update searches.

Weight loss

Arteaga and coworkers[253] reported weight loss of approximately 53.4 kg (n = 20/24) after the first stage of surgery (mean follow-up of 14.1 months). Mean BMI decreased from 63.0 to 46.9, and excess weight loss was 44.3%. Of the

eight people who went on to have the second stage surgery, mean total weight loss was 80.0 kg and excess weight loss 62%.

Of the seven patients who underwent surgery in Regan and coworkers' study,[256] mean weight loss was 36 kg after stage one (mean follow-up 11 months), and 55 kg in total after stage two (mean follow-up 2.5 months, n = 6/7). Mean BMI decreased from 63 kg/m^2 to 50 kg/m^2, and then to 44 kg/m^2 at each stage. Excess weight loss was 33% and 46%, respectively.

Other outcomes

Complication rates were:

- for stage one – 8.3% for major complications and no deaths. At stage two, one major complication (12.5%) and no deaths. Overall, the complication rate was 9.4%[253]
- 35.7% for overall complications, and no deaths.[256]

No quality of life or other outcomes were reported in either study.

15.3.5.3 Evidence review on competencies and training for bariatric surgery

A recently published evidence-based guideline was identified that made recommendations on the competencies and skills required of surgeons undertaking bariatric surgery.[257] Graded recommendations were that:

- 'All surgeons performing obesity surgery should have an adequate technical expertise (based on high quality evidence).
- S/he should be a qualified and certified general or gastrointestinal surgeon with additional training in obesity surgery (based on medium quality evidence).

- Technical expertise in laparoscopic surgery alone is insufficient to start a bariatric surgery programme (based on medium quality evidence).'

Learning curve and the effect on operative outcomes

We identified several papers on the effect of the learning curve for our procedures of interest. Inclusion criteria for this review were as for the other surgical reviews (see above), except that no study duration was defined. Also the effect of the learning curve had to be the focus of the study, or a comparison of initial and the later operations had to be reported.

Seven studies were identified: five on laparoscopic gastric bypass,[237;258-261] one on laparoscopic and open gastric bypass,[262] and one on laparoscopic adjustable gastric banding.[263] No additional studies were identified in the Update searches. Results from the five studies on laparoscopic gastric bypass were as follows.

Ballesta-Lopez and coworkers[237] analysed a consecutive series of 600 patients to determine problems that arise during the learning curve. The rate plateau of morbidity and mortality (no details reported) was reached after the first 18 patients when the surgical technique was revised and fully standardised. The authors concluded that although the complication rate plateau is often cited as 75–100 operations, this could be lower if adequate training was provided.

Kligman and coworkers[258] reported results of the initial 160 consecutive patients undergoing laparoscopic gastric bypass by a single surgeon over a 24-month period. Patients were divided into quartiles for data analysis. Duration of surgery decreased significantly between quartiles ($p < 0.01$). However, the conversion rate (3.1%) and mean hospital length of stay (2.1 ± 2.4 days) were unaffected by surgeon experience. In addition, the complication rates did not change statistically between quartiles. The authors suggested that throughout the learning curve laparoscopic gastric bypass could be accomplished with acceptable complication rates, conversion rates and hospital length of stay, and that the duration of surgery decreases with experience.

Oliak and coworkers[259] aimed to determine the length of the learning curve for a skilled laparoscopic surgeon. The study population consisted of the first 225 consecutive laparoscopic gastric banding procedures attempted by one laparoscopic surgeon. The average operative time decreased (from 189 minutes in the first 75 patients to 125 minutes in the last 75 patients). Most of the improvement in operative time occurred over the first 75 patients. The perioperative complication rate decreased (from 32% in the first 75 patients to 15% in the second and third groups of 75 patients). Complication rates did not significantly decrease after the first 75 patients. Low mortality and conversion rates were achieved early in the series. The authors concluded that low mortality rates and low conversion rates could be achieved early in the learning curve. Complication rates plateaued after approximately 75 operations, and operative times decreased substantially over the initial 75 cases. Operative times continued to decrease at a slower rate beyond the initial 75 cases.

Schauer and coworkers[260] determined the effect of operative experience on outcomes in the first 150 consecutive patients. The patients were divided into three groups (1, 2 and 3) of 50 consecutive patients, and outcomes for each group were compared. The patients in group 3 had a larger BMI ($p < 0.05$), were more likely to have had prior abdominal surgery, and were more likely to have secondary operations at the time of gastric bypass. The operating time decreased (from a mean of 311 minutes in group 1 to 237minutes in group 3), and technical complications were reduced by 50% after 100 cases. The authors concluded that operative time and technically related complications decreased with operative experience even though heavier patients and higher-risk patients were more predominant in the third group.

Shikora and coworkers[261] evaluated technical experience and patient volume on complication rates in the first 750 consecutive patients. For the first 100 cases, the overall complication rate was 26% with a mortality of 1%. This complication rate decreased to approximately 13% and was stable for the next 650 patients (11% to 13.4%). Complications possibly related to technique decreased (trocar

site wound infection 8% to 2%, splenic injury 1% to 0%, bowel obstruction 5% to 0%, GI track leak 3% to 0%), while others (such as intraluminal bleeding, thromboembolism, anastomotic stricture) remained approximately the same. The overall mean operating time was 138 minutes (range, 65–310 minutes). It decreased from 212 minutes for the first 100 cases to 132 minutes for the next 650 and 105 minutes (range, 65–200 minutes) for the last 100 cases. The authors concluded that morbidity and mortality could be reduced by up to 50% with experience.

Ballantyne 2005[262] compared learning curves for three surgeons in terms of surgical time for laparoscopic gastric bypass and open gastric bypass. Median time for the first surgeon reduced for each subsequent 100 operations: (175 minutes, 125 minutes, 110 minutes, and 100 minutes resp). Median time for second surgeon was 120 minutes overall, and for the third surgeon 173 minutes. The length of surgery significantly correlated with surgical experience in terms of numbers of operations and the BMI of patient. The authors concluded that the length of surgery continued to shorten beyond 400 operations for the first surgeon. Previous fellowship training in laparoscopic gastric bypass shortened surgical times during the initial clinical experience as an attending for the second surgeon.

Weiner and coworkers[263] evaluated the outcomes of the first 100 patients and the total number of 984 patients undergoing LAGB. All complications were seen during the first 100 procedures. During the learning curve, more band removals were performed (6/100 compared with 7/884), migration was higher (1/100 compared with 2/884), slippages were higher (12/100 compared with 32/884) and port revisions were higher (3/100 compared with 11/884).

Training and the effect on operative outcomes

We identified only one paper on the effect of the training on our procedures of interest. Inclusion criteria for this review were as for the other surgical reviews (see above), except that no study duration was defined. No additional studies were identified in the Update searches.

Kothari and coworkers[264] reported on the outcomes of laparoscopic gastric bypass following completion of an advance laparoscopic fellowship. Outcomes were measured prospectively and analysed by different time quartiles to assess the effect of the training. Upon quartile analysis, there was no difference in complication rates, and the complication rates were comparable to published outcomes in the literature. The authors concluded that fellowships in advanced laparoscopy with emphasis on laparoscopic gastric bypass provided the optimal training environment for the acquisition of necessary skills. With fellowship training, complication rates were comparable to published outcomes in the literature without a period of higher complications (the learning curve).

15.3.5.4 Evidence review on hospital and surgeon volume and surgical outcomes

Inclusion criteria for this review were as for the other surgical reviews (see above), except that no study duration was defined. Also the effect of the volume of operations had to be the focus of the study. Three relevant studies were identified.[265-267] No additional studies were identified in the Update searches.

Courcoulas and coworkers[265] explored the volume–outcome relation for gastric bypass surgery. They analysed 4685 cases of gastric bypass surgery for obesity, undertaken between 1999 and 2001. Statistical modelling techniques were used to determine whether mortality or the adverse outcome rate was significantly related to hospital and surgeon volume. Outcomes were adjusted for risk factors such as age, gender, comorbidities and others. There was a significant risk-adjusted relation between surgeon volume and adverse outcome (postoperative complications, non-routine hospital transfers), and the same trend was observed for deaths. Surgeons who performed fewer than 10 procedures per year had a 28% risk of adverse outcome and a 5% risk of death, compared with 14% ($p < 0.05$) and 0.3% ($p = 0.06$), respectively, for high-volume surgeons. The effect of hospital volume did not reach statistical significance, but there was an interaction between surgeon and hospital volume. Surgeons who performed 10–50 cases per year operating in low-volume hospitals had a 55% risk of adverse

outcome ($p < 0.01$). The authors concluded that risk-adjusted in-hospital adverse outcome was significantly lower when gastric bypass is performed by higher-volume surgeons.

Flum and coworkers[266] evaluated the risk of early mortality of patients undergoing bariatric surgery. A retrospective cohort study of16,155 Medicare patients undergoing bariatric procedures (mean age 47.7 years, 75.8% women) was conducted. The rate of 30-day, 90-day and 1-year mortality was 2.0%, 2.8% and 4.6%, respectively. The odds of death at 90 days were 1.6 times higher (95% CI 1.3 to 2.0) for patients of surgeons with less than the median surgical volume of bariatric procedures (among Medicare beneficiaries during the study period) after adjusting for age, gender and comorbidity index. The authors concluded that the risk of early death after bariatric surgery was considerably higher overall than previously suggested and associated with lower surgeon volume of bariatric procedures. Other associations with early death were advancing age and male sex.

Nguyen and coworkers[267] examined the effect of hospital volume on morbidity, mortality and costs in academic centres. All patients who underwent Roux-en-Y gastric bypass were included (n = 24,166). There were 22 high-volume (n = 13,810), 27 medium-volume (n = 7634), and 44 low-volume (n = 722) hospitals included in the study. Compared with low-volume hospitals, patients who underwent gastric bypass at high-volume hospitals had a shorter length of hospital stay (3.8 vs 5.1 days, $p < 0.01$), lower overall complications (10.2% vs 14.5%, $p < 0.01$), lower complications of medical care (7.8% vs 10.8%, $p < 0.01$), and lower costs ($10,292 vs $13,908, $p < 0.01$). The expected mortality rate (adjusted for severity) was similar between high- and low-volume hospitals (0.6% vs 0.6%,), demonstrating similarities in characteristics and severity of illness between groups. The observed mortality, however, was significantly lower at high-volume hospitals (0.3% vs 1.2%, $p < 0.01$). In a subset of patients older than 55 years, the observed mortality was 0.9% at high-volume centres compared with 3.1% at low-volume centres ($p < 0.01$). The authors concluded that bariatric

surgery performed at hospitals with more than 100 cases annually was associated with a shorter length of stay, lower morbidity and mortality and decreased costs. This volume–outcome relation was even more pronounced for a subset of patients older than 55 years, for whom in-hospital mortality was three-fold higher at low-volume compared with high-volume hospitals. High-volume hospitals also had a lower rate of overall postoperative and medical care complications, which may have been related in part, to the formalisation of the structures and processes of care.

15.3.5.5 Summary of previous NICE Technology Appraisal – surgery

Surgical Interventions

The Technological Appraisal Guidance- No.46: Guidance on the use of surgery to aid weight reduction for people with morbid obesity (2002) defined people as being morbidly obese if they have a BMI either equal or greater than 40kg/m², or between 35kg/m² and 40kg/m² in the presence of significant co-morbid conditions that could be improved by weight loss. This guideline also recommends surgical intervention as a first line option for people with BMI equal to or greater than 50kg/m² (NICE 1.2.6.7).

The Technological Appraisal Guidance- No.46: Guidance on the use of surgery to aid weight reduction for people with morbid obesity (2002) recommends that choice of intervention should be based upon best available evidence, facilities and equipment available, and experience of the surgeon who would perform the operation. This guideline concurs with this but additionally would include the degree of obesity and the presence of any comorbidities. (NICE 1.2.6.3, full guideline 1.7.6.3).

The Technological Appraisal Guidance- No.46: Guidance on the use of surgery to aid weight reduction for people with morbid obesity (2002) recommended that databases should be established by hospitals wanting to develop their service, to enable outcomes to be monitored in both the short term and the long term. This guideline recommends making arrangements for prospective audits to monitor

outcomes both in the short term and the long term (NICE 1.2.6.5, full guideline 1.7.6.5).

See also Section 6 for the detailed health economic modelling.

15.3.6 Evidence review on referral to specialist care for adults and mature adolescents

In February 2005, the National Guideline Clearinghouse synthesised the recommendations on the assessment and treatment of obesity and overweight in adults from six published guidelines.[1]

There was only one specific set of recommendations on referral (Table 15.36).

Table 15.36 Recommendation on referral

Singapore Ministry of Health (2004)	The presence of depression and binge-eating disorders in obese patients must be evaluated for, with appropriate referral for psychiatric treatment (grade B, level IIa)

The NHMRC[2] recommended that when single-gene mutation obesity is confirmed, the patient should be referred to a specialist who deals with these problems (level B). Reasons for referral from primary to secondary care may include:

- the view that morbid obesity is a condition that cannot be managed effectively in primary care
- failure of conventional treatment or
- for assessment for the suitability for pharmacological treatment.

Most of these referrals would be to registered dietitians, private sector slimming organisations, physicians, community-based programmes/self-help groups, trained exercise specialists or bariatric surgeons. People would normally be

referred from secondary to tertiary care if long-term conventional and pharmacological treatment had failed and if they met the eligibility criteria for surgery.[268]

Due to the lack of evidence in this area, the GDG discussed the role of secondary and tertiary care for people with obesity. Key roles for specialist services were considered to be:

- the assessment of possible causes of severe obesity, including genetic causes, medication for other conditions, rare neurologic/metabolic conditions
- the assessment of people with complex disease states and/or complex needs.

Specialist clinics or services were also considered to be the most appropriate setting for:

- trialling new drugs or using older drugs in novel ways (such as off licence or new combinations)
- pushing the boundaries of management, such as specialised diets
- deciding on treatment (drug or surgery) for people with a BMI greater than 40 kg/m^2
- providing a higher level of care than available in primary or general secondary care
- providing leadership, education and being a source of reference and information for primary or general secondary care.

In the experience of the GDG, people were most often referred to specialist services if:

- BMI was greater than 40 kg/m^2
- treatment in primary care or general secondary care had failed

- the obesity or causes were considered ‘unusual’, and therefore may be of research interest.

No additional studies were identified in the Update searches.

15.3.7 Interventions in a UK clinical setting

The following review was presented to the GDG to inform any recommendations about the delivery of care. The GDG considered that no recommendations could be made based on the available evidence. Therefore, the review is presented here for completeness only.

15.3.7.1 Evidence statements (Table 15.37)

Table 15.37 Evidence statements and grading

No.	Evidence statement	Grade
1	Weight loss of approximately 2.9 kg can be achieved (in people who attend) through dietary advice given every month for four sessions by a dietitian in an outpatient clinic (n = 1)	1–
2	Structured, multifaceted approaches to obesity management in primary care can improve process outcomes, such as recording of data, and increase the number of times weight is discussed in the consultation (n = 2)	1+
3	The Counterweight programme (structured, multifaceted approach) in primary care may be effective in producing clinically significant weight loss in around a third of participants. However, another study evaluating a similar approach found no significant effect on weight. (n = 2)	As above
4	Training of healthcare professionals is an important component of any structured, multifaceted intervention. However, intensive training (6–8 hours), with continued support from dedicated nutritionists, appears to be more effective that training (4.5 hours) alone	As above

15.3.7.2 Evidence review on interventions delivered in a UK clinical setting

This review aims to provide corroborative evidence from the UK on the effectiveness of any intervention designed to address the management of

overweight or obesity in adults and children. The inclusion criteria were as follows:

- **Interventions:** Any intervention which targeted providers' management of obesity and aimed to improve provider practice or patient outcomes or target the individual (such as diet, physical activity). Only studies conducted in the UK were included.
- **Setting**: Only those interventions conducted in a clinical setting are included. Other settings are covered in other evidence reviews.
- **Participants**: All qualified healthcare professionals involved in the management of obesity and/or all individuals classified as overweight or obese (mean initial BMI ≥ 28 kg/m^2 for adults).
- **Outcomes**: Studies reporting weight, diet or physical activity outcomes were included provided that baseline and follow-up data were provided.
- **Length of follow-up**: At least 12 weeks duration. Length of follow-up was measured from commencement of the intervention.
- **Study design**: Only studies with a control or comparison group were included.

Excluded studies are listed in Appendix 16.

The Centre for Reviews and Dissemination (CRD) review on non-clinical settings was cross-referenced, as were other relevant reviews. Excluded references from the intervention reviews were also reassessed for inclusion.

Interventions for the management of obesity and overweight in children

We identified nine studies that could be potentially relevant for this review, although only one of these presented a control/comparison group. However, this study was excluded on the basis of the date of its publication (1971) and therefore being of little relevance to services as they exist currently.[269] We also

identified two informative papers that evaluated the WATCH IT programme[270] in Leeds, and the role of physiotherapists in combating childhood obesity in England.[271] However, none of the identified papers met our inclusion criteria (see Appendix 16).

Interventions targeted at individuals (adults)

Two studies were identified that assessed the effect of an intervention targeted at the individual patient in a clinical setting.[272;273] One study compared the effect of a low-fat (reduced fat intake by 10%) high complex carbohydrate diet, low-fat high simple carbohydrate diet and control (maintenance of fat intake at habitual amounts of approximately 35–40% of energy) in people with at least three identified risk factors for metabolic syndrome (note: however, overweight or obesity was not a requirement). At least 60% of total energy intake was provided free from the study grocery shop. Participants collected their food once or twice a week from the shop, where they could also discuss their energy and macronutrient intakes with the dietitian.[272] This intervention did not appear to be a pragmatic and implementable approach to weight loss, so the results were not reported in this review.

One small (under-powered), quasi-randomised controlled trial[273] compared a 500 kcal deficit diet and a health eating diet (based on the 'Balance of good health') in adults referred to a dietetic department for weight loss. Participants were invited to four sessions with a dietitian. held at 4-weekly intervals. Both groups lost, on average, clinically significant amounts of body weight by 12 weeks. However, the dropout rate for both groups was high (69% overall at 12 weeks).

Complex interventions targeted at healthcare professionals

Two trials were identified the evaluated the effectiveness of implementing programmes for the management of obesity and overweight. Both trials were conducted in primary care and involved elements of training, process and organisational change, and combined lifestyle interventions.

Moore and colleagues evaluated a training programme designed to improve the management of obesity delivered by primary care teams.[274] The programme included several components:

- **A nutrition training programme**: This was delivered in three 90-minute sessions, at intervals of no less that 1 week, and no more than 2 weeks apart. All GPs and practice nurses were invited. The training was delivered by four dietitians trained in the standardised delivery of the programme. A model approach was promoted, which included best practice, and was brief enough to be delivered in primary care. Primary care teams then devised individualised weight management protocols to implement in their practice. Practitioners were given a 'ready reckoner' to calculate the appropriate caloric intake for individuals.

- **Model of management**: Practitioners were expected to see patients approximately every 2 weeks until they lost 10% of initial body weight and then approximately every 1–2 months to support weight maintenance. Current and target weight and dietary and activity targets were to be recorded in the patient records. This was to facilitate the continuity of support from the practice team.

- **Lifestyle information for patients**: This included information on the clinical benefit of weight loss, and effective interventions, including reducing energy intake, increasing physical activity, and the use of obesity drugs. A 500 kcal/day deficit diet was recommended, and diet sheets and other written resources were provided.

Control practices were asked to provide usual care. Consecutively attending adults, aged 16–64 with a BMI of 30 kg/m^2 or over, were asked to participate.

At 12 months, there was no difference between the intervention and control group patients with regard to weight (mean weight change +0.3 kg intervention vs –0.7 kg control, p = 0.5), but some improvements were seen in practitioner

knowledge, the likelihood of weight being discussed in the consultation, and the recording of weight, target weight and dietary targets.

The authors noted limitations of the study: mainly female participants, skewed towards extreme obesity (mean BMI approximately 37 kg/m^2 overall), high dropout rate (although the study remained 80% powered).

Another study aimed to evaluate the effectiveness of the Counterweight Programme in improving the management of obesity in primary care using a structured approach.[275;276] The programme is based on the evidence-based quality assessment cycle and is in four phases.

- **Phase 1 Audit and project development** – **setting priorities**: The aim of the audit was to determine current approaches. Data were collected on weight screening rates, availability of equipment and patient education materials, and the current organisation of care. Also, baseline attitudes, knowledge, confidence and willingness to treat of the GPs and practice nurses were assessed. The health burden of obesity for each practice was also measured.

- **Phase 2 Practice training and support** – **setting guidelines**: Audit results were fed back in a 1-hour workshop with the GPs and practice nurses, and the treatment pathway and priorities for implementation were also discussed. The role of the GP was identify suitable patients for management during routine clinical practice, and to refer on to the practice nurses. GPs were expected to raise weight as an issue as appropriate and to possibly discuss the benefit of a 5–10% weight loss. A desk-top flip chart was provided to facilitate patient screening and the assessment of motivation. The GP intervention was designed to be opportunistic and of 1–5 minutes duration. A 6–8-hour training programme was designed to teach core competencies to practice nurses. A structured approach was used to cover topics such as screening and assessment, principles of healthy eating and energy balance, dietary approaches to weight management, physical activity guidelines, behaviour change strategies, pharmacotherapy, patient monitoring and ethical

considerations. Training manuals were provided to support formal workshops. Guidance was also provided on the use of Counterweight Programme patient education materials. A variety of teaching methods were used, including problem-based learning through case studies, group discussion and practical exercises in line with adult learning theory. A weight management adviser (a state registered dietitian with specialist experience) worked with the practice nurse once or twice a month to facilitate clinics and patient groups. After 6 months, the weight management adviser was mainly involved in data collection and training new practice nurses.

- **Phase 3 Patient intervention** – **measuring performance**: Weight loss targets were set at 5–10% of initial body weight. Patient screening and treatment pathways were developed. Theoretical approaches were used for both changing clinical and patient behaviour. For example, the screening pathway encouraged clinicians to consider stages of change of the individual patient. The screening pathway was designed to target those at highest risk (BMI ≥ 30 kg/m^2 or BMI ≥ 28 kg/m^2 with comorbidities). The treatment pathway suggested a 3-month minimum lifestyle intervention (either in group or individual formats) as the first line approach. Practice nurses were encouraged to see individual patients for six appointments (10–30 minutes each) over the 3-month period, or for six group sessions of 1 hour. Quarterly follow-up appointments were recommended, where treatment and weight loss were reviewed. At 3 months, people who had lost ≥ 5% were recommended to continue with the lifestyle approach, whereas those had not were considered for alternative lifestyle interventions, pharmacotherapy or referral to a dietitian. Additional options were dependent on local obesity policies and services. If 10% of initial body weight was lost, weight maintenance was advised. Relapse prevention was discussed and weight check appointments offered at least quarterly.

- **Phase 4 Evaluation** – **improving performance (back to Phase 1)**: Evaluation (in the form of an RCT) is currently ongoing.

Theoretical approaches to changing practice have been employed to design multifaceted interventions targeting barriers to change (see Table 15.38). Control practices were audited but received no further intervention other than feedback of the audit results.

The trial is currently ongoing and is due to report full results soon. Interim results show however that for those participants who have data at 12 months, that the mean weight change was –3.2 kg (n = 445), and that 32.6% reached greater than 5% weight loss from baseline. One in six people entering the programme achieved a 5% weight loss or more (ITT analysis) at 12 months.[247]

The different interventions used can be seen in Figure 15.32.

Table 15.38 Theoretical approaches to changing clinical practice and Counterweight strategies[247] - see paper for full details

Approach	Counterweight strategy
Internal	
Educational	• Local Counterweight Steering groups established • Use of practice-based training in small interactive groups • Use of case studies, cofacilitating clinics and patient groups
Epidemiological	• Development of treatment pathway consistent with evidence-based obesity guidelines • Counterweight newsletter, practice meetings
Marketing	• Audit and needs assessment, setting practice priorities • Regular feedback
External	
Behavioural	• Baseline audit, regular feedback • Patient recall letters and flagging of notes
Social interaction	• Practice meetings • Cofacilitation of clinics and groups • Local consultant lead • Involvement of key PCT leads
Organisational	• Monitoring and feedback of outcomes • Use of screening and treatment guidelines, group programme
Coercive	• NSFs for CHD and diabetes • NICE guidelines for orlistat and sibutramine • Local HIMPs

Figure 15.32 Proportion of individuals reaching 12 months allocated treatment types over the 12 months[247] (adapted)

Intervention	Percentage of patients allocated over 12 months (n=446)

One-to-one intervention	61%
Group intervention	30%
One-to-one and group intervention	5%
Pharmacotherapy	22%
Dietitian	7%
Exercise referral	8%
Commercial	5%
Weight maintenance	16%
Secondary care	0%

15.3.8 Patients' and healthcare professionals' views and attitudes to the management of overweight or obesity

To inform the development of recommendations relating to patient-centred care, we reviewed evidence on barriers to change and attitudes in the clinical setting (specifically the consultation) reported by healthcare professionals and/or individuals who were overweight or obese.

- **Types of study**: Those that assessed barriers and attitudes (individual/HCP/family/carer/other) to the management of weight **in the clinical setting**. In addition, qualitative studies identifying barriers/motivation to management of overweight/obesity (focus groups, interviews, surveys). Barriers and attitudes had to be identified by participants themselves, not presupposed by researchers, and were restricted to studies from the UK.

- **Types of participant**: (i) Healthcare professionals such as GPs, practice nurses, dietitians and health visitors; (ii) family/carers of obese and/or overweight adults, adolescents, and children; and (iii) obese and/or overweight adults, adolescents, children, and their parents.

We identified two published studies that explored this topic in children and adolescents.

- Types of outcome: participants' views on the management of weight **in the clinical setting**.

General practices are important in the management of overweight and obese people as they are frequently the first access point to care. Approximately 75% of the population see their GP during a year, and about 90% in 5 years.[277] Patients are then seen by a GP directly because of overweight or obesity, associated comorbidities or some condition that is not connected to weight. Thus, GPs, practice nurses, dietitians and health visitors can play a major role in helping people with weight problems.

This review aims to outline and clarify barriers and attitudes to the management of weight in a clinical setting that are felt to exist by healthcare professionals, patient and family/carers.

15.3.8.1 Healthcare professionals' views in primary care

(See also Section 1, Chapter 3 section 3.5.)

Owen[278] conducted a study via focus groups interviews (based on semi-structured questions) among five groups of healthcare professionals (GPs, dietitians, practice nurses, health visitors and school nurses). The findings echoed those of the National Audit Office,[268] calling for a multidisciplinary training and activity programme to be implemented across Wales to ensure healthcare professionals know what advice should be given for weight management.

Despite this call for training, it is frequently unfeasible, as practitioners have expressed their uncertainty of being able to devote so much time for indepth training.[274]

Hankey and coworkers[279] conducted a study on the attitudes, beliefs and eating habits of health professionals with respect to obesity, nutrition and weight management. This study consisted of a postal questionnaire survey of 1400 GPs, 613 practice nurses and 360 practice dietitians who were members of the British Dietetic Association in Scotland. The overall response rate was 65%.

This survey showed that there were discrepancies between professional groups with regard to knowledge of obesity, nutrition and weight management. One

example was the disagreement around the role of fat and sugar in increasing obesity. Nearly half of the GPs and 38% of the practice nurses answered incorrectly, whereas 75% of the dietitians correctly answered that fat was the most enhancing factor. Also, almost 65% of all GPs, practice nurses and dietitians believed that people can adhere to an 800–1200 kcal/day diet without weight loss. Knowledge on the measurement of waist circumference appeared to be weakly understood.[279]

Overall this study demonstrated that health professionals had gaps in their knowledge of nutrition and obesity management, which could create misleading advice. Also, the majority of the respondents felt that weight management advice should be given by professionals with specific training. Practice nurses reported feeling unskilled in regard to giving weight management advice, but many mentioned not having available time to undertake specific training.[279]

In a similar study, Mercer and Tessier[280] carried out interviews with GPs and practice nurses within the Greater Glasgow Healthboard area. Of 30 GPs and 30 practice nurses who were contacted, 10 GPs and 10 practice nurses agreed to be interviewed. The majority of interviews showed that weight management was an unpopular task, with the GPs preferring to delegate it to the practice nurse. This thus created the feeling in practice nurses of patients being ‘off-loaded’ on them. Another issue raised by GPs and practice nurses was a sense of frustration derived from patients’ lack of motivation or lack of success of attempted interventions. Guidelines were also revealed not to be frequently used among GPs, and GPs felt that the Scottish Intercollegiate Guidelines Network (SIGN) was over-promoting the use of slimming pills.[280]

This issue of GPs asserting that treating obesity was not within their professional domain, and that management obesity should chiefly be the responsibility of the patient, arose clearly in a study conducted by Epstein and Ogden[281] and also in a study by Ogden and coworkers[282] Epstein and Ogden[281] conducted semi-structured interviews with 21 GPs (130 GPs were invited to participate) working

in an inner London primary care trust. The GPs claimed that patients tended to see obesity as medical problem, which should be managed by the doctor. According to the authors, this contradiction was then hard to balance with the GPs' lack of faith in the effectiveness of existing treatments, and the urge to ensure good patient–doctor relationships. The second study[282] consisted of a cross-sectional survey with comparisons of models of obesity made between GPs and patients. Questionnaires were completed by 89 GPs and 599 patients. Findings showed that patients pointed out internal uncontrollable causes for the onset of obesity, although would rely on external factors to treat it. On the other hand, GPs blended in cause and solution to internal factors that resided in the patient.

The studies therefore show consistently that GPs and patients have different views. GPs would prefer patient-based interventions in primary care with regard to obesity management, and patients would opt for a professionally led approach.

To briefly summarise the debate on what can hinder or influence the practice of healthcare professionals in primary care, Maryon-Davis[277] enumerated the most commonly reported barriers to effective treatment in this particular clinical setting:

- psychological complexities of cases
- high rate of relapse
- perceived lack of effective interventions
- lack of time
- lack of resources
- lack of onward referral options.

15.3.8.2 Practice nurses' and health visitors' views of managing overweight and/or obesity

Green and coworkers[283] aimed to examine health visitors and practice nurses knowledge regarding the assessment and management of obesity through a postal questionnaire sent to 35 health visitors and 49 practice nurses based at 24 practices within one regional health authority. The questionnaire assessed knowledge concerning diet, behavioural techniques and physical activity regarding obesity management, and was completed and returned by 17 health visitors and 28 practice nurses.

Several respondents were unclear on how to calculate or interpret BMI, and were unaware that a high central fat distribution was linked with greater risk of health problems associated with obesity. In most cases, dietary advice did follow current recommendations, as recommending a low-fat diet, although in some cases this did not occur, as advice would be to follow a reduced carbohydrate diet. Advice on physical activity also varied in quality and quantity. Few respondents mentioned tailoring either dietary or physical activity to cultural or socioeconomic needs.[283]

Similarly in another study,[284] many respondents felt that the advice they gave was useful but was only followed sometimes by patients, and that the responsibility lay with the patients.

Ogden and Hoppe[284] studied ways of improving practice nurses' management of obesity. This was attempted by having practice nurses complete a questionnaire regarding their obesity-related beliefs and behaviours, before and 1 month after being randomly assigned to a 'learner-centred' group (which received a leaflet and was asked to attend an interactive seminar), or 'expert' group (which received a leaflet), or a control group.

The intervention itself did not have any effect on practice nurses' beliefs about obesity, and no effects on the patients' weight. Nevertheless, practice nurses in the 'learner' group reported spending more time on their consultations and being

more patient centred, with the result of having patients more satisfied with the consultation. On the other hand, practice nurses in the 'expert' group reported that they gave advice more frequently and were less patient centred, resulting in an increase in patients' confidence in achieving weight loss.[284]

15.3.8.3 Dietitians' views of managing overweight and/or obesity

Harvey and coworkers[285] explored the role of the level of severity (obese vs overweight) on the perceptions of dietitians towards overweight and obese people, and how their views interacted with their practice. For this, they randomly selected 210 dietitian members of the British Dietetic Association, with a further 68 questionnaires given to dietitians who worked in a clinical capacity. One hundred and fifty-eight were returned from the postal survey and 29 returned by the extra group. The questionnaire explored topics such as causes for overweight and obesity, attitudes, responsibility of those who are obese or overweight, the reported practices of dietitians, and the association between views and practice.

The results showed that attitudes towards overweight and obese people were neutral to positive, although overweight people were rated more positively than those who were obese. Dietitians also perceived obese people as being more responsible for their excess weight than those who were overweight. Interestingly, greater merit was perceived in treating obese rather than overweight people.[285]

15.3.8.4 Patients'/clients' views on the management of obesity

Tod and Lacey[286] conducted a qualitative research project that outlined factors that encouraged or hindered overweight people from low-income groups accessing weight loss services. They recruited 16 people from the South Yorkshire Coalfields Health Action Zone, who attended Slimming World (a slimming club). Semi-structured interviews were conducted with all participants. Despite the sample size and lack of generalisability of this study, some themes emerged.

The main triggers that encouraged people to take action were embarrassment and humiliation, health-related problems or warnings, fear, and critical events such as holidays, weddings or birthdays. Main barriers reported related to issues of denial of their weight and a previous bad experience (such as being the biggest in the group, previous failure, public weighing). The authors contended that, as the experience of being overweight and obese adds frailty and vulnerability, and the triggers to take action are somehow distressing, services should be encouraged to have the adequate level of motivational support.[286]

Barker and Cooke[287] also looked at the perspectives of those who were overweight, obese or in the process of losing weight, by conducting one-to-one interviews and qualitative discussion groups. Those who were defined as overweight had a BMI ranging from 25 kg/m^2 to 29 kg/m^2; and those defined as obese had a BMI of 30 kg/m^2 or more. Slimmers were defined as someone who had been overweight in the last 2 years and had lost at least 6 kg and maintained that loss for at least 6 months. The study addressed issues ranging from perceptions of being overweight to reasons to be overweight, and the strategies that could be undertaken to lose weight.

Most relevant barriers were related to people being unclear about the benefits of weight reduction, and the extreme sacrifices that represented being on a diet which meant having to give up certain pleasures. This then had an effect of inducing long delays in initiating diets.[287]

15.3.8.5 Family/parents' views on the management of obesity

Edmunds[288] explored, through indepth interviews, parental perceptions of help-seeking experiences with healthcare professionals in central and south-west England. The children were aged from 4 to 15 years, and volunteers were recruited through healthcare professionals, posters in primary care settings and advertising in local papers. Children who attended weight loss groups were also recruited. Included in the weight history components of the interview were standardised shapes of children.

Parents were generally quite positive in their responses regarding healthcare professionals, although a diverse range of responses were reported when they sought child weight management help. The authors suggested that such a finding could be due to the healthcare professional's concern in not adding further distress to either parent or child, or simply not knowing in which way to help. Again, there appeared to be a tendency for healthcare professionals to leave weight as an individual responsibility and for blaming the parent for the child being overweight.[288]

15.3.9 Role of professionally organised therapies in the management of overweight and obesity

The following review was presented to the GDG to inform any recommendations about the use of 'alternative' or 'complementary' therapies. The GDG considered that no recommendations could be made based on the available evidence. Therefore, the review is presented here for completeness only.

15.3.9.1 Evidence statements (Table 15.39)

Table 15.39 Evidence statement and grading

No.	Evidence statement	Grade
1	There is little convincing evidence to support the use of complementary therapies in weight loss and/or maintenance in adults.	1++

15.3.9.2 Evidence review on professionally organised therapies

Professionally organised therapies as defined by the House of Commons are: acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy. We found one high-quality systematic review that was both comprehensive and recent.[289] This paper, published by Pittler and Ernst in 2005, aimed to review complementary therapies for reducing body weight, and included six systematic reviews and meta-analyses based on RCTs and 25 additional RCTs. Only one of the included RCTs was eligible for inclusion against our established criteria for

treatment and follow-up duration of a minimum of 12 months for adults, reporting an 18-month trial. No studies on the effectiveness of these therapies on children or adolescents were retrieved. Furthermore, no studies on the effectiveness of chiropractic or osteopathy in the treatment of obesity were found.

Acupuncture/acupressure

Pittler and Ernst referred to one systematic review that included four sham controlled RCTs.[290] Two of the trials reported a decrease in hunger, and the other two did not report any difference in body weight compared with the sham acupuncture. The review concluded that the effect of acupuncture or acupressure for weight loss was not based in the results of rigorous clinical studies. Similar conclusions were drawn in another non-systematic review.[291]

Dietary supplements

Although Pittler and Ernst reviewed the use of over-the-counter dietary, supplements, this was outside the scope of the guidance.

Homeopathy

The authors reported that two RCTs were identified. In one study, *Helianthus tuberosus* D1 was given to patients with a mean BMI of 29 kg/m^2, and after 3 months the treatment groups had lost a mean 7.1 kg which was significantly different from the placebo group. The other trial, which aimed to study Thyroidinum 30 cH, did not reach any difference between treatment group and placebo.

Hypnotherapy

The authors reported one meta-analysis (that included six RCTs) that aimed to compare hypnotherapy plus cognitive behaviour therapy with cognitive behaviour therapy alone. The results showed that adding hypnotherapy to cognitive behaviour therapy only slightly decreased body weight. The authors also referred to a further RCT with hypnotherapy directed at either stress reduction or energy intake, compared to dietary advice. Results showed a significantly greater weight reduction compared with control groups.

15.3.10 Effectiveness of brief interventions in primary care and other general clinical settings in improving outcomes for people who are overweight and obese

15.3.10.1 Evidence statements (Table 15.40)

Table 15.40 Evidence statements and grading

No.	Evidence statement	Grade
Weight loss		
1	Evidence from one study suggests that a brief intervention without nutritional counselling delivered to overweight patients aged between 25 and 65 years does not help achieve weight loss at 12 months	1+
Generalisability (from trials that reported weight loss)		
2	Generalisability of the findings remains unclear, as no study was conducted in the UK	N/A
3	Generalisability of the findings is hindered by the lack of evidence	N/A

N/A, not applicable.

15.3.10.2 Evidence review on brief interventions

This section reviews evidence on the effectiveness of brief interventions in primary care and other general clinical settings in improving outcomes for adults who are overweight and obese.

Types of study

- RCTs
- clinical controlled trials based in the UK (corroborative evidence).

Types of participant

- Children and adults who were overweight or obese.

Types of outcome

- primary outcomes to be measured (not self-reported) estimates of overweight in per cent and BMI

- secondary outcomes to be behaviour change, participants' views, measures of self-esteem, health status, well-being and quality of life.

Only RCTs with a minimum duration of 12 months (including follow-up, 6 months for children) that aimed to assess the effectiveness of brief interventions in primary care and other general clinical settings in improving outcomes for adults who are overweight and obese, were included. Moreover, studies were required to specifically include overweight and/or obese participants.

The majority of studies on such interventions were chiefly in alcohol use disorders and smoking cessation. Beyond the lack of studies that met the above parameters, another challenge was how to define a 'brief intervention'. Across the literature, different studies have given diverse definitions of 'brief interventions'.[292–293] As an example, Babor[294] defines one contact as 'minimal', one to three sessions as 'brief', five to seven sessions as 'moderate' and eight or more sessions as 'intensive' treatment (Moyer et al. 2002[293]). What can also happen is that what is mean by 'brief' can be reported as 'extended' in another study (Jonson et al.[292] quoted by Moyer et al.[293]). Despite these contradictions in the available literature, we chose to use Babor's definition,[294] by including studies with no more than four sessions.

From our searches we retrieved three studies that matched our inclusion criteria. However, two of these were excluded after discussion, as one was based in a blood pressure clinic and was published in 1978, and the other study included non-overweight participants and did not perform subgroup analysis.

Pritchard and coworkers[18] studied the clinical and cost outcomes of providing nutritional counselling to patients aged between 25 and 65 years with either hypertension, type 2 diabetes or were overweight (BMI > 25 kg/m^2). Results of the study were stratified per group, thus its inclusion in the review. Two groups (dietitian and doctor/dietitian) were given counselling focused on principles of good nutrition and exercise and addressed problem areas in lifestyle and dietary patterns. In the latter group, the participants were also seen by the GP at

baseline and by the same GP on two other occasions during the 12 months for 5 minutes each time to encourage and monitor the participant. The control group (which matches Babor's definition of brief intervention) received results of initial screening and were advised to discuss their queries with the GP at appointment. They received usual care (including monitoring, advice and prescriptions) from GP but no dietitian counselling. At 12 months, mean ± SD weight change in kilograms was –5.10 ± 7.36 kg in the dietitian group, 0.60 ± 6.08 kg in the control and –6.20 ± 7.67 kg in the dietitian and doctor group. Weight change in both intervention groups was significant (–5.70 kg [95% CI –8.05 to –3.35]; –6.80 kg [95% CI –9.17 to –4.43], respectively) compared to the control group. Moreover, significant decreases in mean blood pressure in participants with hypertension were reported in both intervention groups compared with the control group.[18]

No studies including children were identified.

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Section 6: Health economics

The following section includes two separate pieces of work on the cost effectiveness of interventions in clinical and public health settings. The literature review for both pieces of work identified a paucity of data on the cost effectiveness of interventions, particularly interventions undertaken in the UK and with more than 1-year follow-up. As a result, additional economic modelling was undertaken.

Although the health economic reviews and analyses were carried out by two different teams; both followed NICE methodologies, as set out in the Guidelines Development Methods manual, and liaised closely on the parameters used in their analyses, such as on diseases to include and QALY scores, so that both the clinical and public health work were consistent and complementary.

16 Cost effectiveness of clinical interventions

16.1 Introduction

Although the management of obesity in itself is potentially beneficial to the quality of life (QoL) of people, the role of obesity management is integral to the management of numerous further conditions. These include (among many others) myocardial infarction,[1] coronary heart disease, stroke and atrial fibrillation,[2] stress incontinence, diabetes, dyslipidaemia, back pain and arthritis.[3] The economic burden of this is increasing as obesity levels rise in England and Wales. Data from the 'Health survey for England' indicated that, in 2001, the prevalence of obesity had reached 21% in males and 23.5% in females. This has cost implications for both the healthcare system and the broader community.

Recent evidence has suggested that, after adjustment for age, sex, deprivation category, country and the presence of a comorbidity, people with a body mass index (BMI) greater than 30 kg/m^2 receive more prescriptions than those with a BMI between 18.5 kg/m^2 and 25 kg/m^2 focusing on prescriptions aimed at tackling problems in the following areas: the cardiovascular system, the central nervous system, the endocrine system, musculoskeletal and joint problems, infections, gastrointestinal problems and skin problems (all p values less than 0.05).[4] Furthermore, evidence from the UK suggests that there is a significantly higher level of medical contacts among the obese than among those of a healthy weight (general practitioner [GP], practice nurse or hospital outpatient attendance [all p values less than 0.001], and hospital inpatient attendance [p = 0.034]).

From a broader perspective, it is important to note that the burden of obesity also falls outside the healthcare sector. National Audit Office figures suggest that the burden on society is approximately £2 billion, significantly higher than the medical burden of £479.4 million spent on treating obesity per se and all obesity-related conditions. This £2 billion figure covers the loss in productivity of the UK economy due to obesity. Furthermore, there are costs to patients and carers of obesity and its effects. Although this area is not explicitly addressed in this discussion, it is potentially a significant factor in the study of the topic. Any recommendation designed to reduce the level and severity of obesity (or prevent weight gain) based

on cost-effectiveness evidence must balance the costs of the intervention against the expected benefit to the individual. This cost implication must account not only for the cost of intervention but also the reduced spending on the management of obesity and all related conditions.

The objective of this work was to assess the cost effectiveness of strategies involved in the management of obese individuals.

16.2 Methods

16.2.1 Research questions

There was no good-quality cost-effectiveness evidence on the identification or assessment of obesity. Therefore, the Guidance Development Group decided to focus on treatment options for people with differing degrees of obesity.

16.2.1.1 Major question

- What is the cost effectiveness of interventions used in the clinical management of obesity?

16.2.1.2 Sub questions

- What is the cost effectiveness of non-pharmacological interventions in the clinical management of obesity?
- What is the cost-effectiveness of orlistat in the clinical management of obesity?
- What is the optimal treatment length in the use of orlistat?
- What is the cost effectiveness of sibutramine in the clinical management of obesity?
- What hurdles should be used in the protocol for sibutramine?
- What is the cost effectiveness of surgery in the clinical management of obesity?
- To what extent are all of these discussions generalisable to children?

16.2.2 Data sources and search strategies

The following information sources were searched:

- Medline
- EMBASE
- Cumulative Index to Nursing and Allied Health Literature (Cinahl)
- PsycINFO
- NHS Economic Evaluation Database (NHS EED)

The electronic search strategies were developed in Medline and adapted for use with the other information sources. A search of titles and abstracts was undertaken and full papers were obtained if they appeared to address the Guidance Development Group's (GDG's) question relevant to the topic. No criteria for study design were imposed a priori. In this way the searches were not constrained to randomised controlled trials (RCTs) containing formal economic evaluations. Papers included were:

- limited to studies with a study population of BMI greater than 27 kg/m^2
- written in English, and reported health economic information that could be generalised to the UK.

The full papers were critically appraisal by a health economist using a standard validated checklist. A general descriptive overview of the studies, their qualities, and conclusions was presented and summarised in the form of a narrative review. Any further work was negotiated in partnership with the GDG, targeting areas with the most uncertainty and/or the greatest capacity for improving health outcomes.

16.3 Cost effectiveness of non-pharmacological interventions

16.3.1 Cost effectiveness statements for non-pharmacological interventions (Table 16.1)

Table 16.1 Cost effectiveness statements

1	There is little evidence specifically on the cost effectiveness of non-pharmacological interventions (diet, physical activity and behavioural treatment) in the treatment of obesity
2	The degree of cost effectiveness of non-pharmacological interventions is highly sensitive to the duration of benefit
3	If weight loss relative to trend remains constant for 5 years post-intervention before returning to baseline, the cost per QALY in the best-performing non-pharmacological studies ranges from £174 to £9971

QALY, quality-adjusted life year.

16.3.2 Approach

In this section, the analysis contains two tributary components. First, there is a full literature search, looking for health economics papers reporting interventions in a population with BMI greater than 28 kg/m^2. Second, the clinical papers selected for this review (but containing little economic evidence) are investigated, looking at the relation between intensity and type of intervention and outcome.

16.3.3 Literature search

The search yielded four papers dealing with the cost effectiveness of non-pharmacological interventions, three of which dealt with interventions primarily in adults and one dealing with families. These are appraised below. Due to the relatively low quality and generalisability of these papers, a further pharmacological paper was identified that provided further useful information.

16.3.3.1 Non-pharmacological interventions in adults

A study conducted in Australia looked at the cost effectiveness of nutrition counselling in general practice (Table 16.2).[5] The researchers employed two treatment arms and a control group, with 273 patients randomly assigned to one of two intervention groups (doctor and dietitian or dietitian alone). Both of the intervention groups received six counselling sessions over 12 months from the

dietitian. In the doctor and dietitian arm, it was the doctor who invited the patient to join the study and to review progress at two of the six sessions. Further details of the intervention are given in Section 5.

Table 16.2 Results of Pritchard and co-workers'' study on cost effectiveness of nutrition counselling in general practice[5]

	Group		
(All costs in Aus$)	**Control**	**Doctor/dietitian**	**Dietitian**
Total cost per group	2103.53	8240.30	5715.06
No. of patients	91	93	89
Cost per patient	23.12	88.61	64.21
Additional cost per patient	–	65.49	41.09
Weight change per patient (kg)	0.58	–6.13	–5.05
Additional weight change per patient (kg)	–	–6.71	–5.63
Additional cost per kg lost	–	9.76	7.30

If these tabulated results are reliable, the cost per kg lost is highly indicative of cost effectiveness of the interventions relative to the control. At October 2005 exchange rates, the incremental cost per kilogram lost is £4.13 and £3.09 for the doctor/dietitian and dietitian groups, respectively.

An American study reviewed the literature on the cost effectiveness of nutrition services.[6] It searched for economic papers published between January 1966 and September 2001 and found 13 studies. Two studies had both an obese population and weight loss as a study outcome,[5,7] one of which did not appear in the guidance literature search results.

A small American study looked at the cost effectiveness of a television-delivered behavioural weight loss programme.[7] A total of 77 patients were randomised to one of four groups: a live-contact group that was videotaped; a live-contact group that was not videotaped; a television-delivered group that observed the videotaped weight loss sessions; and a waiting-list control group. All three treatment groups lost significantly more weight and decreased their percentage of overweight significantly more than the control (Table 16.3). However, the differences between the treatment groups were not statistically significant.

Table 16.3 Results of Meyers and co-workers'' study on cost effectiveness of a television-delivered behavioural weight loss programme[7]

Group and time	Mean ± SD body weight (kg)	Mean ± SD % overweight
Videotaped		
Pre-treatment	82.06 ± 17.87	36.5 ± 22.2
Post-treatment	77.93 ± 13.90	29.8 ± 23.3
Television delivered		
Pre-treatment	88.77 ± 10.66	42.4 ± 17.0
Post-treatment	84.55 ± 10.02	35.6 ± 16.8
Live contact		
Pre-treatment	86.55 ± 15.69	44.2 ± 25.5
Post-treatment	82.06 ± 15.65	36.8 ± 25.4
Waiting-list control		
Pre-treatment	91.72 ± 23.27	40.0 ± 24.4
Post-treatment	90.86 ± 23.63	38.9 ± 25.8

The authors suggested they collected cost data but did not report it in the article. However, their conclusion was that, since the television-delivered care used significantly fewer resources than the similarly successful live contact groups, the television medium should be considered as a cost-effective intervention.

16.3.3.2 Non-pharmacological interventions in adolescents

An American study looked at the cost effectiveness of group and mixed family-based treatment for childhood obesity.[8] Thirty-one families with obese children (child between 20% and 100% overweight, neither parent greater than 100% overweight, one parent willing to attend treatment meetings, no family member participating in an alternative weight control programme, no child or parent having current psychiatric problems, and no dietary or exercise restrictions on the participating parent or child) were randomised to groups with either both group and individualised treatment or group treatment alone.

Group treatment involved eight weekly meetings, followed by four bi-weekly meetings and one monthly meeting. Each group intervention contained 12 adults and 12 children, with the adults and children being seen separately. A mastery approach

to teaching was used to inform families how to alter eating habits. Course material was tailored to the age of the individual. Content included diet, activity, behaviour change techniques, parenting and coping with psychosocial problems experienced by obese children.

Patients in the mixed treatment arm received 15–20-minute individual sessions parallel to the group sessions. Individual therapy was designed to help participants identify weight-affecting behaviour, to determine the accuracy of habit book recording, to evaluate the progress towards goals and to provide performance feedback. The costs per family for the mixed and group-only approaches were US$1390.72 and US$491.48, respectively.

The group treatment was associated with a larger decrease in percentage overweight ($p < 0.05$) and in z-BMI ($p < 0.01$) per dollar spent. At 12 months, a decrease of 0.5% overweight units per US$100 was observed in the mixed treatment branch compared with a 1.4% decrease in the group-only branch. Thus, the mixed therapy provided a lower reduction in weight at a higher cost than group therapy. This paper looked at moderately obese families. The authors noted that, although it was not cost effective to provide individual therapy to this group, it may be cost effective to do so for the more obese population. A further consideration may be the effect of reduced weight on future costs. This is likely to reduce the overall cost burden to the system and make both interventions more cost effective relative to doing nothing.

16.3.3.3 Control branches in pharmacological trials

One study included diet and exercise advice as the control.[9] In this evaluation, monitoring was performed by the GP for the first year (monthly visits each costing £13), and by a nurse for the second year (monthly visits each costing £7.29). Beyond this time, the assumptions used in the model meant that the patients had returned to baseline. Thus, no further costs were accrued beyond year 2. The cost for this is therefore £243.48 per person.

In terms of weight loss, the paper suggested that the placebo group was never more than 3 kg lighter than the trend weight group (who gained weight at 1 kg per year)

and returned to trend in 18 months. The precise weight pathway is not provided. A reduction of 2 kg over 18 months followed by a return to baseline in 6 months was inputted into the guidance economic modelling (described in depth in section 16.5.4.). This modelling includes the effect of weight loss on QoL, diabetes and mortality. This led to an increase of 0.015 quality-adjusted life years (QALYs) in men and 0.014 QALYs in women. Using the cost provided of £243.48, this implies a cost per QALY of £16,232 for men and £17,391 for women.

These values are likely to underestimate cost effectiveness of the intervention for three major reasons. First, the modelling uses a simplifying assumption of limiting benefit to reduction in prevalence of coronary heart disease (CHD), type 2 diabetes and colorectal cancer. Second, the protocol for non-pharmacological care given in the economic evaluation is intensive. If the same (or similar) results can be gained using fewer than the 24 visits suggested by Warren and co-workers', the cost per QALY will fall further. Finally, the benefit of weight loss through non-pharmacological interventions is likely to continue beyond the intervention period. Indeed, it can be argued that a successful non-pharmacological therapy elicits a change in behaviour that lasts for a lifetime. If this is the case, the cost per QALY will fall.

16.3.3.4 Investigating the search results for clinical papers

The clinical review looked at three major areas of non-pharmacological interventions, specifically behavioural treatment, diet and exercise. Since this economics review is investigating the incremental benefit of particular interventions, the clinical reviews were filtered to look at those interventions for which the difference between the intervention and the control was only one approach. Thus, for example, diet versus no intervention was included, as was diet and exercise versus exercise alone. Furthermore, the papers included here had to report sufficient detail regarding the quantity of contact time and the healthcare professional involved. Also, the paper needed to present results at 12 months. For the purpose of the analysis, it is assumed that each intervention continues for this period before being discontinued. The reviews included papers that met these specifications as shown in Table 16.4.

Table 16.4 The number of clinical papers included by intervention[a]

Review	Diet	Behavioural treatment	Physical activity
No. of papers included in review	6	1	2

[a] Many of the studies published in these areas involve components of two or three or these types of intervention. The physical activity review looks for any paper that includes physical activity, the behavioural treatment review looks at papers that combine behaviour therapy with diet, and the diet review looked at papers which include diet alone (thus only those papers in which the control is no intervention).

The aim of this section is to balance the resource implications of these programmes against the benefit to the patients. Effectiveness data for the papers taken from the physical activity review (Table 16.5) are given here.

Table 16.5 The relevant effectiveness papers in the physical activity review

Author(s)	Comparison	Additional Intervention in first year	Relative weight loss at 12 months (kg)
Anderssen SA, Hjermann I, Urdal P et al. Improved carbohydrate metabolism after physical training and dietary intervention in individuals with the 'atherothrombogenic syndrome'. Oslo Diet and Exercise Study (ODES). A randomized trial. *Journal of Internal Medicine* 1996;240:203–9	Physical activity vs no treatment	158 sessions of up to 1 hour by a 'highly qualified instructor' (assumption of physiotherapist taking groups of six)	2.00
Pritchard JE, Nowson CA, Wark JD. A worksite program for overweight middle-aged men achieves lesser weight loss with exercise than with dietary change. *Journal of the American Dietetic Association* 1997;97:37–42	Physical activity vs no treatment	19 compulsory contacts by an unreported healthcare professional (assumption of physiotherapist and 1-hour contacts)	2.90

Similarly, effectiveness data for the papers taken from the diet review (Table 16.6) are given here.

Table 16.6 The relevant effectiveness papers in the diet review

Authors	Comparison	Additional intervention in first year	Relative weight loss at 12 months (kg)
Frey-Hewitt B, Vranizan KM, Dreon DM et al. The effect of weight loss by dieting or exercise on resting metabolic rate in overweight men. *International Journal of Obesity* 1990;14:327–34	600 kcal/day or low fat vs no treatment	23 extra contacts by dietitian (assumption of 1 hour)	7.06
Jones DW, Miller ME, Wofford MRL et al. The effect of weight loss intervention on antihypertensive medication requirements in the hypertension Optimal Treatment (HOT) study. *American Journal of Hypertension* 1999;12:1175–80	600 kcal/day or low fat vs no treatment	18 extra dietitian contacts (assumption of 1 hour)	0.40
Anderssen SA, Hjermann I, Urdal P et al. Improved carbohydrate metabolism after physical training and dietary intervention in individuals with the 'atherothrombogenic syndrome'. Oslo Diet and Exercise Study (ODES). A randomized trial. *Journal of Internal Medicine* 1996;240:203–9	600 kcal/day or low fat vs no treatment	4 consultations with dietitian (assumption of 1 hour)	5.10
Pritchard DA, Hyndman J, Taba F. Nutritional counselling in general practice: a cost effective analysis. Journal of Epidemiology and Community Health 1999;53:311–16	600 kcal/day or low fat vs no treatment	5 contacts by dietitian (assumption of 1 hour)	5.70
Wood PD, Stefanick ML, Williams PT et al. The effects on plasma lipoproteins of a prudent weight-reducing diet, with or without exercise, in overweight men and women. *New England Journal of Medicine* 1991;325:461–6	600 kcal/day or low fat vs no treatment	23 group sessions with dietitian (assumption of 1 hour and a group of six)	6.10

Authors	Comparison	Additional intervention in first year	Relative weight loss at 12 months (kg)
Stenius-Aarniala B, Poussa T, Kvarnstrom J et al. Immediate and long term effects of weight reduction in obese people with asthma: randomised controlled study. *BMJ* 2000;320:827–32	Very-low-calorie diet vs no treatment	No extra intervention (contact time in control used to discuss themes chosen by participants)	13.40

Finally, the effectiveness results for the relevant behavioural treatment papers are given in Table 16.7.

Table 16.7 The relevant effectiveness papers in the behavioural treatment review

Authors	Comparison	Additional Intervention in first year	Relative weight loss at 12 months (kg)
Wadden TA, Sternberg JA, Letizia KA et al. Treatment of obesity by very low calorie diet, behavior therapy, and their combination: a five-year perspective. *International Journal of Obesity* 1989;13 (Suppl. 2):39–46	Diet and behavioural treatment vs diet	14 extra contacts. 90 minute contacts with clinical psychologist	8.19

This information has to be compared with the costs of the staffing resources (which are likely to represent the majority of the total cost; Table 16.8) used in each intervention group relative to each control group (Tables 16.9–16.11).

Table 16.8 Unit costs of various healthcare professionals[10]

Resource per hour	Unit cost (per hour)
Dietitian	£27
Physiotherapist	£28
Clinical psychologist	£32

Table 16.9 The cost, the effect and the cost per kg lost in physical activity papers

Authors	Relative weight loss at 12 months (kg)	Intervention cost per patient (£)	Cost per kg lost (£)
Anderssen SA, Hjermann I, Urdal P et al. Improved carbohydrate metabolism after physical training and dietary intervention in individuals with the 'atherothrombogenic syndrome'. Oslo Diet and Exercise Study (ODES). A randomized trial. *Journal of Internal Medicine* 1996;240:203–9	2.00	737	368.50
Pritchard JE, Nowson CA, Wark JD. A worksite program for overweight middle-aged men achieves lesser weight loss with exercise than with dietary change [see comment]. *Journal of the American Dietetic Association* 1997;97:37–42.	2.90	532	183.45

Table 16.10 The cost, the effect and the cost per kg lost in diet papers

Authors	Relative weight loss at 12 months (kg)	Intervention cost per patient (£)	Cost per kg lost (£)
Frey-Hewitt B, Vranizan KM, Dreon DM et al. The effect of weight loss by dieting or exercise on resting metabolic rate in overweight men. *International Journal of Obesity* 1990;14:327–34	7.06	621	87.96

Authors	Relative weight loss at 12 months (kg)	Intervention cost per patient (£)	Cost per kg lost (£)
Jones DW, Miller ME, Wofford MRL et al. The effect of weight loss intervention on antihypertensive medication requirements in the hypertension Optimal Treatment (HOT) study. *American Journal of Hypertension* 1999;12:1175–80	0.40	486	1215.00
Anderssen SA, Hjermann I, Urdal P et al. Improved carbohydrate metabolism after physical training and dietary intervention in individuals with the 'atherothrombogenic syndrome'. Oslo Diet and Exercise Study (ODES). A randomized trial. *Journal of Internal Medicine* 1996;240:203–9.	5.10	108	21.18
Pritchard DA, Hyndman J, Taba F. Nutritional counselling in general practice: a cost effective analysis. *Journal of Epidemiology and Community Health* 1999;53:311–16	5.70	135	23.68
Wood PD, Stefanick ML, Williams PT et al. The effects on plasma lipoproteins of a prudent weight-reducing diet, with or without exercise, in overweight men and women. *New England Journal of Medicine* 1991;325:461–6	6.10	103.5	16.97
Stenius-Aarniala B, Poussa T, Kvarnstrom J et al. Immediate and long term effects of weight reduction in obese people with asthma: randomised controlled study. *BMJ* 2000;320:827–32	13.40	0	N/A

N/A, not applicable.

Table 16.11 The cost, the effect and the cost per kg lost in behavioural treatment papers

Authors	Relative weight loss at 12 months (kg)	Intervention cost per patient (£)	Cost per kg lost (£)
Wadden TA, Sternberg JA, Letizia KA et al. Treatment of obesity by very low calorie diet, behavior therapy, and their combination: a five-year perspective. *International Journal of Obesity* 1989;13 (Suppl. 2):39–46	8.19	672	82.05

The final question is whether this information suggests the programmes listed above represent a cost-effective use of societal resources, assuming the individual will return to trend. Since there is great heterogeneity of intervention, it is assumed that the study producing the best cost per kg lost represents 'best practice'. The most important assumption is the rate at which the individual returns to trend weight. To illustrate the importance of this, an alternative scenario is presented in Table 16.12.

Table 16.12 The two scenarios to investigate the sensitivity of the modelling to weight regain assumptions

Scenario	Trend weight gain per annum (kg)	Weight gain post-treatment per annum (kg)	Period before weight returns to trend
Base case	0.5	5.6	Dependent on initial weight loss
Scenario 2	0.5	0.5	5 years

Bearing in mind the small sample of papers amenable to this analysis, the results are suggestive of cost effectiveness in these interventions. Using the papers that report the best cost-effectiveness outcomes (thus representing the 'best practice' in the area), the weight loss was inputted into the economic modelling developed for this guidance and is described in the depth in section 16.5 (on orlistat), generating the QALY gain, aggregate costs and incremental cost-effectiveness ratios (ICER) as shown in Tables 16.13 and 16.14.

Table 16.13 Base case results

Intervention	Incremental cost	Incremental QALY	ICER (£)
Diet (Wood et al. 1991)[11]	75.83	0.0371882	2,039
Behavioural treatment (Wadden et al. 1989)[12]	626.13	0.058361	10,729
Exercise (Pritchard et al. 1997)[13]	523.45	0.0127209	41,149

See Tables 16.7, 16.9 and 16.10 for full publication details of the papers.

Table 16.14 Scenario 2 results

Intervention	Incremental cost	Incremental QALY	ICER (£)
Diet (Wood et al. 1991)[11]	16.92	0.0974152	174
Behavioural treatment (Wadden et al. 1989)[12]	554.44	0.1271699	4,360
Exercise (Pritchard et al. 1997)[13]	491.74	0.049318	9,971

See Tables 16.7, 16.9 and 16.10 for full publication details of the papers.

Since these interventions are applicable to similar population groups, incremental analysis can be used to compare options. As the exercise option is both more expensive and less effective (in terms of 12-month weight loss) than the diet option in both scenarios, it is removed from the analysis since it is dominated. The incremental QALY of behavioural treatment relative to diet can be calculated for both scenarios. Under the base case, the ICER is £25,991, suggesting that the cost effectiveness of the more intensive intervention is unproven. Under scenario 2, the equivalent value is £18,065, representing weak evidence of cost effectiveness of behavioural treatment relative to diet. The important point is that, as the duration of weight loss increases, intensive interventions becomes relatively more cost effective as the benefits endure. It should be noted that, since the guidance is aiming at a multifaceted approach to non-pharmacological care, the trade-off between options becomes less important.

16.3.3.5 Conclusions on the cost effectiveness of non-pharmacological interventions

Notwithstanding the limited evidence in an already obese population, these types of interventions appear to be a cost-effective use of resources. Dietary interventions seem particularly cost effective due to the low levels of staff contact needed. These results seem to agree with the analysis undertaken in the prevention component of the guidance as well as what evidence could be found in the literature search.

A number of caveats must be attached to using these results as unequivocal evidence of cost effectiveness of these kinds of interventions. First, the results are particularly sensitive to the rate of weight regain after the intervention. Thus, cost effectiveness depends on the intervention changing behaviour for a time after treatment is discontinued. Second, since the trials used did not collect cost-effectiveness evidence specifically, the costs of the interventions are only approximate, and contain only staffing costs which, although forming the majority of the cost, exclude some other components. Third, the pool of suitable information is small, and the papers contained slightly different populations. Therefore, the generalisability of the results is questionable. Because of these reasons, these results should be treated as corroborative evidence, rather than definite proof of the cost effectiveness of non-pharmacological interventions.

16.4 Cost effectiveness of sibutramine

16.4.1 Cost effectiveness evidence statements (Table 16.15)

Table 16.15 Evidence statements on cost effectiveness of sibutramine

1	Sibutramine is a cost-effective intervention in adults with a BMI greater than 30 kg/m^2 (or 28 kg/m^2 with comorbidities) relative to non-pharmacological interventions
2	The most reliable estimate of a cost per QALY under current licensing is £6 349 (range: £4 542 – 12 227)
3	There is no evidence regarding the cost-effectiveness of a longer regimen (> 12 months) of sibutramine relative to a regimen of 12 months
4	There is no evidence regarding the cost effectiveness of sibutramine in children and adolescents

16.4.2 Current report – summary and analysis

Consideration of: **O'Meara S, Riemsma R, Shirran L et al. The clinical effectiveness and cost-effectiveness of sibutramine in the management of obesity: a technology appraisal. *Health Technology Assessment* 2002;6:1–97.[14]**

This report was commissioned to provide evidence to the NICE Appraisals Committee. This report undertook a comprehensive literature study and found no cost-effectiveness evidence of a satisfactory standard. It then discussed the previous company (Abbott) submission, submitted as part of the HTA process (BASF Pharma/Knoll. Cost-utility analysis of sibutramine. Submission to NICE.).

The hypothetical population used in their model included 1000 patients with a BMI greater than 30 kg/m^2 who were free of comorbidities and complications at the beginning of the modelling period. Each individual simulated by the model received sibutramine according to the product monograph. A description of the sibutramine regimen is given below:

- 'Hurdle 1 (H1): 2 kg must be lost after 4 weeks of treatment
- Hurdle 2 (H2): 5% of initial body weight must be lost by 12 weeks of treatment

- Hurdle 2a (H2a): In patients in whom either hurdle fails can be given a higher 15 mg dosage for 3 months. Five per cent of initial weight must be lost during this 3-month period.'

The authors used published literature on the effectiveness of sibutramine, (Knoll. Report number SB1047 (Smith 1994). Submission to NICE; Knoll Report number SB1048 (James, 1999)) diabetes risk[15–16] and QoL gains through sibutramine-induced weight loss.[17,18] They used these clinical data to produce overall measurements of total costs and total benefit in terms of mortality and morbidity. The submission suggests a cost per QALY of £10,500 for sibutramine treatment in comparison with a diet and exercise regimen alone. This figure includes the reductions in CHD, diabetes and weight per se and would usually be considered cost effective. The submission asserted that including other beneficial reductions in disease incidence would reduce this cost per QALY further. The Health Technology Assessment (HTA) report noted that the side effects of sibutramine treatment were excluded from the analysis. Under univariate analysis, these results were relatively robust to the assumptions used, in that the cost per QALY range was £3,200 to £16,700.

The HTA looked at areas in the model such as the rate of natural weight regain, regain after treatment has been discontinued. They felt that 'a more realistic cost per QALY gained may be of the order of £15,000 to £30,000'.

16.4.3 Literature search

The update literature review looked for cost-effectiveness studies produced since the cut-off point of the HTA report (June 2000). It identified two studies looking at the use of sibutramine treatment for obesity. They were cost–utility or cost–effectiveness analyses, based in developed countries and had sibutramine as part of the treatment branch. Both were limited to the use of sibutramine in the treatment of obesity in adults.

Since there were no cost-effectiveness studies on the use of sibutramine in children and adolescents, the clinical review on the effectiveness in this area was used in

conjunction with the adult cost-effectiveness review to provide guidance on the formulation of recommendations in this group.

A company submission looked at the cost effectiveness of treating obese people with sibutramine [19] and a diet and exercise regimen relative to the 'best non-pharmacological care', comprising a diet and exercise regimen alone. Patients were treated in accordance with the product monograph given previously. Commencing treatment on a daily dose of 10 mg, patients must pass the hurdles to remain in the treatment group.

Effectiveness data comprise weight loss progress over the treatment year, weight regain after the year,[20,21] reduction in (and improvement in QoL associated with) CHD[22]–[23] and diabetes,[24],[25] and QoL life gains through weight loss per se.[26,27] Side effects were not explicitly discussed. The most severe side effects would be partially contained in the dropout rates assumed in the model.

Cost data comprised of costs accrued through following the sibutramine treatment recommendations of the Nutrition Committee of the Royal College of Physicians,[28] the costs of CHD events sourced from the United Kingdom Prospective Diabetes Study (UKPDS) study,[29] and the costs of diabetes treatment taken from a number of sources including the UKPDS. The perspective selected that of the UK NHS and personal social services. Therefore, no calculation of issues such as productivity losses or costs incurred to patients is included. This step follows the approach of the Institute's technical manual. The paper discounts future events at 6% for costs and 1.5% for benefits. This differs from the Institute's current approach of discounting both costs and benefits at 3.5% (although it does follow previous NICE recommendations, used until recently). The effect of this difference is to marginally underestimate the true cost per QALY of the treatment arm relative to the control. The timescale is the lifetime of the person following the maximum treatment period of 12 months. The specific population considered had a BMI of at least 30 kg/m^2 without comorbidities. The population was 80% female, reflecting UK prescription data.

The results were as follows:

- The use of sibutramine in the cohort of 1000 described previously will incur a net cost of £373,529, and will produce 58.8 extra QALYs. The cost per QALY is therefore £6,349.

- Using probabilistic sensitivity analysis, the paper produces a cost-effectiveness acceptability curve. Using their assumptions, one can be 94.5% certain of sibutramine being cost effective relative to the best non-pharmacological intervention at a threshold of £10,000 per QALY. If this threshold were to increase to £20,000, the likelihood of cost effectiveness described above increases to 99.9%. Although the Institute has no formal threshold, a treatment costing £10,000–20,000 per QALY would usually be considered cost effective.

- Undertaking sensitivity analysis on each of the model inputs, the results are most sensitive to utility gain per kg lost (using the lower 95%CI, the cost per QALY increases to £12,227).

- The use of the old discount rates in the paper does not greatly affect the cost per QALY (the figure rises from £6,349 to £6,840).

Focusing on the reliability of the utility gain per kilogram lost, the 'Health survey for England' presents a slightly different picture. Ara and Brennan assume a uniform improvement in quality of life (QoL) of 0.00375/kg lost.[19] Macran presents more detailed information on this issue, stratifying for BMI levels, age and gender [30]. The QoL figures are presented below. The paper does report QoL figures for BMI of greater than 39 kg/m^2. These are reported in Table 16.16 when the number of observations is 5 or greater.

Table 16.16 Quality of life based on gender, age and body mass index (BMI)

	BMI (kg/m^2)				
	Under 21	**21–25**	**26–30**	**31–39**	**Above 39**
Men (by age group)					
18–24	0.91	0.92	0.92	0.86	
25–34	0.9	0.91	0.92	0.89	0.97
35–44	0.82	0.91	0.89	0.89	0.9
45–54	0.87	0.87	0.86	0.84	0.8

	BMI (kg/m^2)				
	Under 21	**21–25**	**26–30**	**31–39**	**Above 39**
55–64	0.75	0.82	0.81	0.72	
65–74	0.71	0.81	0.81	0.78	
75+	0.8	0.76	0.77	0.76	
All men	0.86	0.87	0.86	0.82	0.88
n	220	2078	2358	779	26
Women (by age group)					
18–24	0.9	0.9	0.9	0.88	0.93
25–34	0.88	0.92	0.91	0.88	0.9
35–44	0.89	0.89	0.86	0.82	0.81
45–54	0.89	0.86	0.83	0.83	0.76
55–64	0.76	0.83	0.78	0.74	0.54
65–74	0.79	0.82	0.76	0.71	0.68
75+	0.64	0.76	0.73	0.68	0.53
All women	0.85	0.87	0.82	0.78	0.75
n	486	2730	1995	1040	115
All	0.85	0.87	0.84	0.80	0.77
n	706	4808	4353	1819	141

Ara and Brennan report utility gain per kilogram lost rather than per BMI point reduction. Therefore, if average male and female heights are assumed to be 180 cm and 165 cm, respectively, the conversion required is shown in Table 16.17. It should be noted that all individual BMI values are rounded to the nearest point to ensure the ranges given below are exhaustive.

Table 16.17 Approximate relation between weight and body mass index (BMI [kg/m^2])

	BMI range	Weight range (kg)		BMI range	Weight range (kg)
Women	< 21	< 57.2	Men	< 21	< 68.0
	21–25	57.2–68.1		21–25	68–81
	26–30	68.1–81.7		26–30	81–97.2
	31–39	81.7–106.2		31–39	97.2–126.4
	39+	106.2+		39+	126.4+

Taking the mid-point of each range,* the weight loss and utility gain can be synthesised into a utility gain per kilogram lost and contrasted with Ara and Brennan (Table 16.18).

Table 16.18 Calculating utility gain per kilogram lost in men and women

	BMI (kg/m^2)	kg lost	Utility gain	Utility gain per kg
Women	28–23	13.6	0.05	0.003676471
	35–28	19.1	0.04	0.002094241
	44–35	24.5	0.03	0.00122449
Men	28–23	16.2	0.01	0.000617284
	35–28	22.7	0.04	0.001762115
	44–35	29.2	–0.06	–0.002054795

The Ara and Brennan assumption of a utility gain per kilogram lost of 0.00375 is reasonable for women at lower initial BMI levels. However, the assumption becomes increasingly unrealistic at higher BMIs and among men. In the sensitivity analysis of Ara and Brennan, the lower boundary of this parameter is set at 0.001/kg lost and leads to a cost per QALY of £12,227. This is probably conservative for women as the estimate for QoL gain per kilogram lost ranges from 0.00122 to 0.00368. A cost per QALY between £6349 and £12,227 is realistic. Among men, the cost per QALY figure is likely to be higher. At the extreme (such as the more obese males), it could be said that the QoL figures presented above show no QoL gain through weight loss per se. Under Ara and Brennan's figures, the removal of this component of benefit increases the cost per QALY to £18,400.

One further parameter which the result will be sensitive to, but is not mentioned in the report, is the rate of weight regain. In the company model, the rate of weight regain, and their source for the figures, are as shown in Table 16.19.

* Clearly, there is no mid-point for the lowest and highest BMI groups. This is not important for the lowest group since moving between BMI levels below 21 is beyond the remit. However, a mid-point of 44 was assumed for the group with a BMI greater than 39 kg/m^2.

Table 16.19 The assumed weight gain in Ara and Brennan[19]

Group	Weight regain (kg/month)	Standard error	Distribution
Responders	0.38486	0.0131	Normal
Placebo	0.36964	0.0131	Normal
Natural history	0.08333	0.0108	Normal

The implication of these figures is that the average responder at all hurdles to sibutramine treatment (thus receiving a 1-year regimen of 10 mg) will return to their original weight in 45 months and their trend weight in 58 months. The clinical review found no conclusive evidence regarding the suitability of this assumption. If this assumption exaggerates the length of time at below trend weight, the cost per QALY will be higher than the estimate given in the paper.

One final caveat is that the clinical advice suggested that the sibutramine treatment given by the paper was an exaggeration of the treatment actually provided. If this is an exaggeration, the true cost per QALY would fall as then treatment is relatively less expensive. Their assumption of healthcare professional contact is as shown in Table 16.20.

Table 16.20 Healthcare contact in the sibutramine group in Ara and Brennan[19]

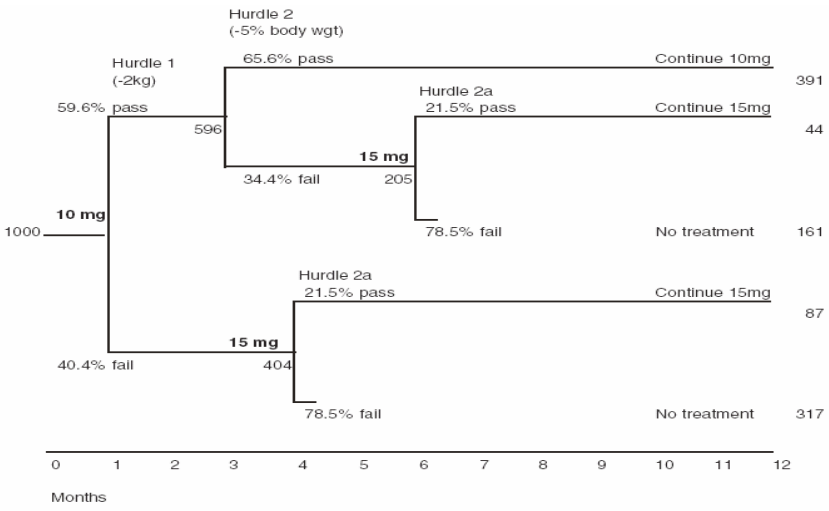
Month	Monitoring
0	All patients have an initial appointment with GP prior to commencing treatment/diet and exercise
1,2,3	Two appointments per month for sibutramine recipients
4,5,6	One appointment per month
9,12	One appointment at month 9 and month 12

An industry-funded paper looked at the cost effectiveness of a 10 mg regimen of sibutramine relative to a group receiving only diet and exercise advice.[31] The population modelled was a cohort of 1000 chosen according to UK prescription data (specifically 20% men, aged 18–65 (mean 42 years) and BMI between 27 kg/m^2 and

40 kg/m^2 [mean 32.7]). After 1 year of treatment, participants were modelled for 5 further years, calculating QoL based upon weight per se, diabetes status and CHD status. The incremental cost per QALY was calculated to be £4780 based on 2003 prices.

The authors undertook a univariate sensitivity analysis on 24 separate model inputs. By altering each of these 24 parameters within pre-defined limits, the cost per QALY remained between £2950 and £9034. The one exception to this was that the model was sensitive to the utility attached to weight loss per se. When this utility gain was set at the lower extreme, the cost per QALY rose to £14,072.

16.4.4 Further analysis



One aspect of the literature the group wanted to investigate was whether hurdle 2a in the product monograph (see above) was a cost-effective intervention, independent of the rest of the treatment. Specifically, given the relatively low success rate at hurdle 2a among people in whom the earlier hurdles failed, does the effect of the 15 mg regimen in this subpopulation represent value for money?

Using the figures from Ara and Brennan[19], 21.4% of people pass hurdle 2a. In their cohort of 1000, this means 131 responders and 478 non-responders (the other 391 do not reach this hurdle). This means each receives the 15 mg dosage for a further 3 months, costing £88,354. Furthermore, the 131 responders will incur drugs costs of £46,426 following success at hurdle 2a (since success means their treatment is

continued for the remainder of the year instead of discontinued). Thus, total drug cost implication of including hurdle 2a is £134,780. Following the approach of Ara and Brennan, this cost is reduced by the decreased incidence of diabetes and CHD by £12,520. In the model, the non-drug costs are comparable between the two groups. Thus this figure represents the incremental cost of including hurdle 2a in the cohort. The net cost per responder of hurdle 2a is £122,260/131 = £933.

(QALYs (sibutramine group) – QALYs (control group))/Proportion of responders in the total cohort

The denominator shows that this calculation assumes that the gains of sibutramine are isolated to those who respond to the hurdles. Thus, the expected QALY gain in those who respond at hurdle 2a compared with those who do not is:

(35.508 – 35.449) / (522/1000) = 0.113 QALYs

If this assumption is made, this gives a cost per QALY of £933/0.113 = £8257.

It is important to note that the real cost per QALY is likely to increase from this estimate. This is because this calculation assumes that those who respond to treatment at hurdle 2a have the same profile as those who respond at hurdle 1. It is likely that those who struggle to respond at the first stage but go on to succeed at the latter may have lower total utility gains. To an extent, this may be counteracted because the effect of the more intense treatment among those in whom the treatment still fails, as defined by losing the required weight to continue, will still have some benefit of reduced weight.

16.4.5 Cost effectiveness of sibutramine in obese children and adolescents

There were no cost-effectiveness studies focusing either exclusively or in part on children. However, statements useful in the consideration of cost effectiveness can be drawn from the clinical literature.[32,33] In Berkowitz and co-workers' study, the focus was on 82 adolescents aged between 13 and 17 years, with a BMI between 32 kg/m^2 and 44 kg/m^2. The intervention group received behavioural treatment and sibutramine for 6 months and the control group received behavioural treatment and placebo. From months 7–12, all received sibutramine alone. At 6 months, the

intervention group had reduced BMI by 8.5% (SD 6.8%). Although the use of BMI z-score would have been informative since it allows for the natural development of children over time, this BMI reduction figure compares favourably with that used in the previously discussed Abbott company submission for adults.[34] However, a comparison is difficult since the papers use different treatment protocols. It cannot be determined whether the cost of treatment for obese children would be different from that for obese adults, given the use of the product monograph employed in the company submission.

In the adult literature, the main driver of cost -effectiveness is the reduction of incidence of obesity-related conditions. Although an increased risk of diabetes should be considered as a consequence of obesity in children, it is less sustainable to include myocardial infarction (MI), stroke or cardiovascular disease (CVD) as a direct benefit of the weight loss elicited by the pharmacological regimen. Although these diseases are being seen in extreme cases in younger groups, using them as the only output measures from drug therapy would surely underestimate the benefit children receive from pharmacological interventions.

It is certainly arguable that the benefits of reduced weight in obese adolescents are much less tangible and include issues such as self-esteem and the motivation to alter behaviour. If this is true, the role of health economics is marginal as the measurement of such benefits is much harder than that of reduced incidence of disease.

16.5 Cost effectiveness of orlistat

16.5.1 Cost effectiveness evidence statements (Table 16.21)

Table 16.21 Evidence statements on cost effectiveness of orlistat

1	Orlistat is a cost-effective intervention in adults with a BMI greater than 30 (or 28 with comorbidities) relative to non-pharmacological interventions
2	The most reliable published estimate of a cost per QALY under current licensing is £24,431(range:£10,856-£77,197)
3	Under the alternative European Agency for the Evaluation of Medicinal Products (EMEA) licence as described by Foxcroft,[24] the cost per QALY is £19,005 (range:£8,840-£57,798)
4	There is no published evidence regarding the cost effectiveness of a longer regimen (> 12 months) of orlistat relative to a regimen of 12 months. However, the cost per QALY is likely to increase as the treatment length extends beyond 12 months
5	The incremental cost-effective ratio of a 48-month regimen of orlistat relative to a 12-month regimen ranges from £22,099 to £39,308 per QALY, dependent on gender, initial BMI, the natural rate of weight gain and the rate of weight regain after conclusion of treatment
6	There is no cost-effectiveness evidence regarding the use of orlistat in children and adolescents

BMI, body mass index; QALY, quality-adjusted life year.

16.5.2 Current report – summary and analysis

Consideration of: **O'Meara S, Riemsma R, Shirran L et al. A systematic review of the clinical effectiveness and cost-effectiveness of orlistat in the management of obesity. *Health Technology Assessment* 2001;5:1–81.**

This report was commissioned to provide evidence to the NICE Appraisals Committee. The existing HTA report literature search identified one suitable cost-effectiveness study published prior to their cut-off in June 2000. (Roche. Cost-utility of orlistat. Company submission. 2000) Furthermore, they appraised one company submission. In the literature search result 'Orlistat for the treatment of obesity'[35] the authors used published evidence to provide costs and clinical effects of a regimen of 120 mg three times daily combined with diet relative to diet alone. The clinical data

came from double-blind RCTs.[31;34;36] These data are combined with cost data to produce a cost–utility analysis.

In a hypothetical cohort of 100 patients, the treatment as per the product monograph costs £73,436. Under the base case, the number of QALYs gained in a year are 1.601. This equates to £45,881 per QALY gained. The authors produced a sensitivity analysis, illustrating the responsiveness of this cost per QALY to changes in the base case assumptions. Altering annual costs, dropout rates, response rates and utility gain gradients within reasonable parameters, the cost per QALY remained between £13,541 and £131,918. In their analysis, Foxcroft and Ludders did not include side effects such as gastrointestinal problems and vitamin malabsorption because it was felt these were *'mild and transient'*.

The other cost-effectiveness paper covered in the HTA report was a company submission by Roche. The company have updated this model.[24]The details of their new analysis are provided later in this narrative.

16.5.3 Literature search

The cost-effectiveness literature search for the use of orlistat for obesity focused on the period following the cut-off in the original report (June 2000). This identified two studies, both of which were of a suitable standard. Both were cost-effectiveness or cost-utility models, based in developed countries and had orlistat treatment as part of the treatment branch. Further to this, there was one company submission. All of these studies focused specifically on adults.

Since no cost-effectiveness studies on the use of orlistat in children and adolescents were identified, the clinical search results were used to provide guidance on the formulation of recommendations in this group.

16.5.3.1 Cost-effectiveness results for papers published after June 2000

A company submission looks at the cost effectiveness of orlistat treatment based on previous NICE guidance for England and Wales.[24] The clinical information comes from three European trials. [24,37,38] The paper also looks at the European Agency for the Evaluation of Medicinal Products (EMEA) approach (treatment discontinued if weight loss < 5% at 3 months).

In line with the SPC at the time, NICE guidance (TA22) gave conditions for the initiation and continuation of treatment. These included a ‘starting criterion’:

1. Orlistat should only be prescribed for people who have lost at least 2.5kg by diet and exercise alone in the preceding month.

As well as two ‘stopping criteria’:

2. Continuation beyond three months should be supported by evidence of a loss of at least 5% of body weight from the start of treatment.

3. Continuation beyond six months should be supported by evidence of a cumulative loss of at least 10% of body weight from the start of treatment.

Foxcroft estimated that the use of the NICE-specified population reduced the cost per QALY to £24,431 (£19,005 under the EMEA approach).

The paper used a utility gain per kilogram lost of 0.017. Using ‘Health survey for England’ figures given in the sibutramine section above, this is a realistic assumption for the general population. The rate of utility gain seems to differ between subgroups, being relatively low in the most obese, and in men. The major change in the costs attributed to treatment was that, unlike the previous company submission, prescriptions were performed in primary care rather than in specialised hospital units (thus reducing the cost).

In this analysis, five GP contacts were required. These were the initial consultation, one at the start of treatment, one at 3 months and two between 3 and 12 months (if there is a hurdle at 6 months, one of these must fall at this point).

The sensitivity analysis in the paper showed the cost per QALY results had lower and upper boundaries of £10,885 and £77,196 for NICE criteria and £8839 and £57,798 for the EMEA criteria. The upper boundaries occurred in a situation with some healthcare professional contacts occurring in a secondary care setting and utility gain from weight loss per se reduced to an arbitrary value of 0.05 QALYs gained per effective year of treatment.

As noted above, the paper included a comparison of the cost-effectiveness of orlistat use under NICE criteria (1, 2 and 3 above) and under 'EMEA' criteria (1 and 2 only). The results suggest that treatment under EMEA criteria is cost-effective: £19,000 per QALY (range £8,800 to £57,800 in sensitivity analysis).

Scenario	Criteria	Cost	QALYs	ICER*
Base case	NICE (1,2 & 3)	£22,745	0.931	£24,431
	EMEA (1 & 2)	£27,824	1.464	£19,005
high QALY/ low cost	NICE (1,2 & 3)	£14,742	1.358	£10,856
	EMEA (1 & 2)	£19,359	2.19	£8,840
high QALY/ high cost	NICE (1,2 & 3)	£28,949	1.358	£21,317
	EMEA (1 & 2)	£34,968	2.19	£15,967
low QALY/ low cost	NICE (1,2 & 3)	£14,742	0.375	£39,312
	EMEA (1 & 2)	£19,359	0.605	£31,998
low QALY/ high cost	NICE (1,2 & 3)	£28,948	0.375	£77,195
	EMEA (1 & 2)	£34,968	0.605	£57,798

* Incremental Cost-Effectiveness Ratio: each option compared with non-pharmacological treatment. Note that for all scenarios NICE criteria are subject to extended dominance.

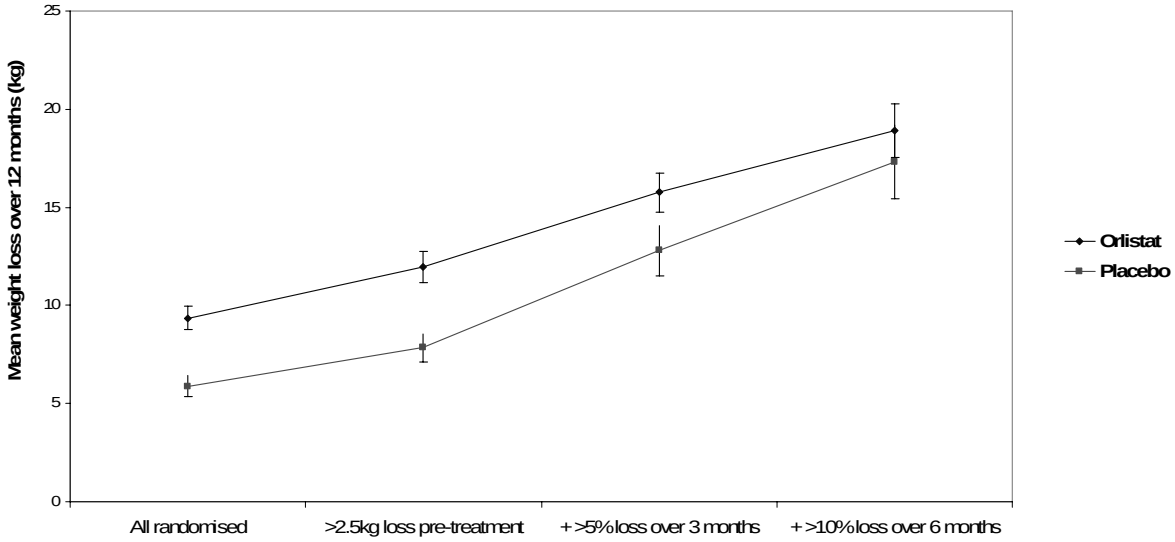
Although the 6-month stopping criterion reduces costs, it does not appear to be a cost-effective addition: the estimated cost per QALY under NICE criteria (£24,400, range £10,900 to £77,200) is higher than under EMEA criteria. However, this rather counterintuitive result could be a consequence of the method used to estimate QALY gains by Foxcroft.

For the EMEA criteria, it was assumed that patients who met 3-month criterion achieved a QALY gain proportional to their mean weight loss over twelve months: with orlistat (compared with placebo) an additional 12.1% of patients met the 3 month criteria and these patients lost an additional 2.95 kg over 12 months. This mean weight loss was then converted to a mean loss in BMI (assuming a mean height of 1.66m), and then to an expected QALY gain (assuming a gain of 0.017 QALYs per unit loss of BMI). It was assumed that patients who stopped treatment at 3 months received no benefit.

For the NICE criteria, it was assumed that only patients who passed the 6-month hurdle would gain any benefit: with orlistat an additional 7.5% of patients passed this hurdle, gaining a mean additional weight loss of 1.6kg each. However, patients treated for between 3 and 6 months under the NICE criteria are also likely to have

achieved additional weight loss and hence QALY gain. Furthermore, it is not apparent why the mean 12-month weight loss should be lower for patients who pass the 6-month hurdle than for those who pass the 3-month hurdle. This could reflect sampling error due to the relatively small number of placebo group patients passing the 6-month hurdle (37 out of 696 patients randomised to placebo, compared with 90 out of 702 randomised to orlistat). It can be seen that the difference in mean weight loss over 12 months is not significant for the subgroup of patients who pass the 6-month stopping criteria (see graph below).

Figure 1. Twelve-month weight loss for all patients and for subgroups responding to pre-treatment, 3-month and 6-month criteria (data from Foxcroft 2005)



The other assumptions in the model appear to be reasonable, and are not expected to introduce bias in favour of orlistat treatment – if anything the model is relatively conservative. However, Foxcroft does discuss some other limitations to the study. Notably, that data beyond one year follow-up, which could show rebound weight gain, was not made available for the analysis. Further, data on a large North American trial was not provided. Foxcroft comments that the results from the two European trials included in the modelling were ‘broadly compatible’ with those from a Cochrane review: mean one-year weight loss, compared with placebo, of 3.45kg and 2.7kg, respectively. The impact of this discrepancy on the estimated cost-

effectiveness cannot be tested as the results are not available separately for ‘responders’ and ‘non-responders’ at 3 and 6 months.

Conclusion: There is no estimate of the impact on cost-effectiveness of removing the requirement that patients lose at least 2.5kg in the month preceding prescribing of orlistat. Cost-effectiveness evidence presented in both the appraisal and the guideline includes this assumption.

There is some evidence to support removal of the requirement that at least 10% of body weight is lost by 6 months for continuation of treatment. One industry-funded model estimated that treatment would be more costly, but also more cost-effective if this requirement were to be removed. However, there are reasons to question the robustness of this conclusion because of some of the modelling assumptions and the exclusion of some relevant data.

One other paper was identified: a Roche-funded Belgian study looked at the cost effectiveness of a 2-year orlistat regimen in an obese (BMI > 30 kg/m^2) Belgian population compared with no treatment.[39] The population was stratified according the occurrence or not of hypercholesterolaemia and hypertension (meaning four subgroups). The authors synthesised the costs and life years gained (LYG) attributable to the intervention. They concluded that the cost per LYG ranged from €3,462 for obese diabetic people with hypertension and hypercholesterolaemia to €19,986 per LYG for obese diabetic people without risk factors.

A response to this article[40] highlighted further problems with the conclusions of this paper, specifically their choice and application of model parameters. The two major issues raised concerning their choice of model parameters were that:

- The author looks at the impact of reductions in HbA1c levels on the risk of macrovascular complications. They used the Diabetes Control and Complications Trial which includes only type 1 diabetic patients. Lamotte and coworkers[39] use these figures on macrovascular complications for people with type 2 diabetes. It is usual to consider that the relation between macrovascular complications and HbA1c is unlikely to be comparable between the variants of diabetes.

- Lamotte and coworkers[39] use the Helsinki Heart Study (HHS) to estimate the relation between low-density lipoprotein (LDL)-cholesterol and coronary events in people with type 2 diabetes. Edelsberg et al.'s response[40] claims that this study has been discredited as underpowered and concludes that figures used understate cost-effectiveness ratios.

The final result from the literature search was an American study[27] comparing the use of orlistat (120 mg, 3 times daily) for 52 weeks plus standard diabetes therapy (sulphonylurea, metformin or insulin) and weight management with standard diabetes therapy and weight management in obese and overweight diabetic people. The authors built a Markov model, populating it with transition probabilities and utility states. These data on the effectiveness (and side effects) of orlistat[34;41;42] complication rates[43] and costs[44–45] came from a variety of published sources. They concluded there was an incremental cost of US$1,122 (2001 values) and an incremental life year figure of 0.13. Combining the two, there is a cost per life year gained of $8,327. At face value, this figure seems to suggest cost effectiveness of the intervention relative to the control. However, this study had some drawbacks.

First, the disease incidence rates were representative of a small demographic (age 50–54, male, Caucasian, diabetic people, duration of diabetes 7.5–12.5 years). Significantly, the authors noted that complications among women occurred at half the rate of men. If the complication rate falls, it is likely that the cost effectiveness reported as baseline was an underestimate. Second, the conclusion was sensitive to the duration of weight loss. In the base case, they assumed responders took 3 years to return to weight trend. However, if this figure was 1 year, the cost per life year gained would rise to around $20,000. The final caveat is that, although effect size is taken from a UK population (so is relevant for this analysis), costs may not be transferable from the USA.

16.5.4 Cost effectiveness of other lengths of treatment relative to a 12-month approach

Most studies follow existing guidance on length of treatment. Therefore, the literature on extending treatment is limited. There are no cost-effectiveness papers that look at this issue. One clinical study that looked at the role of orlistat in lowering weight and

the incidence of diabetes over 4 years.[46] The results presented in the clinical review show that the effect of orlistat beyond 1 year of treatment is to slow down the rate of weight regain. The orlistat group regained 4.8 kg between 12 and 48 months compared with 3.2 kg in the placebo group. The weight regain rate was therefore 133 g per month in the orlistat group. At 48 months, the intervention group had lost an average of 2.8 kg more than those in the control group. Because of the study design, the counterfactual, specifically the rate of weight regain the orlistat group would have experienced between months 12 and 48 had it not been on orlistat, was not given. To investigate this issue, independent modelling (described below) was undertaken within the collaborating centre.

The average pathway of BMI over time under the 12-month and 48-month regimen can be simply modelled using Torgerson and coworkers'[46] results and the evidence from Davidson and coworkers[31] and Sjostrom and coworkers[36] on weight regain. Assuming a linear pathway of BMI (other than the switch at 12 months from weight loss to weight regain), this pathway can be illustrated diagrammatically (Figure 16.1).

Figure 16.1 Pathway of weight over time under different orlistat programmes (initial body mass index [BMI] of 33 kg/m^2)

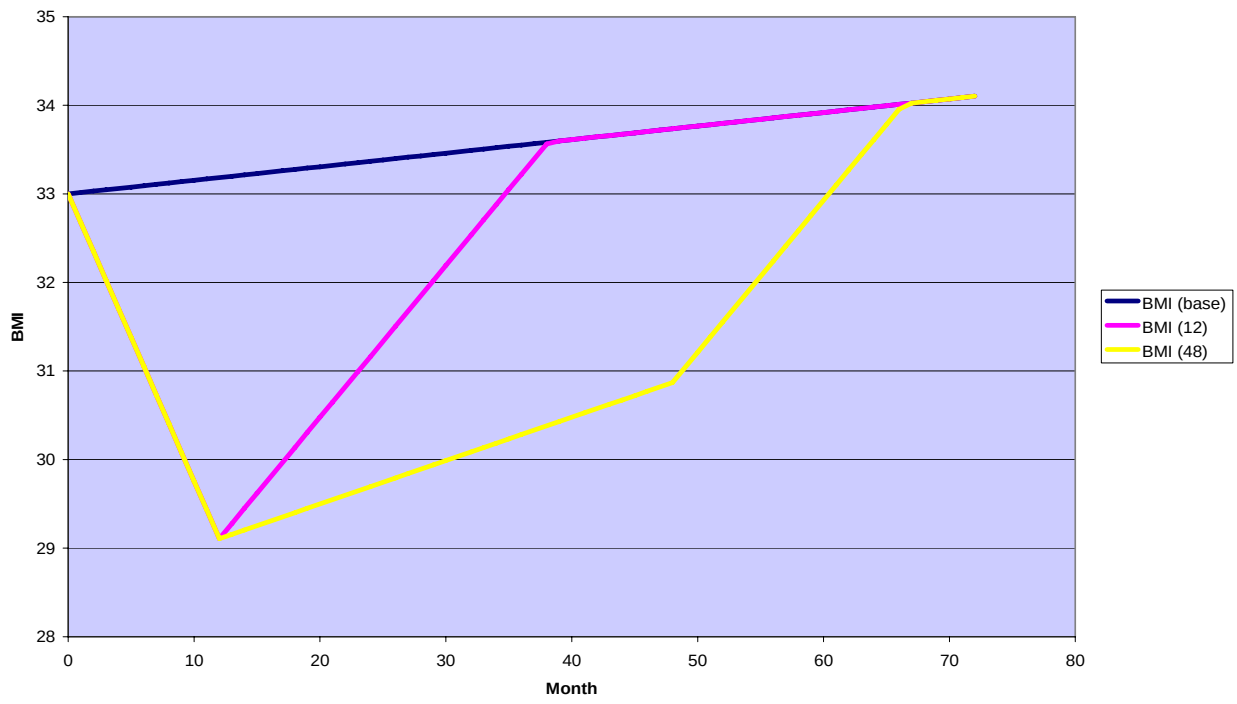


Figure 16.1 shows the path for trend weight regain and BMI over 12- and 48-month regimens in a person with an initial BMI of 33 kg/m^2. The model assumes that the rate of weight regain is the same at the end of the treatment period, be it 12 or 48 months.

The model investigates the costs and benefits of this weight reduction in terms of QoL improvements through weight loss per se, CHD, type 2 diabetes and colorectal cancer, as well as the relation between BMI and mortality. Each BMI level will be associated with a prevalence of the three conditions, a QoL figure independent of disease, and a mortality rate.

Various company submissions have suggested a QoL/weight (or BMI) gradient.[19] However, these estimates assume a constant gradient, an assumption which is unlikely to be realistic. Therefore, estimates were taken from a paper which did identify a different gradient at different BMI levels. [30] This paper provided QoL estimates for five BMI ranges (< 21, 21–25, 26–30, 31–39 and > 39). These figures were ascribed to the central values of each range and a linear trend between mid-points was assumed. Thus, expected QoL values were estimated for each 0.1 increment of BMI.

Information on diabetes prevalence by BMI level was also attained.[47] The principle used was to estimate the likelihood of diabetes at each BMI level, amend the cost of orlistat to reflect the cost offset through reduced diabetes prevalence, and to weight the expected QoL estimates accounting for the disutility this chronic condition brings. A utility multiplier of 0.8661 was identified in the literature and assumed.[19]

The costs of diabetes were developed using the approach of Ara and Brennan.[19] However, it was felt that type 2 diabetes was more likely to be managed in primary care. Therefore, treatment was assumed to contain visits and treatment as shown in Table 16.22.

Table 16.22 Diabetes care suggested by Ara and Brennan[19]

Visit/test/treatment	Units per year	Unit cost (£)	Total cost per year (£)
GP nurse	2	8	16
Specialist nursing	1	22	22
GP clinic	2	15	30
HbA1c test	1	6.5	6.5
Home glucose test	12	0.27	3.24
Eye screening	0.5	10.5	5.25
Angiotensin-converting enzyme inhibitor – ramipril			117
Diuretic			9
Statin therapy (simvastatin)			387
Metformin antiglycaemic therapy			37

CHD figures were identified, stratifying risk of CHD by BMI level.[48] These risk ratios were smoothed by attributing the value of each BMI range to the central value and joining these. The cost of CHD was taken from global costing figures.[49] The paper suggests that 988,000 people received treatment at a total cost of £716 million. This gives an approximate average value per person per year of £725.

The prevalence of colorectal cancer by BMI was calculated by combining data on the relative risk of the condition by BMI level[50] with the prevalence of colorectal cancer in the general population.[51] No UK studies identified a cost of treating colorectal cancer. However, an Australian paper[52] identified a cost of Aus$18,435, which was converted to UK currency and applied as the best cost estimate.

The costs of orlistat treatment are calculated to be the cost of 120 mg three times per day for either 12 months or 48 months (Table 16.23). Since Torgerson's[49] data include lifestyle advice, the model assumes four GP visits in each of the subsequent years of continued treatment. The cost of this is derived through research undertaken by the Personal Social Services Research Unit.[10]

Table 16.23 Baseline results for the cost-effectiveness of longer treatment regimens (genders combined)

	12 months vs 0	48 months vs 0	48 vs 12 months
QoL gains	0.0551	0.1104	0.05526
Cost difference	584	2 130	1 545
Cost/QALY	10 600	19 292	27 965

QALY, quality-adjusted life year; QoL, quality of life.

The incremental cost-effectiveness ratio for a 12-month regimen is comparable to that presented elsewhere. The driver for the slightly lower value is that the efficacy data come from Torgerson and coworkers[46] who suggested a relatively large fall in weight over the first 12 months. The appropriate comparison for the 48-month regimen is the 12-month regimen rather than no treatment. Thus, the cost per QALY in both genders is £25,407. The use of these figures should contain two caveats.

First, the model excludes the effect of orlistat on the occurrence of other conditions. Thus, it underestimates the true benefit. Second, the sensitivity analysis suggests the conclusion does alter as various model parameters (gender of the person, initial BMI, trend weight gain and the rate of weight regain once orlistat treatment is discontinued) alter (Table 16.24).

Table 16.24 Sensitivity analysis for longer treatment regimens

Variable	Value	Cost per QALY (£) (12 months vs 0)	Cost per QALY (£) (48 months vs 12)
Baseline	See below	Male 10,643	Male 29,089
		Female 10,556	Female 26,917
In the base case, initial BMI is 33 kg/m^2, trend weight gain is 0.5 kg/year, and weight gain after discontinuation of treatment is 5.6 kg/year			
Initial BMI	30	Male 13,182	Male 33,134
		Female 10,229	Female 23,982
	38	Male 11,237	Male 29,920
		Female 12,505	Female 30,115
Trend weight gain	0	Male 12,604	Male 36,704
		Female12,448	Female 33,884
	1	Male 9,238	Male 23,923
		Female 9,198	Female 22,099
Weight regain post discontinuation	3.6	Male 7,607	Male 39,308
		Female 7,408	Female 35,486
	7.6	Male 12,982	Male 25,985
		Female13,033	Female 24,249
Cost of type 2 diabetes care p/a	£1,550 (as per CODE2)	Male 9,806	Male 27,985
		Female 9,509	Female 25,648

QALY, quality-adjusted life year.

The results suggest that the cost per QALY depends on the gender of the person, the initial BMI, the cost of treating type 2 diabetes, the trend weight gain without orlistat and the rate of weight regain once orlistat treatment is discontinued. However, within these limits, the incremental cost-effectiveness ratio ranges from £22,099 to £39,308. In comparison with other economic analyses in the Institute, this suggests that the intervention cannot be firmly recommended on cost-effectiveness grounds.

16.5.5 Cost effectiveness of orlistat for obese children and adolescents

There were no cost-effectiveness studies focusing either exclusively or in part on children. However, some guidance might be drawn from the clinical literature which can be used in the cost-effectiveness discussion of orlistat use in obese adolescents.

In both located clinical trials amenable to health economic analysis[53,54] the authors treat children according to the adult dosage (120 mg three times daily). However, McDuffie and co-workers' discontinued treatment after 3 months (contrasting with 1 year by Ozkan and co-workers'). If a shortened period of treatment for adolescents was part of any treatment protocol, this would clearly lead to a significant reduction in drug costs. The pertinent question for cost-effectiveness purposes is then whether there is a clinically worthwhile difference between the 3-month treatment (combined with a diet, exercise and behaviour course) and a similar longer treatment (11.7 ± 3.7 months[53]). Unfortunately, the clinical results do not provide a clear answer since the populations were small (20 in McDuffie,[54] 22 in Ozkan[53]) and may have undertaken radically different lifestyle, diet and behavioural interventions. Both studies suggest a higher dropout rate among children than among adults (32% in Ozkan,[53] 15% in McDuffie[54]). This has cost-effectiveness implications since the expected beneficial effect of treatment is diluted by dropouts.

While the costs may be lower in the orlistat treatment of obese adolescents, the benefits as measured by the adult cost-effectiveness literature may also be lower. However, this may be a consequence of adults and children having different relevant endpoints when prescribed pharmacological interventions for obesity.

In the adult literature, the main driver of cost effectiveness is the reduction of incidence of obesity-related drugs. While an increased risk of diabetes should be considered as a consequence of obesity in children, it is less sustainable to include MI, stroke or CVD as a direct benefit of the weight loss elicited by the pharmacological regimen. Although these diseases are being seen in extreme cases in younger groups, using them as the only output measures from drug therapy would surely underestimate the benefit children receive from pharmacological interventions.

It is certainly arguable that the benefits of reduced weight in obese adolescents are much less tangible and include issues such as self-esteem and the motivation to alter behaviour. If this is true, the role of health economics is marginal as the measurement of such benefits is much harder than that of reduced incidence of disease.

16.6 Cost effectiveness of surgery

16.6.1 Evidence statements related to surgery for obesity (Table 16.25)

Table 16.25 Evidence statements

1	Evidence suggests that surgery in general is a cost-effective intervention relative to a limited non-surgical management option in a typical severely obese group
2	The most reliable cost per QALY estimate is £6289 to £8527

16.6.2 Surgical developments in the period 2001–05

The approach in this report is to consider gastric bypass, gastric banding and the biliopancreatic diversion/duodenal switch (DS-BPD) as the major surgical interventions for consideration. The reason for this, that these best represent the surgical options facing healthcare providers, is described in the clinical review in Section 15.3.5.

16.6.3 Existing report

Consideration of: **Clegg AJ, Colquitt J, Sidhu MK et al. The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation. *Health Technology Assessment* 2002;6:1–153.**[55]

Note: Since this review, the vertical banded gastroplasty (VBG) has become obsolete, having been replaced by the laparoscopic gastric bypass. Details on the vertical banded gastroplasty are given where relevant but otherwise have been removed.

The economic component of the HTA report is split into two broad sections. First, the authors undertook a comprehensive literature review and found four economic evaluations of a suitable quality, all produced from outside England and Wales. The results of this are described below. The second step was to produce a model, synthesising cost and benefit data into measures of cost effectiveness for Roux-en-Y gastric bypass, vertical banded gastroplasty, adjustable gastric banding and non-surgical management. This model is described below. The original intention of this

guidance group was to re-run the modelling with updated assumptions based on newer literature. Unfortunately, the group that was responsible for the preparation of this model was unable to release it. Therefore, this discussion describes the assumptions that need updating to reflect current practice and the likely effect these changes would have on the cost per QALY.

16.6.3.1 The HTA literature search results

The HTA identified four relevant papers, two of which investigated the vertical banded gastroplasty (thus being of limited usefulness to this discussion). An American study compared Roux-en-Y gastric banding with a very-low-calorie diet (VLCD) for at least 12 weeks and weekly behavioural modification meetings for at least 4 months.[56] A total of 201 participants entered surgical and 161 entered medical therapy. They were followed for 6 years after the treatment. Surgical therapy was costed at US$24,000, and the control was US$3000. Rather than calculating QALYs, the paper uses pounds lost as the outcome for the economic evaluation. If participants lost to follow-up are included, the cost per pound lost in surgery was between US$250 and US$750. This compares with the figures for the control of between $100 and $1600. The authors noted that longer-term follow-up would improve the relative position of surgery since the weight loss from this approach continues beyond 6 years, in contrast with their observations of other approaches.

A Swedish study looks at the cost effectiveness of gastric banding, vertical banded gastroplasty and gastric bypass relative to conventional management.[57] The authors noted that the definition of conventional management was not adequately defined. Data from this Swedish Obese Subjects (SOS) trial was used to estimate prevalence rates over 10 years for hypertension and diabetes between surgically -treated groups and conventionally treated control subjects. Using officially published Swedish costs of treatment, the total cost attributable to these diseases will be on average SEK2700 (£199 as of August 2005)/subject/year higher in the control group. However, the authors note that the cost implication of these diseases is likely to overlap. Second, there will be other diseases which should be factored in to produce an accurate cost of illness figure.

16.6.3.2 The HTA modelling

Below is an exposition of the HTA method and results. As stated previously, the limitations of the useful health economics data published since the HTA means that the best approach is to assess where the original model uses outdated assumptions and the likely effect of replacing these with those representing current practice.

The authors[†] illustrate four areas of potential benefit from surgery for severe obesity. These are:

- excess weight reduction and the gains in health-related quality of life (HRQoL) through weight loss per se
- gains in HRQoL as a result of reduced morbidity from diseases resulting from obesity
- benefit of death averted through reduction in weight and weight-related illnesses
- indirect benefits from the above areas, such as gains in economic productivity.

Each of the components of benefit are a function of the initial level of BMI and the loss attributable to the surgery. The quality of life gain through weight loss per se is based on a company submission from Roche[58] on orlistat cited in the orlistat section (section 16.5). The assumption is that utility gain due to a 1 BMI point reduction is 0.0159 in males and 0.0166 in females. In the Sibutramine section (section 16.4) of this report, it is illustrated that this is an unrealistic assumption, especially in males. Tables 16.16–16.18 estimate the utility gain per BMI point reduction in various subpopulations. If the QoL improvements calculated using the 'Health survey for England' figures are more accurate, the cost per QALY will rise from that stated in Clegg's analysis.[55]

The HTA report ran a model using a hypothetical cohort of 100 patients. The members of the cohort had an average weight of 135 kg, average BMI of 45 kg/m^2, average age of 40, and 90% were women. Under each of the treatment options, the

[†] Clegg AJ, Colquitt J, Sidhu MK et al. The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation. *Health Technology Assessment* 2002;6:1–153.

cohort was observed for 20 years after surgery. Costs were discounted at 6% per year and benefits at 6%, 0% and 1.5%.

The authors began by creating efficacy scenarios. This was an attempt to create a consensus from the clinical literature outlining the expected efficacy of the different types of surgery. Details of how they came to their assumptions are provided in the HTA report. The baseline assumptions regarding weight reduction, actual weight and BMI levels are presented in Tables 16.26 and 16.27.

Table 16.26 Percentage weight loss over time under gastric bypass, vertical banded gastroplasty, adjustable silicone gastric banding and non-surgical management

Year	Gastric bypass	Gastric banding	Non-surgical
1	36	20	0
2	36	28	0
3	36	31	0
4	36	30	0
5	36	33	0

Note that these gains used in Table 16.26 are relative to baseline rather than cumulative.

Table 16.27 Body mass index ([BMI] kg/m^2) under the treatment options over time

Year	Gastric bypass	Gastric banding	Non-surgical
Baseline BMI	45	45	45
1	29	36	45
2	29	32	45
3	29	31	45
4	29	32	45
5	29	30	45

The authors presume that the year 5 condition is permanent for people undergoing gastric bypass and gastric banding.

Since VBG is obsolete and the DS-BPD is now being used, the comparable BMI pathway over time needs to be calculated to compare options. These figures can be approximated using a study looking at the DS-BPD.[59] The paper reports excess weight lost at 2, 4, 6 and 8 years. Mean per cent loss initial excess weight (IEW) at 2, 4, 6 and 8 years was 78, 75, 78 and 77, respectively, in the patients with IEW up to 120% and 74, 73, 73 and 72, respectively, in those with IEW more than 120%. Using the population described in the HTA modelling (falling into the less obese group in the Scopinaro paper[60]), this translates to a BMI at 2, 4, 6 and 8 years of 27.45, 28.125, 27.45 and 27.675, respectively. Thus, it is reasonable to assume that the DS-BPD is at least as effective in terms of weight loss as the other surgical options.

The model then included the effect of surgery for the severely obese on diabetes rates alone. Evidence on prevalence of diabetes in severely obese patients was varied. Looking at 11 clinical papers reporting diabetes prevalence, the authors took 10% to be a reasonable baseline assumption. They then assumed that 75% of people are off medication at 3 years. In the baseline, it was assumed that this continued until year 8 (as per SOS) when previous prevalence was reasserted. Incidence rates were taken from SOS, suggesting 2.3% per annum without surgery or 0.45% with surgery. The effect of diabetes reduction on mortality was not included in the baseline analysis since the clinical evidence was considered unreliable. Regarding the cost of diabetes, the authors used the CODE2 study of people with type 2 diabetes. This suggested a cost of £1550, including all diabetes-associated costs and complications.

16.6.3.3 Costs of surgery and complication rates

Gastric bypass

First, the HTA report considered preoperative costs. Under baseline, it assumed for each surgical patient, two underwent work-up and four were screened for suitability. Furthermore, each patient received seven outpatient visits, four dietitian consultations and one session with a psychologist. Regarding surgery, there was further complication in that approximately 10% of gastric bypass was undertaken as an open procedure. Thus, the authors costed 235 minutes in surgery, 6 days postoperative stay and intensive care unit (ITU) admittance for 7.6% of patients for

the patients undergoing a laparoscopic gastric bypass. For the open procedure patients, the figures were 147.5 minutes, 7 days and 21.1% of patients.

Additional complications and procedures were assumed to be:

- mortality – 1%
- incisional hernia – 5% after open operation (based on 10% hernia rate, with half the patients having their repair alongside apronectomy)
- apronectomy in 10% after 3 years.

The HTA report assumed that standard postoperative healthcare contacts were delivered as shown in Table 16.28.

Table 16.28 Postoperative healthcare contacts in gastric bypass patients

	GP	Practice nurse	District nurse	Outpatient clinic contacts	Community dietitian contacts	Psychology consultation
Month 1	6	2	4			
Year 1				4	12	2
Year 2				4	4	2
Year 3+				2	2	1

Adjustable silicone gastric band (ASGB)

Preoperative and postoperative costs were as per gastric bypass. In the baseline analysis, surgical costs for the laparoscopic approach were based on:

- 150 minutes in theatre
- 5 days preoperative inpatient ward stay
- 1 night in either ITU or high-dependency unit (HDU)

Under the assumption that 8% of patients needed an open operation, they required on average:

- 76 minutes in theatre

- 6 days on ward
- 1 night in either ITU or HDU.

The complication rates were as per VBG except that:

- reservoir infection – 5% (all requiring revision surgery)
- band leakage – 5% (requiring revision surgery)
- band slippage – 5% (all requiring revision surgery).

Patients undergoing laparoscopic banding needed 2.9 days in hospital post discharge and patients undergoing open banding required 4.6 days. This includes dealing with hernia repair and cholecystectomy.

Non-surgical management

Annual follow-up involved:

- four GP visits
- two dietitian contacts
- two practice nurse contacts
- two district nurse contacts
- every 3 years – VLCD for 12 weeks (two cans of Slim-Fast daily).

The authors then used published costs to calculate the expected costs of the treatment regimens outlined above.

16.6.3.4 Current practice

It is important to note that expert advice has highlighted that assumptions on resource use given above may no longer represent current practice.

It was suggested that in general, the support contacts reported in the HTA, both preoperative and postoperative, exaggerated current practice. If modelling was

undertaken in this area, this clinical expertise should be combined with the clinical evidence review to produce more realistic assumptions.

Regarding gastric banding, it was suggested that:

- with regard to preoperative care, a patient could expect one outpatient contact and one dietitian contact
- an average of 90 minutes in theatre was realistic rather than the 120 minutes assumed in the HTA
- patients would only be admitted 1–2 days prior to surgery at the earliest
- mortality was likely to be below the assumed 0.5%
- reservoir infection was likely to be below the assumed 5%
- band leakage was possibly below the assumed 3%
- with regard to postoperative care, a patient can expect fewer than six GP contacts, two practice nurse visits and four district nurse visits in the first month
- a patient can expect less than 12 community dietitian contacts and two psychology consultations in the first year after the surgery
- a patient can expect fewer than four dietitian visits and two psychology consultations in the second year after the surgery
- a patient can expect fewer than two dietitian visits and one psychology consultation in subsequent years.

Regarding gastric bypass, it was suggested that:

- with regard to preoperative care, a patient could expect one outpatient contact and one dietitian contact
- conversion rate from laparoscopic bypass to open occurs in around 2%, rather than the assumed 10%

- with regard to postoperative care, a patient can expect fewer than six GP contacts, one to two practice nurse visits and four district nurse visits in the first month
- a patient can expect less than 12 dietitian contacts and two psychology consultations in the first year after the surgery
- a patient can expect fewer than four dietitian visits and two psychology consultations in the second year after the surgery
- a patient can expect fewer than two dietitian visits and one psychology consultation in subsequent years.

Furthermore, the group's co-opted expert suggested that complication rates are likely to be below that of the HTA model. This is due in part to increased experience of bariatric surgery in England and Wales, and partly a result of an increased proportion of operations being performed laparoscopically. The advantage of laparoscopic surgery is twofold. First, it has the capacity for reducing healthcare resource use. Second, there is mixed evidence which suggests it has the possibility of reducing complication rates.[60–61] The acceptance and inclusion of both of these trends into the HTA modelling is likely to reduce the incremental cost-effectiveness ratio. Regarding the cost of surgery, Table 16.29 shows the total cost of the surgical options assumed in the HTA report.

Table 16.29 The cost of surgical options in the HTA report[55]

Surgery option	Laparoscopic	Open
Vertical gastric banding	*£3223*	
Gastric bypass	£3992	£3 333
Adjustable silicone gastric band	£4450	£4 753
Non-surgical care	£336	

Since the original model was not released, it is not clear how resource use was integrated into the model. Therefore, it is difficult to estimate the effect of the changes outlined above on the results presented below. However, it seems the original model overestimated the support costs of surgery. Based on this, it is likely

that, ceteris paribus, the cost per QALY stated in the HTA model will fall with the updated assumptions.[‡] No good-quality alternative costing data were identified in the development of the guidance. However, national Reference Cost figures for surgery on the stomach suggests a baseline cost of £5190 for complex procedures.

16.6.3.5 HTA modelling results

Using the previously discussed cohort of 100 patients, the combinations of costs and benefits under each treatment option was compiled as in Table 16.30 (modified from Table 27 in the original report).

Table 16.30 Benefits and costs of the three surgical options and usual care (table adapted from the HTA report)[55]

Intervention	QALYs	Total net cost (£)
Usual care	1,123	696,415
Vertical gastric banding	*1.149*	*962,690*
Adjustable silicone gastric band	1.168	1,079,516
Gastric bypass	1.167	976,435

QALY, quality-adjusted life year.

Using these figures, we can create a cost-effectiveness ratio for each surgical option relative to usual care (Table 16.31 and Figure 16.2).

Table 16.31 Cost-effectiveness of each surgical options

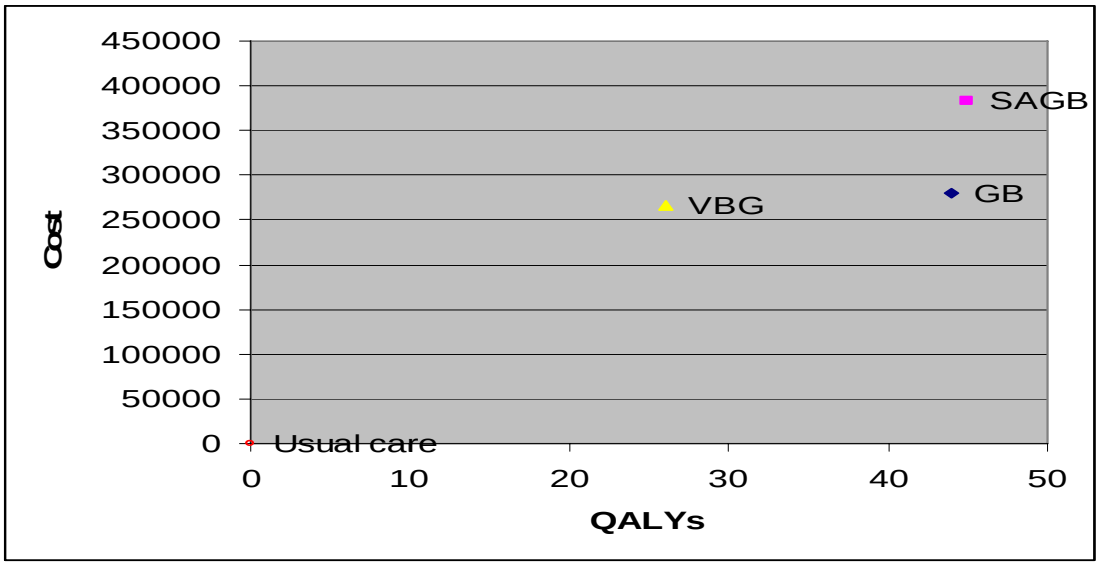
Surgical option	Cost per QALY (£)
Vertical gastric banding	*10,237*
Adjustable silicone gastric band	8,527
Gastric bypass	6,289

QALY, quality-adjusted life year.

Figure 16.2 The incremental costs and benefits of the three surgical options relative to usual care (Note: the incremental cost-effectiveness ratios for gastric

[‡] It should be noted that a Dutch economic evaluation was published subsequent to the guidance literature cut-off and corroborates this improvement on cost effectiveness (van Mastrigt GAPG, van Dielen FMH, Severens JL, et al. One-year cost-effectiveness of surgical treatment of morbid obesity: vertical banded gastroplasty versus Lap-Band. *Obesisty Surgery* 2006;16:75–84). This reports Lap-Bands as dominating the control, suggesting it actually reduces total costs for the health service.

bypass (GB) against vertical gastric banding (VBG) and for adjustable silicone gastric band (ASGB) against GB are £742 and £256,856, respectively)[§]



The conclusion the authors drew was that each of the options is cost-effective relative to usual care. They warn that comparison between surgical interventions is difficult and unlikely to produce a definitive answer. However, they do argue that the results, if taken at face value suggest gastric banding to be the most cost-effective option.

The authors undertake a sensitivity analysis based on areas considered most uncertain or important. The cost per QALY under these amended assumptions ranges from £7255 to £18,278. The important conclusion from this sensitivity analysis is that gastric bypass, and surgery in general, seems to produce QALYs at a level that would usually be considered to be cost effective. This result is robust to uncertainty in the model parameters.

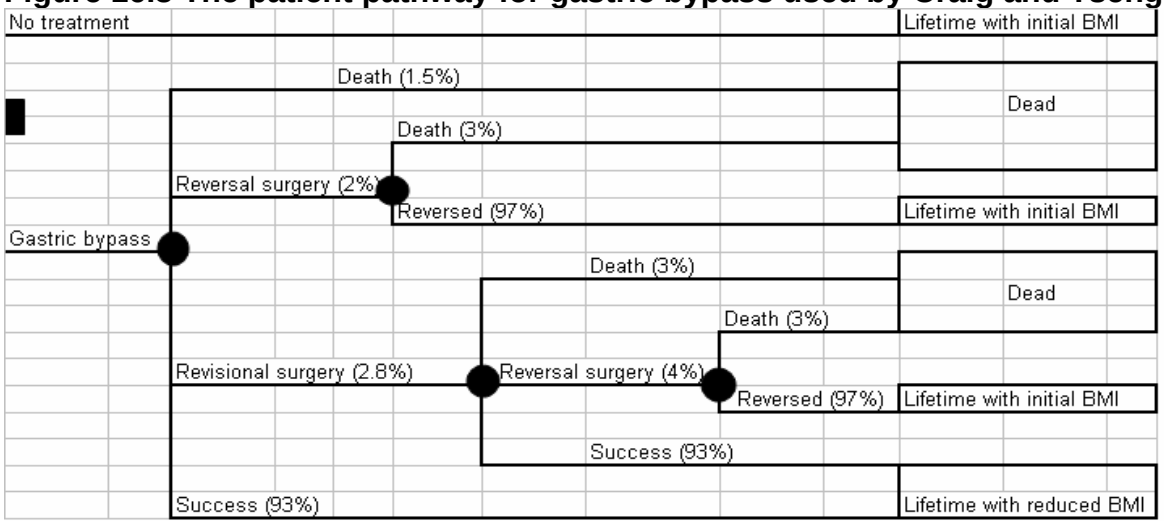
16.6.4 Literature search

The cost-effectiveness literature search for the use of surgery for severe obesity focused on the period following the cut-off in the original report (October 2001). This produced only one study. This study was a cost–utility model, was based in a developed country and had surgery as part of the treatment branch.

[§] SAGB in the figure = ASGB.[DN: change at second draft. Also add commas in numbers [y axis]).

An American study looked at the cost effectiveness of gastric bypass in the treatment of severe obesity.[62] The authors undertook a deterministic decision analysis (Figure 16.3) comparing the lifetime expected costs and benefits from open gastric bypass relative to no treatment. The population group consisted of men and women between 35 and 55 years old, with a BMI between 40 kg/m^2 and 50 kg/m^2, without cardiac disease and who had failed more conservative treatment (such as pharmacotherapy).

Figure 16.3 The patient pathway for gastric bypass used by Craig and Tseng[62]



Costs and benefits were assigned to each of the members of the cohort within each health state. The costs were those of initial surgery, treatment of complications, follow-up care and treatment of obesity-related diseases (CHD, stroke, type 2 diabetes, hypercholesterolaemia and hypertension). QoL was estimated for gender, age and BMI levels from US national statistics. Under their base case, the cost-effectiveness ratios ranged from US$5000 to US$16,100 per QALY for women and from US$10,000 to US$35,600 per QALY for men depending on age and initial BMI (Table 16.32).

Table 16.32 Incremental cost-effectiveness ratios for gastric bypass (Craig and Tseng[62]), stratified by gender and BMI

	Cost per QALY ($)	
BMI (kg/m^2)	**Men**	**Women**
Risk subgroup at age 35 years		
40	28,600	14,700
50	10,700	5,700
Risk subgroup at age 55 years		
40	35,600	16,100
50	13,300	5,400

BMI, body mass index; QALY, quality-adjusted life year.

At face value, these ICERs seem to be promising in favour of the intervention. At current (August 2005) exchange rates, the highest ICER (55-year-old men, BMI of 40 kg/m^2) is £19,900. This would likely be lower since medical costs in the USA tend to exceed those in England and Wales. There is one caveat to this result and this lies in the choice of comparator. In this group of severely obese patients, the alternative to surgery is pharmacology or lifestyle interventions, rather than nothing. The choice of no treatment as the comparator in the study is likely to artificially deflate the cost per QALY.

17 Cost effectiveness of public health interventions

The following is based on work undertaken by the York Health Economics Consortium at the University of York. Detailed evidence tables and supporting information are in Appendix 18.

17.1 Introduction

Obesity is an underlying risk factor for a number of potentially life-threatening diseases, such as coronary heart disease (CHD), diabetes mellitus, and some cancers. For instance, according to the 2001 report by the National Audit Office (NAO), 'Tackling obesity in England', the relative risk of developing type 2 diabetes was 12.7 for obese women and 5.2 for their male counterparts.[63] Consequently, costs arise not only with the direct treatment of obesity but also with the treatment of these associated comorbidities. The NAO has estimated that the costs of treating obesity amounted to £9.5 million in 1998, while the costs of treating consequences associated with obesity equalled the considerably larger figure of £469.9 million. Thus, in total, the burden placed on the National Health Service (NHS) through the treatment of obesity in 1998 was valued at £0.5 billion. This figure is in addition to the indirect costs of £2 billion stemming from productivity losses attributable to obesity.

These substantial, and presumably rising, costs provide overwhelming evidence for the need to implement strategies for the promotion of weight loss, as well as the prevention of weight gain.[64] Treatment options range from changes in lifestyle behaviour or diet to counselling, pharmacotherapy and surgery. This research was commissioned to assess the economics of strategies to prevent obesity through public health interventions. Strategies that can be implemented at a local level, as opposed to national initiatives, were within the scope of the research.

The objective of this work was to assess the cost effectiveness of strategies aimed at preventing individuals from becoming obese. The work was split into two phases:

1. An review of the evidence base on the cost effectiveness of public health interventions to prevent obesity.

2. A modelling exercise.

The modelling exercise was an essential part of this work due to the paucity of data found on cost effectiveness through the evidence reviews.

17.2 Evidence review

17.2.1 Data sources and search strategies

The following information sources were searched:

- Medline
- EMBASE
- Cumulative Index to Nursing and Allied Health Literature (Cinahl)
- Health Management Information Consortium (HMIC)
- Science Citation Index and Social Science Citation Index
- PsycINFO
- Applied Social Sciences Index and Abstracts (ASSIA)
- NHS Economic Evaluation Database (NHS EED)
- Health Economic Evaluation Database (HEED)

The electronic search strategies were developed in Medline and adapted for use with the other information sources.

Parameters for review were as public health review parameters (see Appendix 2). Additional criteria for inclusion were:

- Studies had to have a defined intervention to prevent obesity.
- The study population was not obese at the start of the study (although if drawn from a general population it is accepted that some participants may be obese).

- Studies were included if they reported both the costs and effectiveness of an intervention to prevent obesity (although costs and effectiveness were not necessarily combined into a single cost-effectiveness ratio).
- Studies that only reported the cost of managing obesity in the absence of a well defined intervention or any outcomes data were excluded from the review.

The searches identified 214 potentially relevant references. On the basis of reviewing the title and abstract, 16 full text papers were obtained for further assessment. Once publications had been collated into individual trials and bibliographies checked, the total number of included cohorts was nine. The detailed evidence tables to this review are in Appendix 18.

17.2.2 Results

A total of eight papers were identified which considered the prevention of obesity and included data on cost effectiveness: four randomised controlled trials (RCTs),[65–66], one before-and-after study,[67] one discrete choice experiment,[68] one Markov model[69] and one controlled non-randomised study.[70] No UK studies were identified; studies were carried out in Australia, Denmark, the Netherlands, USA and Canada. The length of follow-up ranged from 16 weeks to 3 years. Overall there was limited information concerning the cost effectiveness of interventions to prevent obesity.

17.2.2.1 Diet and exercise programme

There is some evidence that a diet and physical activity intervention incorporating interactive educational sessions is cost effective when compared with a similar intervention using only mail shot advice for couples living together for the first time.

Dzator and coworkers[65] aimed to investigate the effect a diet and physical activity programme had on Australian couples, living together for the first time. Couples were randomised to a low-level intervention or a high-level intervention or a control group. Patients in the low-level intervention group received an introductory group workshop, followed by mail outs. The high intervention group received mail outs alternated with interactive sessions, with a dietitian and an exercise physiologist. The results show that the intervention was more effective than doing nothing. The high intervention group showed substantial marginal improvement compared to the low intervention

group. This was particularly the case for blood cholesterol, blood pressure, fat intake and fitness. The total cost for the high intervention group was US$41,854.34 (US$445.30 per participant, US$111.33 per month). The total cost for the low intervention group was US$41,847.26 ($445.18 per participant, US$111.30 per month). At 12-month follow-up the total and average incremental costs were US$43,282.10 (US$460.44 per participant, US$38.37 per month) for the high intervention group and US$431,09.43 (US$458.61 per participant, US$38.22 per month) for the low intervention group. The authors report that the high intervention group achieved greater marginal effectiveness and cost effectiveness than the low level intervention. There was no significant difference in BMI at either 4 or 12-month follow up. The average cost of having interactive workshops every 2–3 weeks post-intervention is US$445.50 per unit change in the outcome variable, for the high intervention group, this is US$445.18 for the low intervention group. This shows that the high intervention group costs US$0.12 per participant at the end of the programme and US$1.84 at the 12 months' follow-up, to achieve an additional average unit of improvement (increase or decrease) in the outcomes additional to that achieved in the low intervention group.

Roux and coworkers[68] aimed to assess the cost effectiveness of population wide strategies to promote physical activity in adults. A Markov model was developed to estimate the costs, health gains and cost effectiveness. Efficacy data were taken from randomised controlled trials. A systematic review of disease burden by exercise status was used to obtain the relative risk of five diseases (CHD, ischaemic stroke, colorectal cancer, breast cancer, type 2 diabetes). Four public health strategies that had been strongly recommended by the US Task Force for Preventative Services were investigated. The results show that physical activity access intervention was the most effective intervention but social support was the most cost-effective intervention at US$9000 per quality-adjusted life year (QALY), assuming a 40-year time horizon. All the physical activities were cost effective (with cost-effective ratios ranging from US$9000/QALY to US$30,000/QALY). The results were sensitive to intervention costs and efficacy and analytic time horizon. (Note: the information provided here is taken from an abstract presentation at the North American

Association for the Study of Obesity's (NAASO) 2004 annual conference, and therefore full descriptions were not provided.)

17.2.2.2 Workplace interventions

The evidence did not suggest that physical activity counselling at a workplace resulted in any cost-effective gains in health outcomes and studies on the benefits in terms of lost productivity are equivocal.

Proper and coworkers[71] investigated the cost benefit and cost effectiveness of a workplace physical activity programme among civil servants in three municipal services of a Dutch town. Participants were randomised to an intervention group (n = 94) or control (n = 159). Participants were more likely to be men and of higher education. Participants in the intervention group were offered seven sessions of workplace-based tailored counselling which promoted physical activity and healthy dietary habits. Both the intervention group and the control group received written information about lifestyle factors (physical activity, nutrition, alcohol, smoking, [work] stress) and musculoskeletal symptoms.

The results show that the intervention costs were €430 per participant. There were no statistically significant differences between the total costs or sick leave costs between the two groups. During the intervention the costs due to sick leave were lower in the intervention group, in the year after the intervention the benefits had increased further. During the intervention the mean total costs were higher in the intervention group. The cost-effectiveness results show that improvements in energy expenditure and cardio-respiratory were gained at a higher cost. The authors note that 'due to the very wide (statistically non-significant) confidence intervals, we cannot say with certainty that this is the amount of money to be invested in order to achieve improved energy expenditure and fitness levels'.

Aldana and coworkers[66] investigated the effect the Washoe County School District (WCSD) Wellness Programme had on employee healthcare costs and the rates of absenteeism. Participants were employees and retirees of the WCSD for the years 1997–2002. Participants were eligible if they had been employed full time by the district for 3 or more years, including 2001 and 2002. A total of 6246 were eligible, of

this 1441 were retired. Participants enrolled on line or at any of the different district schools or facilities. Eleven different programmes were offered to all participants, with the programmes being prompted via the internet and email. The programmes addressed weight management, water intake, fruit and vegetables intake, television viewing and various 'exercise' activities. The results show that for every certified and classified employee who was absent from work, on average, the WCSD paid US$231/day and US$103/day, respectively. The cost per day of a substitute employee was US$75. Programme participation was associated with a US$3,041,290 difference in absenteeism cost during 2001 and 2002, when compared with non-participants. This value is '15.6 times greater than the total cost for all wellness programmes during the same time period'. The authors comment that 'these savings translate into a cost saving of US$15.6 for every dollar spent on programming'. Although there were immediate difference in healthcare costs between those who participated and those who did not, there was a significant difference on absenteeism.

17.2.2.3 School-based intervention to reduce obesity

There is some evidence that school-based interventions can result in cost effective health gains. Both interventions identified resulted in weight loss at acceptable costs although the latter is only available in abstract form at present.

Wang and coworkers[72] studied 310 school girls (aged 14 years and under) in the USA, randomised to intervention or the control. The control students received their usual curricula and physical education classes. The intervention group received Planet Health which aimed to infuse the intervention material into the curriculum. The intervention focused on decreasing television viewing, decreasing consumption of high fat foods, increasing fruit and vegetable intake, and increasing moderate and vigorous physical activity. The results show that for the five schools in the study the total intervention cost, over the 2 years, was US$33,677, or US$14 per student. The intervention would lead to 4.1 QALYs being saved. Society would save an estimated US$15,887 in medical costs and US$25,104 in productivity costs. This results in US$4305 per QALY saved and a net saving of US$7313 to society. Sensitivity analysis showed that the cost effectiveness of the programme was relatively

unaffected by changes to most parameters but was more sensitive to changes in the discount rate.

Wang and coworkers[70] investigated the cost effectiveness of an after-school obesity prevention programme, which included third grade students in nine elementary schools. The results show that the cost-effectiveness ratio was US$190 per 1% body fat reduction. For students who attended at least 40% and 80% of the sessions, the programme resulted in an average 0.8% ($p < 0.01$) and 1.2% ($p < 0.01$) body fat reduction, respectively. This was achieved at a cost of US$634 and US$839 per student in after-school care costs. Resulting in a per capita net savings of US$88 and US$293, respectively. The authors concluded that the programme was cost effective and cost saving for students who attended at least 40% of the intervention sessions.

17.2.2.4 Community weight loss programme

There is some evidence that all population-wide strategies to promote physical activity in adults, as identified by the US Task Force for Preventative Services, were cost effective although the outcomes have only been presented in abstract form to date.

Roux and coworkers[69] investigated factors that impact on individuals decisions to adhere to a community weight loss programme by the use of a discrete choice experiment. The study included members of a US-based community weight loss programmes. Participants were 25 years or older with BMI greater than or equal to 25 kg/m^2), had recently enrolled on the scheme, and did not have any comorbidities. The study showed that attributes with a positive coefficient (that is, participants were willing to give up something else to move up a level) were the amount of doctor time, programme components emphasis and the programme focus. Attributes with a negative coefficient (that is, become less preferable as the absolute magnitude of the coefficient rises) were the programme cost for 3 months and one-way travel time. Service attributes do play a marked role in the decisions users of a weight loss programme make. Participants were willing to pay an extra US$600 out of pocket for a 3-month weight loss programme that was more accessible, comprehensive and tailored to the individual when compared with the current available programme.

17.2.2.5 Nutritional counselling

There is some evidence that nutritional counselling by a general practitioner (GP), compared with counselling by a dietitian is cost effective.

Rajgopal and coworkers[67] evaluated the economic efficacy of the Virginia Expanded Food and Nutrition Education Programme (EFNEP) in a controlled before-and-after (CBA) study aiming to improve health and disease prevention. The study was split into three phases:

- investigation of behaviours taught in the EFNEP that might 'contribute to delay or avoidance of diet-related chronic diseases and conditions that are believed to be most prevalent among the low-income population'
- selection of participants from the 3100 graduated homemakers who had met the selected criteria for optimal nutritional behaviour (ONB)
- gleaning data from the previous phases into a CBA formula.

The results show that the initial benefit-cost ratio was US$10.64:$1.00, indicating that for every one dollar spent over 10 dollars may be saved in future healthcare costs. Sensitivity analysis on the initial assumptions and the lack of incidence data for some disease areas gave a benefit-cost ratio ranging from $2.66:$1.00 to $17.04:$1.00:

- On reducing the number of graduates to achieve the optimal behaviours by 75%, the ratio is $2.66:$1.00, and when it is reduced by 50% the ratio is $5.32:$1.00.
- When the portion of osteoporosis due to dietary factors is assumed to be 50%, the ratio is $5.91:$1.00.
- Using only estimated disease incidence rates for low-income populations the ratio is $17.01:$1.00.

It should be noted that this was a general dietary initiative and was not targeted at obesity.

17.2.3 Sub question: variation by gender, age, ethnicity, religious practices or social group

17.2.3.1 Age

From the evidence available this question cannot be answered. No studies were identified that compared outcomes for participants of different ages. There is some evidence to suggest that school-based interventions are cost effective but these studies did not involve comparisons with another age group.

17.2.3.2 Gender

Dzator (2004)[65] investigated the impact diet and physical activity programmes have on couples living together for the first time, the cost-effectiveness analysis was performed on the group as a whole and was not separated out by gender.

17.2.3.3 Social group

In Wang and co-workers'' study of the Planet Health scheme (2003)[72] all the schools involved in the study had a median household income lower than for all the households in Massachusetts, USA. Where the median household income in Massachusetts is US$41,000 and was US$36,020 for the intervention group and US$34,200 ($33,952 for the USA). However, as there were no direct comparisons between different social or income groups no firm conclusions on the relative cost effectiveness of interventions can be drawn.

17.2.4 Limitations of the review

There are only single studies to support each intervention. Although the design of the majority of the studies was of a relatively high standard (that is, RCTs) it is not clear as to whether any of the studies are applicable to the UK. The longest length of follow-up was 3 years; this could affect the generalisability of the results to a longer time period. Based on reviews of the published literature, there is also some difficulty in defining precisely what the interventions involved. Two of the studies[70,70] discussed above are only currently reported in abstract form.

17.3 Economic modelling

17.3.1 Methods

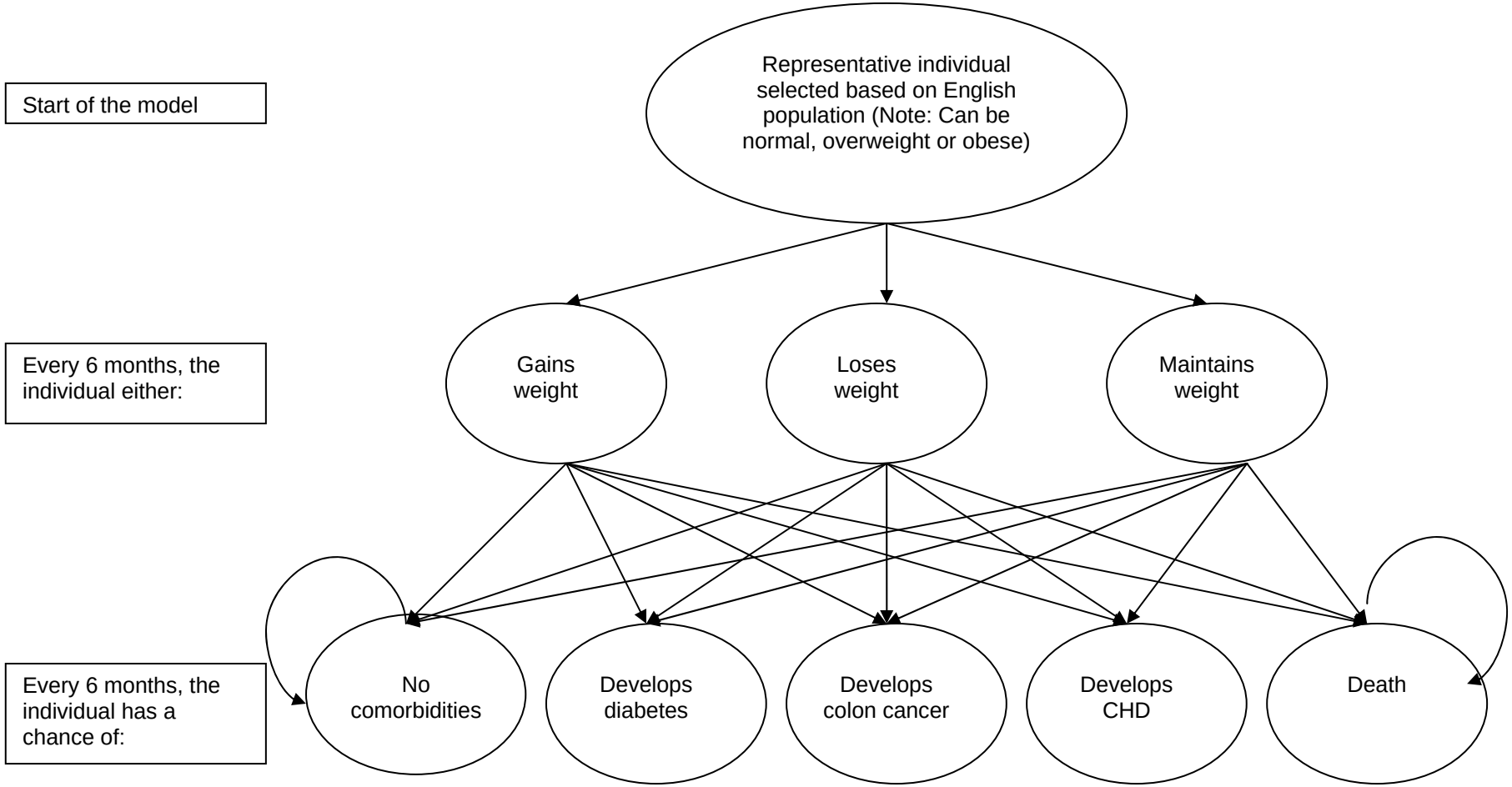
A patient-level simulation model was designed to estimate the costs and QALYs associated with obesity. These costs were compared to the costs and QALYs obtained from three interventions aimed at preventing obesity.

The higher an individual's BMI the more likely they are to develop related co-morbidities, including diabetes, CHD and some forms of cancer. Due to data constraints, the model focused on the increased risk of developing diabetes, CHD and colon cancer. Obesity is recognised as being a risk factor for other conditions, including other cancers, musculoskeletal disease and chronic obstructive pulmonary disease (COPD) however, in the absence of accurate data on these risk factors they are currently excluded from the model. As such, the model provides a conservative estimate of the cost effectiveness of strategies to prevent obesity.

17.3.1.1 The model

The model is defined to assess how a prevention strategy would work in a population that is representative of the population of England as a whole (as data are largely derived from the 'Health survey for England'). The model works by randomly selecting an individual whose characteristics are based on those of the population (for example, BMI, age, gender all determined by population data). Each individual is followed until death and their healthcare costs and outcomes are recorded. This process is repeated 10,000 times to provide a sample population that is broadly reflective of the English population as a whole. It should be noted that the population will include people of 'normal' weight as well as people who are overweight or obese in order to reflect the population of England. This is believed to be an appropriate population to study for a public health intervention. We have not attempted to identify the cost effectiveness of interventions in high-risk subgroups nor have we excluded obese individuals who may be more suitable for treatment than prevention. A schematic diagram of the model is shown in Figure 17.1.

Figure 17.1 Schematic diagram of the model to assess how a prevention strategy would work (CHD, coronary artery disease)



The characteristics of each individual are shown in Table 17.1 below.

Table 17.1 Characteristics of each individual

Characteristics	Parameters	The percentage of people in each group is taken from:
Gender	Male, female	Office for National Statistics[73]
Age (years)	0–16	'Health survey for England 2003'[74]
	16–24	
	25–34	
	35–44	
	45–54	
	55–64	
	65–74	
	75+	
BMI (kg/m^2)	20 or under (not less than 15 if a child, and not less than 18.5 if an adult)	For adults – 'Health survey for England 2003'[74]
	20–25	
	25–30	
	30–40	
		For children – The British Heart Foundation[75] and Cole et al. 2000[76]

The percentage of people in the general population who are male or female and the percentage of people in each of the above age bands are taken from data provided by the Office for National Statistics.[73] The 'Health survey for England 2003'[74] provided the mean BMI for men and women in each age band.

The British Heart Foundation[75] provides the percentage of children who have a 'normal', 'overweight' and 'obese' BMI. Where the definition of 'normal', 'overweight' or 'obese' was taken from Cole and coworkers.[76] The paper focused on children aged between 2 and 18 years, we have assumed that the cut-off points for 2-year-olds are the same for 0- and 1-year-olds. Cole states that the cut-off point for 'normal' BMI is the second BMI percentile. Using BMI charts provided by the Scottish

Intercollegiate Guidelines Network (SIGN)[77] we were able to read off the 'normal' BMI cut-off point. All cut-off points are provided in Table 17.2.

Table 17.2 Cut-off points used in the model

	Boys			Girls		
Age	**Normal**	**Overweight**	**Obese**	**Normal**	**Overweight**	**Obese**
0	14.50	18.41	20.09	14.00	18.02	19.81
1	14.50	18.41	20.09	14.00	18.02	19.81
2	14.50	18.41	20.09	14.00	18.02	19.81
3	14.00	17.89	19.57	13.60	17.56	19.36
4	13.60	17.55	19.29	13.40	17.28	19.29
5	13.40	17.42	19.30	13.00	17.15	19.30
6	13.60	17.55	19.78	13.00	17.34	19.78
7	13.00	17.92	20.63	12.90	17.75	20.63
8	13.20	18.44	21.60	13.00	18.35	21.57
9	13.40	19.10	22.77	13.20	19.07	22.81
10	13.80	19.84	24.00	13.60	19.86	24.11
11	14.00	20.55	25.10	14.00	20.74	25.42
12	14.50	21.22	26.02	15.50	21.68	26.67
13	14.80	21.91	26.84	15.00	22.58	27.76
14	15.20	22.62	27.63	15.40	23.34	28.57
15	15.60	23.29	28.30	16.00	23.94	29.11

Due to data constraints, a simplifying assumption is made when modelling the impact of obesity in children. The model assumes that the only risk factor applicable to children is diabetes and that the increased risk of CHD and cancer only emerges once they are aged more than 16. Although there is emerging evidence on the increased risk of CHD in populations under the age of 16, the data were not felt to be robust enough to include in the model at this point in time. As such, any results in this population should be regarded as conservative estimates of cost effectiveness.

The model assesses people over 6-month cycles over the course of their life. Every 6 months each individual will experience a change in BMI. This will either be an increase, a decrease or no change. The individual can develop diabetes, CHD or colon cancer depending on the prevalence of each disease at the BMI level they are currently experiencing. There is a QALY associated with being at each BMI level and

a QALY associated with each health state defined by the comorbidities. The total cost and outcomes are calculated for the whole cohort.

The strategies for the prevention of obesity were selected by the Guidance Development Group (GDG). These were prioritised based on their relevance to UK practice and also the availability of evidence (although not necessarily conclusive evidence from UK settings) to support them from rapid reviews of their effectiveness. The shortlist considered is:

- **Workplace counselling**: Proper and coworkers[71] investigated the cost benefit and cost effectiveness of a workplace physical activity programme in a Dutch town. Participants in the intervention group were given counselling, which promoted physical activity and healthy dietary habits. Advice offered was tailored to the individual. Both the intervention group and the control group received written information about lifestyle factors (physical activity, nutrition, alcohol, smoking, [work] stress) and musculoskeletal symptoms.

- **Counselling from primary care staff**.

- **Whole-school approach**: Wang and coworkers[72] studied 310 school (aged less than 14) girls in Boston, Massachusetts, USA. The control students received their usual curricula and physical education classes. The intervention group received 'Planet Health' sessions that focused on 'decreasing television viewing, decreasing consumption of high fat foods, increasing fruit and vegetable intake, and increasing moderate and vigorous physical activity'.

- Family based interventions including the family

  Family programmes lead by health professionals to prevent obesity, improve dietary intake and/or physical activity should provide on-going tailored support and incorporate a range of behaviour change techniques. A number of studies were identified from the clinical reviews which examined this intervention. Whilst all were considered as part of the economic evaluation, only the findings from the study by Israel published in 1985 (referred to in the McLean systematic review[78]) are reported below. The rationale for choosing this particular study is that it is a randomised controlled trial and it provided sufficient detail to allow the intervention to be costed.

A second family-based intervention recommended interventions targeted at children with obese or overweight parents. Whilst this was found to have good quality clinical evidence to recommend its use, it was unfortunately outside of the remit of the economic model. The economic model relies on individuals' characteristics to identify how their weight will progress in the future and how any intervention may impact on future weight gain. However, the individual characteristics considered take no account of the weight of parents. Although the model could be run on a population of children or varying BMI levels, the model is not set up to identify children with obese or overweight parents. Therefore, it was not possible to analyse this recommendation in the economic analysis although some thoughts on the likely cost effectiveness of this intervention are provided in this report.

These strategies impact on the likelihood of an individual gaining or maintaining weight over a given period of time. Ideally, the efficacy of these interventions and their impact on weight maintenance or weight loss would be derived from clinical trials. However, rapid reviews of these interventions were equivocal in their findings with some studies reporting benefits whereas others reported no significant changes. The quality of the research and the reporting of results also meant that deriving data to populate the model from these sources was not always possible. In the absence of data derived from clinical trials, assumptions which are deemed to be reflective of how the intervention may work in the real world have been used. Where assumptions have been used these are clearly stated and have been reviewed by the GDG. Sensitivity analysis has also been conducted to assess the impact of varying any assumptions.

When assessing the cost effectiveness of the prevention strategies the *ceteris paribus* principle, often used in economic modelling, applies which assumes that all other things remain equal. As such, the impact of the interventions is considered in isolation from any other potential positive or negative influences which may be in the environment, such as changes in general awareness of healthy eating, physical activity, etc.

17.3.1.2 Data

Change in weight over time

Fine and coworkers[79] demonstrated that in a population of women aged 46–71 years (mean age 58.5) two-fifths will maintain their weight, two-fifths will gain weight and

one-fifth will lose weight over a 4-year period. It was assumed that these figures would be applicable to the whole population and were used in the model to determine the path of an individual's weight over their lifetime. This approach was adopted as it was perceived as being reflective of how individuals manage their weight in the real world. The alternative approach would be to assume that all individuals gain weight steadily over the course of their lives and have a gradually increasing BMI. Whereas the 'average' individual in the model will steadily gain weight over time, some individuals will maintain a healthy weight over the course of their lifetime in the model. While we accept that this assumed distribution may not be generalisable to the entire population, it is used in the absence of any other source of long-term data.

The net impact of the above distribution is an average increase in weight of 1 kg/year across all individuals (that is, although some individuals will lose weight, some gain weight and some maintain a steady weight, the average individual will gain 1 kg/year). This is consistent with the findings of Heitmann and Garby,[80] who performed a retrospective semi-longitudinal study to determine the pattern of weight changes over 11 years in a Danish population that became overweight in adulthood. To calculate the associated BMI change the average height (from the 'Health survey for England 2003') for each age group and gender was used to calculate the change in BMI for each type of individual.

The relation between BMI and each of the risk factors was derived based on published sources.

The prevalence of diabetes by BMI was taken from a paper by Gregg and co-workers'. [47] These authors used data from several surveys that followed US citizens. In the paper the National Health and Nutrition Examination Survey (NHANES) followed individuals from 1999 to 2000. The results of this survey provided the prevalence of diagnosed and undiagnosed diabetes by BMI level (see Table 17.3) below. These were used to find the prevalence for all BMI levels between 15 kg/m^2 and 40 kg/m^2.

Table 17.3 Prevalence of diagnosed and undiagnosed diabetes

	Diagnosed	**Undiagnosed**
< 25	0.03	0.011
25–29.9	0.041	0.024

30–34.9	0.067	0.043
> 35	0.151	0.032

Diagnosed cases of diabetes will impact on both the costs and outcomes in the model, whereas undiagnosed cases are only assumed to impact on outcomes as they are assumed to be untreated while undiagnosed.

The prevalence of CHD was calculated using the Framingham equation as set out by Brindle and coworkers.[81] The equation is as follows:

$$\alpha = \exp\left(-0.3155 - 0.2784 * (\mu - 4.4151)\right)$$

where:

$$\mu = \left(15.503 - \left[0.9119 - \log\left(systolic_blood_pressure\right)\right] - \left[0.2767 * smoking\right] - \left[0.7181 * \log\left(\frac{total}{high_density} cholesterol\right)\right] - \left[0.5865 * electrocardiographic_left_ventricular_hypertrophy\right] - \left[1.4792 * \log\left(age\right)\right] - \left[0.1759 * diabetes\right]\right.$$

The variables used in the equation are:

- whether the individual smokes[82]
- systolic blood pressure, of the individual[83]
- total cholesterol (mmol/l), of the individual[84]
- high-density lipoprotein (HDL)-cholesterol (mmol/l), of the individual[85]
- probability of having left ventricular hypertrophy[86]
- whether the individual has diabetes (taken from the model)
- age of the individual (taken from the model).

The above calculation is repeated every 6 months. If the individuals is aged less than or equal to 16 years the prevalence of CHD and cancer is 0 (that is, children can not develop CHD or cancer).

To obtain the prevalence of colon cancer the relative risk of colon cancer for men and women by BMI level[50] was applied to the prevalence of colon cancer in the general population (176 per 100,000 per year[30]) (Table 17.4). The relative risk was assumed to be the same for men and women. This is consistent with a statement by the National Institutes of Health which reported that the relation between colon cancer and obesity may be the same in men and women.[87] It was not possible to stratify the mortality risk associated with colon cancer by age in addition to BMI and sex, so this risk factor remains unadjusted for age.

Table 17.4 Relative risk of colon cancer by body mass index (BMI)

BMI	Relative risk
< 22	1
22–24.9	0.84
25–26.9	1.33
27–28.9	1.62
> 29	1.82

Mortality stratified by age was obtained from interim life tables provided by the Government Actuary's Department.[88] The interim life tables for 2002–04 are based on the mid-year population estimates for 2002, 2003 and 2004. Mortality figures, as used in the model are shown in Appendix 18.

Additional mortality could be due to:

(i) CHD:

- Wood and co-workers' (1994) [89] report that there is no evidence that reducing obesity will have any effect on the mortality from CHD.
- In 2003, a total of 62,400 men and 51,495 women died from CHD.[75]
- A total of 764,800 men and 697,530 women in the UK have CHD.[90]
- This gives a mortality of 8.2% for men and 7.4% for women.
- The relative risk of dying for people with CHD who smoke is 2.9. for men and 3.6 for women.[91]

(ii) Colon cancer:

- The mortality from colon cancer is 14% each year. [51]

Diabetes was not assumed to impact mortality in the model as any deaths attributed to diabetes will be due to complications of the condition rather than diabetes per se.

To determine whether the individual is experiencing each particular health state at any one time, the incidence of diabetes, CHD and colon cancer was calculated. Incidence is calculated from the prevalence using the following equation:

$$Incidence = \frac{\left[\frac{\Pr evalence * percentage_of_people_with_BMI}{Length_of_life_with_healthstat\ e}\right]}{Percentage_of_people_with_BMI}$$

This equation uses the percentage of people with each BMI, calculated from the data provided by the 'Health survey for England 2003', and the length of life associated with each health state, shown in Table 17.5.

Table 17.5 Length of life

Health state	Age at onset	Length of life	Source
Diabetes	35	33.27	Hoerger et al. 2004[92]
	45	26.20	
	55	18.90	
	65	12.30	
	75	7.28	
CHD (reduction in length of life)		5	Assumed
Colon cancer (reduction in length of life)		5	Based on the fact that 5-year survival is low[93]

17.3.1.3 Effectiveness data

Effectiveness data used in the model were derived from a combination of published studies and assumptions.

For each of the prevention strategies, it was assumed that the prevention would result in weight maintenance for 1 year. This was based on the fact that the majority of clinical studies which had shown any effect on weight were of limited duration and there are few studies which have followed interventions beyond 1 year. As such,

making any assumption about weight maintenance beyond this timeframe would bias the results in favour of the intervention. A we accept that some interventions may have a more lasting effect, in the base case the conservative assumption of 1-year duration is used. This assumption was varied in the scenario analysis to reflect interventions that may have a more lasting impact on weight maintenance.

The efficacy of the prevention strategy relates to the number of people who respond to the prevention. In the base case, it was assumed that the efficacy of each prevention strategy was 75%. The majority of studies reviewed reported efficacy as an aggregated average weight change, rather than achieving a target weight in a given population. However, it seems unreasonable to assume that all individuals will respond to a given intervention so we chose to assume that 75% will respond while 25% will not. The efficacy was varied in during scenario analysis to see its effect on the cost per QALY.

17.3.1.4 Utility weights

Macran[94] provides QALYs by gender and BMI (see Table 17.6). This is the QALY for the general population and not for individuals free from diabetes, CHD and cancer. The unweighted QALY was calculated to correct for this.

Multipliers were applied to this QALY to obtain the QALY for individuals with any of the relevant comorbidities, such as diabetes and CHD. The multipliers for diabetes and CHD were provided by Ara and Brennan (Ara, R and Brennan, A. Economic evaluation of sibutramine for the treatment of obesity in adults without other co-morbidities in the UK. Company submission. 2005) (0.8661 and 0.8670, respectively). Lewis and coworkers[95] reported that the when an individual has colon cancer their QALY is reduce by 5%; this was applied in the model.

Table 17.6 Quality of life by body mass index (BMI) and gender

BMI (kg/m^2)	Male	Female
< 21	0.86	0.85
21–25	0.87	0.87
26–30	0.86	0.82
31–39	0.82	0.78
> 39	0.88	0.75

As such, a man with a BMI of 31–39 who also has CHD, diabetes and colon cancer would have a utility value of 0.58 compared with the 0.82 reported in Table 17.6 for an individual with no comorbidities.

17.3.1.5 Cost data

All costs were converted to January 2005 prices and are presented in Table 17.7. The cost of diabetes and CHD is based on the information provided by Ara and Brennan. (Ara, R and Brennan, A. Economic evaluation of sibutramine for the treatment of obesity in adults without other co-morbidities in the UK. Company submission. 2005) The cost of colon cancer is taken from an Australian paper[96] in the absence of any cost data derived from UK settings. The paper reports the cost of treatment for individuals diagnosed with Duke's A, B, C and D colon cancer. The crude average cost of treatment for these individuals was used in the model. The cost of diabetes was only applied to diagnosed diabetes, where the cost of diabetes includes:

- two GP visits
- one specialist nurse visit
- two visits to a GP clinic
- one HbA1c test
- 12 home glucose tests
- half an eye screening
- blood pressure control using angiotensin-converting enzyme inhibitor – ramipril
- a diuretic
- statin therapy (simvastatin)
- metformin antiglycaemic therapy.

No costs were included for undiagnosed diabetes as these individuals are assumed not to present to a healthcare professional and as such do not represent a burden to the NHS. However, the losses in utility related to undiagnosed diabetes cases was

included in the model as these would occur regardless of whether the case was diagnosed or treated.

Table 17.7 Costs per patient per year (as January 2005 prices)

Annual cost	Cost, as reported in paper	2005 UK cost	Source
Diabetes cost components	£633	£653	a
Coronary heart disease	£1587	£1637	a
Colon cancer	Aus$18,435	£7320	O'Leary 2004[52]
Workplace counselling	€430	£296	Proper et al. 2004[71]
Counselling from primary care staff (a year)	–	£728	This is assumed to be the cost of half an hour of practice nurse time, once a week[97]
Whole-school approach (per child)	$14	£12	Cost converted to UK £ and inflated to 2005 prices[72]

[a] Ara, R and Brennan, A. Economic evaluation of sibutramine for the treatment of obesity in adults without other co-morbidities in the UK. Company submission. 2005.

17.3.1.6 Economic evaluation

Incremental cost effectiveness was performed for the base case compared to each intervention. Cost-effectiveness models are used to assess the relative benefits of a given treatment using patient outcomes and the costs incurred in achieving those outcomes. The calculation of the additional cost per additional unit gain of benefit is known as the incremental analysis and results are presented as incremental cost-effectiveness ratios (ICERs).

After incremental costs and QALYs were estimated, the ICERs were calculated using the following formula:

$$ICER = \frac{Cost_{prevention} - Cost_{base_case}}{Effect_{prevention} - Effect_{base_case}}$$

17.3.1.7 Scenario analysis

The base case for each of the strategies reviewed was assumed to be weight maintenance (that is, no change in weight), over a 1-year period, after which

individuals would revert to the normal weight trend in the underlying model. The efficacy of each of the interventions was assumed to be 75%.

Due to uncertainty around the assumptions used in the prevention strategies, a number of scenarios were run for each prevention (using a cohort of 10,000). These scenarios were intended to capture best and worst case scenarios as well as a number of scenarios that may be feasible but are currently not supported by long-term evidence. These scenarios are shown in Table 17.8.

Table 17.8 Scenario analysis

	Scenario				
	1	**2**	**3**	**4**	**5**
Weight change (kg)	0	0	0	0	–10
Time (years)	20	40	90	1	2
Time to regain weight where loss occurs (years)	0	0	0	0	2
Efficacy (%)	75	75	75	100	75
Cost (time costs are applied)	1	1	As in the base case[a]	As in the base case[a]	As in the base case[a]

[a] The costs for work place counselling are applied for 1 year, the costs for primary care for half a year and the costs for the whole-school approach for 2 years.

The scenarios used allow the duration of weight maintenance to be changed from the 1 year used in the base case. Longer episodes of effect are allowed to model the best case scenario whereby public health interventions have a lasting impact on lifestyle and weight maintenance. The duration of effect has been varied from 1 year to 20 years, to 40 years and finally to a lifetime effect (90 years captures the entire duration of the model and the individuals within it). In addition to this, we have varied the efficacy from our assumption of 75–100% to determine the impact on outcomes and also varied the weight maintenance assumption. In one scenario we have assumed that the prevention strategy results in weight loss of 10 kg over a 2-year period which is then regained over the following 2 years.

17.3.2 Results

In this section the costs and QALYs for the prevention strategies compared with a 'do nothing' strategy are presented. It should be emphasised that 'do nothing' means that no additional active interventions are established but normal care continues. In the prevention arms, the prevention strategies are assumed to be in addition to ongoing normal care. Incremental analysis is presented in Table 17.9. These results are followed by the scenario analysis.

17.3.2.1 Base case results

Table 17.9 presents the results of the base case analysis. The base case assumes that weight is maintained over 1 year, and that all preventions have an efficacy of 75%.

Table 17.9 Base case analysis

Prevention	Prevention				Do nothing			
	Costs	SD	QALY	SD	Costs	SD	QALY	SD
Work place counselling	£2,072.16	£5,451.83	28.24	12.62	£1,810.67	£4,794.02	28.15	12.65
Counselling from primary care staff	£2,148.65	£5,220.63	28.12	12.66	£1,842.26	£5,234.97	27.99	12.79
Whole-school approach	£1,817.48	£5,011.64	28.19	12.74	£1,810.89	£5,131.78	28.17	12.76
Family-based intervention	£2,233.17	£5420.55	28.38	12.60	£1807.72	£4820.34	28.15	12.61

QALY, quality-adjusted life year; SD, standard deviation.

The results show that all the prevention strategies result in more QALYs than the 'do nothing' model. Over a lifetime the average cost of the prevention strategy is more expensive than doing nothing which is to be expected.

Figures 17.2–17.5 present graphs of BMI plotted over time for the first 10 years for all the prevention strategies. The graphs show that during the first year of the model BMI is marginally reduced compared with the underlying trend in weight gain and then gradually increases for the next 9 years. BMI for the prevention stays below BMI for the 'do nothing' model and for the most part runs parallel.

During the first year the BMI line for the prevention is not horizontal. This is because:

- the efficacy is only 75% (that is, 25% of individuals are assumed to not respond to the intervention and do not maintain their weight);
- each prevention may only be given to some of the population, with:
    - workplace counselling being given to adults only
    - counselling by primary care staff being given to both adults and children
    - whole-school approach only being given to children.

Figure 17.2 Work place counselling – body mass index (BMI [kg/m^2]) over time

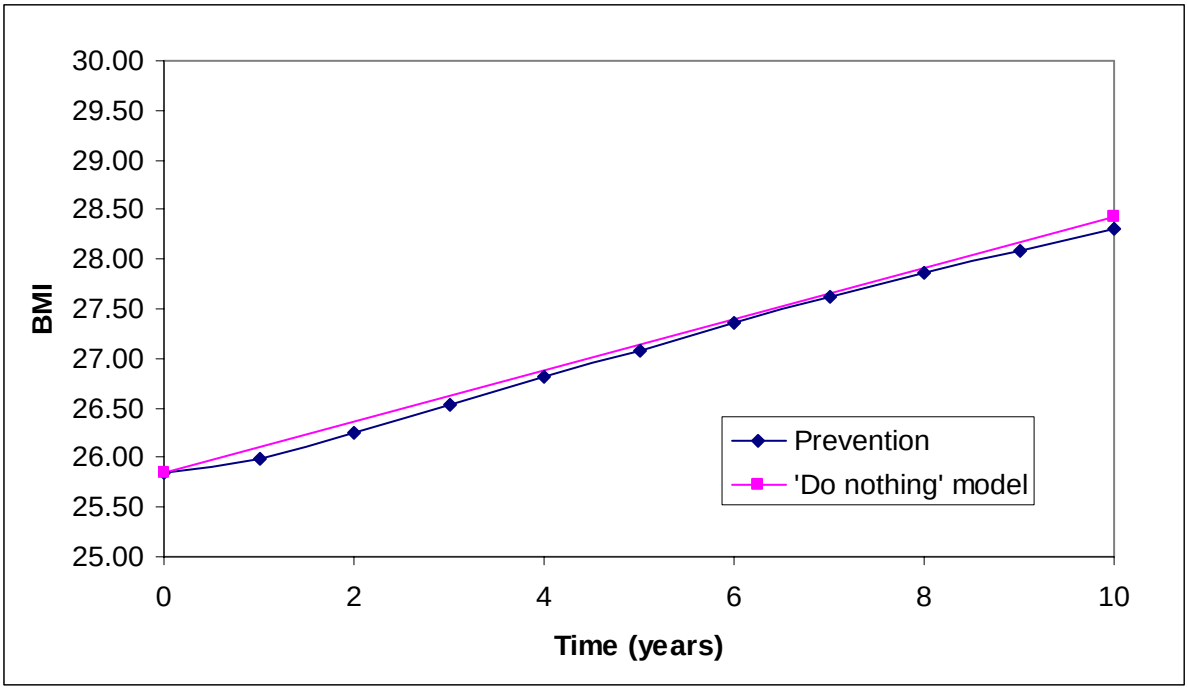


Figure 17.3 Counselling by primary care staff – body mass index (BMI [kg/m^2]) over time

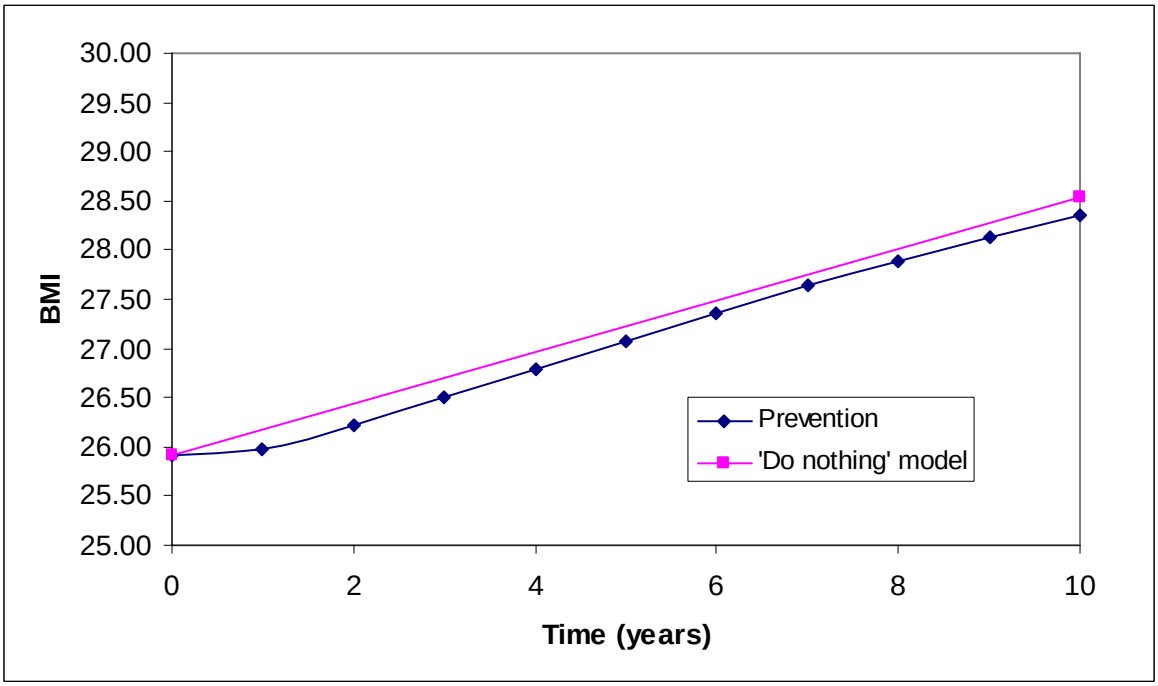


Figure 17.4 Whole school approach – body mass index (BMI [kg/m^2]) over time

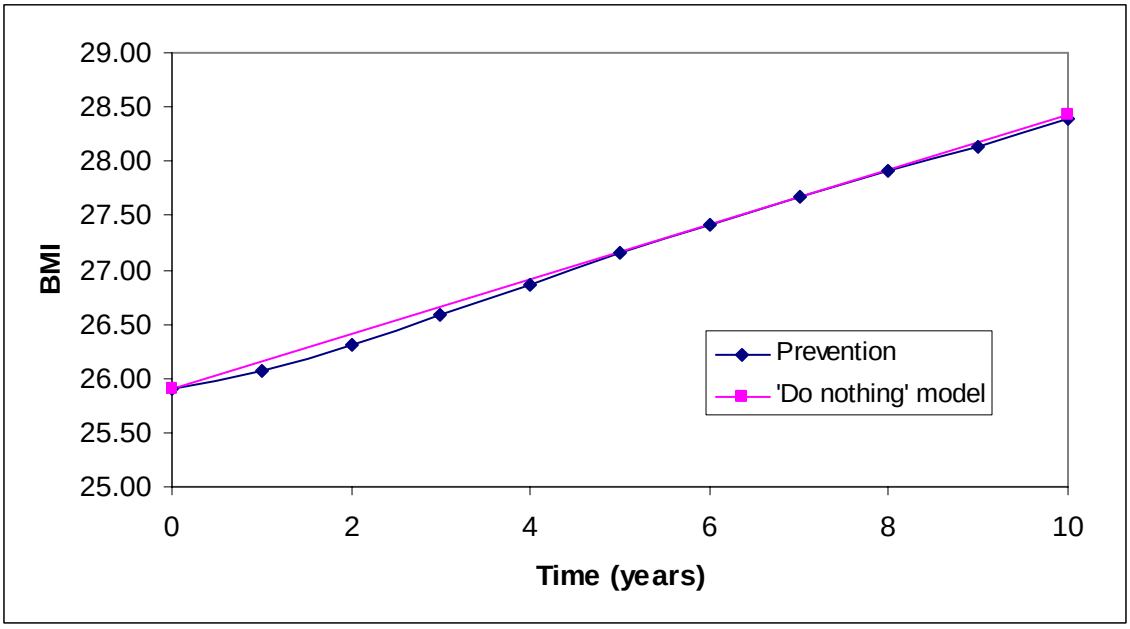
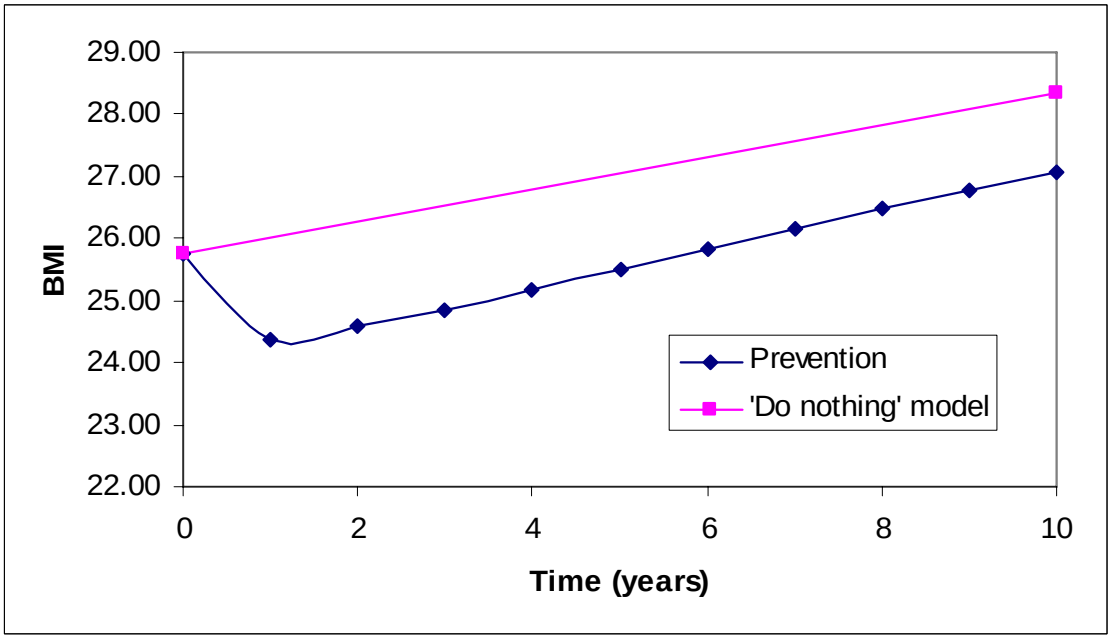


Figure 17.5 **Family-based interventions, BMI over time**



17.3.2.2 Incremental analysis

The incremental results are presented in Table 17.10 below. These results show that all the approaches produce a relatively low incremental cost per QALY which is well within accepted ranges. Although this is positive, it should be noted that the ICER is low as a result of low intervention costs and low QALY gains. The QALY gains in

particular are low and close to 0 in some cases. Further explanation of this is included in the discussion (section 17.3.3).

Table 17.10 Workplace counselling

	Incremental cost	Incremental QALY	ICER
Workplace counselling	£261.49	0.087	£3018.31
Counselling by primary care staff	£306.39	0.132	£2313.51
Whole-school approach	£6.59	0.025	£265.98
Family-based interventions	£425.16	0.23	£1,826.13

ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year.

Although it was not possible to assess the cost effectiveness of family based interventions that target children with overweight/obese parents, there is no reason to suggest that this would differ substantially from the above results. Indeed, it could be argued that targeting an intervention to children with an increased risk of weight gain may result in the intervention being even more cost effective than interventions which are aimed at a general population.

17.3.2.3 Scenario analysis

The results of the scenario analysis are shown in Table 17.11.

As the analysis of family-based interventions was run at a later stage based on the recommendations of the Guideline Development Group, the scenario analyses have not been run on this intervention.

Table 17.11 Scenarios analysis for workplace counselling

Scenario	Workplace counselling			Counselling by primary care staff			Whole-school approach		
	Incremental cost	Incremental QALY	ICER	Incremental cost	Incremental QALY	ICER	Incremental cost	Incremental QALY	ICER
1	£247.36	0.222	£1113.38	£715.25	0.393	£1818.87	-£33.71	0.117	Dominant
2	£269.39	0.213	£1264.56	£451.28	0.439	£1027.66	-£103.40	0.282	Dominant
3	£287.44	0.214	£1345.29	£201.46	0.483	£416.97	£26.28	0.163	£161.44
4	£150.52	0.012	£12154.42	£430.80	0.008	£55320.01	£47.32	-0.018	-£2600.74
5	£167.96	0.170	£987.35	£258.29	0.118	£2190.50	£27.14	0.026	£1035.60

ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year.

Each of the scenarios used in the sensitivity analysis was defined to address extreme values of a single parameter or changes to a number of parameters.

17.3.2.4 Sensitivity analysis of duration of weight maintenance/loss

Scenarios 1, 2 and 3 model the impact of extending the duration of weight maintenance from 1 year in the base case to 20 years, 40 years and 90 years, respectively. Given that costs are accrued over a single year and benefits accrue long into the future, it is not surprising that these scenarios produce cost-effective outcomes. The QALY gains should be expected to increase under each of the scenarios. Whereas this is true in the case of primary care counselling, the gains are less consistent for workplace counselling and school-based interventions. One explanation of this is that primary care counselling is the only intervention assumed to benefit the entire population, whereas workplace and school-based interventions benefit only a sub group of the population. As such, benefits will accrue in these groups over time but may decrease in the long term as members of these subgroups die.

Under each of these scenarios the QALY gains are significantly greater than those of the base case suggesting that the duration of the impact of an intervention is an important factor from an economic perspective.

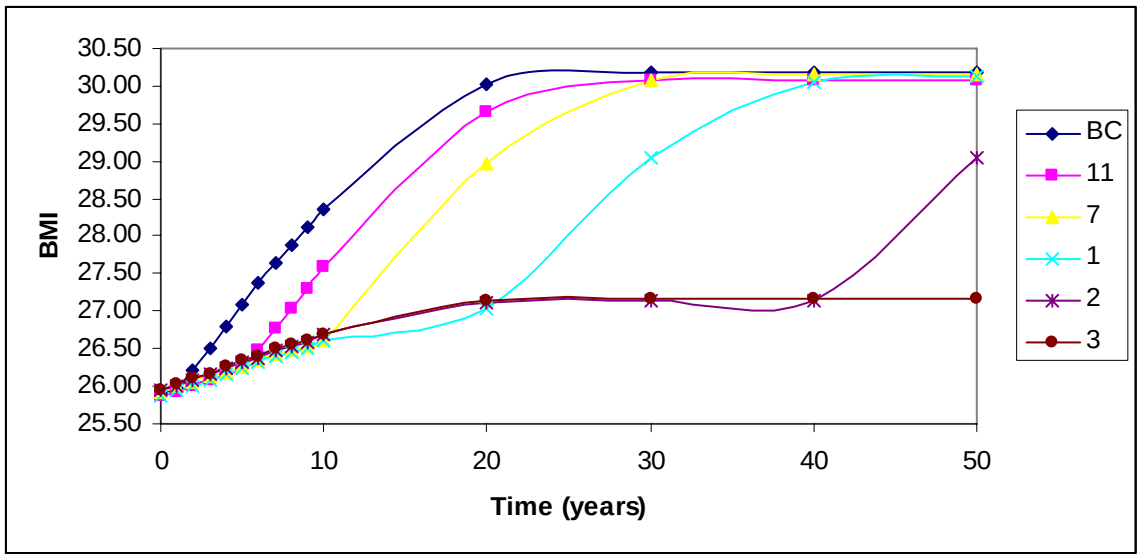
Further analysis was carried out to see whether the pattern of increasing QALY and decreasing cost per QALY would be seen when the duration of weight maintenance was one, five and ten years. The counselling by primary care staff model was rerun; this scenario was chosen because it targets the whole population. Table 17.12 provides the results; the duration of weight maintenance modelled by each scenario is recorded in the table. These results clearly show that the incremental QALYS gradually increase, and that on the whole the ICERS gradually decrease, as the duration of weight maintenance increases. Figure 17.5 plot BMI over time for all the scenarios as would be expected.

Table 17.12: Further analysis, duration of weight maintenance

Scenario	Time (years)	Incremental cost	Incremental QALY	ICER
BC	1	£306.39	0.13	£2,313.51
11	5	£174.54	0.21	£825.45
7	10	£401.85	0.28	£1,439.55
1 [a]	20	£715.25	0.39	£1,818.87
2 [a]	40	£451.28	0.44	£1,027.66
3	90	£201.46	0.48	£416.97

[a] Costs are over one year not .5 of a year as in the base case.

Figure 17.5 Counselling by primary care staff – increasing the duration of weight maintenance



17.3.2.5 Sensitivity analysis of amount of weight maintenance/loss

Under scenario 5 the intervention leads to an assumed weight loss of 10 kg over the course of 2 years which is then regained over the following 2 years. All of the interventions showed small QALY gains under this scenario similar to those of the base case.

17.3.2.6 Sensitivity analysis of the efficacy of the interventions

Under scenario 4, weight is maintained for 1 year as in the base case but the efficacy of the interventions is increased to 100%. Under this scenario the QALY gains are close to 0 or negative in some cases which increases the cost-effective ratios. One would expect the outcome to be more cost effective than the base case so these results may be a statistical anomaly.

Graphs of BMI over time for all scenarios compared with the base case for each of the preventions and each of the corresponding 'do nothing' models are shown in Appendix 18.

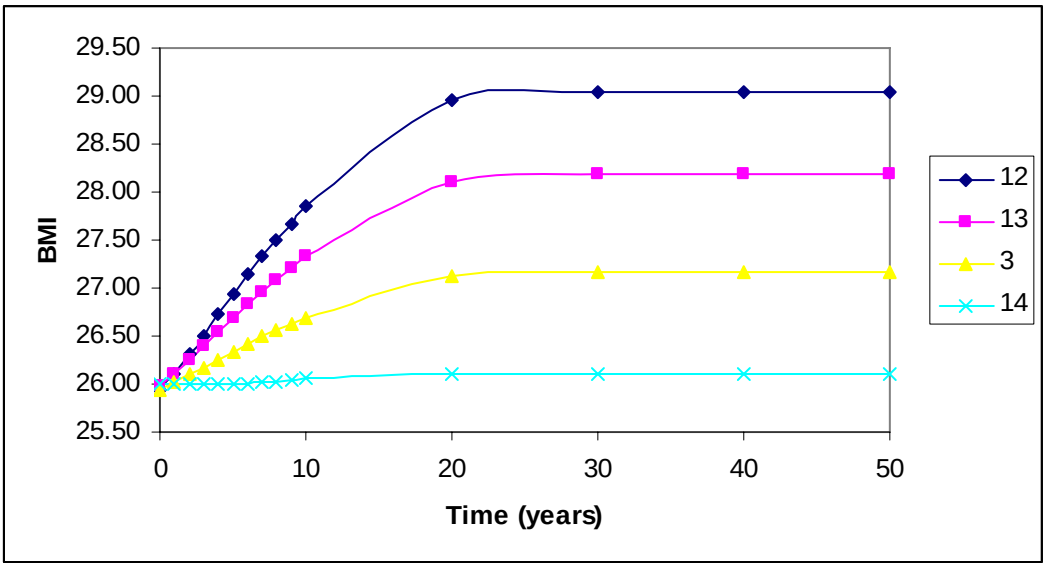
Further analysis was carried out to see whether, when weight is maintained for 90 years, and the efficacy is increased from 25% to 100% the results become more cost-effective. Whilst it is accepted that this duration of effect represents an extreme analysis, this approach was used to ensure that the model was producing logical findings. The use of extreme inputs should ensure that the ICER follows a downward trajectory as efficacy is increased. Given the relatively small impact that a 1 year intervention has on lifetime QALYs, interventions which a short duration may show a less consistent trend. Again the counselling by primary care staff model was run.

The results are presented in Table 17.13 and show that as the efficacy is increased the scenario becomes more cost-effective as would be expected. Figure 17.6 plots BMI over time for these scenarios.

Table 17.13: Further analysis, efficacy of the intervention

Scenario	Time (years)	Efficacy	Incremental cost	Incremental QALY	ICER
12	90	25	£194.77	0.04	£5,343.32
13	90	50	£233.74	0.27	£857.96
3	90	75	£201.46	0.48	£416.97
14	90	100	£213.24	0.67	£318.57

Figure 17.6 Counselling by primary care staff – increasing the efficacy



17.3.3 Discussion

17.3.3.1 Main results and key drivers

The model evaluates the incremental cost effectiveness of a number of obesity prevention strategies. The costs for each of the strategies have been based on published sources of assumptions of the resource use involved and are believed to be robust. Due to an absence of robust clinical evidence derived from long-term studies relevant to UK settings, we have assessed the cost effectiveness of the interventions using a number of scenarios. In the base case, interventions are assumed to be 75% efficacious (that is, three=quarters of people respond to them) and result in weight maintenance over the course of 1 year. The results of the base case analysis show that all the interventions produce marginal QALY gains at a relatively low cost per person. Targeting children appears to be the most cost-effective prevention strategy under these assumptions.

However, it should be noted that although the ICER is low, this arises because both the incremental cost and the incremental QALY gains are relatively low. In

the base case, the QALY gains are marginal and close to zero in some cases, suggesting that short-term weight maintenance does not have a significant long-term impact on health. The reason for this is that the prevention strategies have only a short-term impact on BMI. When this is multiplied by the probability of developing any risk factors in the average individual in the population (as opposed to a high-risk or obese individual), the QALY gains over the course of a lifetime are relatively small. When the trends in weight are mapped, it becomes apparent that both the 'do nothing' and the prevention group's weight continues to increase (reflecting the underlying trend for weight gain and an efficacy less than 100% in the prevention strategies) until the average BMI of both populations plateaus at around 30 kg/m^2. This is because we have assumed that when BMI reaches 40 kg/m^2 it can not increase any further. Any gains from reductions in mortality are minimal as the majority of people in the model die from old age as opposed to one of the predefined risk factors.

The impact of this is shown graphically in Figure 17.5, which shows the costs and benefits of the 10,000 individuals that are sampled in the model. In this case, the costs and benefits associated with primary care counselling produced by the model are distributed around the origin. As such, for each individual who is predicted to have QALY gains there are almost as many who have QALY losses. The net impact is close to zero.

Figure 17.5 Incremental quality-adjusted life years (QALYs) against the incremental costs – counselling by primary care staff

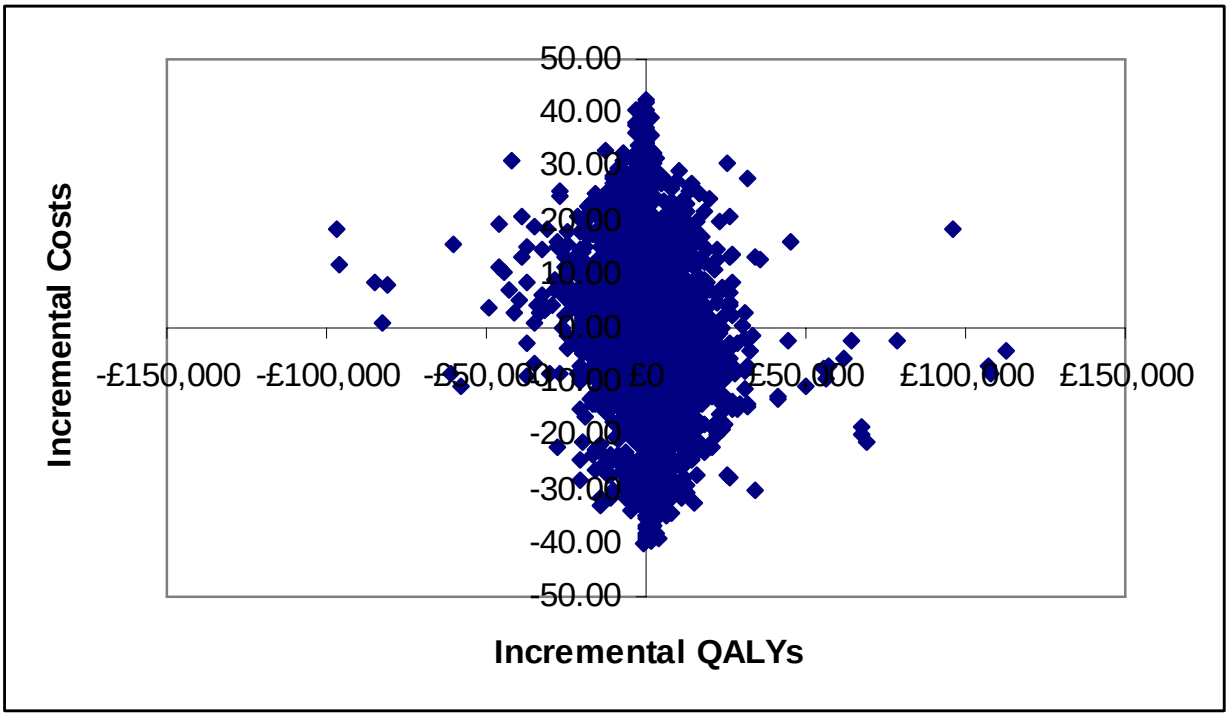


Figure 17.5 shows that the incremental QALYs are concentrated around zero and helps to demonstrate why the average incremental QALYs are so low.

Of the interventions considered in this analysis, there is little reason to suggest that any particular intervention is more cost effective than the others. The results of the base case and the scenarios run above do not lead to a consistent outcome across all scenarios. However, it does appear that the QALY gains resulting from the whole-school approach tend to be slightly lower than the other two interventions. This may reflect the fact that this intervention only benefits a subgroup of the total population assessed (for example, children) and as such has a relatively moderate impact across the total population in the model. In addition to this, the assumption in the model that diabetes is the only risk factor that is applied to children under the age of 16 (that is, we exclude any risk of CHD or cancer until after this age) may also result in underestimates of the QALY gains in this population. However, this needs to be balanced against the

lower costs associated with the whole school intervention which produces a relatively low cost effectiveness ratio.

In general it would appear that strategies to prevent obesity are broadly cost-effective although the QALY gains are low in some cases but these are offset by the low costs of the interventions. The key to improving the cost-effectiveness of such interventions is to ensure that the interventions have a lasting effect on weight maintenance or result in weight gain. Whilst interventions that have only a short-term impact on weight gain may result in some initial improvements in outcomes, these are unlikely to translate into longer-term gains in quality adjusted life-years when considered over the course of an individual's life. Therefore, from an economic perspective, interventions to prevent obesity should look to reduce or maintain weight with ongoing follow-up to ensure that any effect is long-lasting.

It should also be noted that the quality of the clinical evidence underlying the economic evaluation was relatively poor, hence the use of extensive scenario analysis to determine the cost effectiveness of the interventions under different assumptions. The scenario analysis suggests that the interventions under consideration are cost effective under a wide range of assumptions. However, improvements in the reporting of clinical studies in this field would allow for a more robust economic evaluation.

17.3.3.2 Sensitivity analysis

The model is sensitive to changes in the duration of effect. For example, under scenario 2, we assumed that a 1-year intervention leads to a 40-year impact on weight maintenance. Although this scenario is based on extreme values, it could be seen to reflect an educational campaign that leads to a long-term impact on weight management. In this case the cost-effectiveness ratio is consistently low across all the prevention strategies suggesting that the duration of effect of interventions is a key determinant of the cost effectiveness. As such, studies

should attempt to capture long-term outcomes resulting from short-term prevention strategies.

The model is largely insensitive to whether the intervention results in weight maintenance or weight loss. One of the reasons for this is that weight loss is assumed to be temporary and that individuals ‘rebound,’ putting the weight back on over a period of time.

Although changes in efficacy had an inconsistent impact in the modelling exercise, this parameter does need to be clearly reported in clinical trials of prevention strategies. Studies should clearly define the criteria for response to an intervention and ensure that the results are reported transparently. All too often, studies report outcomes such as average weight loss across a study sample, rather than reporting the proportion of individuals that lost weight and their weight loss. Such reporting would help with future economic studies.

17.3.3.3 Limitations of the model

There are a number of limitations to the model which need to be highlighted. These limitations were mainly put in place due to the absence of accurate data or the computational complexity of the modelling exercise. In line with the best practice in modelling, any simplifying assumptions have erred on the conservative side, so as not to add favourable bias to the study outcomes.

The model occasionally provides unpredictable outcomes which are unexpected, for example, smaller QALY gains when a lifetime (90-year) duration of effect is assumed that a 40-year duration of effect. Some of these can be explained by interventions that target particular subgroups, but some differences remain unexplained. In examining the prevalence of particular conditions in the model it becomes apparent that the QALY gains are easily influenced by a small number of individuals who have multiple comorbidities. For example, if a small number of hypothetical individuals in the sample of 10,000 used in the model develop diabetes, CHD and colon cancer or experience premature mortality, this reduces QALY gains in the whole cohort significantly. Running the model for a sample of

10,000 individuals would normally overcome these sort of inconsistencies. However, due to the relatively small reductions in risk and the resulting increases in QALYs that occur from weight maintenance, these ‘outliers’ can impact the ICERs and in some cases result in small QALY losses in the prevention group. This may be overcome by running even larger samples in the model, but this would increase the computational burden of an already complicated model. In order to ensure that these instances are a true statistical anomaly, a number of extreme scenarios have been run, such as assuming that interventions have a 90 year effect but a variable efficacy from 25% to 100%. These extreme scenarios have produced logical changes in the ICER that would be expected (e.g. increasing ICER when effectiveness or amount of weight lost is decreased). This testing of the model suggests that the variability in the findings mentioned above arises from the limited impact of short-term interventions on lifetime outcomes and costs rather than any shortcomings in the model structure.

The model only takes into account three key risk factors arising from obesity, namely diabetes, CHD and colon cancer. However, there is limited evidence suggesting that obesity has the potential to increase the risk of other cancers, musculoskeletal disease as well as respiratory conditions such as chronic obstructive pulmonary disease. These were excluded from the model due to the limited information available to accurately predict the increased risk of acquiring any of these conditions based on an individual’s age, sex and BMI. As such, any estimates of QALY gains resulting from the model should be regarded as conservative assumptions as they are not assumed to impact on any of these other factors. The relative risks of death associated with the risk factors has also not been age adjusted in the case of colon cancer, which could also reduce the QALY gains that may result from any prevention strategy which impacts this condition.

Another limitation of the model that applies only to children is the assumption that children are only at an increased risk of developing diabetes as a result of being overweight or obese. Once again, due to limitations of the data that are available,

we have assumed that the risks of CHD and colon cancer do not increase until the individual is aged over 16 years. This may result in underestimates of the QALY gains in children.

An additional point for consideration is that the model only captures direct costs (that is, those which fall on the NHS). Once again, this is a conservative assumption as many of the costs associated with obesity may fall on individuals as well as society more broadly. However, for the purposes of this exercise these have not been considered.

In addition to the above structural limitations of the model, there were also limitations due to the lack of data concerning the prevention strategies considered. In the available clinical literature (as identified by the accompanying rapid reviews) many studies reported incomplete costs and benefits resulting from an intervention. For example, many studies reported aggregated results of weight loss or changes in BMI over a study period but did not provide sufficiently disaggregated data on the efficacy of interventions (that is, how many people responded) or the average weight loss in particular subgroups. All studies reviewed were of relatively short duration meaning the duration of effect could not be reported accurately. As shown in the scenario analysis above, this is a key determinant of the cost effectiveness. There were also significant concerns over the use of data from non-UK settings and how applicable these would be to a UK population.

In order to overcome this, a number of scenarios were modelled to assess the likely cost effectiveness of the interventions. The costs of each intervention were based on published sources or assumptions of practice patterns. The base case assumptions took a conservative perspective of the likely impact of interventions, assuming that they were effective in 75% of all participants and that weight loss was managed for 1 year. This was chosen as a realistic assumption as not all individuals would be expected to respond to an intervention and what evidence

there is available did not report any weight maintenance outcomes beyond 1 year.

In the sensitivity analysis, a number of scenarios were developed to reflect more extreme values as well as scenarios which reflected particular behaviours seen in clinical data (for example, the assumption that any weight loss is regained over a period of time following an intervention). These scenarios helped to identify the parameters that are most sensitive to change.

Other authors who have investigated strategies to prevent obesity are Avenell and coworkers[98] and the Health Development Agency.[99] Both studies faced problems similar to this research and were confronted by the lack of appropriate data to support their modelling exercises. Avenell used a Markov model to estimate the cost effectiveness of lifestyle treatments for obesity. The model looked at the effectiveness of lifestyle interventions on preventing the onset of diabetes among people with impaired glucose intolerance. Diet and exercise were compared with no intervention, the ICER or cost per additional QALY was £13,389 at 6 years' follow-up. In 2003 the Health Development Agency report on the management of obesity and overweight found there is an urgent need for more evidence concerning the prevention of obesity and weight maintenance.[99]

17.3.4 Conclusions

The interventions to prevent obesity included in this assessment appear to be a cost-effective use of resources. The cost effectiveness of the interventions is dependent on the duration of effect as well as the extent of any weight loss, suggesting that interventions such as education or counselling should be designed to ensure that they have a lasting effect on individuals' behaviour and weight management, ideally over the course of their lifetime. The clinical literature on the effectiveness of the interventions reviewed was equivocal in some cases which lead to the use of extensive scenario analysis. Whilst the scenario analysis has shown the interventions to be cost effective under a wide-range of assumptions, it would be preferable to have access to clinical studies

that report detailed information on the impact of interventions and include long-term follow-up to support future economic evaluations.

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