UNIVERSITY OF CAMBRIDGE
Institute of Public Health

DISABILITY, DEMENTIA AND FRAILTY IN LATER LIFE: MID-LIFE APPROACHES TO PREVENT OR DELAY THE ONSET OF THESE CONDITIONS

REVIEW 3 - Effectiveness and cost-effectiveness of mid-life interventions for increasing the uptake and maintenance of healthy lifestyle behaviours and the prevention or delay of dementia, disability, frailty and non-communicable chronic diseases related to modifiable lifestyle risk factors.

FINAL REPORT (v3)

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Abbreviations

ADL	Activities of Daily Living
AL	Alcohol
CIPH	Cambridge Institute of Public Health
COPD	Chronic Obstructive Pulmonary Disease
CPH	Centre for Public Health
CPHE	Centre for Public Health Excellence
CVD	Cardiovascular disease
DH	Department of Health
DI	Diet
IADL	Instrumental Activities of Daily Living
LGBT	Lesbian, gay, bisexual and transgender
MCI	Mild Cognitive Impairment
NICE	National Institute for Health and Care Excellence
NIHR SPHR	National Institute of Health Research School of Public Health Research
NCCs	Non-communicable chronic conditions
PA	Physical Activity
OECD	Organisation for Economic Co-operation and Development
RCT	Randomised controlled trials
SES	Socioeconomic status
SM	Smoking
SR	Systematic Review
WCRF	World Cancer Research Fund
WHO	World Health Organisation

Operational definitions

Successful ageing	Successful ageing is defined as survival to an advanced age while maintaining physical and cognitive function, functional independence and a full and active life. It means that morbidity and disability are compressed into a relatively short period before death, in line with the 'compression of morbidity' theory.
Disability	Disability will refer to any long-term restriction on the ability to perform an activity in the manner, or within the range, considered normal.
Dementia	Dementia will refer to a progressive, degenerative condition caused by diseases of the brain. Whether it occurs alone, in addition to, or as a combination of, chronic conditions, it is characterised by cognitive and non-cognitive symptoms of variable frequency and severity.
Frailty	Frailty will refer to a syndrome characterised by age-related declines in functional reserves where a small insult (e.g. infection, loss of partner) results in a striking and disproportionate change in health state. Frail older adults experience an increased risk of adverse outcomes such as falls, fractures, comorbidity, disability, dependency, hospitalisation, need for long-term care and mortality.
Non-communicable chronic conditions	Non-communicable chronic conditions will include cardiovascular diseases, diabetes, chronic obstructive pulmonary diseases, obesity, visual and hearing conditions, and some cancers that may be associated with behavioural risk factors.
Disadvantaged populations	Disadvantaged populations will include (but are not limited to) low socioeconomic status, ethnic minority groups, lesbians, gay, bisexual and transsexual (LGBT) community groups, travellers and other groups with protected characteristics under the equality and diversity legislation.

EXECUTIVE SUMMARY

1. INTRODUCTION

1.1 Background

Despite a wealth of evidence on the association between low physical activity, smoking, alcohol consumption, diet, and ill health in later life, an alarming proportion of the adult population continues to engage in unhealthy behaviours. These behaviours are strongly associated with the development of a range of non-communicable chronic conditions in later life; though the multiple processes leading to it have been shown to start much earlier. Most public health guidelines provide general and specific recommendations to promote healthy behaviours in children, the adult population, and to some extent the older population, yet very few recommendations exist for adults in midlife.

To address this gap, the Department of Health (DH) has asked the National Institute for Health and Care Excellence (NICE) to produce public health guidance on preventive approaches to be adopted in mid-life to delay the onset of disability, dementia and frailty in later life. Three evidence reviews and an economic model will underpin the guidance. The reviews assess evidence on a wide range of potential influences on well-being in later life (i.e. demographic, economic, geographical, physical, cultural and social factors), and at the effectiveness and cost effectiveness of available interventions to act on these factors.

1.2 Aims and review questions

The overarching aim of the suite of three evidence reviews is to identify which primary prevention approaches to be adopted in mid-life are most effective and cost-effective to prevent and delay the onset of disability, dementia, frailty, and other non-communicable chronic conditions in later life.

The specific questions addressed in this review (Review 3) are:
- What are the most effective and cost-effective midlife interventions for increasing the uptake and maintenance of healthy behaviours?
- To what extent do interventions targeted at these different health behaviours prevent or delay dementia, prevent or delay frailty and disability related to modifiable lifestyle risk factors, or prevent or delay non-communicable chronic diseases?

The two other reviews focus on key issues for people in midlife that prevent or limit, or which help or motivate them to take up and maintain healthy behaviours (Review 1), and the association between behavioural risk factor in midlife and disability, dementia, frailty, and other non-communicable chronic conditions in later-life (Review 2).

2. METHODS

The focus of this review is on the effectiveness and cost-effectiveness of midlife interventions for increasing the uptake and maintenance of healthy lifestyle behaviours (at individual, family, community, subnational or national level and in a range of settings), and the extent to which interventions targeted at these health behaviours prevent or delay dementia, disability, frailty and non-communicable chronic diseases related to behavioural risk factors.

The review includes quantitative effectiveness and economic outcomes of intervention studies relating to:

a) Measures of uptake or maintenance or change in health behaviours e.g. rates of smoking cessation, physical activity uptake, participation or amount, change in diet or components of diet, such as increase in fruit and vegetable intake, prevention of weight gain, weight loss, control or maintenance in people who are overweight.

b) Delivery/design of interventions e.g. setting, mode of delivery, personnel (e.g. lay, healthcare professionals).

c) Measures of successful ageing, or outcomes related to dementia, disability, frailty, non-communicable chronic conditions, e.g. activities of daily living (ADL), instrumental activities of daily living (IADL), mobility, physical function, cognitive function, bone health (e.g. osteoporosis, fractures, bone mineral density), healthy life span, mortality, mental health, participation, incidence of cardiovascular diseases (CVD), cancer, diabetes, renal disease, chronic obstructive pulmonary diseases (COPD), mental health.

d) Outcomes relating to cost-effectiveness would include (but are not limited to): resource use, costs, cost-effectiveness, cost-utility.

Interventions to promote lifestyle and/or behaviour change such as the primary prevention of overweight or obesity are covered by the scope of the review and the guidance. However, interventions for the secondary prevention or management of such conditions or for people with existing dementia, disability, chronic disability or frailty fall outside the scope of this review and the guidance, except for weight loss interventions in people who are overweight (but not obese). The scope of the review does not cover use of drugs, diagnosis, national

policies, laws and taxation, assessments of implementation or translation of interventions, changes in knowledge and attitudes related to health behaviours.

The population covered by the review (as for the other two reviews) includes adults aged 40 to 64 years for the general population, and adults aged 18-39 from disadvantaged populations. The review does not cover people with and treated for pre-existing conditions (i.e. dementia, frailty, disability, non-chronic communicable conditions) nor does it cover the treatment (i.e. drugs, dietary supplements), diagnostic and care and management of these conditions.

We conducted a thorough search of the scientific and grey literature to identify intervention studies and systematic reviews that reported the outcomes listed above. Systematic reviews and primary studies focused on midlife populations published from year 2000 onwards were processed. Where evidence was not identified, systematic reviews with a broader age range than midlife from 2010 onwards were included. It was not practically possible to look at primary studies with a broad age range that may have included a predominantly mid-life sample.

Two reviewers screened the title and abstract of identified references independently. Primary studies that met the inclusion criteria were assessed for quality using available tools from NICE (CPH methods manual).

Quantitative evidence from primary studies and systematic reviews is synthesised thematically (e.g. by behavioural risk factors, subpopulations) where themes emerged and descriptively otherwise. Data specific to health inequalities and vulnerable communities are assessed and findings are summarised separately where sufficient data is available.

For each key issue or factor of interest an evidence statement was generated which provides an aggregated summary of all of the relevant studies. Applicability ratings (i.e. directly applicable, partially applicable or not applicable) are proposed for each evidence statement to judge how similar the population(s), setting(s), intervention(s) and outcome(s) of the included studies are to those outlined in the review question.

3. RESULTS

This review includes 52 primary studies and 35 systematic reviews. A summary of the characteristics of included studies is presented for individual risk factors. For each risk

factor, a table summarises the key findings of included studies (Tables 1 through 7), with more details about the population, design, intervention, effectiveness and limitations provided in the evidence tables (Appendix A). Appendix B summarises the quality of included studies. Overall, the evidence cited in the review is good (or very good) and the applicability directly or partially applicable.

Evidence statements are structured as follows:

Level 1 - for each risk factor:

- Physical activity
- Diet
- Smoking
- Alcohol
- Weight management
- Multicomponent, lifestyle, behavioural
- Disadvantaged and minority groups

Level 2 - type of outcomes:

- Effect of PA interventions on uptake and maintenance of healthy behaviours
- Effect of PA interventions on SHORT TERM dementia, disability, frailty or non-communicable diseases outcomes (in mid-life)
- Effect of PA on LONG-TERM dementia, disability, frailty or non-communicable diseases outcomes (in later life).

4. DISCUSSION

This review found evidence for a number of interventions that have been shown to be effective in promoting the uptake and maintenance of healthy behaviours in midlife. Effective interventions were found for promotion of positive physical activity and diet behaviours; reduction or cessation of smoking and alcohol behaviour; weight prevention, weight maintenance and weight loss (in those overweight) in midlife; and interventions addressing combinations of multiple health behaviours. No evidence from intervention studies specifically conducted in midlife was found that met the review inclusion criteria for social, leisure and cognitive interventions, or programmes to address hearing or sight behaviours. While healthier behaviours earlier in life will reduce risks and need for intervention, the evidence suggests that some modification of health behavioural risks can

occur in mid-life. However, only limited evidence was found relating to the effectiveness of midlife interventions on long term successful ageing and dementia, disability and frailty or outcomes related to non-communicable chronic diseases. We found no evidence describing adverse events associated with these interventions.

There is limited but good quality evidence from intervention studies conducted exclusively in the UK health care context (10 primary studies and 2 economic evaluations), yet few large scale experimental or population based studies seeking to develop and evaluate the effect and cots of midlife interventions on late life outcomes. Nevertheless, a number of good quality economic evaluations based on primary data and Markov or decision analytic models (directly and partially applicable to the UK because conducted in OECD countries) suggest that interventions targeting behavioural risk factors are likely to be cost-effective from a societal perspective - with the caveat that findings are sensitive to effectiveness and maintenance assumptions in the long term (mainly due to the lack of evidence base). Also, different sociocultural, environmental and economic factors may influence the success or failure of interventions when implemented in the UK context or sub-populations.

Some evidence was also found relevant to health inequalities with interventions conducted in some ethnic minority groups, socioeconomically disadvantaged groups, homeless populations and for men and women. Interventions delivered in these groups were also successful in changing some health behaviours. There is however a paucity of research in midlife for LGBT groups and other groups protected under the equality and diversity legislation; or vulnerable groups including migrants, asylum seekers, refugees, prisoners and Roma. This has implications for the generalizability of our findings to whole populations because contextual factors that may have favoured intervention efficacy may differ between and within communities.

Similar to Review 1 and Review 2, the main limitation of this review relates to the search strategies, which were focused on studies with midlife-related terms in the title, abstract or related MeSH indexing to identify interventions studies specifically delivered in midlife. The implication is that intervention studies that have recruited only/mainly individuals in mid-life without specifying midlife terms in the title or abstract were not identified by the searches. This might explain some of the gaps in evidence and further work is ongoing (though beyond the scope of this report) to address this limitation.

Other limitations include short follow-up periods; small sample sizes which compromise the power to detect significant associations namely where small effects are expected; different

operationalization of behavioural risk factors and outcomes which make comparison between studies (pooling effect estimates) problematic; and self-reported as opposed to objective measures of outcomes, which may result in biased differences in reported behaviours before and after the intervention, for example quantity of alcohol or tobacco consumed.

OVERALL SUMMARY OF FINDINGS AND RECOMMENDATIONS

Physical activity

1. **Structured physical activity programmes**. Evidence suggests provision of a structured exercise programme can influence decisions to start and maintain PA. Programmes included stretching, aerobic exercise, walking, weight training, cycling, yoga and tai chi. A wide choice of exercise programmes could be made available so that there are programmes of interest to a broad population.

2. **Provision of tailored individual and group support for changing physical activity levels:** Evidence suggests that PA individual and group support interventions produce moderate but statistically significant increases in PA behaviour, in particular when participants were involved with behavioural interventions. Interventions were multimodal and ranged from a single motivational education session (although these were less effective) to extensive supervised exercise sessions. Intervention components such as support, self-monitoring, stimuli to increase PA, self-regulation techniques, rewards, behavioural goal setting, personalised activity goals, provision of information about local opportunities and modelling PA behaviour produced better health and behavioural outcomes; however due to the lack of longitudinal data the impact beyond 12 months is unclear. Evidence from economic papers suggests that the least cost-effective categories were the high-intensity "individually adapted behaviour change" and "social support" programmes yet these programmes also had the largest effect on PA behaviour. Overall physical activity interventions were shown to be cost effective from a societal perspective in a majority of studies (but the findings are sensitive to long-term effectiveness and maintenance assumptions).

3. **Provision of combined diet and exercise interventions:** Evidence suggests that combined diet and exercise modification can have significant improvements in nutrition and PA behaviour; in particular these interventions can improve dietary and/or PA behaviour in South Asian populations. Components included exercise and nutrition information, and support and were usually delivered by a PA specialist and registered

dietician. Due to short duration of studies the long-term impact is uncertain.

4. **Internet and telephone support:** Evidence suggests that Internet and telephone services are beneficial when attempting to produce positive changes in PA. Telephone contact to provide feedback and to support also appeared to positively change PA levels. Educational components in the intervention significantly increased effectiveness. There could be an increase in the provision of Internet and telephone-based physical activity programmes. However effect sizes were small and some evidence suggested that technological solutions are no more effective than print materials, face-to-face programmes and other health promotion methods. There is insufficient evidence to assess whether face-to-face interventions or remote approaches are more effective at promoting PA. Internet and telephone technologies should therefore be considered as an addition to other delivery methods and not seen or used as a replacement for services until further evidence is available. The ability of Internet and telephone delivered interventions to produce change in long-term PA remains unclear.

5. **Raise awareness in mass media:** Evidence suggests that mass media campaigns increase awareness in the population. However, there is limited evidence of campaign effects on increasing PA. Campaigns that promoted PA as a 'social norm' seemed to be more effective in reducing sedentary behaviour; however effect sizes were small**.**

6. **Combined physical activity, support and awareness raising:** Consideration could be given to an approach which combines the provision of support and exercise programmes; awareness raising would be more beneficial to population-level health as it may both provide the context in which behaviours can be adopted and maintained into old age. Although due to limited evidence the long-term effects of each component is unknown.

Diet

7. **Dietary advice can be effective in improving dietary behaviour:** There is some limited evidence that individually tailored advice is effective and that group programmes or printed individual dietary advice can be effective.

8. **Reduction of fat/saturated fat intake as part of dietary advice/recommendations**: Reduction of fat/saturated fat intake as part of dietary advice/recommendations. However consideration should also be given to the balance of foods required for prevention of osteoporosis.

Smoking

9. **Increase provision of reduction interventions:** Evidence suggests reduction interventions can be carried out using self-help materials or aided by behavioural support, and can be carried out with the aid of pre-quit NRT (studies suggest that pre-quit NRT does not increase adverse events). Reducing cigarettes smoked is an important contribution to prevention of non-communicable chronic diseases. Patients can be given the choice of a variety of strategies (before quit day and quitting abruptly, with no prior reduction) to assist in behavioural change**.**

10. **Increase provision of cessation interventions:** Evidence suggests that interventions consisting of self-help, NRT, and community-based, individual based, group, and telephone counselling can promote smoking cessation; however effects were attenuated in the longer term. Where evidence exist telephone care intervention versus usual care using the provider's perspective was more cost-effective. There is a paucity of evidence from a societal perspective**.**

11. **Increase provision of culturally sensitive interventions:** Evidence suggests smoking cessation outreach workers who are members of BME and other minority groups can more effectively improve access to and the success of smoking cessation services compared with standard care. Evidence however was primarily on Pakistani and Bangladeshi men. Costs of these interventions per quality-adjusted life year proved feasible and acceptable.

12. **Increase provision of quitting intention interventions:** Evidence suggests that the intention to quit was a strong predictor of smoking reduction or cessation. Interventions often combined behavioural, counselling, and educational components to impact on smoking attitudes. There were a variety of methods used to deliver the interventions such as information leaflets, practice nurses, outreach workers, the Internet and telephone. Programs could be designed to address contextual factors, which may change attitudes and increase the efficacy of reduction and cessation interventions.

Alcohol

13. **Limiting licensed premises:** Evidence suggests that the availability of alcohol does have an impact on consumption (review 1 and 3). Alcohol prevention targeting licensed premises resulted in fewer assaults, unlawful threats and violence towards officials. Economic analysis shows that the monetary and human benefits may be considerable. It

may therefore be necessary to reduce alcohol outlet density, defined as shops, bars and restaurants in communities.

14. **Improve availability of behavioural, counselling and therapy programs:** Evidence suggests that behavioural counselling and therapy have positive impacts on excessive alcohol use; however effect sizes vary. Interventions can include provision of brief information for minor problem drinking, psychotherapy for mild to moderate dependence and drug-therapy adjuvant to counselling for detoxified patients with a history of severe physical dependence. Internet-based interventions are effective at changing alcohol consumption, treatment response, and quality of life in the short term; however long-term data is unavailable. Internet-based therapy may therefore offer better value for money as an adjunct to existing service provision, and be considered as an additional treatment option.

Weight management

The inclusion criteria for this review include weight prevention, maintenance and management in overweight populations (to prevent obesity) at midlife but does not include management or treatment of obesity in populations with existing obesity (BMI >30). Primary studies in populations with BMI > 30 have therefore been excluded.

15. **Programmes involving promotion of healthy balanced diet and exercise or dietary advice:** There is some evidence that dietary advice based on the American Heart Association step 2 diet plus endurance exercise or dietary advice to reduce fat intake to <20% are effective for weight loss in midlife populations. The evidence included men and women and ethnic minority groups.

16. **Delivery of programmes**: There is some evidence that a lifestyle intervention aimed initially at reducing total fat (which allowed participants to reduce total energy intake) and promotion of healthy eating, and the subsequent introduction of a concept of calorie balance, is effective for weight reduction in people at risk of diabetes in midlife whether delivered by clinically trained professionals or lay educators and with a range of delivery methods.

17. **Programmes involving yoga** (delivered in a group format) may be effective for weight management in midlife, particularly for those for whom more intensive exercise programmes may be unsuitable. However, most studies (from a systematic review) were conducted in India so the applicability of the evidence to the UK may be limited.

Multiple component/lifestyle/behavioural

18. **Lifestyle interventions targeting more than one health behaviour** (multiple risk factor interventions) can be effective in improving health behaviour. The evidence found relates to different combinations of health behaviours (from diet, physical activity, smoking) but all studies found reported improvements in overall health behaviour.

19. **A range of type of intervention** (e.g. cognitive behavioural therapy, motivational interviewing and problems solving or educational and counselling interventions) can be effective in delivering lifestyle interventions targeting more than one health behaviour.

20. **Internet based interventions can be effective** for delivering lifestyle interventions targeting more than one health behaviour. There was some evidence that when interventions were delivered via the internet that complex interventions were more effective than single component interventions.

21. **Social networking sites are not recommended** for delivery of lifestyle interventions to people in midlife – current evidence suggest these are not effective in midlife.

Disadvantaged or minority groups

22. **Provision of supporting PA interventions:** The findings on PA suggest that support, provided by instructors, facilitators, family and friends is important for supporting individual efforts to increase PA. Evidence suggests those interventions focused on improving the PA in ethnic minority and disadvantaged groups have greater success if they incorporate social support, group delivery and motivational components.

23. **Provision of community level PA interventions:** Evidence suggests that community-based interventions can be more effective, than individual focused interventions, in socioeconomically disadvantaged communities**.**

24. **Provision of community outreach workers from ethnic minorities for changing smoking behaviours:** Evidence suggests trained culturally sensitive community outreach workers can be effective in promoting smoking cessation behaviour among Pakistani and Bangladeshi men. Smoking cessation outreach workers compared with

standard care were able to improve rates of access to smoking cessation services. Trained community outreach workers could be applied in the UK amongst similar populations. If rolled out to other communities such a program would require recruitment and training of individuals from diverse ethnic groups. Economic evaluation demonstrated the intervention proved feasible and acceptable.

25. **Increase provision of culturally sensitive smoking cessation/reduction programs:** Evidence suggests culturally sensitive interventions can help improve smoking reduction, cessation rates and improved uptake of dental health check-ups. Interventions consisted of self-help, NRT, and community-based interventions, as well as individual, group, and telephone counselling. Due to the lack of longitudinal research the long-term impact is unclear.

26. **Increase provision of cultural and gender sensitive diet and/or physical activity interventions:** Evidence suggests these interventions can improve dietary and/or physical activity behaviour in BME communities, in particular the South Asian population. Interventions were delivered at community-level or in primary care. Components included individual tests and CHD/diabetes risk profile, nutritional support from dietetic clinics, optional practical activities including cookery workshops, exercise classes and awareness sessions. Delivered at into the community by health visitors and South Asian community workers with interpreter and translator services.

27. **Increase provision of health promotion interventions in homeless shelters:** Evidence suggests that homeless individuals are at high risk of a number of and non-communicable chronic diseases. Interventions delivered directly into a homeless shelter setting were more likely to increase attendance at community mental health centres.

1. INTRODUCTION

1.1 Background

Despite a wealth of evidence on the association between low physical activity, smoking, alcohol consumption, diet, and with ill health in later life, an alarming proportion of the adult population continues to engage in unhealthy behaviours. These behaviours are strongly associated with the development of non-communicable chronic diseases in later life; though the multiple processes leading to it have been shown to start much earlier. A comprehensive public health strategy aimed at preventing chronic diseases, frailty, disability, and dementia would thus support a range of interventions across the life cycle to increase the uptake and maintenance of healthy behaviours.

Along those lines, most public health guidelines provide general and specific recommendations to promote healthy behaviours in children, adults, and to some extent older people. However, very few recommendations exist to date for adults *in midlife*. This segment of the population is highly heterogeneous and individuals that make up this segment are likely to share some of the same issues and challenges when it comes to changing or maintaining behaviours. To effectively "reach" that population and have it engage in health promotion initiatives, interventions need to be tailored to – or at least consider – their specific needs and circumstances.

The Department of Health (DH) has asked the National Institute for Health and Care Excellence (NICE) to produce public health guidance on preventive approaches to be adopted in mid-life to delay the onset of disability, dementia and frailty in later life. Three evidence reviews and an economic model underpin the guidance. The reviews assess evidence on a wide range of potential influences on well-being in later life (i.e. demographic, economic, geographical, physical, cultural and social factors). The effectiveness and cost effectiveness of available interventions to act on these factors is the focus of this third report.

1.2 Aims of the review

This review is the third of three to be conducted to inform the guidance on which primary prevention behaviours to be adopted in mid-life are most effective and cost-effective to prevent and delay the onset of disability, dementia and frailty in later life. The full scope of the guidance is available in the final scope document (Final Scope, NICE 2013) that incorporates stakeholder comments from a 4-week consultation (21 March to 18 April 2013).

1.3 Research questions

The specific questions addressed in this review (Review 3) are:

- What are the most effective and cost-effective midlife interventions for increasing the uptake and maintenance of healthy lifestyle behaviours?

- To what extent do interventions targeted at these different health behaviours prevent or delay dementia, prevent or delay frailty and disability related to modifiable lifestyle risk factors, or prevent or delay non-communicable chronic diseases?

The two other reviews (and study protocols) related to this one addressed the following questions:

Review 1: A review of the key issues for people in midlife that prevent or limit or which help and motivate them to take up and maintain healthy behaviours.

- What are the key issues for people in midlife that prevent or limit, or which help or motivate them to take up and maintain healthy lifestyle behaviours and to what extent do they have an effect?

- How does this differ for subpopulations, for example by ethnicity, socioeconomic status or gender?

Review 2: What lifestyle factors in midlife are associated with successful ageing and the primary prevention or delay of dementia, non-communicable chronic conditions, frailty and disability? How strong are the associations and how does this vary for different subpopulations?

A conceptual overview of the three reviews and how Review 3 fits into the overall scheme is presented in Figure 1. The model details behavioural risk factors in midlife, interventions to improve or maintain healthy behaviours, intermediate biological risk factors that can be influenced by healthy behaviours and preventable outcomes relating to dementia, disability, frailty or non-communicable chronic conditions in later life. The model informed the searches and the selection of studies for the three reviews.

Figure 1.

Healthy behaviours

- Physical activity / Sedentary behaviours
- Diet
- Tobacco smoking
- Alcohol consumption
- Cognitive activities
- Noise exposure
- Work / Social activities / Participation

REVIEW 2

Association between behavioural risk factors and ageing well outcomes & common chronic conditions

REVIEW 1

Facilitators

Uptake & maintenance of healthy behaviours in mid-life

Barriers

- Personal factors (e.g. gender, SES, ethnicity, employment, family, previous experiences, expectations)
- Social factors (e.g. norms, support)
- Environmental factors (e.g. access to resources/interventions; residential & work environment)
- Organisational factors (e.g. design & delivery of intervention, resources)

REVIEW 3

Intervention

Effectiveness & cost effectiveness…

Effect on healthy behaviours

- Increase/maintain "good" levels of physical activity OR decrease sedentary life styles OR maintain balance, strength and weight-bearing functions
- Improve/maintain good diet & nutrition
- Reduce/prevent/stop tobacco consumption
- Decrease/prevent excessive alcohol consumption
- Maintain/increase cognitive and social activities, and participation
- Prevent / decrease excessive noise/ sun exposure
- Improve/modify multiple behavioural risk factors
- Remove barriers / facilitate uptake & maintenance of any life style behaviours WITH demonstration of impact.

Primary prevention of preconditions

- Impaired glucose intolerance
- High blood pressure
- High cholesterol
- Overweight / Obesity (weight loss or control)
- Impaired cognitive function (MCI)
- Mood disorders & mental health
- Functional limitations

Other relevant outcomes

- Resource use, costs, cost effectiveness

Effect on ageing Well Outcomes

- Disability (ADL, IADL, independence, mobility)
- Dementia
- Frailty
- Healthy life span
- Quality of life
- Participation

Effect on non-communicable conditions

- Cardiovascular diseases & stroke
- Renal disease
- Life style related cancers
- COPD
- Type II diabetes
- Osteoporosis / Bone health
- Hearing & Sight loss

1.4 Operational definitions

- Successful ageing is defined as survival to an advanced age while maintaining physical and cognitive function, functional independence and a full and active life. It means that morbidity and disability are compressed into a relatively short period before death, in line with the 'compression of morbidity' theory (Fries 2011).

- Disability will refer to any long-term restriction on the ability to perform an activity in the manner, or within the range, considered normal.

- Dementia will refer to a progressive, degenerative condition caused by diseases of the brain. Whether it occurs alone, in addition to, or as a combination of, chronic conditions, it is characterised by cognitive and non-cognitive symptoms of variable frequency and severity.

- Frailty will refer to a syndrome characterised by age-related declines in functional reserves where a small insult (e.g. infection, loss of partner) results in a striking and disproportionate change in health state. Frail older adults experience an increased risk of adverse outcomes such as falls, fractures, comorbidity, disability, dependency, hospitalisation, need for long-term care and mortality (Clegg 2013).

- Non-communicable chronic conditions (NCCs) will include cardiovascular diseases, diabetes, chronic obstructive pulmonary diseases, obesity, visual and hearing conditions, and some cancers that may be associated with behavioural risk factors.

- Disadvantaged populations will include (but are not limited to) low socioeconomic status, ethnic minority groups, lesbians, gay, bisexual and transsexual (LGBT) community groups, travellers and other groups with protected characteristics under the equality and diversity legislation.

1.5 Equality and equity issues

A core aim of this programme of evidence reviews is to identify prevention approaches that are tailored to midlife populations, focusing on those that have the greatest potential to maintain well-being in later life and avoid or reduce health inequalities. The reviews synthesise and highlight the evidence pertaining to groups or subgroups of the population that are at increased risk of ill health or less likely to benefit from preventive interventions because of biological, psychosocial factors, environmental factors – or a combination thereof (Ben-Shlomo 2003).

It is hoped that the combined outputs will provide an evidence base to address areas of concern for government and society – how to optimise health and well-being, and reduce

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inequalities in our ageing societies; how to tackle at a population level increasing health and social care demand; and how to change policy and practice through better use of research.

1.6 Review team

The expertise of the review team and the role of each member in the review are presented in Appendix C.

2. METHODOLOGY

2.1 Searches

The searches for this review (Review 3) were developed at the same time as the searches for Review 1 as both reviews focus on issues and interventions that prevent or limit the uptake or maintenance of healthy behaviours in midlife. Screening of search results however was conducted separately. An iterative approach involving the whole team was undertaken to develop the search strategies. The key steps were:

a) Initial team discussions around research questions

b) Initial drafting of search building at least (but not exclusively) on the final scope for this guidance, comments received from key stakeholders on the draft scope, high quality peer-review systematic reviews (when available) on same or similar topics for each key domains of the strategy, (e.g. health, preventative interventions, behaviours, etc.)

c) Testing of individual components and development of the review specific strategies in key databases

d) Refining of specific review strategies upon discussion with information specialist

e) Updating of search strategies based on reviewers comments

f) Adaptation of strategies to individual databases (i.e. Mesh terms or filters in one database don't usually apply to other databases)

g) Running of search and uploading of references in individual Endnote databases (for specified time period, i.e. since 2000).

h) Create a combined Endnote database (master file); delete duplicate and prepare for title screening

i) Identification of potential included studies; selection of full text for further assessment; identification of included and excluded studies (with reason for exclusion)

As initial searches suggest a large volume of search hits, searching was conducted in three stages: 1) searching for systematic reviews in midlife using a systematic review filter agreed with CPH; 2) targeted searches (e.g. vision and hearing loss, disadvantaged groups) for

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primary studies conducted in midlife where no SR were found; and 3) searching for systematic reviews that include studies with a broader age range than midlife. Due to the high number of search hits (and time constraints), we did not process the search results for primary studies that did not specify a mid-life focus in the title or abstract.

We searched the following electronic databases (with host platform) for peer-reviewed primary studies, systematic reviews and economic evaluations published since year 2000:

- MEDLINE (including MEDLINE – in-process) (Ovid)
- EMBASE (Ovid)
- PsycINFO (Ovid)
- CINAHL (EBSCO host)
- Health Management Information Consortium (Ovid)
- Social Science Citation Index (Web of Knowledge)

The following additional databases were searched for systematic reviews published since year 2000:

- HTA database
- The Cochrane Collaboration databases (www.thecochranelibrary.com)
    - Cochrane Database of Systematic reviews
    - Database of Abstracts of Reviews of Effectiveness

Searches were restricted to publications in English language. The detailed search strategies used to identify primary studies and systematic reviews are presented in Appendix D.

Finally, we conducted a thorough grey literature search (simultaneously for Reviews 1 through 3) to identify publications that may provide a source of relevant data. The websites searched are:

- NHS Evidence Search (www.evidence.nhs.uk)
- Open Grey (www.opengrey.eu)
- Public Health Observatories (www.apho.org.uk)
- Health Evidence Canada (www.healthevidence.org)
- Alzheimer's Society (www.alzheimers.org.uk)
- RNIB (www.fightforsight.org.uk)
- Fight for Sight (www.fightforsight.org.uk)
- Action on Hearing Loss (www.actiononhearingloss.org.uk)
- Beth Johnson Foundation (www.bjf.org.uk)
- British Library (http://www.bl.uk)

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- Campbell Collaboration (http://www.campbellcollaboration.org)
- Department of Health (https://www.gov.uk/government/publications)
- E-Print Network (http://www.osti.gov/eprints/)
- Google Scholar (http://scholar.google.co.uk)
- Grey Literature Report (http://www.greylit.org)
- Lenus (http://www.lenus.ie/hse/)
- OAIster (http://www.oclc.org)
- Public Health Europe (http://ec.europa.eu/health/index_en.htm)
- RAND Health (http://www.rand.org/health.html)
- Scirus (http://www.scirus.com)
- World Health Organisation (http://www.who.int/en/)

We did not conduct additional hand searches nor did we contact authors for additional data. However, the publication list of the Behaviour and Health Research Unit at the University of Cambridge (led by Professor Theresa Marteau) was searched for relevant publications as well as the responses to the NICE call for evidence relating to this guidance conducted between 31/5/2013 and 28/6/2013.

Records retrieved from the searches are reported according to Appendix C of the CPHE methods manual in Appendix F - these can be found in Appendices E and F of this report.

NOTE: the searches conducted in October 2013 (for Review 1) were updated on 3rd March 2014. The search results were processed exactly the same way as for the original searches. Appendices E and F present the breakdown of these searches.

2.2 Population

The populations covered by this review include:
- Adults aged 40-64 years, with a particular focus on people at increased risk of disability, dementia, frailty, or other NCCs due to behavioural risk factors.
- Adults aged 39 and younger from disadvantaged populations (as they are at increased risk of ill health and more likely to develop multiple morbidities). Disadvantaged populations include (but is not limited to) low socioeconomic status, ethnic minority groups, LGBT groups, travellers, and other groups with protected characteristics under the equality and diversity legislation.

This review does not cover the following populations:
- Adults with any type of dementia or pre-existing cognitive impairments in midlife

- Adults who are receiving treatment for a non-communicable chronic condition
- Adults who have a disability associated with behavioural risk factors were not included for that particular condition or disability

2.3 Interventions – scope

This review focuses on the effectiveness and cost-effectiveness of:

- Interventions in people in midlife (age 40-64 years) which help and motivate the uptake and maintenance of healthy behaviours that may impact on successful ageing, or to prevent or delay dementia, disability, frailty (including bone health) and common NCCs.

- Interventions in people in midlife (age 40-64 years) which impact on successful ageing, or to prevent or delay dementia, disability, frailty (including bone health) or NCCs related to behavioural risk factors.

- Interventions in adults aged 18-39 from disadvantaged populations (as they are at increased risk of ill health and more likely to develop multiple morbidities) which help and motivate the uptake and maintenance of healthy behaviours that may impact on successful ageing, or to prevent or delay dementia, disability, frailty (including bone health) and common NCCs.

- Disadvantaged populations are defined above in section 2.2. Examples of NCCs include (but are not limited to) cardiovascular diseases, diabetes, chronic obstructive pulmonary disease (COPD), visual and hearing conditions and some cancers that may be associated with behavioural factors and lifestyle.

The scope includes (but is not limited to):

- Uptake or maintenance of healthy behaviours including less sedentary behaviour, increased physical activity, improved diet or components of diet (e.g. fat and salt intake, fruit and vegetable intake), weight loss or control, cessation or reduction of smoking, reduction or modification of alcohol consumption, maintain sufficient levels of social activity and avoid loneliness (this may vary for individuals), to avoid excessive exposure to noise and address hearing and/or sight loss, or to improve/modify multiple behavioural risk factors and health behaviours in general.

- Uptake or maintenance of healthy behaviours at individual, family, community, subnational or national level (these may be targeted at specific groups, particularly those who are at increased risk, or who are from disadvantaged groups, or are healthcare professionals).

- Uptake or maintenance of healthy behaviours in a range of settings including primary and

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secondary care, and workplace and community settings in the private, public, voluntary or commercial sectors.

Interventions to promote lifestyle and/or behaviour change such as the primary prevention of overweight or obesity or are covered by the scope of the review and the guidance. However, interventions for the secondary prevention or management of such conditions or for people with existing dementia, disability, chronic disability or frailty fall outside the scope of this review and the guidance, except for weight loss interventions in people who are overweight (but not obese).

Finally, the scope of the review does <u>not</u> cover interventions in the areas of:

- Use of drugs to prevent or treat dementia and NCCs
- Use of drugs for smoking cessation
- Use of dietary supplements
- Diagnosis and care of disability, dementia, frailty and NCCs
- Management of existing disability, dementia, frailty and NCCs
- Recreational drug use (except for alcohol and tobacco/smokeless tobacco)
- Management of obesity, including medical and surgical interventions for obesity
- National policies, laws and taxation
- Assessments of implementation or translation of interventions
- Changes in knowledge and attitudes related to health behaviours

2.4 Review outcomes

The focus of this review is on the effectiveness and cost-effectiveness of midlife interventions for increasing the uptake and maintenance of healthy behaviours and the extent to which interventions targeted at these different health behaviours prevent or delay dementia, disability, frailty and NCCs related to modifiable lifestyle risk factors.

The review includes quantitative effectiveness and economic outcomes of intervention studies relating to:

a) Measures of uptake or maintenance or change in healthy lifestyle behaviours. e.g. rates of smoking cessation, physical activity uptake, participation or amount, change in diet or components of diet, such as increase in fruit and vegetable intake, prevention of weight gain, weight loss, control or maintenance in people who are overweight.

b) Delivery/design of interventions e.g. setting, mode of delivery, personnel (e.g. lay, healthcare professionals).

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c) Measures of successful ageing, or outcomes related to dementia, disability, frailty, NCCs e.g. ADL, IADL, independence, mobility, physical function, cognitive function, bone health (e.g. osteoporosis, fractures, bone mineral density), healthy life span, mortality, mental health, participation, incidence of CVD, cancer, diabetes, renal disease, COPD, mental health.

d) Outcomes relating to cost-effectiveness would include (but are not limited to): resource use, costs, cost-effectiveness, and cost-utility.

The following outcomes are not included:

e) Preconditions for dementia, disability, frailty or NCCs except those included in c) above. Impaired glucose intolerance, blood pressure/hypertension, lipids (including cholesterol) were excluded.

f) Biochemical or physiological markers of mechanisms for dementia, disability, frailty or NCCs or preconditions e.g. C-reactive protein, endothelial function, DNA damage were excluded.

2.5. Inclusion criteria – types of studies

Types of studies included in this review are quantitative intervention studies including randomised controlled trials (RCTs), controlled trials and systematic reviews.

Priority was given to:

a) Primary studies in midlife (age 40-64) populations or in disadvantaged groups (age 18-39) published from 2000 onwards.

b) Systematic reviews of studies in midlife (age 40-64) populations or in disadvantaged groups (age 18-39) published from 2000 onwards.

c) However, there are a large number of systematic reviews relating to interventions in this area that cover a broader, general population age range e.g. 18-64. Such systematic reviews in the broader population were included where there were gaps in the evidence after including the types of studies in a) and b).

Initially, priority was given to identifying such general systematic reviews published from 2010 onwards. However when substantial gaps in the evidence remained, earlier systematic reviews were screened in stages e.g. from 2008 onwards, from 2005 onwards, and so on to 2000 to identify relevant reviews.

Priority was given to systematic reviews in which the majority of included studies are in

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populations with a mean age at midlife (40-64 years).

The review was developed in line with the 2012 editions of the CPHE methods manual and the CPHE process manual; and build on other methodological resources available through experts groups (such as the Cochrane and Campbell Collaborations)[1], the team expertise and an extended network of collaborators.

2.6 Inclusion criteria – dates of studies to be included

Systematic reviews and primary studies in midlife populations published from year 2000 onwards.

Systematic reviews with a broader age range for inclusion than midlife from 2010 onwards and then in stages back to 2000 onwards as described above.

2.7 Inclusion criteria – intervention studies

Populations: Adults at midlife (aged 40 to 64 years for the general population) with a particular focus on people at increased risk of the target conditions and adults in disadvantaged populations aged 18-39. Only studies from countries included in the Organisation for Economic Co-operation and Development (OECD) were included. However studies conducted in the UK were prioritised in the synthesis of data.

Interventions: The effectiveness and cost-effectiveness of:

- Interventions in people in midlife (age 40-64 years) which help and motivate the uptake and maintenance of healthy behaviours that may impact on successful ageing, or to prevent or delay dementia, disability, frailty (including bone health) and NCCs.

- Interventions in people in midlife (age 40-64 years) which impact on successful ageing, or to prevent or delay dementia, disability, frailty (including bone health) or NCCs related to behavioural risk factors.

- Interventions in adults aged 18-39 from disadvantaged populations (as they are at increased risk of ill health and more likely to develop multiple morbidities) which help and motivate the uptake and maintenance of healthy behaviours or that impact on successful ageing or prevent or delay dementia, disability, frailty (including bone health) and common NCCs.

Disadvantaged populations are defined above in section 2.2.

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[1] For example, the *Methodological Standards for the conduct of new Cochrane Intervention Reviews* and the *Guidelines for Systematic Reviews of Health Promotion and Public Health Interventions*.

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<u>Outcomes</u>**:** Quantitative outcomes from intervention studies comprise measures of effectiveness or cost-effectiveness relating to:

a) Measures of uptake or maintenance or change in healthy lifestyle behaviours, e.g. rates of smoking cessation, physical activity uptake, participation or amount, change in diet or components of diet, such as increase in fruit and vegetable intake, prevention of weight gain.

b) Delivery/design of interventions, e.g. setting, mode of delivery, personnel (e.g. lay, healthcare professionals).

c) Measures of successful ageing, or outcomes related to dementia, disability, frailty, NCCs, e.g. ADL, IADL, independence, mobility, physical function, cognitive function, bone health (e.g. osteoporosis, fractures, bone mineral density), healthy life span, mental health, participation, incidence of CVD, cancer, diabetes, renal disease, COPD, mental health, weight loss, control or maintenance in people who are overweight.

d) Outcomes relating to cost-effectiveness would include (but are not limited to): resource use, costs, cost-effectiveness, and cost-utility.

<u>Timescale</u>: No lower limit for study duration. Studies were included if outcomes are in midlife (40 to 64 years) or later life (>65 years).

<u>Language</u>: English language studies only.

2.8 Inclusion criteria – systematic reviews

Systematic reviews were included if they answered the review question and all were quality assessed (see 2.10). Evidence from systematic reviews and primary studies were checked and any overlapping data was excluded or reported to avoid over reporting of effect. The process for using review level material is described in more detail in section 2.13.

2.9 Identification of relevant studies

Titles and abstracts were screened independently by two reviewers using the inclusion criteria described above. Differences between reviewer's results were resolved by discussion and when necessary in consultation with a third reviewer. If after discussion, there was still doubt about a study's relevance for the review the full paper was obtained.

Full paper copies were obtained for studies identified at the title/abstract screening stage. For primary studies, decisions were made based on inclusion and exclusion criteria. Full paper

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screening was carried out independently by two reviewers. Any difference of opinion about inclusion/exclusion was resolved by discussion between the two reviewers or by consultation with a third reviewer. If after discussion there was still doubt about a study's relevance for the review, the paper was retained and reassessed after quality assessment and data extraction.

A flow chart summarises the number of papers included and excluded at each stage of the process (Figures 2 and 3). Studies excluded at the full paper screening stage are listed in Appendix G along with the reason for exclusion.

2.10 Quality Assessment

Study designs were assigned using the glossary of study designs (Appendix D, CPHE methods manual) and the algorithm for classifying study designs (Appendix E, CPHE methods manual). Quality appraisal was then conducted using the relevant quality appraisal checklist in the NICE methods manual (Appendices F, G, H, I; CPHE methods manual) except for systematic reviews (see below).

Each full paper was assessed by one reviewer and checked for accuracy by another. A minimum of 10% of the studies was fully double assessed.

Systematic reviews

The methodological quality of each systematic review was assessed using the AMSTAR tool (www.amstar.ca). Each full review was assessed by one reviewer and checked for accuracy by another. A minimum of 10% of the studies was fully double assessed. Any discrepancy between reviewers was resolved by discussion.

The quality of the evidence presented in the included systematic reviews was not reassessed by the authors. The results were extracted into the evidence tables and a narrative summary is provided of the evidence presented in each of the systematic reviews.

2.11 Description of overall Quality Ratings

++   All or most of the checklist criteria have been fulfilled; where they have not been fulfilled the conclusions are very unlikely to alter.

+   Some of the checklist criteria have been fulfilled, where they have not been fulfilled or adequately described the conclusions are unlikely to alter.

-    Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

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QA ratings included in evidence summary statements: [++]/[+]/[-].

2.12 Data extraction

Data was extracted (SM, SK, LL) on study detail, population and setting, study design, outcomes, method of analysis, and results. To ensure accurate reporting the data extraction pro-forma was piloted against several included papers. Due to the number of studies and the timeframe we had to complete the review, double extraction was not done; data extraction was instead verified while writing the evidence statements.

2.13 Synthesis of evidence

Only quantitative evidence is included in this review. Findings are narratively synthesised and presented to inform guidance. Data specific to health inequalities and vulnerable communities are assessed and findings are summarised separately where sufficient data is available.

Information about included studies is presented in the summary and evidence tables in sufficient detail to ensure clear and transparent links between recommendations and evidence (Section 5, Appendix K, CPHE methods manual).

Key themes based on analysis of the evidence tables across each topic area are synthesised in a narrative format (where sufficient data is available to identify themes). Otherwise, a descriptive approach to the available evidence is taken (see section 5.4.5 CPHE methods manual).

For each key question or issue an evidence statement provides an aggregated summary of all of the relevant studies (Sections 5.5.1 to 5.5.5 CPHE methods manual). Applicability ratings are used to assess each evidence statement to judge how similar the population(s), setting(s), exposure(s) and outcome(s) of the included studies are to those outlined in the review question (Section 5.6 CPHE methods manual). Each evidence statement are rated as 'directly applicable, partially applicable or not applicable' by the reviewers.

3. FINDINGS

3.1 Searches

The searches for systematic reviews (Figure 2; Appendix E) located 11 389 articles after removing duplicates, 224 of which had relevant titles and abstracts. Of the 224 selected for full text assessment, 35 are included in the review. The searches for primary studies (Figure

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3; Appendix E) located 13 033 articles after removing duplicates, 335 of which had relevant titles and abstracts. Of the 335 selected for full text assessment, 51 are included in the review. One additional primary study supporting an economic evaluation is also included for a total of 52. Appendix G lists the excluded studies and the reasons for exclusion. In total, 87 studies are included in the review and form the basis of the evidence statements.
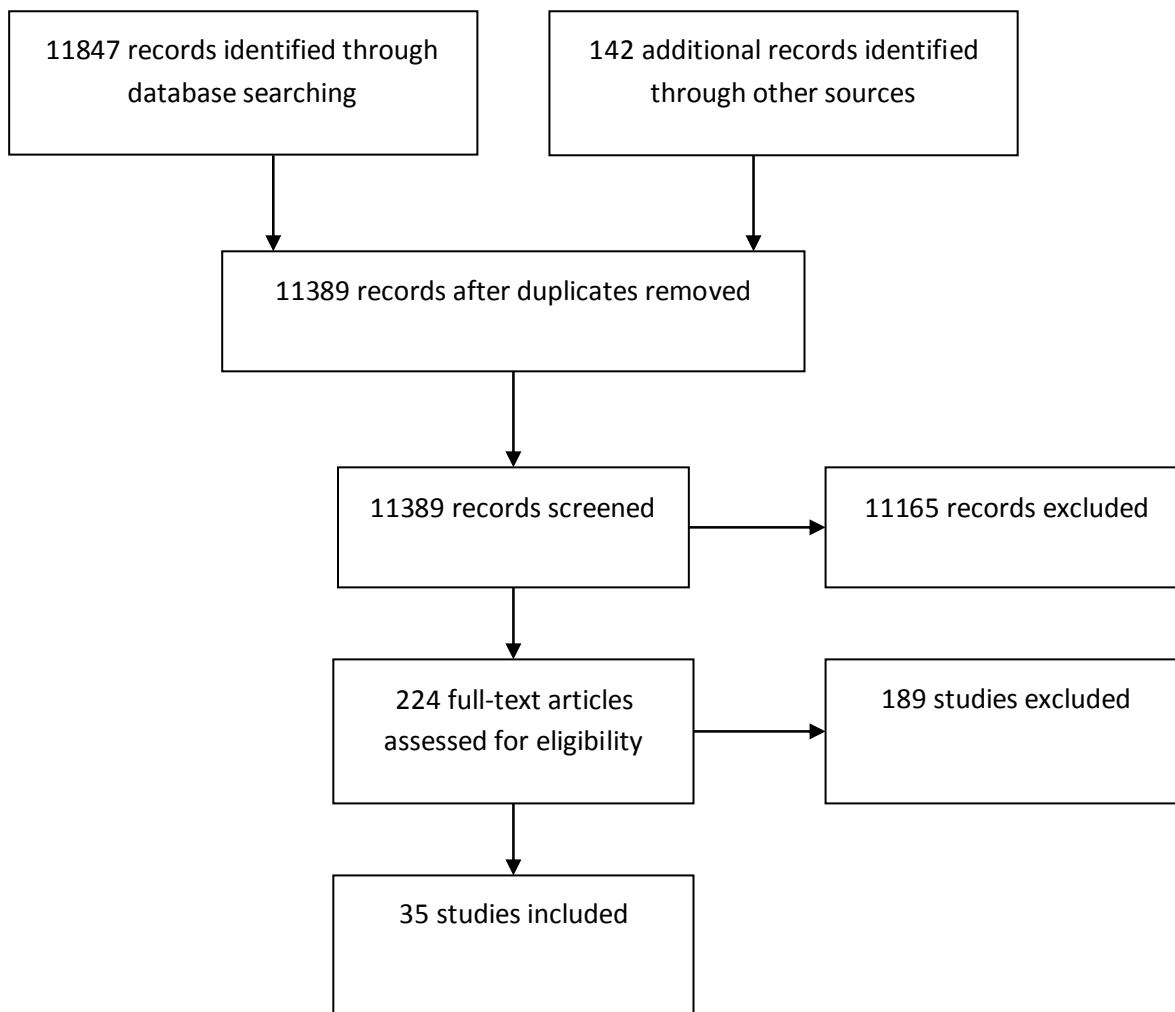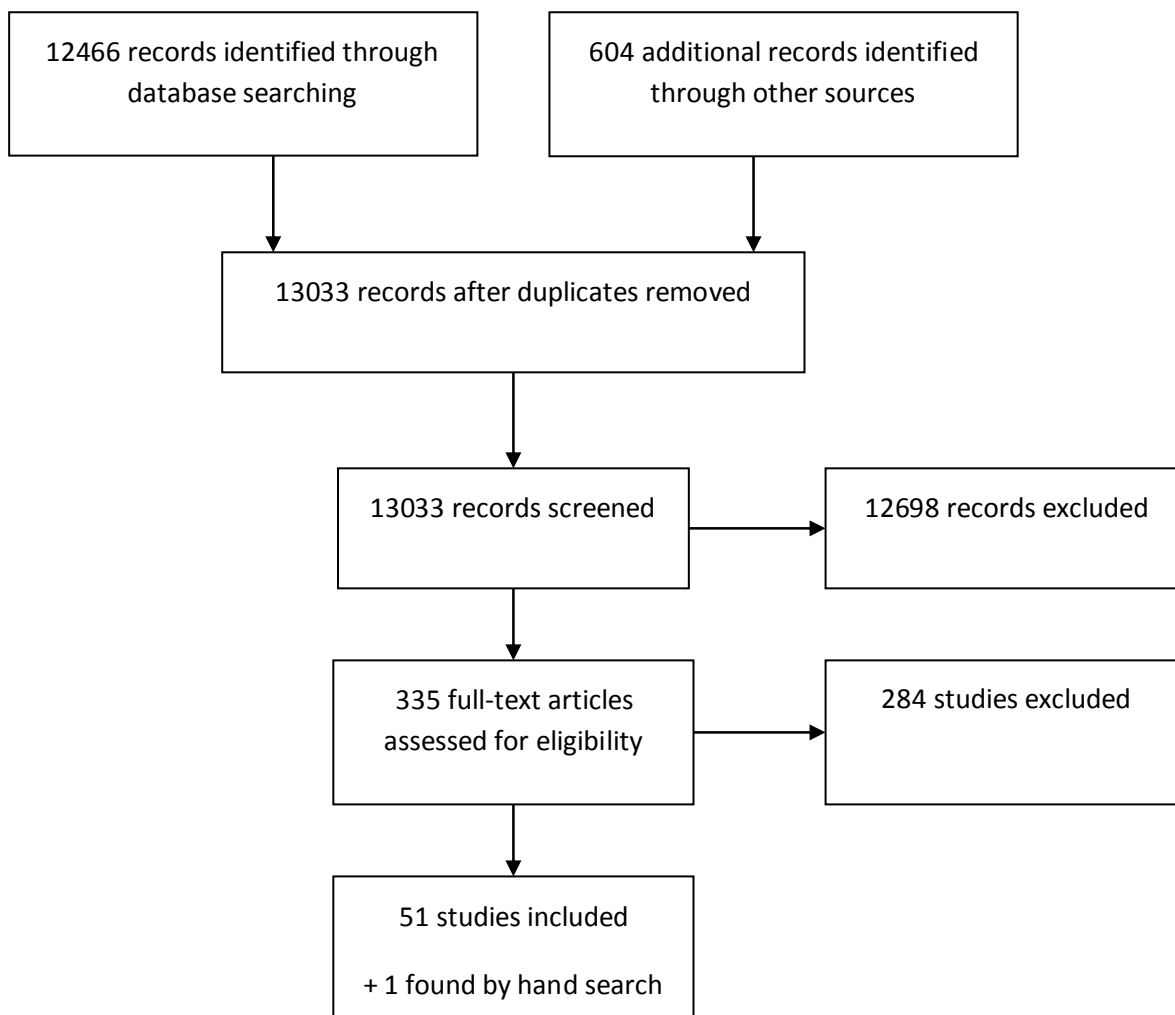
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Figure 2. Systematic Reviews

```
┌─────────────────────────────┐        ┌─────────────────────────────┐
│ 11847 records identified     │        │ 142 additional records       │
│ through database searching   │        │ identified through other     │
│                              │        │ sources                      │
└──────────────┬──────────────┘        └──────────────┬──────────────┘
               │                                       │
               └───────────────┬───────────────────────┘
                               ▼
               ┌─────────────────────────────┐
               │ 11389 records after          │
               │ duplicates removed           │
               └──────────────┬──────────────┘
                              ▼
               ┌─────────────────────────────┐      ┌─────────────────────────────┐
               │ 11389 records screened       │─────▶│ 11165 records excluded        │
               └──────────────┬──────────────┘      └─────────────────────────────┘
                              ▼
               ┌─────────────────────────────┐      ┌─────────────────────────────┐
               │ 224 full-text articles       │─────▶│ 189 studies excluded          │
               │ assessed for eligibility     │      └─────────────────────────────┘
               └──────────────┬──────────────┘
                              ▼
               ┌─────────────────────────────┐
               │ 35 studies included          │
               └─────────────────────────────┘
```

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Figure 3. Primary Studies

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┌─────────────────────────────┐        ┌─────────────────────────────┐
│ 12466 records identified    │        │ 604 additional records      │
│ through database searching  │        │ identified through other    │
│                             │        │ sources                     │
└─────────────────────────────┘        └─────────────────────────────┘
              │                                       │
              ▼                                       ▼
        ┌──────────────────────────────────────────────────┐
        │ 13033 records after duplicates removed           │
        │                                                  │
        └──────────────────────────────────────────────────┘
                              │
                              ▼
        ┌──────────────────────────┐        ┌──────────────────────────┐
        │ 13033 records screened   │───────▶│ 12698 records excluded   │
        │                          │        │                          │
        └──────────────────────────┘        └──────────────────────────┘
                      │
                      ▼
        ┌──────────────────────────┐        ┌──────────────────────────┐
        │ 335 full-text articles   │───────▶│ 284 studies excluded     │
        │ assessed for eligibility │        │                          │
        └──────────────────────────┘        └──────────────────────────┘
                      │
                      ▼
        ┌──────────────────────────┐
        │ 51 studies included      │
        │                          │
        │ + 1 found by hand search │
        └──────────────────────────┘
```

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3.2 Characteristics of included studies

This review includes 52 primary studies and 35 systematic reviews. A summary of the characteristics of included studies is presented for individual risk factors. For each risk factor, a table summarises the key findings of included studies (Tables 1 through 7), with more details about the population, design, intervention, effectiveness and limitations provided in the evidence tables (Appendix A).

3.2.1 Quality and applicability of studies

Appendix B summarises the quality of included studies. These scores are also integrated in the summary statements and the evidence tables. An applicability statement is provided for each evidence statement.

Overall, the evidence cited in the review is good (or very good) and the applicability directly or partially applicable.

3.3 Evidence for PHYSICAL ACTIVITY (PA)

Characteristics of included studies PA

We included 44 papers on interventions aimed at changing physical activity levels in mid-life: 22 primary studies (including two combining PA and diet; published since 2000), 17 systematic reviews (SR) (published since 2010), and five economic studies (of which one is also a primary study; published since 2010). Tables 1a-1e present a summary of the data and Appendix A1-A3 the data extraction tables.

Primary Studies

The mid-life focused searches (from 2000 to March 2014) identified 22 papers on physical activity meeting our inclusion criteria. These were conducted in the UK (n=3); the USA (n=7); Canada (n=1); Norway (1); Japan (n=3); Mexico (n=1); Australia (n=2); Greece (n=1), Germany (n=2) and Norway (n=1). The length of follow-up ranged from eight weeks (King 2008; King 2013; Moustaka 2012) to two years (Elavsky 2010). There were a total of ten (n=10) studies recruiting only female participants, four (n=4) recruited only male samples, and mixed samples were recruited in seven (n=7) studies. One study did not report gender or age distribution (Maiorana 2001). One primary study focused on deprived urban neighbourhoods (Goyder 2014), and one in men of Pakistani origin (Andersen 2014).

There is great variety in the types of interventions assessed in these studies. The studies are broadly grouped to help with recommendations:

- Walking, cycling

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- Yoga, tai chi, stretching

- Motivational intervention (with varied underpinning theoretical models)

- Exercise/training programmes (in home, groups or class, including weight training and cardiovascular training)

- Supportive, educational and awareness raising (information, media campaigns, etc.)

- Diet & exercise

We also present evidence statements pertaining to mode of delivery, namely new media, and for disadvantaged and minority communities.

These studies are summarised in **Table 1a**.

<u>Systematic Reviews (SR)</u>

We found 17 SR looking specifically at the effect of physical activity interventions in midlife or that have a majority of included studies focused on midlife. Of these, four (n=4) were specifically targeting interventions delivered in mid-life (Bolam 2013; Cavill 2012; Ferreira 2012; Hobbs 2013), eight (n=8) included a majority of studies conducted in midlife (Abioye 2013; Conn 2011; Davies 2012; Foster 2013a-c; Leavy 2011), three SR focused on interventions delivered in minority ethnic groups (Chapman 2013; Conn 2012; Ickes 2012), and two in disadvantaged groups (Cleland 2012; 2013).

There is also great variability in the scope of included SR, which makes it difficult to link each one to one of the categories described above. Eight (n=8) studies (including the papers in disadvantaged and minority groups) covered a broad range of interventions delivered across settings: four (n=4) on online/web application, two (n=2) exercise/training programmes, and two (n=2) focused on media campaigns.

Broad ranging interventions

- Conn et al 2011 [+] conducted a comprehensive meta-analysis to estimate the overall effect of interventions to increase physical activity among healthy adults, and to conduct moderator analyses to identify intervention characteristics associated with the best outcomes.

- Foster's et al 2013a [++] Cochrane review compared the effectiveness of face-to-face interventions for physical activity promotion in community dwelling adults (aged 16 years and above) with a control exposed to placebo or no or minimal intervention.

- Hobbs et al 2013 [++] evaluated the evidence and conducted a meta-analysis for the effect of behavioural interventions on self-reported physical activity in adults aged 55 to

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70 years (i.e. in around the retirement transition), focusing on studies that reported long-term effectiveness (≥ 12 months).

Online/web based

- Davies et al 2012 [+] conducted a meta-analysis of internet-delivered interventions to increase physical activity levels.
- Foster et al 2013b [++] did a Cochrane review compared the effectiveness of remote and web 2.0 interventions for PA promotion in community dwelling adults (aged 16 years and above) with a control group exposed to placebo or no or minimal intervention.
- Foster's et al 2013c [++] Cochrane review looked for studies comparing the effectiveness of face-to-face versus remote and web 2.0 interventions for PA promotion in community dwelling adults (aged 16 years and above); they found only one study (King 1991; excluded here based on date in this study) reporting the effect of a PA on cardio-respiratory fitness. The difference between the remote and web 2.0 versus face-to-face arms was not significant (SMD -0.02; 95% CI -0.30 to 0.26; high quality evidence).
- Cavill et al 2012 [-] performed a review and made recommendations for online physical activity and nutrition programmes targeted at over 40s.

Exercise/training programmes

- Bolam et al 2013 [++] systematically reviewed trials examining the effect of weight-bearing and resistance-based exercise modalities on the bone mineral density of hip and lumbar spine of middle-aged and older men.
- Ferreira et al 2012 [-] focused on programmes that involved the performance of any physical activity in community settings and workplaces and how these improve strength, balance, endurance and falls in adults aged 40-65 years.

Media campaigns

- Abioye et al 2013 [++] selected prospective studies that evaluated the effect of mass media campaigns on physical activity in adults (until 2012).
- Leavy et al 2011 [-] looked at the literature on physical activity mass media campaigns in general with a search limited to 2003-2010.

Disadvantaged groups

- Chapman et al (2013) [+] looked at the effectiveness of physical activity and dietary interventions (conducted in Western countries) in South Asian populations.

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- Conn et al (2012) [-] performed a meta-analysis of behaviour and health outcomes for physical activity interventions with healthy minority adults, including healthy African American, Hispanic, Native American, and Native Hawaiian adults.

- Ickes et al (2012) [+] conducted a SR of physical activity interventions in Hispanic adults.

- Cleland et al (2012) [+] conducted a SR looking at the effectiveness of physical activity interventions among socio-economically disadvantaged communities free of pre-existing disease. A follow-up paper was published (Cleland et al 2013) [+] presenting a meta-analysis looking at the effectiveness of interventions to promote physical activity among socioeconomically disadvantaged women; the intervention factors (i.e. physical activity measure, delivery mode, delivery channel, setting, duration, use of theory, behavioural techniques, participant age, risk of bias) associated with effectiveness were also studied.

These SR are summarised in **Table 1b**. **Table 1c** presents data from studies conducted in minority or disadvantaged groups, with **Table 1d** presenting data for combined PA and diet interventions in these groups.

Economic evaluations

We identified five papers pertaining to the cost effectiveness of physical activity in mid-life, four primary studies (Annemans 2007; Anokye 2011; Dalziel 2006; Goyder 2014), and one systematic review (Wu 2011).

- Annemans et al (2007) developed a 25-year Markov model to evaluate the long-term health and economic outcomes (cost-utility) of controlled and maintained physical exercise in a fitness setting for three types of target populations in the prevention of diabetes, coronary hearth disease, stroke, colon cancer and breast cancer.

- Anokye et al (2011) developed a decision analytic model to evaluate the cost-effectiveness of exercise referral schemes compared with usual care in UK primary care setting.

- Dalziel et al (2006) developed a Markov-model to estimate the cost-utility of the New Zealand Green Prescription physical activity counselling programme in general practice.

- Goyder et al (2014) conducted a RCT and cost-effectiveness evaluation of a community based 'booster' interventions to sustain increases in physical activity in middle-aged adults in deprived UK urban neighbourhoods. Although some individuals found community-based intervention supportive, the low levels of recruitment and retention and the lack of impact on objectively measured physical activity levels in those with adequate outcome data suggest that it is unlikely to represent a clinically effective or cost-effective intervention for the maintenance of recently acquired physical activity increases in

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deprived, middle-aged urban populations. The findings of the economic evaluation are not discussed further (but data is extracted in Appendix A).

- Finally, Wu et al (2011) [+] performed a systematic review of physical activity interventions and calculated their cost-effectiveness ratios.

These studies are summarised in **Table 1e.**

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Evidence statements for PHYSICAL ACTIVITY (PA)

Effect of PA interventions on uptake and maintenance of healthy behaviours

<u>**3.3.1PA** Effect across broad range of PA intervention types</u>

There is strong evidence from three systematic reviews [+][1] [++][2] [++][3] that physical activity interventions produced moderate, statistically significant increases in physical activity behaviour at 12 months; however maintenance beyond this is unclear. There is moderate evidence [+][1] that behavioural interventions appeared to be more effective than were cognitive interventions. There is moderate evidence [++][2] from moderate quality studies that the most effective interventions are those that offered both individual and group support for changing PA levels using a tailored approach; and that provision of information about local opportunities in the environment may be more effective [++][3].

One SR [+][1] conducted a comprehensive meta-analysis to estimate the overall effect of interventions to increase physical activity among healthy adults, and to conduct moderator analyses to identify intervention characteristics associated with the best outcomes. They calculated effect sizes from about 99,011 participants' data. Treatment versus control post intervention analyses comprised 74,852 participants (206 comparisons). The median of the mean age was 44 year, the median sample size was 72 participants (range = 5–17,579) with a median of 74% women; the median for minority participants was only 14% among studies. Interventions ranged from a single motivational education session to extensive supervised exercise sessions occurring over many weeks. The median duration of supervised exercise was 45 minutes. The median number of sessions was 27 supervised exercise encounters. Motivational interventions' median duration was 60 minutes, delivered in a median of five sessions. They found a mean effect size (*d*) estimate of 0.19 for treatment versus control post intervention comparisons and for treatment versus control pre–post comparisons. A mean effect size (*d*) of 0.33 was documented for treatment pre–post comparisons. These effect sizes indicate that, on average, interventions did increase overall physical activity after completion of the intervention. In contrast, control participants did not experience increased physical activity by participating in studies, as evidenced by a mean effect size of 0.00 (*d*). *Note*: findings from heterogeneity analyses (Q and I^2) suggest substantial variation in true effect size among studies. The two-group comparison mean effect size of 0.19 is consistent with a mean difference of 14.7 minutes per week of physical activity or 496 steps per day between the treatment and control groups – <u>so a modest effect</u>. If we assume true effect sizes are normally distributed (mean: 0.19; SD: 0.17 - Table 2, then the middle 95% of true effect sizes expressed in original metric gives (–11.0– 40.3) minutes per week or (–371–1363) steps per day. Moderator analyses identified several robust and moderately robust

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effect-size moderators associated with larger physical activity effect size: behavioural interventions (vs cognitive interventions that targeted knowledge, attitudes, or beliefs), interventions delivered directly to individuals (vs mass-media interventions and interventions targeting entire communities), interventions delivered by project staff (vs train-the-trainer models), physical activity behaviour being modelled by research staff, standardised interventions (vs individually tailored interventions), and absence of interventions based on social cognitive theory or the trans theoretical model.

One Cochrane review [++][2] compared the effectiveness of face-to-face interventions for PA promotion in community dwelling adults (aged 16 years and above) with a control exposed to placebo or no or minimal intervention, and a minimum of 12 month follow-up from the start of the intervention to the final results. A total of 10 studies recruiting 6292 apparently healthy adults from high income countries were included. The effect of interventions on self-reported PA at one year (eight studies; 6725 participants) was positive and moderate with significant heterogeneity ($I^2 = 74\%$) (SMD 0.19; 95% CI 0.06 to 0.31; moderate quality evidence) but not sustained in three studies at 24 months (4235 participants) (SMD 0.18; 95% CI -0.10 to 0.46). Although there were limited data, there was no evidence of an increased risk of adverse events (one study; 149 participants). Risk of bias was assessed as low (four studies; 4822 participants) or moderate (six studies; 1543 participants). There was some indication that the most effective interventions were those that offered both individual and group support for changing PA levels using a tailored approach. The long term impact, cost effectiveness and rates of adverse events for these interventions was not established because the majority of studies stopped after 12 months.

One meta-analysis [++][3] looked at the effect of behavioural interventions (published between 2000 and 2010) on self-reported physical activity in adults aged 55 to 70 years (i.e. in around the retirement transition), focusing on studies that reported long-term effectiveness (≥ 12 months). The review included results from 21 individual trials where the majority of interventions were multimodal and provided physical activity and lifestyle counselling. Interventions to promote physical activity were effective at 12 months (standardised mean difference (SMD) = 1.08, 95% confidence interval (CI) = 0.16 to 1.99, pedometer step-count, approximating to an increase of 2,197 steps per day; SMD = 0.19, 95% CI = 0.10 to 0.28, self-reported physical activity duration outcome), but not at 24 months based on a small subset of trials. There was no evidence for a relationship between intervention effectiveness and mode of delivery or number of intervention contacts; however, interventions which involved individually tailoring with personalized activity goals or provision of information about local opportunities in the environment may be more effective.

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[1] Conn 2011 [+]; [2] Foster 2013a [++]; [3] Hobbs 2013b [++]

- **Applicability**: Directly applicable – in all three SR the majority of included studies were conducted on adults (median age 44 years) in high income countries.

3.3.2PA Cost-Effectiveness across broad range of PA intervention types

Moderate evidence from a SR [+][1] suggest the most cost-effective strategies were for point-of-decision prompts (e.g., signs to prompt stair use), with a median cost of £0.04/MET-hour/day/person*; these strategies had tiny effects, adding only 0.2% of minimum recommended physical activity levels. The least cost-effective categories were the high-intensity "individually adapted behaviour change" and "social support" programs, with median cost-effectiveness ratios of £0.49 and £0.68 per MET-hour/day/person. However, they also had the largest effect sizes, adding 35%-43% of recommended physical activity, respectively. It is important to consider that the great majority of intervention increased physical activity by modest amount.

In addition there is moderate evidence from three cost utility analyses [+][2], [++][3], [++][4] that exercise referral schemes (UK and New Zealand) and controlled and maintained physical exercise in a fitness setting are cost effective approaches, with the caveat that cost per QALY estimates are sensitive to effectiveness and maintenance assumptions (due to limitation in evidence base).

* Based simply on currency exchange rate (updated 4th July 2104). Original data in US dollars $0.84* and $1.16 per MET-hour/day/person. Full indexation of original study findings is beyond the scope of this analysis.

The SR [+][1] calculates the cost-effectiveness ratios of PA interventions building on 91 effective interventions promoting physical activity identified by a SR (for a total of 141 intervention arms, across age groups), with enough information to translate effects into MET-hours gained. The approach tried to control for great variability across studies. Cost-effectiveness ratios were then calculated as cost per MET-hour gained per day per individual reached. Physical activity benefits were compared to U.S. guideline-recommended levels (1.5 MET-hours per day for adults and 3.0 MET-hours per day for children, equivalent to walking 30 and 60 minutes, respectively). Interventions are grouped as following categories: Point-of-decision prompts; community campaign; individually adapted behaviour change (low and high intensity); social support (low and high intensity); creation or enhanced access to places for physical activity.

Among the 141 study arms, 36 (26%) were, on average, able to increase the physical activity

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of participants who did not meet guidelines at baseline to achieving over 100% of recommended physical activity. Based on a benchmark of $1.00/MET-hour (or £0.58/MET hour)*, 97/141 arms of the 91 interventions (across age groups) could be considered cost effective. Most of the interventions targeting adults cost considerably less than $1.00/MET-hour (or £0.58/MET hour), with 62/115 arms costing less than $0.50/MET-hour (or £0.29/MET hour). Although the studies were analysed at face value, there is a large potential for measurement error and biases. In fact, the cost-effectiveness ratios varied dramatically even across interventions in the same category, targeting similar populations. Interventions with low cost-effectiveness ratios were found in all six intervention categories, although only a few were of the highest quality and also had objective measures. Nevertheless, these studies comprise evidence that increasing physical activity at a population level is likely to be feasible.

Annemans et al [+][2] developed a 25-year Markov model for maintained physical exercise in the prevention of cardiovascular and other prosperity diseases with a 12-month cycle-length and states representing diabetes, coronary heart disease, stroke, colon cancer and breast cancer to predict cumulative costs and QALYs for three defined population cohorts, of different risk levels. Physical exercise was thereby compared with no intervention. Costs were taken from a societal perspective; Belgium was selected as the setting. For each of the cohorts, physical exercise is predicted to increase the QALYs and to offset a large part of the initial investment. The cost per QALY varies from €2000 to €15 000 per QALY (£1590 to £11 926 per QALY)* depending on the risk levels. The authors concluded that controlled and maintained physical exercise is projected to be cost-effective, which is likely to be explained by its simultaneous effect on several diseases and the associated weight loss, which affects quality of life positively.

Dalziel et al [++][3] evaluated the economic performance of the 'Green Prescription' physical activity counselling program in New Zealand general practice (similar to ERS). A cost utility analysis using a Markov model was used to estimate the cost utility of the program over full life expectancy. Incremental, modelled cost utility of the Green Prescription program compared with 'usual care' was $NZ2,053 (£1048 per QALY)* per QALY gained over full life expectancy (range $NZ827 to $NZ37,516 per QALY; £422 to £19158 per QALY). Based on the probabilistic sensitivity analysis, 90% of ICERs fell below $NZ7,500 per QALY (£3830 per QALY) . Based on a plausible and conservative set of assumptions, if decision makers are willing to pay at least $NZ2,000 per QALY (or £1020 per QALY) gained the Green Prescription program is likely to represent better value for money than 'usual care'. The authors recommend that policy makers consider encouraging general practitioners to prescribe physical activity advice in the primary care setting, in association with support from

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exercise specialists.

In Anokye et al [++][3] a decision analytic model was developed to estimate the cost-effectiveness of ERS from a UK NHS perspective. The costs and outcomes of ERS were modelled over the patient's lifetime. Data were derived from a systematic review of the literature on the clinical and cost-effectiveness of ERS. Compared with usual care, the mean incremental lifetime cost per patient for ERS was £169 and the mean incremental QALY was 0.008, generating a base-case incremental cost-effectiveness ratio (ICER) for ERS at £20,876 per QALY in sedentary individuals without a diagnosed medical condition. There was a 51% probability that ERS was cost-effective at £20,000 per QALY and 88% probability that ERS was cost-effective at £30,000 per QALY. In sub-group analyses, cost per QALY for ERS in sedentary obese individuals was £14,618, and in sedentary hypertensives and sedentary individuals with depression the estimated cost per QALY was £12,834 and £8,414 respectively. Incremental lifetime costs and benefits associated with ERS were small, reflecting the preventative public health context of the intervention, with this resulting in estimates of cost-effectiveness that are sensitive to variations in the relative risk of becoming physically active, the cost of ERS and small changes in the effectiveness (due to limitations in the clinical effectiveness evidence base).

*Based simply on currency exchange rate (updated 4[th] July 2104).

[1] Wu 2011 [+], [2]Annemans 2007 [+],[3]Dalziel et al (2006) [++]; [4]Anokye 2011 [++]

- **Applicability:** Directly applicable; data from comprehensive review of the literature; one cost utility analysis conducted in UK setting.

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3.3.3PA Effect of Online / web based PA interventions

There is strong and consistent evidence from two SR ([++][4], [+][5]) to support the effectiveness of internet-delivered interventions in producing positive changes in physical activity at least at 12 months, however effect sizes were small [5][+] to moderate [4][++]. Screening for baseline physical activity levels and including educational components in the intervention significantly increased effectiveness. The ability of internet-delivered interventions to produce meaningful change in long-term physical activity however remains unclear. The most effective interventions tailored PA schedules and used telephone contact to provide feedback and to support changes in PA levels.

Findings from three primary studies focused on midlife (detailed below) are consistent with this statement (Ferney 2009 [++]; King 2008[+], King 2013 [++]).

One Cochrane review [++][4] compared the effectiveness of remote and web 2.0 interventions for PA promotion in community dwelling adults (aged 16 years and above) with a control group exposed to placebo or no or minimal intervention; included studies had a minimum of 12 months follow-up from the start of the intervention to the final results. A total of 11 studies recruiting 5,862 apparently healthy adults met the inclusion criteria. All of the studies took place in high-income countries. The effect of the interventions on self-reported PA at one year (nine studies; 4,547 participants) was positive and moderate (SMD 0.20; 95% CI 0.11 to 0.28; moderate quality evidence) with heterogeneity (I2 = 37%) in the observed effects. One study reported positive results at two years (SMD 0.20; 95% CI 0.08 to 0.32; moderate quality evidence). When studies were stratified by risk of bias, the studies at low risk of bias (eight studies; 3,403 participants) had an increased effect (SMD 0.28; 95% CI 0.16 to 0.40; moderate quality evidence). The most effective interventions applied a tailored approach to the type of PA and used telephone contact to provide feedback and to support changes in PA levels (telephone as the remote intervention). There was no evidence of an increased risk of adverse events (seven studies; 2892 participants). Risk of bias was assessed as low (eight studies; 3,060 participants) or moderate (three studies; 2,677 participants). There were no differences in effectiveness between studies using different types of professionals delivering the intervention (for example health professional, exercise specialist). There was no difference in pooled estimates between studies that generated the prescribed PA using an automated computer programme versus a human, nor between studies that used pedometers as part of their intervention compared to studies that did not.

Note: The effect of the interventions on cardiovascular fitness at one year (two studies; 444 participants) was positive and moderate with significant heterogeneity of the observed effects (SMD 0.40; 95% CI 0.04 to 0.76; high quality evidence).

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One meta-analysis [+][5] analysed the effectiveness of internet-delivered interventions to increase physical activity levels, whilst also examining the effect of intervention moderators. A total of 34 articles (January 1990 - June 2011) were identified for inclusion. The overall mean effect of internet-delivered interventions on physical activity was d = 0.14 (p = 0.00). Fixed-effect analysis revealed significant heterogeneity across studies (Q = 73.75; p = 0.00). Moderating variables such as larger sample size, screening for baseline physical activity levels and the inclusion of educational components significantly increased intervention effectiveness. Results of the meta-analysis support the delivery of internet-delivered interventions in producing positive changes in physical activity, however effect sizes were small. The ability of internet-delivered interventions to produce meaningful change in long-term physical activity remains unclear.

One additional review [-][6] reviewed online physical activity and nutrition programmes targeted at over 40s. The literature review resulted in 18 articles discussing specific online computer-based programmes, with ten (n=10) looking at PA alone, and eight (n=8) reporting on PA & nutrition (reported below). Age ranges varied greatly in the PA interventions, with five studies reporting general age ranges of between 18 and 59 years, over 18 years, or between 20 and 55 years; and three studies reporting age ranges of older adults 56 to 60 years, 50 to 69 years and 65 to 97 years. Sample sizes varied from 30 to 7,483 participants. Evidence suggests that the Internet is no more effective than print materials, face-to-face programmes and other health promotion methods. Several studies found positive short-term effects from using Internet-based programmes, including those aimed at our target group (40 years or more). Because it is not possible from this narrative review to extract data from studies focused in midlife (and the low quality of the review), these findings are not included in the evidence statements, although overall the conclusion appears consistent.

[4] Foster 2013b [++]; [5] Davies 2012 [+]; [6] Cavill 2011 [-]

- **Applicability**: Directly applicable – in all three SR the majority of included studies were conducted on adults (median age 44 years) in high income countries.

3.3.4PA Effect of Online versus face to face PA interventions
There is insufficient evidence ([7][++]; [1][+]) to assess whether face-to-face interventions or remote and web 2.0 approaches are more effective at promoting PA.

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One Cochrane review [++][7] looked for studies comparing the effectiveness of face-to-face versus remote and web 2.0 interventions for PA promotion in community dwelling adults (aged 16 years and above). One study recruiting 225 apparently healthy adults met the inclusion criteria and reported the effect of a PA on cardio-respiratory fitness. The difference between the remote and web 2.0 versus face-to-face arms was not significant (SMD -0.02; 95% CI -0.30 to 0.26; high quality evidence). There were no reported data for PA, quality of life, or cost effectiveness. The risk of bias in the included study was assessed as low, and there was no evidence of an increased risk of adverse events.

Moderator's analyses (i.e. results of dichotomous and continuous moderator analyses of treatment versus control post intervention effect sizes) in [+][1] showed that interventions with mediated delivery of interventions (e.g., mail, phone) had smaller effect sizes (0.15) than did interventions that were delivered face-to-face (0.29) in the single-variable analysis. The joint moderator analyses did not confirm the better effect size for face-to-face interventions.

[7] Foster 2013c [++]; [1] Conn 2011 [+]

3.3.5PA Effect of supportive, educational and awareness raising interventions in mid-life –
Mass media
There is moderate evidence from three SR ([++][8]; [-][9]; [+][1]) that mass media campaigns may increase awareness and may promote walking but may not reduce sedentary behaviour or lead to achieving recommended levels of overall physical activity [++][8]. Campaigns that promoted physical activity as a 'social norm' seemed to be more effective in reducing sedentary behaviour [++][8]; but were less effective than other strategies to increase physical activity [+][1].

In one SR [++][8] the authors meta-analysed the effect of mass media campaigns on physical activity. They included nine prospective cohorts and before-after studies (of moderate to high quality) conducted in high income countries (including the UK Active for Life campaign) that followed-up 27,601 people over eight weeks to three years. Mean age across studies ranged from 42.5 to 57 years, with proportion of male ranging from 31% to 45.9%; campaigns were delivered at local (n=3), regional (n=1), state (n=1) and national (n=4) levels. Based on the pooled results from these studies, mass media campaigns had a significant effect on promoting moderate intensity walking (pooled relative risk (RR) from three studies=1.53, 95% Confidence Interval: 1.25 to 1.87), but did not help participants achieve recommended levels of physical activity [four studies pooled RR=1.02, 95% CI: 0.91 to 1.14)]. The apparent effect of media campaigns on reducing sedentary behaviour (pooled RR=1.15, 95% CI: 1.03 to 1.30) was lost when a relatively low-quality study with large effects was excluded in a

sensitivity analysis. In subgroup analyses, campaigns that promoted physical activity as a 'social norm' seemed to be more effective in reducing sedentary behaviour.

Another SR [-][9] looked at physical activity mass media campaigns published between 2003 and 2010. The SR included 18 individual adult mass media campaigns (varied population target but mainly adults and mid-life), mostly in high-income regions and two in middle-income regions. Designs included: quasi experimental (n=5); non experimental (n=12); a mixed methods design (n=1). One half used formative research. Awareness levels ranged from 17 to 95%. Seven campaigns reported significant increases in physical activity levels. The review found that beyond awareness raising there is limited evidence of campaign effects.

In another broad SR [+][1] moderator analyses (i.e. results of dichotomous and continuous moderator analyses of treatment versus control post intervention effect sizes) also demonstrated that studies with mass-media approaches (0.08) were less effective than were studies using other strategies to increase physical activity (0.19), a results confirmed in the joint analyses.

[8] Abioye 2013 [++]; [9] Leavy 2011 [-]; [1] Conn 2011 [+]

- **Applicability:** Directly applicable. Studies from Western countries.

3.3.6PA Effect of supportive, educational and awareness raising interventions in mid-life – Individual based

There is little evidence to demonstrate a positive effect of individual supportive and educational interventions in mid-life on levels of physical activity. In some studies the authors report significant differences between groups; however, in other studies differences were reported as insignificant and interventions have not significantly promoted PA.

Effect on behavioural outcomes: One primary study reported a non-significant but positive difference [++][18], while another reported no effect [++][17] on physical activity. In one study [++][17] a total of 4,414 residents aged 40 to 79 years were recruited. The intervention consisted of three components: information delivery, education delivery and support delivery, all of which were implemented in all intervention communities (communities with a low population tended to have a quasi-population coverage rate greater than 100%, indicating that some residents received the educational activities multiple times). The results indicate that the proportion of respondents engaging in regular PA decreased from 64.6% to 60.3% in

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the control group and from 63.9% to 58.7% in the intervention group over 12 months; differences between groups were insignificant and the intervention did not significantly promote PA (adjusted OR: 0.97; 95%CI: 0.84–1.14).

Another intervention study ([++])[18] recruited 467 members of an angling club in the north of England (293 participants reported at the seven-month follow-up; response rate 62.74%). The intervention was delivered through a questionnaire and consisted of mental contrasting induction and measures of theory of planned behaviour variables. The mental contrasting induction included items which asked the participant to describe positive aspects of attaining their PA goal such as losing weight. Participants then identified impediments to reaching their goal for example finding the time. Those in the control condition did not complete the mental contrasting exercise instead they proceeded directly to the theory of planned behaviour items. No significant change in physical activity was observed among control participants (M_{change} = .43), $F(1, 41)$ = 1.08, ns, d = .32, whereas a significant, large increase in physical activity was observed among mental contrasting participants (M_{change} = 1.14), $F(1, 41)$ = 12.02, p < .001, d = 1.10.

Effect on non-behavioural outcomes: Evidence from supportive, educational and awareness raising interventions shows that physical activity can have a positive impact on blood pressure [++][17]. One intervention had significant influence for body fat and perceived barriers; however the authors reported no impact on selected biomarkers [+][19].

In another study [+][19] 31 healthy women with an average age of 56.1±4.9 years were randomly assigned to either tailored or standard newsletter groups. Three newsletters were delivered to the women via the Internet. The content encouraged participants to meet the Healthy People 2010 goals for physical activity and flexibility. Each newsletter had a content template of five to seven brief articles on physical activity goals, benefits and barriers to activity, and self-efficacy for activity. Tailoring was accomplished by creating a library of 350 text messages that corresponded to individual responses obtained at the baseline assessment. Repeated measures ANOVAs revealed improvement in perceived barriers to exercise for both groups. Changes also occurred in some of the physical activity biomarkers. Significant time effects were found in the sit-and-reach test, with both groups improving in flexibility. Post-hoc comparisons revealed that body fat decreased in the standard group (P = 0.039) and did not change in the tailored group. Significant time effects were found for perceived barriers ($F(1,27)$ = 5.62, P = 0.025) , with both groups declining in perception of barriers from pre- to post-intervention. Evidence also suggests that intention of an individual to undertake exercise was a significant predictor of behaviour of both women [+][19] and men [++][18].

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Duration of interventions lasted from equal to or less than seven months [++][18] [+][19] to over 12 months [++][17].

[17] Kamada 2013 [+]; [18] Sheeran 2013 [++]; [19] Hageman 2005 [+]

- **Applicability**: Directly applicable. One study was conducted in Japan [++][17], one was conducted in the UK [++][18] and one in the USA [+][19].

3.3.7PA Effect of walking, cycling, yoga, tai chi interventions in mid-life
There is moderate evidence from four experimental studies, three controlled [1][++], [3][+], [4][++] and uncontrolled [2][-], conducted in mid-life, to suggest that interventions, such as exercise prescription, yoga, walking, can influence decisions to start and to maintain physical activity.

In one study [++][1] a total of 143 sedentary or low active middle-aged (42–58 years) women completed a two-year follow-up survey to examine the impact of two structured exercise programs, walking and yoga, on self-esteem. The authors report that the intention of an individual to undertake exercise was a significant predictor of behaviour for women.

Effect on non-behavioural outcomes: In one study [++][1] evidence suggests that exercise for middle-aged women may have positive impacts on depression and self-efficacy which helped maintain healthy BMI levels; however, the only statistically significant long-term effect of the intervention was in the yoga group where participants continued to experience increases in self-efficacy across the two-year follow-up period ($\beta = -0.12$, $p < .05$).

Evidence from lifestyle-based weight management programs shows that physical activity can have a positive impact on blood pressure but not food consumption [-][2]. Four physically active middle-aged (43.2 ± 3.1 years) conventional Hatha Yoga practicing females were enrolled into an 11-week intensive yoga programme consisting of five sessions a week for 90mins (55 sessions). Each intensive session consisted of five minutes of supine relaxation in a savasana pose, five minutes of dynamic warm-up exercises and 80 minutes of asanas (yogic postures). All this included five minutes of pranayamas (breath-control exercises) and ten minutes of meditation in a lotus pose.

Evidence from a cardiovascular fitness intervention suggests physical exercise has beneficial effects very specific to memory functions rather than a wider range of cognitive functions [+][3].

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A total of 68 participants aged between 40 and 56 years were recruited and assigned to one of two training programs: aerobic endurance training (cycling) or non-endurance training (stretching/coordination). Mean age of these participants was 48.13 years (SD = 4.33), and 66% were female. Both groups exercised for 60 minutes, twice a week for six months, the cycling and stretching training took place at different times but in the same hall and were instructed by the same professional trainers. Participants not able to attend were allowed to take part in three sessions the following week. The training was completed when a participant had attended approximately 48 sessions. On average the intervention lasted 6.8 months (range: 4.7–10.3 months). The aerobic endurance group exercised on stationary indoor bicycles. Each participant was told a target heart rate that corresponded to 85% of their individual aerobic–anaerobic threshold (based on the cardiovascular fitness test at baseline). The goal was to exercise within this intensity range for approximately 45 minutes. The stretching and coordination training was intended to be similar to the cycling training but without the improvement to cardiovascular fitness. The programme encompassed stretching and toning of the whole body as well as exercises to improve coordination and flexibility. Results showed that the average heart rates were well below the aerobic–anaerobic threshold for the stretching group (average heart rate across all participants and all sessions: 101 beats/min, SD=9).

Effect on non-behavioural outcomes: In one primary study [+][4] there were non-significant improvements in mental health, stress and general health after participating in an exercise class. A total of 14 older nurses participated in a 15-week worksite Tai Chi program [+][4] which consisted of on-site Tai Chi classes once a week and ten-minutes practice each day alone at least four days per week for 15 weeks. Each Tai Chi class lasted 45 minutes, with ten minutes of breathing exercises, followed by 30 minutes of Tai Chi practice, and ended with five minutes of cool down exercises. The majority of the outcome measures did not show statistically significant group differences in their changes over time, the Tai Chi group did show larger improvements than the control group on all measures. The Tai Chi group showed non-significant improvement in general health and mental health (+1.2% and +2.1%, respectively) while the control group showed a decline in both (−4.6% and −3.8%, respectively). The Tai Chi group showed a greater reduction in work stress (−20% in NSS) than the control group did (−8.5%) post exercise (p = 0.89). The reduction in "lack of support" related stress nearly reached significant group effect (p=0.06). The Tai Chi group also showed a larger reduction in general stress (−23% in PSS) than the control group did (−17.5%) (p = 0.42).

Duration of interventions lasted from 11 weeks [-][2] to over one year [++][1].

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[1] Elavsky 2010 [++]; [2] Ramos-Jiménez 2009 [-]; [3] Hötting 2012 [+]; [4] Palumbo 2012 [++]

- **Applicability**: Directly applicable. Two studies were conducted in the USA ([++])[1], ([+])[4], Mexico ([+])[2], and Germany ([+])[3]

3.3.8PA Effect of motivational/behavioural PA interventions in mid-life

There is moderate evidence from six controlled experimental studies [5][+], [6][+], [7][++], [8][+], [9][+], [10][++] conducted in mid-life to suggest that motivational PA interventions can influence behaviour.

Effect on behavioural outcomes: One study [+][5] found an association between scheduling efficacy and uptake of behaviour, and found that the intention of an individual to undertake exercise was a significant predictor of behaviour for women [+][5]. The authors also reported positive impacts on levels of depression but no change on physical activity [+][5]. This intervention included 47 women (mean age 46.6 years) who were allocated to an implementation intentions or control condition. These women reported engaging in two or less strenuous bouts of physical activity per week over the past year. The participants then watched a presentation of a 30-minute video promoting exercise on how to include physical activity into their leisure time and introduced various types of activities participants could perform. Those in the experimental condition then formulated implementation intentions; these consisted of calendars to record the type of regular physical activity that was planned, the place where this activity would be performed, and the specific day and time period. Those in the control condition were given a calendar and were asked to list possible activities (mentioned in the video) that they might like to perform. Regression analyses showed that intentions were a significant predictor of behaviour for women in the experimental condition (p < .01). A significant Condition x Time interaction was found for scheduling efficacy (p < .03) and a non-significant interaction was found for perceived behavioural control (p = .06), indicating that only the experimental group increased scheduling self-efficacy and perceived behavioural control.

Interventions also reported increases in autonomy and competence, regulation and motivation [+][6]. A total of 35 female exercise participants age 30 to 58 years were recruited into an exercise programme which lasted for 24 classes. Each session was taught using either an autonomy-supportive or a lack of autonomy support instructing style. The exercise session lasted for 60 minutes in total, and in both comprised of dance aerobic exercises during the first 35 minutes and pilates-based strengthening exercises during the last 20 minutes with five minutes of stretching/cool down at the end. In the autonomy-supportive condition the exercise leader provided a rationale for the exercise activities pointing to the

health benefits and effects of exercise. Participants could also choose the music they preferred. In the control condition (lack of autonomy support) the instructor did not provide rationales and did not allow choices but she used neutral and not pressuring language. A 2×3 repeated-measures ANOVA indicated significant differences for Perceived Autonomy Support [$F(2, 66) = 174.60$, $P < .001$, $\eta^2 = .84$)] between the experimental and the control group. The experimental group displayed higher competence and autonomy compared with the control group ($P < .001$). Repeated-measures ANOVAs showed significant mean differences for amotivation [$F(3, 99) = 12.64$, $P < .001$, $\eta^2 = .27$)], external regulation [$F(3, 99) = 25.42$, $P < .001$, $\eta^2 = .43$)], introjected regulation [$F(3, 99) = 10.11$, $P < .001$, $\eta^2 = .23$)], identified regulation [$F(3, 99) = 10.16$, $P < .001$, $\eta^2 = .23$)], and intrinsic motivation [$F(3, 99) = 25.27$, $P < .001$, $\eta^2 = .43$)]. Independent samples t test showed that participants in the experimental group participated significantly more frequently during the exercise program than individuals in the control group ($t = 6.60$, $P < .001$). The experimental group participants (mean = 19.26 ± 1.45) attended the exercise classes more often than the control group participants (mean = 16.19 ± 1.28).

Effect on non-behavioural outcomes: There is also evidence to suggest that interventions based around the adoption of physical activity increases the level of physical activity in individuals ([++][7]; [++][9]; [++][10]) and caloric expenditure levels [+][8] and decrease sedentary behaviours (for example, leisure-time sitting) [++][10]. In one study [++][7] 256 women aged 30–50 years were allocated to receive either a health information intervention, or an information plus self-regulation intervention. All participants received the same information which consisted of three phases: an information phase in which participants studied a health education leaflet, a knowledge self-check phase in which participants worked through a multiple-choice test about a healthy lifestyle and a discussion phase in which participants compared their own answers with the correct answers provided by the interventionist. Participants also received a diary equivalent to the baseline diary to take home and use to record their physical activity. Those allocated to the information plus self-regulation group additionally learned a technique that integrates mental contrasting with implementation intentions. These participants wrote four items including their most important current wish regarding physical activity, the most positive outcome of realising their wish and events and experiences they associated with this positive outcome and the most critical obstacle. They also wrote three implementation intentions to the following questions: (1) When and where does the obstacle occur, and what can I do to overcome or circumvent the obstacle?; (2) When and where is an opportunity to prevent the obstacle from occurring, and what can I do to prevent it from occurring?; and (3) When and where is a good opportunity for me to act on my wish, and what would this action be? During the intervention session participants applied the self-regulation technique four times; twice to a long-term wish for the coming weeks and

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twice to a short-term wish for the next 24 hours. Participants also received a diary which contained two forms in a designated space on each day's page to be used to practice the self-regulation technique in the four follow-up diaries. Participants were encouraged to practice the self-regulation technique on their own each day, both in writing, using their diary, and mentally throughout the day.

In another study [+][8] 37 healthy, initially underactive, adults aged 50 years and older were recruited, the mean age of intervention participants was 60.7 (SD 6.8) and for controls it was 59.6 (SD 7.6). Participants included in the intervention arm received an instructional session and a hand-held computer programmed to monitor their physical activity levels twice per day and provide daily and weekly individualised feedback, goal setting, and support. The device was programmed to ask a series of 36 questions assessing contextual variables, amount and types of physical activities undertaken, behavioural and motivational factors. Participants also received standard physical activity education materials at the beginning of the intervention. Participants in the control group received standard, age-appropriate written physical activity educational materials. Intervention participants reported significantly higher levels relative to controls for minutes per week (baseline-adjusted mean = 310.6, SD= 267.4; control =125.5, SD=267.8; $F_{[1,36]}$ =4.2, $p=0.048$) and mean caloric expenditure (baseline-adjusted mean =1653.9, SD=1362.4; control mean =605.3, SD=1406.8; $F_{[1,36]}=5.0$, $p=0.03$). The most commonly reported facilitators of physical activity across eight weeks were good weather (33% of the time), good location (25%), enjoyable scenery (19%), scheduling in physical activity (18%), and having others join the participant (12%).

One study evaluated the impact of web-based interventions on physical activity [++][9]. One-hundred and six (72% women) inactive adults aged 52±4.6 years were randomised to receive either access to a neighbourhood environment-focused website or a motivational-information website. Website design and content focussed on promoting local opportunities for walking and other activities and contained 11 content areas; 'fact sheets'; 'activities'; links to relevant websites; an interactive goal-setting and self-monitoring tool; a searchable database of local opportunities for PA; a calendar of events; a map of the walking trail; PA profiles of each suburb; access to individualised email advice; a bulletin-board, and 'news' items updated bi-weekly. The emails sent to participants focused on cognitive and behavioural strategies for increasing PA as well as on opportunities for PA in the local area. The comparator website had four main sections corresponding to the motivational stages of change, and directed sequential movement. Statistically significant increases in walking and total physical activity were observed in both groups. There was also a statistically significant interaction effect for total physical activity, with neighbourhood group participants maintaining more of their initial increase in physical activity at week-26 ($p<0.05$).

In another study conducted with 68 adults [++][10], who were mostly women (73.5%) in mid-life (59.1 ± 9.2 years; range 45 to 81 years) three behaviour change apps were assessed for their impact. All three apps shared the following structural and behavioural elements: a glance-able display providing feedback of the user's current daily activity levels; passive activity assessment via the smartphone's built-in accelerometer; brief daily self-monitoring of activity and behaviour levels and contexts. A major focus was placed on health-enhancing moderate-intensity physical activities undertaken in episodes lasting at least ten minutes. Hours of sedentary activities per day also were also incorporated into the personalised feedback. Each app also had distinct elements; for the analytic app these included a user-specific goal-setting occurring weekly and based on the individual's preference. The social app included a live wallpaper display of individual avatars representing the user and other study participants randomised to use this app. For the affect app, an avatar in the form of a bird was used to reflect how active/sedentary the user was throughout the day. Participants across all three apps reported significant mean increases in weekly minutes of brisk walking across the eight-week intervention period (paired t = 5.3, p<0.0001) (between-group difference non-significant, p>0.73). The sample's mean baseline brisk walking minutes per week from the CHAMPS questionnaire was 79.9±92.3 (range = 73.7–88.6 across apps). Post intervention the increase in weekly minutes of brisk walking across the three apps averaged 100.8±167.0 minutes (Group Mean minutes/week increase ± SD: Analytic = 71.1±147.3; Social = 122.9±153.3; Affect = 105.7±187.2).

Interventions included exercise promotion via internet and smart phone apps ([+][8]; [++][10]) and motivational materials such as video [+][5]. Duration of interventions lasted from eight weeks ([+][8]; [++][10]; [+][5]) and 26 weeks [++][9], to over one year [+][6].

[5] Arbour 2004 [+]; [6] Moustaka 2012 [+]; [7] Stadler 2009 [++]; [8] King 2008 [+]; [9] Ferney 2009 [+]; [10] King 2013 [++]

- **Applicability**: Directly applicable. One study was conducted in Canada [+][5], one in Greece [+][6], and one in Germany [++][7]. Two studies were conducted in the USA ([+][8]; [++][10]) and one in Australia [++][9].

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3.3.9PA Effect of Diet and PA interventions in mid-life on uptake and maintenance of healthy behaviours

There is moderate evidence from two primary studies ([+][16], [++][20]) to suggest that combined diet and exercise modification in mid-life can lead to significant improvements in nutrition (decrease in dietary fat intake) [++][20] and physical activity behaviour ([+][16] [++][20]).

One 12-month RCT study [++][20] assessed the effectiveness of a motivational interviewing intervention on physical activity in the UK primary care setting. Primary-care patients were randomised to an intervention group that received standard exercise and nutrition information plus up to five face-to-face MI sessions, delivered by a physical activity specialist and registered dietician over a six-month period, or to a minimal intervention comparison group that received the standard information only. Intent-to-treat analyses revealed significant differences between groups for walking. Significant decrease in dietary fat intake that was maintained at 18 months (p< .001, d = 0.38) for the minimal intervention group (no difference in the motivational interviewing intervention group). The present study suggests that a low-intensity MI counselling intervention is effective in bringing about long-term changes in some health-related outcomes associated with CVD risk. The intervention was particularly effective for patients with elevated levels of CVD risk factors at baseline. The intervention lasted 12 months.

Another study [+][16] examined the single and combined effects of a one-year diet and exercise intervention. Participants were randomly allocated to four groups: diet counselling alone, exercise alone, the combination of the diet and exercise or control. Dietary counselling was given together with the spouse at the start, and then to the participants alone after 3 and 9 months and focussed on energy restriction. All participants (especially those with elevated total cholesterol) were recommended to consume fish and fish products, and reduce intake of saturated fat and cholesterol. Dietary compliance was assessed through a food frequency questionnaire. Participants underwent supervised endurance-based exercise (aerobics, circuit training and fast walking/jogging) three times per week. The attendance of each workout was recorded. The average exercise adherence was 61.3% in the exercise and 64.7% in the combined group. This corresponds to an average of 110 and 116 minutes of exercise per week throughout the year, respectively. The diet-only and control group did not change their physical activity habits; however there were no statistically significant differences in smoking habits between either of the groups. The composition of the diet changed in those who received dietary counseling, with a significant decrease in total fat

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intake in conjunction with increased polyunsaturated/saturated fatty acids ratio compared with control (p<0.05) and exercise-only groups (p<0.05).

[20] Hardcastle 2013 [++];[16] Anderssen 2007 [+]

- **Applicability**: Directly applicable. Studies conducted in the UK[20] and in Norway[16]

See section 3.9.5 for Diet & PA interventions in ethnic minorities.

Effect of PA interventions on SHORT TERM dementia, disability, frailty or non-communicable diseases outcomes (in mid-life)

Effect of exercise/training programme interventions in mid-life

3.3.10PA Bone health

There is evidence from one SR [++][1] that regular resistance training and impact-loading activities should be considered as an efficacious strategy to prevent osteoporosis in middle-aged and older men.

One SR [++][1] reviewed both randomised controlled and controlled trials examining the effect of weight-bearing and resistance-based exercise modalities on the BMD of hip and lumbar spine of middle-aged and older men. Eight trials detailed in nine papers were included. The interventions included walking (n = 2), resistance training (n=3), walking + resistance training (n=1), resistance training + impact-loading activities (n = 1) and resistance training + Tai Chi (n=1). Five of the eight trials achieved a score of less than 50% on the modified Delphi quality rating scale. Further, there was heterogeneity in the type, intensity, frequency and duration of the exercise regimens. Effects of exercise varied greatly among studies, with six interventions having a positive effect on BMD and two interventions having no significant effect. It appears that resistance training alone or in combination with impact-loading activities are most osteogenic for this population, whereas the walking trials had limited effect on BMD. Therefore, regular resistance training and impact-loading activities should be considered as a strategy to prevent osteoporosis in middle-aged and older men. High quality randomised controlled trials are needed to establish the optimal exercise prescription.

[1] Bolam 2013 [++]

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3.3.11PA Other outcomes

Cardio-respiratory fitness

There is limited evidence to suggest that combined exercise and dietary interventions can improve cardio-respiratory fitness [+][16].

In one study [+][16] authors examined the single and combined effects of a one-year diet and exercise intervention on cardio-respiratory fitness among middle-aged males (n=137; aged 40-49). The study was a randomised, controlled, 2x2 factorial intervention study. Participants were randomly allocated to four intervention groups: diet alone (n= 34), exercise alone (n=34), the combination of the diet and exercise intervention (n= 43) or control (n= 26). The average exercise adherence was 61.3% in the exercise and 64.7% in the combined group. This corresponds to an average of 110 and 116 minutes of exercise per week throughout the year, respectively. Cardio-respiratory fitness (measured during a maximal exercise test on a treadmill) increased significantly in the exercise groups compared with the control and diet-only group. The net change in percent vs control was 20.4% in the combined group and 15.0% in the exercise-only group. The intervention lasted 12 months.

[16] Anderssen 2007 [+]

- **Applicability**: Low applicability. Study conducted in Norway [+][16].

Metabolic syndrome

There is limited evidence to suggest that combined exercise and dietary interventions can reduce metabolic syndrome [+][16].

In one study [+][16] authors examined the single and combined effects of a one-year diet and exercise intervention on metabolic syndrome among middle-aged males (n=137; aged 40-49). The study was a randomised, controlled, 2x2 factorial intervention study. Participants were randomly allocated to four intervention groups: diet alone (n= 34), exercise alone (n=34), the combination of the diet and exercise intervention (n= 43) or control (n= 26). The average exercise adherence was 61.3% in the exercise and 64.7% in the combined group. This corresponds to an average of 110 and 116 minutes of exercise per week throughout the year, respectively. In the combined diet and exercise group, 14 participants (32.6%) (P<0.0001 as compared with control [n=26]) had the metabolic syndrome after one-year intervention. In the diet-only group, 22 participants (64.7%) (P<0.023 vs control) and in the exercise-only group 26 participants (76.5%) (P<0.23 vs control) had the metabolic syndrome following the intervention. Utilising the factorial design, both dietary and exercise intervention

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had significant effects (P<0.005) on the resolution of the metabolic syndrome. However, the combined diet and exercise intervention was significantly more effective than diet or exercise alone in the treatment of the metabolic syndrome. The intervention lasted 12 months.

[16] Anderssen 2007 [+];

- **Applicability**: Low applicability. Study conducted in Norway [+][16].

3.3.12PA Strength, balance, endurance, functional capacity and falls

There is moderate evidence SR [-][2] that exercise and training programs in community settings or workplaces has a moderate effect on strength, balance, endurance, but there is no evidence for falls. There is evidence from a primary study [++][11] to suggest that moderate intensity exercise may improve body composition, muscular strength and functional capacity in healthy middle-aged subjects. ***

Ferreira et al 2012 [-][2] focused on programs that involved the performance of any physical activity in community settings and workplaces and how these improve strength, balance, endurance and falls in adults aged 40-65 years. Twenty-three eligible trials were identified and 17 of these were pooled in the meta-analyses. The meta-analysis of strength outcomes found a moderate effect of physical activity on strength (SMD = 0.54, 95% CI 0.38 to 0.70). Larger effects were observed from programs that specifically targeted strength (SMD = 0.68, 95% CI 0.49 to 0.87), when compared to those that did not (SMD = 0.32, 95% CI 0.09 to 0.55). This difference was statistically significant (effect of strength in meta-regression p = 0.045). Physical activity also had a moderate effect on both balance (SMD = 0.52, 95% CI 0.24 to 0.79) and endurance (SMD = 0.73, 95% CI 0.50 to 0.96). No trials reported effects of physical activity on falls soon after receiving the intervention. A statistically non-significant effect on falls 15 years after receiving a physical activity intervention was found in one trial (RR = 0.82, 95% CI 0.53 to 1.26).

A primary study [++][11] to suggest that moderate intensity exercise may improve muscular strength and functional capacity in healthy middle-aged subjects. The study included 19 subjects (17 male, two female) aged 47 ± 2yrs (mean ± SE) who undertook circuit training consisting of combined aerobic and resistance exercise over an eight-week period. Exercise testing was undertaken on an electronic bicycle, with initial resistance set at 60 W and 20-W step-wise increments every three minutes. Duration of intervention lasted 16 weeks [++][11]. After the exercise programme:

- muscular strength (465 ± 27 to 535 ± 27 kg, P < 0.001) significantly increased.

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- improve functional capacity

*** The limitation of the searches are particularly relevant for these short term midlife outcomes – more studies are likely to be available documenting these effects in midlife.

[2]Ferreira 2012 [-]; [11] Maiorana et al 2001 [++]

- **Applicability**: Partially applicable. Quality of SR is low; primary study was conducted Australia [++][11]. These are reported here because no other data identified for these outcomes.

3.3.13PA Other outcomes

Waist to hip ratio and waist circumference

There is evidence from two primary studies [++][11], [+][12] conducted in midlife that aerobic exercise positively impact body composition. ***

There is evidence from a primary study [++][11] to suggest that moderate intensity exercise may improve body composition, in healthy middle-aged subjects. The study included 19 subjects (17 male, two female) aged 47 ± 2yrs (mean ± SE) who undertook circuit training consisting of combined aerobic and resistance exercise over an eight-week period. Exercise testing was undertaken on an electronic bicycle, with initial resistance set at 60 W and 20-W step-wise increments every three minutes. Duration of intervention lasted 16 weeks [++][11]. After the exercise programme, skinfolds decreased (144 ± 10 vs 134 ± 9 mm, P < 0.001).

Another study [+][12] reported that aerobic exercise was also significantly related to waist to hip ratio and waist circumference in healthy older men. In this study [+][12] a total of 17 healthy, sedentary, non-smoking 45- to 75-year-olds (mean 59.0 ± 2.0) were recruited from the community. A physiologist prepared individualised aerobic exercise training programmes for subjects. All training sessions began with ten minutes of low-intensity warm-up and flexibility exercises. The aerobic exercise training programme included stationary bicycling, walking, and jogging three times per week under the direct supervision of an exercise physiologist. Initially, subjects trained at 50-60% of heart rate reserve for short periods (3 x 5-10 minutes). The intensity and duration of the training were gradually increased to 75 to 85% of heart rate reserve for 30 to 45 minutes based on subjective responses.

*** The limitation of the searches are particularly relevant for these short term midlife outcomes – more studies are likely to be available documenting these effects in midlife.

[11] Maiorana et al 2001 [++]; [12] Pratley et al 2000 [+]

- **Applicability**: Low applicability. Study was conducted Australia [++][11] and the US [+][12]

General and mental Health

In another study [+][13] sedentary postmenopausal women aged 50 to 75 years were recruited and allocated into an intervention consisting of an exercise prescription (treadmill walking, stationary bicycling and light weight training) which lasted 12 months. Participants were asked to undertake moderate-intensity aerobic exercise five days per week (three sessions per week at the exercise facility plus two sessions at home) for at least 45 minutes. The intervention group showed a significant improvement in General Health after 12 months but non-significant changes in mental health. The authors also reported that the intention of an individual to undertake exercise was a significant predictor of behaviour for women [+][13]. Duration of intervention lasted over one year [+][13].

[13] Bowen et al 2006 [+];

- **Applicability**: Low applicability. Study was conducted in the USA [+][13]

Climacteric, psychosomatic symptoms, nervousness, quality of life

A study conducted with of 35 women aged 40-60 years (48.4±9.8) with climacteric symptoms found that interventions may also alleviate climacteric and psychosomatic symptoms in women but had no improvement on quality of life or attitudes towards exercise [+][15]. These women participated in a structured education and exercise program lasting 12 weeks, in which they learned about the menopause, nutrition, the environment and character, while also participating in physical activity (stretching, aerobic exercise, walking and weight training) at least three times a week. Women exercised for about 60 minutes during each session.

[15] Ueda et al 2004 [+]

- **Applicability**: Low applicability. Study was conducted in Japan [+][14]

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Effect of PA on long-term dementia, disability, frailty or non-communicable diseases outcomes (in later life).

No study found.

SEE SECTION 3.9.1, 3.9.2 AND 3.9.5 FOR EVIDENCE STATEMENTS FOR PA IN DISADVANTAGED GROUPS AND ETHNIC MINORITIES.

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Table 1a. Summary PHYSICAL ACTIVITY primary intervention studies (focus on mid-life)

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Walking, cycling, stretching promotion, yoga, tai chi								
Elavsky 2010	USA	Middle-aged women (n=143)	42-58 at enrolment 100% women	Walking: Structured & supervised walking program meeting three times per week for 1 hour OR Yoga: supervised yoga program meeting twice per week for 90 minutes.	Wait-list control condition	Physical Activity Body Mass Index Self-Esteem Self-Efficacy (2 years)	There were statistically significant path coefficients (p ≤ .05) for direct effects of physical activity (.14), exercise self-efficacy (.49) and BMI (−.27) on the physical condition self-perceptions. Increases in physical activity (.29), self-efficacy (.34) and decreased BMI (−.19) were significantly associated with improvements in physical condition.	++
Hötting 2012	Germany	Sedentary, healthy, middle-aged adults between 40 and 56 years of age	Cycling 48.06 (SD 4.32) Stretching 48.22 (SD 4.41) Control 47.06 (SD 4.33)	Cycling: Structured & supervised cycling program meeting two times per week for 1 hour OR Stretching: Structured & supervised cycling program meeting two times per week for 1 hour	Control	Physical activity, cognition (6.8 months)	Both the cycling and stretching group reported a similar amount of physical activity in hours per week (11.2 hours [SD 8.4] vs. 10.9 hours [SD 6.5], t(66)=0.14, p<.888). Participants of the stretching group improved more in the attention task than the cycling group (Time x Treatment F[1, 65]=7.10, p<.01). Both training groups showed a higher increase in the learning score of the episodic memory test than the control group (Time x Group, F[2, 83]=4.10, p<.020).	+

| Palumbo 2012 | USA | Registered Nurses or Licensed Practical Nurses (n=14) | Over 45 years of age | Tai Chi : 15-week, once a week 45 min worksite Tai Chi classes & 10min. on their own at least 4 days/week for 15 weeks. | Control | Physical and mental health (15 weeks) | The Tai Chi group showed non-significant improvement in general health and mental health (+1.2% and +2.1%) while the controls declined in both (−4.6% and −3.8%). The Tai Chi group showed a greater reduction in work stress (−20%) than controls (−8.5%) post exercise (p= 0.89). The Tai Chi group also showed a larger reduction in general stress (−23%) than the controls (−17.5%) (p=0.42) | + |
| Ramos-Jiménez 2009 | Mexico | Middle-aged and older women (n=4 in midlife; 9 older adults) | 43.2 ± 3.1 | Intensive Hatha Yoga: The IHY intervention consisted of 5 sessions/week for 90 min for 11 weeks (55 sessions) | No comparator | Body mass index, % body fat and Σ skin folds, Systolic and diastolic blood pressure and cholesterol (11 weeks) | Food consumption was not different between groups neither in terms of total energy intake (~1,916 kcal/day) nor in the energy contribution from protein (~17.2%), fat (~33.2%), and carbohydrates (~49.6%). After training, glucose, HDL-C, and TC increased in both groups (P < 0.05) | - |

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Motivational interventions								
Ferney 2009	Australia	Middle-aged adults (n=106)	Intervention 51.7±4.1 Control 52.2±5.0 72% women	Neighbourhood environment website & email advice (11 emails) (content areas: fact sheets; activities; links to websites; goal-setting & self-monitoring tool; searchable database of local opportunities for PA; calendar of events; map of local walking trails; PA profiles of each suburb a bulletin-board; news items.	Motivational-information website intervention	Walking Physical activity (26 weeks)	Statistically significant increases in walking and total physical activity were observed in both groups. Statistically significant interaction effect for total physical activity, with neighbourhood group participants maintaining more of their initial increase in physical activity at week-26 (p<0.05). *Conclusion*: A local neighbourhood-environment focused physical activity website was more effective at engaging participants and resulted in meaningful increases in physical activity relative to the motivational-information website.	++
King 2013	USA	Community-dwelling adults ages >45 years (n=68)	59.1±9.2 (range = 45–81) 73.5% women	3 daily activity smartphone app. based on motivational frames drawn from behaviour science theory to promote regular physical activity and reduce sedentary behaviour	Analytically framed app.: personalized goal setting, self monitoring, active problem solving re barriers to behaviour change	Changes in Moderate-to-Vigorous intensity physical activity Changes in discretionary sitting Time (8 weeks)	Participants across all three apps reported significant mean increases in weekly minutes of brisk walking across the 8-week intervention period (paired t = 5.3, p<0.0001) (between-group difference non-significant, p>0.73). Participants across all apps reported significant mean weekly increases in total moderate-to-vigorous physical activities (paired t = 4.5, p<0.0001) (between-group difference non-significant, p>0.99).	++

					Social app.: focused on social comparisons, norms, and support Affect app.: operant conditioning principles of reinforcemen t scheduling & emotional transference to an avatar, whose movements & behaviors reflected the physical activity & sedentary levels of the user			
King 2008	USA	>50 years old (n=37)	Interventi on 60.7 (SD 6.8) Control 59.6 (SD 7.6)	Self-regulatory behavioural strategies included: daily and weekly physical activity goal-setting; daily and weekly cumulative feedback; formats, and assessment of barriers and	Control: standard, age-appropriate written physical activity educational materials	Caloric expenditure/k g/wk and reported minutes/wk in moderate intensity or more vigorous physical activity	Intervention participants reported significantly higher levels relative to controls for mean minutes/week in MOD+PA (baseline-adjusted intervention Mean=310.6, SD 267.4 minutes; control mean=125.5, SD 267.8 minutes; F[1,36]=4.2, p=0.048); Mean caloric expenditure (baseline adjusted intervention mean=19.1, SD 16.8; control mean=7.8, SD 16.8; F[1,36]=4.0, p=0.05); and mean caloric expenditure in kcal/week in MODPA	+

						Barriers and facilitators (8 weeks)	(baseline-adjusted intervention mean=1653.9, SD 1362.4; control mean=605.3, SD 1406.8; F[1,36]=5.0, p=0.03). Conclusion: Hand-held computers may be effective tools for increasing initial physical activity levels among underactive adults.	
Arbour 2004	Canada	Female university and bank office employees (n=47)	46.6 (not reported)	Group session: 30-min video promoting exercise (to show how to include PA in leisure time) & participants formulated detailed implementation intentions over 8 weeks.	Group session: 30-min video promoting exercise (to show how to include PA in leisure time) & list activities seen in video that they might do	Leisure-time physical activity and physical activity (2 months)	There were no significant differences between the two groups on number of weeks that physical activity was performed twice (p > .60, two-tailed) or three or more times (p > .50, two-tailed).	+
Stadler 2009	Germany	Women aged 30–50 years (n=256)	41.28 (SD 6.19)	Information and cognitive behavioural strategies	Health information and information + self-regulation	Physical activity (4 months)	The mixed-effects model showed an effect of condition (F[1,204]=18.92, p<0.001) indicating that participants in the information + self-regulation group were more physically active than participants in the information group.	++
Moustaka 2012	Greece	Women aged 30 to	44.26 (SD 7.40)	Autonomy-supportive intervention based	Lack of autonomy support	Regulations in exercise; psychological	Significant differences in the needs for competence [F(2, 66) = 17.46, P < .001, η^2 = .34)] and autonomy [F(2, 66)	+

| | | 58 years | | on self-determination theory | instructing | needs; frequency of exercise (8 weeks) | = 37.48, P < .001, η^2 = .53]. Significant mean differences for a motivation [F(3, 99) =12.64, P<.001, η^2 = .27)], external regulation [F(3, 99)=25.42, P<.001, η^2=.43)], introjected regulation [F(3, 99) = 10.11, P<.001, η^2=.23)], identified regulation [F(3, 99) = 10.16, P<.001, η^2=.23)], and intrinsic motivation [F(3, 99) = 25.27, P<.001, η^2=.43)] between the groups. | |
| | | (n=35) | | | | | | |

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Exercise/Training programmes								
Bowen 2006	USA	Postmenopausal women (n=173)	(50 to 75yrs at entry; mean 61 – no details)	Exercise prescription: at least 45 minutes of moderate-intensity aerobic exercise 5 days per week for 12 months; combined exercise facility and home exercise program offered (3 sessions/week at facility for months 1,2,3; then at least 1 in facility for remaining 9 months)	Control: Weekly 45-min stretching sessions for the entire year-long study period, and were asked not to change other exercise habits during the study	Mental, physical & general health (SF36) Emotional symptoms (BSI) Social support Perceived stress Exercise adherence Cardio resp. fitness; knee pain; (1 year)	The intervention group showed non-significant between-groups difference in mental health at 12 months but showed a significant improvement in General Health from baseline to 12 months (p < .01). Some group specific mean values for other listed outcomes were significant: • The control group also had a significant improvement in Social Support – Affection from baseline to 12 months (p = .05), which was significantly higher than the improvement in the intervention group (p = .04). • Knee pain worsened in both groups • No significant between-groups or within-group differences for the remaining variables	+
Maiorana 2001	Australia	Middle-aged subjects (n=19)	47±2)	8 wk of supervised moderate intensity circuit training consisting of combined aerobic and resistance exercise (exercise bicycle, seven resistance	No comparator	Body composition (16 weeks)	There were no significant differences in plasma total, high density lipoprotein, low density lipoprotein cholesterol, or triglycerides after training. Body weight and segment girths did not significantly change after training, although the sum of skinfolds	++

				exercises)			(144±10 vs 134±9 mm, P<0.001) and waist:hip ratio (0.92±0.02 vs 0.90±0.02, P<0.05) significantly decreased	
Pratley 2000	USA	Healthy, nonsmoking 45- to 75-year-old men (n=17)	59.0±2.0	Moderate-intensity aerobic exercise: walked, jogged, or cycled at 50 to 60% heart rate reserve (HRR) three times per week for 30 to 45 minutes; progressed over 6 to 9 months until subjects were training at 80 to 85% of HRR for 45 to 60 minutes three to four times per week. Diets were stabilized to American Heart Association *Step* I diets before training, and calories increased to prevent weight loss.	No comparator or not reported	Body fat, fat distribution, diet intake, PA, Dietary Control (9 months)	Aerobic exercise training decreased body fat from 22.8 ± 1.6 to 20.8 ± 1.5% P<.0001), waist circumference by 2% (P=.038), and hip:waist ration by 1% (P=.035). Insulin responses during the oral glucose tolerance tests decreased 16% (P =.027) after training. Conclusion: Regular physical exercise may prevent or ameliorate conditions associated with hyperinsulinemia including dyslipidemia, hypertension, and atherosclerosis in this group	+
Ueda 2004	Japan	Middle aged women (with climacteric symptoms)	48.4±9.8	Structured education and exercise program (i.e. at least three times a week 90 minutes sessions,	Control (n=15): instructed to refrain from exercising!!!	Climacteric symptoms Quality of life Attitude	The program had significant effects on Kupperman index and psychosomatic symptoms, particularly paresthesia and nervousness.	+

				with 30 min learning about menopause which included info about diet, sleep and rest; and 60 min. aerobic class) (n=20)		towards exercise (12 weeks)	The program demonstrated no significant effect on QOL or attitudes towards exercise.	
Yoshika wa 2009	Japan	Middle aged women (n=29)	56±8	Educational session (e.g. measuring heart rate); walking daily & 90 minute exercise sessions once a week for 12 weeks (15min warm-up; 60min aerobic & strength exercises; 15 min cool down)	Control	BMI, % fat, SBP, DBP, T-Cho, HDL-Cho, Glucose, Insulin (3 months)	Significant reductions in BMI (P<0.001); weight (P<0.01); diastolic blood pressure (P<0.001). No statistically significant differences in systolic blood, plasma glucose, insulin, pressure or total cholesterol	+

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Effectiveness of supportive, educational and awareness raising interventions in midlife								
Hageman 2005	USA	Women ages 50-69 years	Not reported.	Newsletters from the Internet	Standard newsletter groups	Physical activity, perceived barriers and benefits (3 months)	Significant time x group interactions were observed for % body fat ($F_{(1,28)}$ = 6.46, P = 0.017). Significant time effects were found for perceived barriers ($F_{(1,27)}$ = 5.62, P = 0.025), with both groups declining in perception of barriers from pre- to post-intervention.	+
Kamada 2013	Japan	Residents aged 40 to 79 years.	Control 61.0 ± 10.6 Intervention 60.7 ± 10.5	Physical activity, information, education, and support delivery	Information leaflets or control	Physical activity, pain (1 year)	The proportion of respondents who engaged in regular PA decreased from 64.6% to 60.3% in the control group and from 63.9% to 58.7% in the intervention group in the intervention year. The effect size (OR, 95%CI) was not significant (0.97; 0.84–1.14).	++
Sheeran 2013	UK	Overweight, middle-aged, and low-SES men	53.88 (SD 12.42)	Mentally contrasting fantasy with reality	No comparator	Physical activity (7 months)	Significant difference in physical activity that favoured participants who had engaged in mental contrasting $F_{(1, 82)}$=15.50, p<.001, d=.87. No significant change in physical activity was observed among control participants (M_{change} = .43), $F_{(1, 41)}$=1.08, ns, d=.32, whereas a significant, large increase in physical activity was observed among mental contrasting participants (M_{change}=1.14), $F_{(1, 41)}$=12.02, p<.001, d=1.10.	++

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Effectiveness of diet and exercise midlife interventions								
Anderssen 2007	Norway	Middle-aged men aged 40 with metabolic syndrome (n=137)	44.9 (SD 2.5)	<u>Diet counselling alone</u>: given to participants & spouse at tart; then to participants only at 3 & 9mths; individualised reco which included fish, reduce sat. fat & cholesterol; energy restriction in overweight participants. <u>Exercise alone</u>: Supervised endurance-based exercise sessions (60 min) three times/week at intensity of 60–80% of the participant's individual peak heart rate as measured by a treadmill test at baseline.	Control: don't change your life style (Both groups advised against smoking)	Exercise Body composition Resolution of metabolic syndrome (1 year)	The net change in percent vs control was 20.4% in the combined group and 15.0% in the exercise-only group. The diet-only and control group did not change their physical activity habits. Both dietary and exercise intervention had significant effects (P<0.005) on the resolution of the metabolic syndrome.	+

				Dietary counselling + exercise program				
Hardcastle. 2013	UK	Aged 18–65 years and needed to exhibit at least one CVD risk factor	50.22 (0.58)	Low-intensity motivational interviewing	Minimal intervention counselling	Blood pressure, Cholesterol, Physical activity, Diet (18 months)	There was a significant increase in walking between baseline 18-months (p=.032, d = 0.20) in the intervention. For the biomedical outcomes, there were significant interaction effects for BMI, DBP, and cholesterol.	++

Table 1b. Summary PHYSICAL ACTIVITY systematic reviews (focus & with majority of primary studies in mid-life)

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Broad ranging								
Conn 2011	International	Healthy adults	Median 44 (18 to 88 years)	Behavioural and cognitive interventions	Interventions delivered face-to-face versus mediated interventions (e.g., via telephone or mail)	Physical activity behaviours or reducing sedentary behaviour (>6 months)	Interventions did increase overall physical activity. Overall mean effect size for comparisons of treatment vs control was 0.19. A mean effect size (d) of 0.33 was documented for treatment pre–post comparisons. Mean difference of 496 ambulatory steps per day between treatment and control participants. Control participants did not experience increased physical activity by participating in studies, mean effect size of 0.00 (d).	+
Foster 2013a	International	Community dwelling adults free from pre-existing medical conditions	(18 to 90 years)	Face-to-face interventions for PA promotion. They could involve one-off or ongoing interactions between the implementer and the participants that included counselling or advice, or both; self-directed or prescribed exercise, or both;	Placebo or no or minimal intervention control group	Cardio-respiratory fitness and PA levels expressed as an estimate of total energy expenditure (12 to 24 months)	The effect on self-reported PA at one year was positive and moderate (SMD 0.19; 95% CI 0.06 to 0.31) but not sustained in three studies at 24 months (4235 participants) (SMD 0.18; 95% CI -0.10 to 0.46). There was significant heterogeneity (I^2 = 74%). The effect on cardiovascular fitness at one year was positive and moderate (SMD 0.50; 95% CI 0.28 to 0.71). There was no significant heterogeneity.	++

				home based or facility based exercise, or both; written education or motivational support material, or both.				
Hobbs 2013	International	Adults	(55 to 70 years)	Interventions to promote long-term PA change. Seven trials compared multiple interventions at 12 months after randomisation	No intervention control condition	Physical activity behaviours 17 months (12 to 36 months)	Interventions were effective at 12 months SMD=1.08 (95% CI) 0.16 to 1.99, pedometer step-count, approximating to an increase of 2,197 steps per day; SMD=0.19 (95% CI) 0.10 to 0.28, self-reported physical activity duration outcome, but not at 24 months.	++

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Online / Web base								
Foster 2013b	International	Community dwelling adults free from pre-existing medical conditions	(18 to 74 years)	Remote and web 2.0 interventions. They could involve one-off or ongoing interactions between the implementer and the participants that included counselling or advice, or both; self-directed or prescribed exercise, or both; home based or facility based exercise, or both; written education or motivational support material, or both.	Placebo or no or minimal intervention control group	Cardio-respiratory fitness and PA levels expressed as an estimate of total energy expenditure (12 to 24 months)	The effect of the interventions on at one year was positive and moderate with significant heterogeneity of the observed effects (SMD 0.40; 95% CI 0.04 to 0.76) - difference in VO2 max. The effect of the interventions on self-reported PA at one year was positive and moderate (SMD 0.20; 95% CI 0.11 to 0.28). One study reported positive results at two years (SMD 0.20; 95% CI 0.08 to 0.32). There was no difference in pooled estimates between studies that generated the prescribed PA using an automated computer programme versus a human, or between studies that used pedometers as part of their intervention compared to studies that did not.	++
Davies 2012	International	Adults	43.06 years (18 to 69.5 years)	Internet-delivered physical activity behaviour change programs and the inclusion of educational component. 21	Group that did not receive internet-delivered materials	Physical activity 12.64 weeks (2 to 52 weeks)	The (small but positive) overall mean effect of internet-delivered interventions on physical activity was d = 0.14 (p = 0.00). Fixed-effect analysis revealed significant heterogeneity across studies (Q = 73.75; p = 0.00).	+

				studies included a combination of internet and email, 9 used internet only and 4 used email only				
Cavill 2012	Internatio nal	Adults aged 40 years and over	(18 to 97 years)	Online physical activity; and online physical activity and nutrition interventions	**PA** Comparison groups were used in 15 of the studies, with nine of these comparing tailored websites with non-tailored or standard websites; and six comparing websites with offline or usual care methods

PA/NUT Three studies compared online tailored | Physical activity and nutrition promotion; weight loss

(8 weeks to 13 months) | Twelve studies reported significant short-term effects on behaviour change or weight loss. Five out of the 10 online PA programmes reviewed reported positive results in behaviour change. The online PA/Nut programme studies showed mixed results, with seven studies reporting positive outcomes, and one having no significant results. Users benefited from strength and balance training online advice, increasing total physical activity and neighbourhood walking and some were successful in reducing weight and waist circumference. Unable to calculate pooled results given some numerical data not reported. | - |

					strategies with online non tailored/ standard strategies. Four studies compared Internet programmes with offline or usual care control groups			
Foster 2013c	Internatio nal	Community dwelling adults free from pre-existing medical conditions	(50 to 65 years)	Face-to-face/Remote Intervention with deliberate attempt to increase the PA levels of the participants. They could involve one-off or ongoing interactions between the implementer and the participants that included counselling or advice, or both; self-directed or prescribed exercise, or both; home based or facility based	Face-to-face versus remote and web 2.0	Cardio-respiratory fitness and PA levels expressed as an estimate of total energy expenditure

(12 months) | One paper was included in this review. Therefore there is insufficient evidence to assess whether face-to-face interventions or remote and web 2.0 approaches are more effective at promoting PA. The difference between the remote and web 2.0 versus face-to-face arms was not significant (SMD -0.02; 95% CI -0.30 to 0.26; high quality evidence). | ++ |

				exercise, or both; written education or motivational support material, or both.				

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Media Campaign								
Abioye 2013	International	Adults	(16 to 75 years)	Mass media campaigns conducted on local, regional or national levels with coverage ranging from 11 to 90%.	"proper control group"	Physical activity or reducing sedentary behaviour

(8 weeks to 3 years) | Mass media campaigns had a significant effect on promoting moderate intensity walking (pooled RR from 3 studies=1.53, 95% CI 1.25 to 1.87), but did not help participants achieve sufficient levels of physical activity [4 studies pooled RR=1.02, 95% CI: 0.91 to 1.14]. | ++ |
| Leavy 2011 | International | Community dwelling adults | (18-75 years) | Mass media campaigns including television commercials, public service announcements, radio commercials, paid and unpaid print media inserts, bus backs and wraps, billboards, | One study has control group; simply described as control | Moderate-intensity physical activity

(8 weeks to 5 years) | Only one campaign found a significant increase in any intention to be more active; however statistical data was not reported. Others reported smaller non-significant changes in intention to be more active. Seven studies reported a statistically significant increase in physical activity levels. Effect sizes ranged between these studies and *P* values ranged from < 0.05 to <0.001 however we are unable to calculate pooled results | - |

				print media, website traffic, public health activities, policy and environmental change			given some numerical data not reported.	

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Exercise training / programme								
Bolam 2013	International	Middle-aged and older men	(50 to 79 years)	Weight-bearing and resistance-based exercise modalities. Two included walking only, three included resistance training only, one included walking and resistance training, one included resistance training and impact loading activities and one included resistance training and Tai Chi.	Inactive controls or not described	Bone mineral density of hip and lumbar spine (3 months to 4 years: mean 13 months)	Significant increases in BMD in most of the resistance training programmes range from 0.7% to 3.8%, but unable to calculate given some numerical data not reported. Although not statistically significant, the exercise groups all lost less BMD than the control groups, in all but one of the studies.	++
Ferreira (2012)	International	Healthy adults	(40 to 65 years)	Performance of any physical activity in community settings	Compared a physical activity	Strength, balance, endurance,	A moderate effect of physical activity on strength (SMD = 0.54, 95% CI 0.38 to 0.70). Programmes that specifically	-

| | | | | and workplaces | program to a no-intervention control condition | falls

(8 weeks to 18 months) | targeted strength (SMD = 0.68, 95% CI 0.49 to 0.87), when compared to those that did not (SMD = 0.32, 95% CI 0.09 to 0.55).   Physical activity had a moderate effect on both balance (SMD = 0.52, 95% CI 0.24 to 0.79) and endurance (SMD = 0.73, 95% CI 0.50 to 0.96). There were greater effects on strength in trials that targeted strength specifically using resistance exercise (p = 0.045 for difference in effects in the meta-regression). | |

Table 1c. Summary PA intervention studies in disadvantaged and minority groups

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
Primary mid-life studies									
Physical activity – primary midlife studies in ethnic minority groups									
Andersen 2013	Norway	Men of Pakistani origin living in Oslo (n=150)	Intervention 35.7 (6.1); control 39.7 (9.2) years.	Physical activity intervention based on social cognitive theory with structured supervised group exercises, group lectures, individual counselling and telephone follow up	Control gp – no intervention (offered exercise, lecture, information AFTER completion)	5 months	PA level (assessed by accelerometer)	Mean difference in PA between the 2 groups of 49 counts per min/day representing a 15% (95% CI 8.7, 21.2, p=0.01) higher increase in PA in the intervention group than the control group.	+
Gaston 2007	USA	African-American women aged >35	54.4 (SD 9.46)	A curriculum-based, culture- and gender specific health intervention, aimed at assisting mid-life African-American women to decrease physical inactivity, poor nutrition and stress. Cognitive behavioural approach based on three theoretical	Comparison group with educational book	1 year	Nutrition and eating patterns, physical activity behaviour Perception of overall health, self-care,	There were significant changes in physical activity from pre-test to post-test. At six months post-test, the women reported participating in aerobic exercise, on average, 2.48 days per week at six months [t(30)=2.02, p<0.05] and 3.21 days at 12 months [t(42)=3.0 A significant.10-week difference was found in the women's diet, with them reporting eating more nutritious foods, t(77)=3.32, p<0.001. The women also indicated from pretest to 10 weeks, and six and 12 months that they changed what they ate to prevent disease (40.4%, 62.8%, 97.5% and 100%, respectively). A majority of the women at 10 weeks	-

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
				approaches to reduce risk factors and promote positive health changes.				(62.7%) and 12 months (65.9%) reported utilizing stress management strategies. There was also a 60% increase in yearly mammograms and a 54% increase in blood pressures checks. Finally, 83.7% of the women at 12 months felt that the positive changes could be maintained over their lifetime.5, p<0.01].	
Physical activity – primary mid-life studies in disadvantaged communities									
Goyder 2014	Deprived areas of Sheffield, UK.	Previously sedentary people, aged 40–64 years, living in deprived areas of Sheffield, UK, who had increased their physical activity levels after receiving a brief intervention..	Mean age 54.6 (7.3)	'Booster' interventions to sustain increases in physical activity in middle-aged men from deprived urban neighbourhoods. Participants were randomised to the control group (no further intervention) or to two sessions of motivational interviews (MI),either face to face ('full booster') or by telephone ('mini booster'). Sessions were	To determine whether objectively measured physical activity, 6 months after a brief intervention, is increased in those receiving physical activity 'booster' consultations delivered in a motivational interviewing (MI) style,	Intervention sessions at 1 and 2 months, follow-up at 6 months.	Total energy expenditure (TEE) per day in kcal from 7-day accelerometry, cost-effectiveness	The mean difference in TEE per day between baseline and 3 months favoured the control arm over the combined booster arm but this was not statistically significant (–39 kcal, 95% confidence interval −173 to 95, p = 0.57). The autonomy-enabled MI communication style was generally acceptable, although some participants wanted a more paternalistic approach and most expressed enthusiasm for monitoring and feedback components of the intervention and research. Full boosters were more popular than mini boosters. Cost-effectiveness Two alternative modelling approaches both suggested that neither intervention was likely to be cost-effective.	++

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
				delivered 1 and 2 months post-randomisation.	either face to face or by telephone.				
Systematic Reviews									
Systematic reviews of physical activity interventions in ethnic minority groups									
Ickes 2012	US	> 35% Hispanic adults, male and female, age >18 (age range 18-95)	Age range 18 - 95	Intervention settings of included studies varied, but included community, clinical, family and faith-based interventions. A range of theoretical frameworks, and intervention strategies were used. 45% if the interventions used walking groups, 30% group aerobics, dance or structured activities, 45% used culturally appropriate	Any comparison group	Any follow-up	90% (n=18) of included studies measured behaviour change relating to PA, in 15 outcomes were self-reported, one used a pedometer and 2 used accelerometers.	Community, clinical, family-based and faith-based interventions were effective in improving the level or frequency of PA participation. Of those studies measuring PA as an outcome, 72% reported an improvement in PA (13 studies). Five interventions reported an increase in minutes walking and/or associated METS, three interventions reported an increase in individuals meeting recommended PA levels, 2 found an increase in MVPA and one an increase in VPA. Social support was incorporated into 65% of the interventions and 60% of those resulted in an increase in PA levels.	+

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
				activities and materials, 30% used bilingual instructors, 30% used self-management strategies including goal setting and problem solving in 30%, 15% used behavioural counselling.					
Conn 2012	US	African American, Hispanic, Native American and Native Hawaiian, adults > 18 years	Not reported	PA motivation interventions, the typical intervention was of 10 sessions lasting 49 minutes.\n\nSupervised exercise interventions, typically 40 minutes of verified exercise 3 times weekly over 11 weeks, mostly moderate intensity exercise, (n=19), low intensity (n=3) and high intensity (n=1)	Any control group	Any follow up	PA behaviour (also fitness, anthropometric outcomes, lipids, diabetes risk, mood, QoL)	PA motivation interventions\nMotivational and educational interventions designed to increase PA significantly increased PA behaviour in meta-analysis of 21 studies with treatment versus control group comparison. Effect size reported (units?) as 0.172 (95% CI 0.023\n\nSupervised exercise interventions,\nTypically 40 minutes of verified exercise 3 times weekly over 11 weeks, mostly moderate intensity exercise, (n=19), low intensity (n=3) and high intensity (n=1) There was a significant increase in fitness levels in treatment versus control groups but compliance and uptake of the interventions not reported.	-
Systematic reviews of physical activity interventions in disadvantaged communities									

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
Cleland 2012	International Mainly US (20/27), also UK (2/27) studies)	Socioeconomically disadvantaged communities (adults and children but reported separately) (measured by low education, low income, unemployed, low status occupation or living in low SES area).	Adults and children: but reported separately	Interventions aiming to promote PA Interventions included education, organised exercise classes, information distribution, exercise consultation, fitness assessment, lifestyle advice, including individually targeted and group interventions.	Any relevant control	Any follow up	Measures of PA behaviour measures included self-report, pedometers, accelerometers	In adults, 4 studies targeted individuals, 12 were group interventions and 5 were community interventions. No meta-analysis. Group interventions: There was sufficient evidence to recommend that group interventions are effective to influence PA behaviour in adults. Community interventions: There was sufficient but limited evidence of effectiveness. (Based on additional expert opinion, the authors made a recommendation that community based interventions are effective in socioeconomically disadvantaged communities). Individual interventions There was insufficient evidence to assess the effectiveness of interventions targeting individuals.	+
Cleland 2013	International (10 of 19 studies from US, no UK studies)	Socioeconomically disadvantaged women (measured by low education, low income, unemploye	Women aged 18-64 years	Any intervention focused on increasing PA in any setting. Included: education, organised exercise classes, information distribution,	Any relevant control	Any follow up	Measures of PA behaviour	Nineteen studies were included. No pooled effect because of heterogeneity. In sub-group analyses, studies with a group delivery mode had a significantly greater effect on PA than either individual or community based delivery.	+

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
		d, low status occupation or living in low SES area).		exercise consultation, fitness assessment, lifestyle advice, including individually targeted and group interventions.					

Table 1d. Summary PA & DIET intervention studies in disadvantaged and minority groups

Systematic reviews of physical activity and diet interventions in ethnic minority groups									
Chapman (2013)	International (developed countries)	South Asian populations	Adults	Community or primary care based intervention studies (randomised and non-randomised designs included) Four studies were included in the review. Only 2 studies were found that reported outcomes related to dietary behaviours. Both were before and after studies (no control group) with self-reported changes in dietary behaviour.	Any relevant control	Any follow up	Behavioural (e.g. dietary intake, physical activity participation), physical (weight, BP, lipids)	In one study, the intervention included individual tests and CHD/diabetes risk profile, nutritional support from dietetic clinics, optional practical activities including cookery workshops, exercise classes and awareness sessions. The intervention was delivered at the project base and community venues by health visitors, South Asian community workers with interpreter and translator services. Significant improvements in salt intake and consumption of fried meat snacks was reported. For physical activity, an average of 49% of participants reported taking more moderate exercise (defined as 'physical activity that makes one out of breath but not sweaty') 6–12 months after intervention. Weight change in males was -2.1kg (from mean 71.8kg at baseline) and in females was -1.9 kg (63.3kg) at baseline). Error limits not reported in review. The other study involved community based PA and diet group education sessions, with food guides, healthy lifestyle hand-outs, pedometers, waist measurements, pedometer diary and 3 monthly follow up sessions. No outcome data relating to behavioural changes was reported only physical data e.g.	

							anthropometric, blood pressure, lipids and other biochemistry. Weight change was -0.9 kg (from 30.8 kg) and BMI change -1.1kg/m2 (from mean of 28.6 at baseline). Error limits not reported in review.	

Table 1e. Summary of economic evaluation for PA

Author (year)	Intervention (comparator)	Approach (Population)	Effectiveness measure	Costing (Discounting)	ICER (sensitivity)	Quality (-/+/0)
Annemans 2007 (Belgium)	PA in fitness centre setting (no PA) Detail of PA intervention not provided	Markov Cost utility – Simulating cohorts with variable levels of risk (i.e. BP, Cholesterol, BMI) ICER presented for three types of cohorts, depending on BMI, cholesterol and hypertension. Cohort 1: 30 years old, BMI = 26; cholesterol = 190; systolic BP = 120 Cohort 2: 40 years old, BMI = 30, cholesterol = 210, systolic BP = 130 Cohort 3: 50 years old, BMI = 32, cholesterol = 250, systolic BP = 140	Clinical & Epi data from literature for following states: healthy, CHD, diabetes, colon cancer, breast cancer. Utility based on literature: CVD: based on BMI & complications (no details) Diabetes: assumed 95% of non-diabetic Breast cancer: 0.19 utility penalty Colon cancer: 0.27 utility penalty (3% discounting)	Healthcare payer: direct healthcare costs & cost of gym membership €500 Societal : cost of absenteeism but not cost of travel & opportunity No primary date collection of resource use; based on literature (3% discounting) Sensitivity: proportion of gym cost subsidised (from €0 through €500)	According to size of the public payment per year for controlled exercise (**€0 to €500**) Societal / Healthcare payer **Cohort 1 (low risk)** **€0 -** Dominant **€500 -** ICER €13 920 / €15338 **Cohort 2 (med risk)** **€0 -** Dominant **€500 -** ICER €9351 / €13016 **Cohort 3 (high risk)** **€0 -** Dominant **€500 -** ICER €2349 / €8530 In all circumstances, the cost effectiveness is well below a threshold of €20000 per QALY gained. The results are systematically better from a societal perspective. Results not sensitive to time horizon (5 to 25 years) but sensitive to compliance. Assuming a 25 years time horizon, a drop in compliance of 50% leads to a worsening of the incremental cost-effectiveness ratio to €25235, € 22175 and €16358 per QALY for cohorts 1, 2 and 3, respectively	+

Author (year)	Intervention (comparator)	Approach (Population)	Effectiveness measure	Costing (Discounting)	ICER (sensitivity)	Quality (-/+/0)
Anokye 2011 UK	Exercise referral scheme (primary care). Individuals referred to a third party service (often a sports centre or leisure facility), which then prescribes and monitors an exercise programme tailored to the individual needs of the patients. Comparator: Usual care (primary care)	Decision analytic model; life time horizon; estimates likelihood of becoming physically active & effects on development of coronary heart disease, stroke and type II diabetes. (People who are sedentary and/or have risk factor(s) for conditions known to benefit from physical activity)	Probability of becoming active after exposure to ERS: **0.345** Probability of becoming active after exposure to usual care: 0.**297** Active state: doing at least 90-150 min of at least moderate intensity physical activity per week. Utility derived from health state value for each condition and data on life expectancy after the onset of the condition.	Cost of ERS intervention based on microcosting (published literature): resource use in a health service/local authority that consists of provision of facilities, exercise trainers and administrative support. Cost estimates are up-rated to £2010 prices; Total lifetime costs of CHD, stroke, Type II diabetes from literature I**ntervention costs**: Cost of intervention per participant to the provider: **£222** Future costs and benefits are discount rate: 3.5% per annum	**Base case** ERS Lifetime total healthcare costs per person: £2,492 Total QALYs per person: 16.743 Usual care Lifetime total healthcare costs per person £2,322 Total QALYs per person 16.735 Incremental cost per QALY (ICER): **£20,876** Subgroup ICER: Obese £14,618 Hypertensive £12,834 Depressive £8,414 Overall The cost per QALY of ERS compared with usual care is between £8,414 and £14,618 and thus can be considered cost-effective at the £20,000 per QALY threshold. At a threshold of £20,000 per QALY, there is a 0.508 probability that ERS is cost-effective. This increases to 0.879 when a threshold of £30,000 per QALY is considered.	++

Author (year)	Intervention (comparator)	Approach (Population)	Effectiveness measure	Costing (Discounting)	ICER (sensitivity)	Quality (-/+/0)
Dalziel 2006 New Zealand	New Zealand Green Prescription Programme (written PA advise tailored according to readiness to change; general practice setting); followed by telephone support by exercise specialist over 3 months.	Markov Cost utility – Simulating cohorts of 1000 active and inactive extended over full life expectancy (with one, 10 and 25 years presented in sensitivity analyses)	Utility – based on mean utility values for active (0.7635) and inactive (0.7380) persons derived by transforming SF36 data using published literature; mortality for various PA states derived from literature Effectiveness – From RCT; change in proportion of people who became active. At 12 months: RR of achieving 2.5 hours of PA/week was 2.98 (95%CI 1-85-4.77) for intervention group; small significant change in QoL Discounting 5% per annum	Costs were collected as part of the trial for program set-up and co-ordination; regional sports trusts' patient support; and general practice advice and follow-up in New Zealand $ 2001, total program cost $170 per program participant. Discounting 5% per annum	Incremental, modelled cost utility of the Green Prescription program compared with 'usual care' was $NZ2,053 per QALY gained over full life expectancy (range $NZ827 to $NZ37,516 per QALY). Based on the probabilistic sensitivity analysis, 90% of ICERs fell below $NZ7,500 per QALY.	++

Author (year)	Intervention (comparator)	Approach (Population)	Effectiveness measure	Costing (Discounting)	ICER (sensitivity)	Quality (-/+/0)
Wu 2011 (International)	Any type of PA interventions that has shown positive effects Grouped as follows: • Point-of-decision prompts Community campaign (4 studies) • Individually adapted behaviour change (all) / low and high intensity • Social support (all) / low and high intensity • Creation or enhanced access to places for physical activity	Cost effectiveness of each intervention calculated using the population in the selected published study (outcome with the best cost-effectiveness ratio was kept). Duration of intervention standardized to 1 year for a potential 10 000 target population; effect sustained for 1 year; Total standardized annual intervention cost to reach 10,000 people was calculated as the cost per person per month multi- plying by 12 months and then by 10,000.	Quantity of physical activity produced among the population reached, measured in MET-hours gained per person per day multiplied by 1-year duration and then by 10,000 A MET represents the ratio of energy expended divided by resting energy expenditure, either measured or estimated from body size). Benchmark used for adequate physical activity for an adult was 1.5 MET-hours gained per day, equivalent to a half hour of moderate physical activity.	Program costs were considered as the total cost to the public health system to implement the intervention, regardless of sources of funds. The final cost parameter used is the total program cost for all people reached in the program, not only those who participated in the evaluation. All costs are reported in US2007 dollars. Potential opportunity costs and potential effects on healthcare costs or productivity of physical activity not included.	<u>Median (range) annual cost for 10,000 people to add 3–5 MET hr/wk ($)</u> • Point-of-decision prompts (28) N/A • Community campaign (4) 3,350,000; 1,431 • Individual adapted behaviour change (49) 688,000 (71,000–11,000,000) • Social support (31) 9,500,000 (700,000–14,780,000) • School-based physical activity intervention (26) 300,000 (188,000–3,586,000,000) Creation or enhanced access to places for physical activity (3) 50,000	+

3.4 Evidence for DIET interventions in midlife

Note: This section includes only those studies specifically about diet. A number of studies were identified that examined combined diet and physical activity or other combinations of diet with other interventions and these are reported separately.

Characteristics of included studies for DIET

Primary Studies

For DIET, three primary studies conducted in mid-life populations were identified from searches from 2000 onwards. Two were RCTs (Hjerkinn 2004, Wright 2011) and one was a before and after study with no control group (Turner 2003).

Systematic Reviews

Additionally four relevant systematic reviews were identified from searches from 2010 onwards. Of the four systematic reviews, none specifically recruited people at mid-life but in all four, the mean age of the majority of included studies (>2/3) was within the mid-life range (Rees 2013a, Rees 2013b, Hooper 2012, Esposito 2012).

Economic studies

Additionally one study that reported cost-effectiveness (and effectiveness) of a low fat diet for prevention of breast cancer was identified (Bos 2011).

These studies are presented in **Table 2**.

Evidence statements for DIET & NUTRITION (DN) interventions in midlife

From primary studies published from 2000 onwards and up-to-date systematic reviews published from 2010 onwards that include predominantly studies with people with mean age in mid-life.

Effect of midlife interventions on uptake and maintenance of healthy dietary behaviours at midlife

3.4.1DN Effect of tailored, printed dietary feedback or group education for improving dietary behaviours

There is evidence from one RCT of moderate quality [+][1] that printed dietary feedback, tailored based on individual dietary intake, and delivered in three instalments over three months is more effective for improving fruit intake behaviour (0.3 servings/day, p=0.031) than either two dietician-led small group nutrition education sessions or a

waiting list control. No significant differences between groups were found for saturated fat intake, vegetables, grains or whole grains.

The RCT was conducted in Australia on 178 men and women aged between 40 and 65 years who had one or more risk factors for CVD (overweight or obesity, hypercholesterolaemia, hypertension, smoking, family history or a previous cardiovascular event) and reported the effect of three instalments of printed dietary feedback delivered over three months [+][1].

[1] Wright 2011 [+]

- **Applicability**: Partially applicable. The RCT was conducted in Australia among men and women and only recruited those specifically at midlife (age 40-65). The delivery method of the intervention could be applied in the UK. While the delivery of the intervention was fairly low intensity, individual feedback was based on analysis of a FFQ and psychosocial questionnaire at baseline which would be fairly resource intensive.

3.4.2DN Effect of midlife dietary modification intervention (lower fat, healthier eating) for improving dietary behaviours

There is evidence from one large scale, high quality RCT [++][1], the Women's Health Initiative Randomized Controlled Dietary Modification Trial, that an intensive behavioural modification program can effect dietary change in postmenopausal women with high dietary fat intakes (women consuming>36.8% of energy from fat at baseline and women at high risk of breast cancer consuming >/= 32%.of energy from fat at baseline). There was a significant difference between groups (p<0.001) for fat, energy, fruit and vegetable and grain intake at one, three and six years.
(This study is also reported in section relating to 3.4.6DN effectiveness of the intervention for cancer outcomes and section 3.4.7DN relating to cost-effectiveness of the intervention).

The RCT was conducted in the US in postmenopausal women (83.4% of participants were aged 50-69 at baseline) with high fat intake and/or increased risk of breast cancer. The aim was to decrease total fat intake to 20% of total energy intake and increase consumption of fruits and vegetables to at least five servings per day, and of grains to at least six servings per day. The intervention had two components, a dietary modification component and the assessment of effect of dietary modification on cancer outcomes. Dietary modification involved 18 group sessions in the first year and quarterly maintenance sessions each year after. Comparison group participants received dietary guidelines and other health related materials but were not asked to make changes to their diet. Each group had eight to 15

women and was led by a specially trained and certified nutritionist. Each participant was given his/her own goal for total fat intake. The intervention emphasised self-monitoring techniques and involved other individually tailored strategies, such as motivational interviewing.

[1] Prentice 2006 [++]

- **Applicability**: Partially applicable. The RCT was conducted in the US among women only. Eighty three percent of women recruited were aged 50 to 69 at baseline. The delivery method of the intervention could be applied in the UK but was fairly high intensity and was delivered by a nutritionist.

3.4.3DN Effect of an osteoporosis prevention program on changing diet behaviours related to osteoporosis

There is very weak evidence from one before and after study (no control group) that an osteoporosis prevention programme involving educational classes, hip and spine bone mineral density testing and individual consultation can have a beneficial effect on osteoporosis related behaviours [-][1]. Proportion of participants consuming excessive caffeine containing beverages decreased from 28% before intervention to 11% after; one or more servings of milk per day increased from 25% to 30%; one or more servings of yogurt increased from 9 to 10%, one or more servings of cheese per day increased from 15 to 20% (error limits not reported).

[1] Turner et al 2003 [-]

- **Applicability**: Partially applicable. The RCT was conducted in the US among middle-aged women (mean age 49.5). However, the paper reports very few details about the methods and delivery of the intervention.

Effect of midlife diet interventions on long term dementia, disability, frailty or non-communicable diseases outcomes (in later life)

3.4.4DN Effect of midlife diet interventions on mortality

There is evidence from one RCT of moderate quality [+][1] that a long-term lipid-lowering diet with emphasis on reduction of saturated fat, total energy intake and body weight is effective in reducing overall long-term mortality in healthy middle-aged men with hyperlipidaemia.

The RCT was conducted in Norway and reported the effect of a five-year diet intervention on 24-year mortality in 104 healthy middle-aged men (aged 40 to 49 at baseline in 1972) [+][1] with combined hyperlipidaemia [+][1]. The intervention diet was a lipid-lowering diet with emphasis on reduction of saturated fat, total energy intake (mainly by reducing sugar, alcohol and fat) and body weight. Participants were followed up for 24 years with a follow-up examination every six months and adherence to the diet assessed at each follow-up.

Note: Intervention participants also received anti-smoking advice; however, there was no significant difference between the proportion of smokers in the intervention and control groups at baseline and after five years. After a total of 24 years (from baseline) overall mortality was significantly lower in the intervention group compared to the control group (RR 0.47, 95% CI 0.23- 0.96), p= 0.038) and remained significant in regression after adjusting for age and smoking status. While mortality is the primary outcome of interest for this review, shorter term outcomes after five years (at the end of the intervention) total cholesterol, triglycerides and BMI were all significantly lower in the diet group compared to the control group. These outcomes have been included here as secondary shorter term outcomes.

[1] Hjerkinn 2004 [+]

- **Applicability**: Partially applicable. The RCT was conducted in Norway, among men only. The men were aged 40 to 49 at baseline. The delivery method of the intervention not stated but appears to have been delivered by researchers.

3.4.5DN Effect of diet interventions on cardiovascular disease (CVD)
No primary studies specifically in midlife were found.

Reduced fat - **There is evidence from one high quality systematic review [++][1] on the effect of reduction or modification of dietary fat on CVD mortality, morbidity and CVD risk factors from RCTs of interventions of over six months in length.**

The included interventions were dietary advice, or provision of low fat foods or diets. The review included 27 RCTs. Participants were adults aged over 18. From trials of all lengths, there was no significant effect on total mortality (rate ratio 0.98, 95% CI 0.86 to 1.12), or cardiovascular mortality (rate ratio 0.91, 95% CI 0.77 to 1.07), but there was a significant effect on cardiovascular events (rate ratio 0.84, 95% CI 0.72 to 0.99) however after sensitivity analysis this was not significant. Trials where participants were involved for more than two years showed significant reductions in the rate of cardiovascular events. Protection

from cardiovascular events was similar in high and low risk groups, but was only statistically significant in high risk groups.

[1] Hooper 2012

- **Applicability**: Partially applicable. The systematic review included international studies. While the review included studies in all adults, the mean age of the majority of included studies was at mid-life. The review also reported long-term cardiovascular outcomes.

Dietary advice - One up-to-date, high quality systematic review reports that dietary advice can bring about modest improvements to diet and to cardiovascular risk factors over 12 months but there is insufficient evidence available for longer term effects [++][1]. The review included 44 RCTs in healthy adults and in the majority of included trials the mean age was at midlife.

Twenty-nine of the 44 included trials were conducted in the USA. Compared to no advice, dietary advice increased fruit and vegetable intake by 1.18 servings/day (95% CI 0.65 to 1.71). Dietary fibre intake increased by 6.5 g/day (95% CI 2.2 to 10.82), while total dietary fat as a percentage of total energy intake fell by 4.48% (95% CI 2.47 to 6.48) with dietary advice, and saturated fat intake fell by 2.39% (95% CI 1.4 to 3.37). There was data from two trials of incident cardiovascular disease (CVD) events. Follow-up was 77% complete at 10 to 15 years after the end of the intervention period and there was a lack of precision in CVD events estimates. Data suggested a reduction in CVD events with lower dietary sodium but results were not significant. As there was limited evidence available relating to cardiovascular events, the secondary outcomes of effect on lipids and blood pressure, are also included here as follows. Dietary advice reduced total serum cholesterol by 0.15 mmol/L (95% CI 0.06 to 0.23) and LDL cholesterol by 0.16 mmol/L (95% CI 0.08 to 0.24) after three to 24 months. Mean HDL cholesterol levels and triglyceride levels were unchanged. Dietary advice reduced blood pressure by 2.61 mm Hg systolic (95% CI 1.31 to 3.91) and 1.45 mm Hg diastolic (95% CI 0.68 to 2.22).

[1] Rees et al 2013a [++]

- **Applicability**: Partially applicable. The systematic review included international studies. While the review included studies in all adults, the mean age of the majority of included studies was at mid-life. The review sought long-term cardiovascular outcomes but there was insufficient data available to make robust conclusions. However, there was sufficient

evidence to demonstrate a beneficial effect of dietary advice on intake of fruit, vegetables, total and saturated fat, lipids and blood pressure.

Mediterranean dietary pattern – One up-to-date, high quality systematic review reports limited available evidence for the effectiveness of a Mediterranean diet pattern for the primary prevention of CVD [++][1]. The review included 11 RCTs in healthy adults and in the majority of included trials the mean age was at mid-life. Only one trial reported clinical events and the effects of the intervention were not statistically significant.

As limited data on clinical events was available, the secondary outcomes are also reported here as follows: small reductions in total cholesterol (-0.16 mmol/L, 95% confidence interval (CI) -0.26 to -0.06; random-effects model) and low-density lipoprotein (LDL) cholesterol (-0.07 mmol/L, 95% CI -0.13 to -0.01) were seen with the intervention.

[1] Rees et al 2013b [++]

- **Applicability**: Partially applicable. The systematic review included international studies. While the review included studies in all adults, the mean age of the majority of included studies was at midlife. The review sought long term cardiovascular outcomes but there was insufficient data available to make robust conclusions, however small reductions in total and LDL cholesterol were reported.

3.4.6DN Effect of diet interventions on cancer

One large scale, RCT [++][1] the Women's Health Initiative Randomized Controlled Dietary Modification Trial has shown that an intensive behavioural modification program can effect dietary change in people with high dietary fat intakes (>/= 32% of energy). (This study is also reported in section 3.4.2DN relating to change in dietary behaviour). There was a significant difference between groups (p<0.001) for fat, energy, fruit and vegetable and grain intake at one, three and six years. However, there was no significant difference in breast cancer incidence over a mean of eight years.

The RCT was conducted in the US in women with high fat intake and/or increased risk of breast cancer. The intervention had two components, a dietary modification component and the assessment of effect of dietary modification on cancer outcomes. All women were postmenopausal and aged 50 to 79 years at baseline (83.4% of participants were aged 50-69 at baseline). The number of women randomised was 48,835 and 19,541 were assigned to the modified diet group.

Dietary modification involved 18 group sessions in the first year and quarterly maintenance sessions each year after. Each group had eight to 15 women and was led by a specially trained and certified nutritionist. Each participant was given their own goal for total fat intake. The intervention emphasised self-monitoring techniques and involved other individually tailored strategies, such as motivational interviewing.

Target was to decrease total fat intake to 20% of total energy intake and increase consumption of fruits and vegetables to at least five servings/day and of grains to at least six servings/day. Comparison group participants received dietary guidelines and other health related materials but were not asked to make changes to their diet. There was a significant difference between groups ($p < 0.001$) for fat, energy, fruit and vegetables and grains at one, three and six years.

For the development of invasive breast cancer (annualised incidence rate) over a mean follow up period of 8.1 years, the hazard ratio for the modified diet group compared to the control group was 0.91 (95% CI 0.83 – 1.01). There was no statistically significant reduction in breast cancer although the study reports non-significant trends observed suggesting reduced risk associated with a low-fat dietary pattern.

[1] Bos 2011 [++]

- **Applicability**: Partially applicable. The RCT was conducted in the US among women only. Eighty three percent of women recruited were aged 50 to 69 at baseline. The delivery method of the intervention could be applied in the UK but was fairly high intensity and was delivered by a nutritionist.

Effect of diet interventions on short term dementia, disability, frailty or non-communicable diseases outcomes (in mid-life)

No primary studies were found specifically in people at midlife

3.4.7DN Effect of diet interventions on body weight

There is evidence from one systematic review of RCTs on the effect of Mediterranean diets on body weight [+][1]. Sixteen RCTs in adults in general were included, the majority of which had mean age at midlife. Participants in studies were overweight or obese at baseline and had risk factors for or existing CHD. Overall, the Mediterranean

diet group had a significant effect on weight [mean difference between Mediterranean diet and control diet, 1.75 kg; 95% confidence interval (CI), 2.86 to 0.64 kg] and body mass index (mean difference, 0.57 kg/m2, 0.93 to 0.21 kg/m2). No study reported significant weight gain with a Mediterranean diet. However, in the individual included studies in the review in only those who were overweight, results were more equivocal with 3 of 6 studies reporting no significant effect on body weight.

[1] Esposito et al 2011 [+]

- **Applicability**: Partially applicable. The systematic review included international studies. While the review included studies in all adults, the mean age of the majority of included studies was at midlife.

Cost-effectiveness of dietary interventions

3.4.7DN Cost-effectiveness of dietary interventions for cancer

Summary of intervention: There is evidence from one RCT (reported previously in sections 3.4.2DN; the Women's Health Initiative Randomized Controlled Dietary Modification Trial) that an intensive behavioural modification program aimed at fat reduction can effect dietary change in people with high dietary fat intakes (>/= 32% of energy). There was a significant difference between groups (p<0.001) for fat, energy, fruit and vegetable and grain intake at one, three and six years. However, there was no significant difference in breast cancer incidence over a mean of eight years, although the study reports non-significant trends observed suggesting reduced risk associated with a low-fat dietary pattern.

Cost-effectiveness [++]: The objective of the cost-effectiveness study was to measure the cost effectiveness: 1) as a public health intervention, and 2) under the sponsorship of private health insurers and Medicare (US). Analysis was performed for hypothetical cohorts of women at midlife aged 50, 55 and 60. Results at age 50 are reported here:

Public health perspective, for participants with fat intake >36.8%E and age 50 at baseline, total cost of intervention (2011 costs) would be $45,211(low fat diet) compared to $44,100 (regular diet); QALYs 15.927 (low fat) compared to 15.841 (regular diet); incremental cost-effectiveness ratio (ICER) $12,944/QALY (6170-22,026).

Public health perspective, for participants with fat intake >32%E, high risk breast cancer and age 50 at baseline, total cost of intervention (2011 costs) would be $59,733(low fat diet) compared to $58,730 (regular diet); QALYs 15.490 (low fat) compared to 15.395 (regular diet); incremental cost-effectiveness ratio (ICER) $10,544/QALY (2096-23,673).

[1] Bos 2011 **[++]**

- **Applicability**: Partially applicable. The RCT was conducted in the US among women only. Eighty three percent of women recruited were aged 50 to 69 at baseline. The delivery method of the intervention could be applied in the UK but was fairly high intensity and was delivered by a nutritionist.

Table 2. Summary DIET primary intervention studies and systematic reviews

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
Primary mid-life studies									
Hjerkinn 2004	Norway	Middle-aged men aged 40-49 y	46 (3)	Lipid-lowering diet	Usual diet	5 years	Mortality	For intervention compared to control group, relative risk of mortality was 0.44, 95% CI 0.23-0.96, P= 0.038.	+
Wright 2011	Australia	Middle-aged adults with CVD risk factors	40-65 (mean 54)	Printed dietary feedback	Group nutrition education or waiting list control	3 months	Dietary intake and behaviours	Significant increase in fruit intake (+0.3 servings/d, p=0.047) but no sig change for sat fat, vegetables, grains or wholegrains.	+
Turner 2003	US	Middle-aged women	Mean age 49.5 years	Osteoporosis prevention diet (increase milk, cheese, yoghurt, decrease caffeine beverages)	N/A	Not reported	Osteoporosis related dietary behaviours	Increase in number of participants consuming one or more portions of milk, cheese, yoghurt/day and decrease in number drinking excessive caffeinated beverages.	-
Primary cost-effectiveness studies									
Bos 2011 (and primary studies referenced – Prentice)	US	Women on high fat diets or at risk of breast cancer	50-70 but 84% age 50-69 years	Low fat diet (and cost-effectiveness analysis)	*Usual* diet	24 years	Breast cancer (and cost-effectiveness)	Reduction in breast cancer incidence (at 24 years) with trends towards lower incidence with lower fat intakes but not stat significant.	++

Systematic reviews									
Rees 2013a	International	Adults	Majority of studies in midlife	Dietary advice	No advice	Mixed	Mortality, CVD events and risk factors	Improved fruit and veg intake, total fat, sat fat, lipids, cholesterol. Insufficient data for CVD events and mortality.	++
Rees 2013b	International	Adults	Majority of studies in midlife	Mediterranean diet	Other diets	Mixed	Mortality, CVD events and risk factors	Small reductions in total and LDL cholesterol. Insufficient data for CVD events and mortality.	++
Hooper 2012	International	Adults	Majority of studies in midlife	Reduced fat diet	Usual diets	Mixed	Mortality, CVD events and risk factors	No sig effect on total or CVD mortality but sig effect for CVD events (which was lost in sensitivity analyses).	++
Esposito 2012	International	Adults	Majority of studies in midlife	Mediterranean diet	Usual diets	Mixed	Weight	Significant effect on weight and BMI	+

3.5 Evidence for SMOKING

Characteristics of included studies SMOKING

We included 13 papers on interventions aimed at changing alcohol consumption in mid-life: eight primary studies, two systematic reviews and three economic studies. **Table 3** presents a summary of the data and **Appendix A.9** the data extraction and further details.

Primary Studies

A total of eight primary studies on smoking were identified. These were conducted in the UK (n=6) and USA (n=2). The length of follow-up ranged from one week (McDermott et al, 2011) to one year (Hollis et al, 2007; Vogt et al, 2012). There were a total of five studies which recruited mixed samples, two studies recruiting only female participants (Hall et al, 2003 and 2007) and one study recruited only Pakistani and Bangladeshi men (Begh et al, 2011). All included studies are experimental or quasi-experimental. All studies use some self-reported smoking data, with some studies also using objective methods to measure smoking. Overall, there is a significant positive association between smoking cessation support and quitting intention (Hall et al, 2003 and 2007; Vogt et al, 2012), quit attempts (Begh et al, 2011), and cessation (Brown et al, 2007; Hollis et al, 2007). Some studies found no impact (Halpin et al, 2006). These studies are summarised in **Table 3**.

Systematic Reviews (SR)

We found no SR focused on a mid-life population for smoking. However, since 2010 we identified three SR focused on smoking interventions in the general population (Zbikowski et al 2012, Rooke et al 2010, Lindson-Hawley et al 2010), and one looking at smoking cessation among Hispanics in the United States (Webb et al, 2010).

- Zbikowski conducted a review of smoking cessation interventions for smokers aged 50 and older with the majority of included studies focusing on an older population and was excluded.

- Rooke et al (2010) looked at computer-delivered interventions for alcohol and tobacco use and conducted a meta-analysis of 42 effect sizes from randomised controlled trials, based on the responses predominantly in young adults and was excluded. For information, the weighted average effect size (d) was 0.20, P < 0.001, with a lower effect sizes were associated with studies addressing tobacco use (d = 0.14) that may well reflect differences in the types of outcome measure used. Findings suggest that minimal contact computer-delivered treatments that can be accessed via the Internet may represent a cost-effective means of treating uncomplicated substance use and related

problems.

- Lindson-Hawley et al (2010, Cochrane review) included a majority of studies conducted in population with an average age in mid-life and is included. The objectives were to compare the success of reducing smoking before quitting and abrupt quitting interventions, and to compare adverse events between arms in studies that used pharmacotherapy to aid reduction (the latter is not within the scope of this review). The review included RCTs that recruited adults who wanted to quit smoking. Studies included at least one condition which instructed participants to reduce their smoking and then quit and one condition which instructed participants to quit abruptly, and the outcome measure was abstinence from smoking after at least six months follow-up. Trials were split for two sub-group analyses: pharmacotherapy vs no pharmacotherapy, self-help therapy vs behavioural support. Most studies included a population with a mean age in mid-life. Neither reduction or abrupt quitting had superior abstinence rates when all the studies were combined in the main analysis (RR= 0.94, 95% CI= 0.79 to 1.13), whether pharmacotherapy was used (RR= 0.87, 95% CI= 0.65 to 1.22), or not (RR= 0.97, 95% CI= 0.78 to 1.21), whether studies included behavioural support (RR= 0.87, 95% CI= 0.64 to 1.17) or self-help therapy (RR= 0.98, 95% CI= 0.78 to1.23). We were unable to draw conclusions about the difference in adverse events between interventions; however recent studies suggest that pre-quit NRT does not increase adverse events. The authors concluded that reducing cigarettes smoked before quit day and quitting abruptly, with no prior reduction, produced comparable quit rates, therefore patients can be given the choice to quit in either of these ways. Reduction interventions can be carried out using self-help materials or aided by behavioural support, and can be carried out with the aid of pre-quit NRT.

- Webb et al. (2010) sought to systematically review smoking cessation interventions targeting healthy Hispanic adults living in the United States, to conduct a "mini" meta-analysis of randomised controlled trials, and to offer recommendations for future research. Twelve studies were eligible for the systematic review and five studies for the meta-analysis. The age range of included studies was 35-44 (mean 40.70 SD 3.21) – it is included. Interventions consisted of self-help, nicotine replacement therapy, and community-based interventions, as well as individual, group, and telephone counselling. There was evidence for the efficacy of smoking cessation interventions at the end of treatment (odds ratio, 1.54; 95% confidence interval, 1.09-2.16), which was attenuated in the longer term. More randomised trials evaluating tobacco interventions are warranted, with examination of the effect of cultural specificity and acculturation.

Economic Evaluations

We identified two economic studies of smoking interventions (Smith 2010; Rasmussen et al 2012). The primary study by Begh et al (2011) also presents cost data.

- Smith et al (2011) looked at the cost-effectiveness of an intensive telephone-based intervention for smoking cessation alongside RCT (TELESTOP, includes a series of seven counselling telephone calls over a two-month period; 12 month follow-up; US Veteran affairs primary care clinics; mean age 57 SD 11). They estimated the incremental cost-per-quit of a telephone care intervention versus usual care using the provider's perspective. On average, the intervention cost $142 per person, excluding medications. Under a standard intent-to-treat analysis the average cost-per-quit was $11,408 and thus the intervention was deemed cost-effective by conventional standards.

- Begh et al (2011; details presented in Table 3) conducted a pilot cluster randomised controlled trial in Birmingham comparing the effectiveness of Pakistani and Bangladeshi smoking cessation outreach workers with standard care to improve access to and the success of English smoking cessation services. The study found that more Pakistani and Bangladeshi men made quit attempts with NHS services in intervention areas compared with control areas, rate ratio (RR) 1.32 (95%CI: 1.03-1.69). There was a small increase in the number of four-week abstinent smokers in intervention areas (RR 1.30, 95%CI: 0.82-2.06). The proportion of service users attending weekly appointments was lower in intervention areas than control areas. No difference was found between intervention and control areas in choice and adherence to treatments or patient satisfaction with the service. The total cost of the intervention was £124,000; an estimated cost per quality-adjusted life year (QALY) gained of £8,500. The authors concluded the intervention proved feasible and acceptable. The outreach worker model has the potential to increase community cessation rates and could prove cost-effective, but needs evaluating in a larger, appropriately powered, randomised controlled trial.

- Rasmussen et al (2012) modelled the cost effectiveness of telephone counselling to aid smoking cessation in Denmark, in terms of costs per life year saved (LYS). The included population covered the life span and was excluded. For information, with discounting LYS at 3% p.a., the costs per LYS are €213 for ex-smokers with continued abstinence and €137 for ex-smokers with point prevalence abstinence. For comparison the average costs per LYS of smoking cessation interventions in other Danish settings are €1592 (95% CI €1547-1636). The authors concluded that the Danish reactive telephone counselling to aid smoking cessation appears to be cost-effective in comparison with other Danish smoking cessation interventions.

Evidence statements for SMOKING (SM)

3.5.1SM Effect of intervention on uptake and maintenance of behaviours

There is strong evidence from primary studies to suggest that interventions can significantly influence quitting intention ([++][1], [++][2], [++][3]), quit attempts ([+][4]) and smoking cessation([+][5], [++][6]); however some studies found little [++][7] or no impact [+][8], although it must be noted that the trial [++][7] was not powered to detect such a difference. Also, there is strong evidence from a Cochrane SR [++][9] of RCTs conducted predominantly in mid-life which demonstrates that reducing cigarettes smoked before quit day and quitting abruptly, with no prior reduction, produced comparable quit rates. The authors conclude that patients can be given the choice to quit in either of these ways. Finally, there is limited evidence from a SR focused on Hispanic adults living in the US [-][10] for the efficacy of smoking cessation interventions at the end of treatment (odds ratio, 1.54; 95% confidence interval, 1.09-2.16), which was attenuated in the longer term.

The interventions in these primary studies often combined behavioural [+][4], counselling [++][2], [++][6] and educational [++][1], [++][3], [+][5], [++][7] components to impact on smoking attitudes; two studies offered free nicotine replacement therapy (NRT) as an adjunct to multisession counselling and/or telephone support [++][6], [+][8]. There were a variety of methods used to deliver the interventions; one study used information leaflets [++][1]; one study delivered the intervention through practice nurses [++][2]; one delivered the intervention via outreach workers [+][4]; one study used the internet [+][5] and one study used telephony [++][6] ([+][8] has a component of telephony); for a number of studies the delivery mechanism is mixed or unclear [++][3], [++][7], [+][8].

The evidence from a Cochrane SR [++][9] suggest that reduction interventions can be carried out using self-help materials or aided by behavioural support, and can be conducted with the aid of pre-quit NRT. The authors were unable to draw conclusions about the difference in adverse events between interventions; however recent studies suggest that pre-quit NRT does not increase adverse events.

The evidence from the SR in Hispanic adults living in the US [-][10] also included a range of interventions, albeit very little detail about the SR methodology and the individual studies and interventions is provided.

[1] Hall et al 2003 [++]; [2] Hall et al 2007 [++]; [3] Vogt et al 2012 [++]; [4] Begh et al 2011 [+]; [5] Brown et al 2007 [+]; [6] Hollis et al 2007 [++]; [7] McDermott et al 2011 [++]; [8] Halpin et al 2006 [+]; [9] Lindson-Hawley et al 2010 [++]; [10] Webb et al 2010 [-]

- **Applicability**: Directly applicable. Five studies reporting a beneficial association were conducted in the UK [++][1], [++][2], [++][3], [+][4], [+][5]. One reporting a significant association was conducted in the USA ([++][6]). Two studies reporting little impact were conducted in UK [++][7] and USA [+][8]. One SR [+][9] with majority of studies conducted in target population was international and reported a positive impact of reduction interventions. The evidence about Hispanic adults is less applicable as the study was conducted in the US population with little resemblance to UK's ethnic sub-groups.

3.5.2SM Cost effectiveness of intervention on uptake and maintenance of behaviours

i) Cost-effectiveness of telephone based intervention: **There is moderate evidence from one US RCT [+][10] that intensive telephone-based intervention for smoking cessation might be cost-effective. The intervention cost $142 per person, excluding medications. Under a standard intent-to-treat analysis the incremental average cost-per-quit of a telephone care intervention versus usual care using the provider's perspective was $11,408. The intervention was thus deemed cost-effective by conventional standards.**

[10] Smith 2011 [+]

- **Applicability:** Partially applicable. One study conducted in the US alongside a clinical trial.

ii) Cost-utility of outreach workers for subpopulations: There is limited evidence from a UK pilot cluster randomised controlled trial [+][4] that smoking cessation outreach workers (compared to standard care) has the potential to increase community cessation rates and could prove cost-effective in Pakistani and Bangladeshi men. The total cost of the intervention was £124,000, for an estimated cost per QALY gained of £8,500.

[4] Begh et al, 2011 [+]

- **Applicability**: Directly applicable; study conducted in the UK but larger appropriately powered, randomised controlled trial is needed to confirm findings.

3.5.3SM Effect of intervention on Healthy Ageing/Quality of Life/Well-being/Depression

No studies reported the impact of smoking interventions on healthy ageing, quality of life, wellbeing or depression.

- **Applicability**: No studies were identified

3.5.4SM Effect of intervention on weight and body composition

No studies reported the impact of smoking interventions on weight and body composition.

- **Applicability**: No studies were identified

3.5.5SM Effect of intervention on physical health

No studies reported the impact of smoking interventions on physical activity and physical health.

- **Applicability**: No studies were identified

3.5.6SM Effect of intervention on perception of vulnerability to cancer

One study [++][1] found, after the provision of leaflets (either long or short versions) containing two threat and two efficacy messages, significant differences between study groups in perceptions of vulnerability to cervical cancer (x^2 [4, N=170]=26.3, p<.0001). Compared with women not sent a leaflet, those sent either of the two leaflets had higher perceptions of vulnerability to cervical cancer and greater expectations that stopping smoking would reduce this risk.

[1] Hall et al 2003 [++]

- **Applicability**: High applicability. One study reporting a beneficial association was conducted in UK [++][1]

Table 3a. Summary SMOKING primary intervention studies (focus on mid-life)

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Begh 2011	UK	Pakistani and Bangladeshi men	36 (34-58)	Four male, community based, stop smoking advisors of Bangladeshi and Pakistani origin delivering behavioural support and medication management for smoking cessation, general health promotion, communication skills, and the cultural specific norms of Pakistani and Bangladeshi smokers	NHS smoking cessation support as normal	Quit attempts, abstinence (6 month)	More Pakistani and Bangladeshi men made quit attempts with NHS services in intervention areas compared with control areas, rate ratio (RR) 1.32 (95%CI: 1.03 1.69). There was a small increase in the number of 4-week abstinent smokers in intervention areas (RR 1.30, 95%CI: 0.82-2.06).	+
Brown 2007	UK	Adult daily smokers	38 (27-49)	Smoking cessation website; expert virtual Stop Smoking Advisor source of useful information and a guide through the process of stopping using a structured quit plan.	No comparator	Abstinence (8 weeks)	Post-enrolment, 19.6% of participants were abstinent according to the primary outcome criteria (95% C.I.=14.1% to 25.1%).	+

Hall 2003	UK	Women smokers	43 (20-64)	Leaflets informed women of the threat of cervical cancer, how stopping smoking would decrease their vulnerability to it, and the effectiveness of smoking cessation services	Extended leaflet, a brief leaflet, or no leaflet	Readiness to stop smoking within the next 6mo, perceptions of severity and vulnerability to cervical cancer, beliefs about effectiveness of reducing susceptibility by stopping smoking, and self-efficacy (6 months)	Women sent the briefer leaflet were more likely to be ready to stop smoking within the next 6 months compared with those sent the extended leaflet (75% vs. 46%, 95% CI~11%–48%) and those not sent a leaflet (75% vs. 40%, 95% CI~19%–52%). Significant differences between study groups in perceptions of vulnerability to cervical cancer (x^2 [4, N=170]=26.3, p<.0001).	++
Hall 2007	UK	Smokers attending for cervical screening	39 (27-51)	Advice on the '5 As' for health professionals assisting patients in stopping smoking (Ask, Advise, Assess, Assist and Arrange) delivered as part of cervical screening.	Information to read. In control weeks nurses did not give smoking cessation advice.	Intention to stop smoking; intention to attend for future cervical screening; duration of intervention (10 weeks)	Compared to women in the control group, those in the intervention group had higher intentions to stop smoking at 10-weeks (adjusted mean difference 0.80, 95% CI 0.10 to 1.50, P=0.03).	++
Halpin 2006	USA	Smokers enrolled in a California	Not reported (18-50+)	Drugs only (NRT patch, nasal spray, inhaler, and	Drugs only; drugs and counselling;	Making a quit attempt, quitting	There were no significant increases in quit attempts or quit rates in the groups with covered drugs and counselling compared	+

		preferred provider organisatio n		Zyban); drugs and counselling (drugs and proactive telephone counselling); and drugs if counselling (drugs conditional on enrolment in counselling).	and drugs if counselling	during the study, and prevalent abstinence and total cost of coverage (8 months)	to the group with drug coverage only	
Hollis 2007	USA	Tobacco quitline callers	41 (28-54)	Brief, moderate and intensive telephone counselling, with or without an offer of free NRT patches.	Brief, moderate and intensive intervention	Tobacco cessation, satisfaction (12 months)	Abstinence odds ratios were significant for moderate (OR = 1.22, CI = 1.01 to 1.48) and intensive (OR = 1.29, CI = 1.07 to 1.56) intervention, and for NRT (OR = 1.58, CI = 1.35 to 1.85). Intent to treat quit rates: brief no NRT (12%); brief NRT (17%); moderate no NRT (14%); moderate NRT (20%); intensive no NRT (14%); and intensive NRT (21%).	++
McDerm ott 2011	UK	Smokers treated at the NHS SSS at The Royal London Hospital	43 (17-79)	Presentation negative reinforcement explanation for smoking with discussion; leaflet summarising presentation; and self-monitoring task	Received either a brief intervention communicati ng the negative reinforcemen t explanation for smoking, or control intervention matched on contact time	Acceptance, positive outcome expectations for smoking, self-efficacy and urges to smoke reported at one week post-cessation (1 week)	Post-cessation urges to smoke were similar in the two groups (Adjusted expt. group mean = 2.50, Control group mean = 2.75, F(1,60) = 0.98, p = .33). Other cognitive measures were also unchanged.	++
Vogt 2012	UK	Smokers older than	46 (18-87)	Group 1 received a brief introduction of	"No Effectiveness	Perceived effectiveness	Numerical and visual absolute effectiveness information compared with	++

		18 years		a stop smoking program Group 2 received (in addition), information from NHS to demonstrate effectiveness of program Group 3) received (in addition), numerical and visual absolute effectiveness information about the program	Information" or "Standard Numerical Effectiveness Information" or "Numerical and Visual Absolute Effectiveness Information"	of stop smoking interventions and intentions to use them (12 months)	no effectiveness information resulted in greater perceived effectiveness (Scheffé test, p=.033, Cohen's d=0.36) and intentions to use stop smoking interventions (Scheffé test, p=.012, d=0.43). Short-term quit rate compared with long-term quit rate resulted in greater perceived effectiveness, t(318) = 3.2, p=.002, d=0.35, but not significantly greater intentions to use stop smoking interventions, t(318) = 1.59, p=.11, d=0.18.	
Smith 2011	USA	Military veterans (n=838)	57 ± 11	Smoking cessation programmes Intensive telephone-based intervention for smoking cessation	Standard care	Cost of US Veterans Affairs services and the cost of care purchased by the VA from others (12 months)	The intervention cost $142 per person, excluding medications. Under a standard intent-to-treat analysis the average cost-per-quit was $11,408 and thus the intervention was deemed cost-effective by conventional standards.	X

Table 3b. Summary SMOKING systematic reviews

Lindson-Hawley 2010	Various	General population (n=487)	42.8	<u>Smoking cessation programmes</u> Reducing smoking before quitting and abrupt quitting interventions	Pharmacotherapy vs. no pharmacotherapy	Abstinence from smoking after at least six months follow-up, adverse events, behavioural support utilised (Various)	Neither reduction or abrupt quitting had superior abstinence rates when all the studies were combined in the main analysis (RR= 0.94, 95% CI= 0.79 to 1.13), whether pharmacotherapy was used (RR= 0.87, 95% CI= 0.65 to 1.22), or not (RR= 0.97, 95% CI= 0.78 to 1.21), whether studies included behavioural support (RR= 0.87, 95% CI= 0.64 to 1.17) or self-help therapy (RR= 0.98, 95% CI= 0.78 to1.23).	++
Webb 2010	USA	Hispanic populations in the US (189.40 ± 106.80)	40.70 ± 3.21	<u>Smoking cessation programmes</u> Including telephone counselling, individual and group counselling, provision of self-help materials	Various	Smoking cessation, abstinence (Various)	From all the five studies included in meta-analysis, there was evidence for the efficacy of smoking cessation interventions at the end of treatment (odds ratio, 1.54; 95% confidence interval, 1.09-2.16), which was attenuated in the longer term.	-

Table 3c. Summary SMOKING economic evaluation

Author (year)	Intervention (comparator)	Approach (Population)	Effectiveness measure	Costing (Discounting)	ICER (sensitivity)	Quality (-/+/0)
Begh 2011 (UK)	Smoking cessation outreach worker in Pakistani and Bangladeshi community • Community campaign focussed on improving access and behaviour change compared to standard care	Calculated the estimated total costs and quality adjusted life years gained from the programme as a whole. Produced the number of lifetime abstainers modelled from the short-term abstinence rate and the projected long-term abstinence rate using data evaluation of NHS SSS and from studies with long-term follow up Used the 95% confidence interval of the rate ratio for abstinence as the only sensitivity analysis of cost-effectiveness.	Targets were for outreach workers to treat a minimum of 10 smokers and achieve five 4-week quitters per month. Quit proportion was defined as the proportion of people achieving four weeks, three months, or six months prolonged abstinence allowing a standard two week grace period, with a denominator of all those who attended the service and set a quit date. Self-reporting at four weeks was verified by expired CO less than 10 parts per million	Perspective of the NHS as payer and assessed the costs of the intervention, with benefits and costs discounted at 3.5%. All costs are reported in UK pounds.	Estimated this intervention would yield an additional 14.6 QALYs. • Point estimate of the rate ratio for service use suggests effect of the intervention increases the number of smokers trying to quit by 83 (after adjustment for secular trends). • Applying the intervention four-week abstinence rates to this number yielded an additional 32 achieving four-week confirmed abstinence (estimated result is additional 5.6 lifetime abstainers applying relapse rates to one year and beyond). • The total cost of the intervention was £124,000; an estimated cost per QALY gained of £8,500 (upper limit of the 95% CI gave an estimated cost/QALY gained of £2,000; lower limit estimated cost/QALY gained of over £100,000).	+
Smith 2011 (USA)	Intensive telephone-based intervention for smoking cessation	Payer perspective The cost per quit was calculated and	VA records were used to extract the cost of VA services over 12	Discounting was deemed unnecessary for costs during a	Average cost-per-quit was $11,408 and deemed cost-effective by	+

	• Military veterans via US Department of Veterans Affairs compared with standard care	associated 95% CI were estimated. Two alternative assumptions about missing data. The initial intent-to-treat analysis treated decedents and persons lost to follow-up as smokers	months, and the cost of care purchased by the VA from others. Clinical data on quit rates, demographic characteristics and use of cessation-related services also extracted	study period of only 12 months. All costs are reported in USDollars 2009.	conventional standards. • The intervention cost $142 per person, excluding medications. • The average cost of all VA-funded medical care during the study period was $8959 in the telephone-care arm and $7939 in the usual care arm (P = 0.37).	

3.6 Evidence for ALCOHOL

Characteristics of included studies ALCOHOL

We included five papers on interventions aimed at changing alcohol consumption in mid-life: four primary studies, no systematic reviews and one economic study. **Table 4** presents a summary of the data and **Appendix A.10** the full data extraction.

Primary Studies

The mid-life focused searches identified three primary studies, one in the UK (Lock 2006), one in the US (Williams 2010) and one in the Netherlands (Boon 2011). One additional study identified by hand-search (Blankers 2011a; Netherlands) supports Blankers et al (2011b) economic evaluation of Internet based interventions and was also included. The follow-up time ranges from six to 18 months, with all studies using self-report of alcohol consumption as outcome measures. No primary studies focused on disadvantaged or minority groups in mid-life. Two of these studies (Boon 2011, Blankers 2011a) present results for Internet based interventions; one study (Lock 2006) assessed a face-to-face intervention and one (Williams 2010) a system wide level intervention.

Three core modalities of Internet-based interventions addressing problematic alcohol use are discernible: (a) *self-assessment* with automatised personalised feedback and comparison of behaviour with drinking norms; (b) multisession, internet-based *self-help* based on cognitive–behavioural therapy (CBT) and/or motivational interviewing techniques, and (c) individual internet-based *therapy* that incorporates non-automatised, personally tailored feedback with interaction with a therapist. Blankers et al (2011a) compared the effectiveness of Internet self-help (b) versus Internet based therapy versus (c) versus no treatment for problematic alcohol use. Boon et al. (2011) present the results of a RCT to assess the effectiveness of computer-based personalised feedback, i.e. self-assessment, so (a) versus information only on heavy alcohol use in Dutch male adults.

Lock et al (2006) present the results of a UK based cluster RCT looking at the effectiveness and cost-effectiveness of face-to-face nurse-led screening and brief intervention in reducing excessive alcohol consumption among patients (predominantly men) in primary health care. That RCT was supported by a systematic review published in 2006 (Hyman 2006) that concluded that very little had been done to develop and define the role of the nurse in delivering interventions to high-risk drinkers.

We found no primary studies in mid-life comparing face-to-face versus computer-based interventions.

Williams et al (2010) evaluated a system-level electronic clinical reminder to facilitate brief alcohol counselling intervention in primary care (i.e. at a single Veterans Affairs general medicine clinic). These studies are summarised in **Table 4a**.

Systematic Reviews (SR)

We found no SR looking specifically at the effect of alcohol focused interventions in mid-life or that have a majority of included studies focused on mid-life. Of the six alcohol focused SR published since 2010, one was based in China and was excluded on that basis, two looked at facilitators/barriers and are included in Review 1 (Bryden 2012; Bryden 2013). The three other SR cover a broad age range with the majority of studies not in mid-life (Khadjesari 2011; Rooke 2010; White 2010 and were excluded[2] (see Appendix A11 for abstracts). All three SR looked at computer-based interventions, and the evidence points to a beneficial effect of these. We searched back to 2000 to try and identify SR focused on sub/disadvantaged groups, however no reviews were identified.

Finally, between 2000 and 2009, six SR were published that were not focused on mid-life - these were also excluded (see Appendix A11 for abstracts). Five of these focused on the effectiveness of brief interventions (delivered mainly face-to-face by physicians, with short term follow-up, in primary care and emergency department settings) and one looked at behavioural counselling (as supporting evidence for the US Preventive Task Force). All six SR concluded these interventions could provide an effective component of a public health approach to reduce risky/harmful alcohol use.

Economic Evaluations

We identified six economic studies focused on Alcohol, only one with a focus on mid-life population (Blankers 2011b). That study builds on the results of Blankers et al (2001a) presented above, to evaluate the cost effectiveness and cost utility of Internet-based interventions for harmful use of alcohol through the assessment of the incremental cost effectiveness of Internet based therapy (c) compared with Internet based self-help (b) (**Table 4b**). The other five studies (Tariq 2009; Mansdotter 2007; Mortimer 2005; Fleming 2002) were not focused on mid-life and are excluded[1].

- Tariq et al (2009) investigated the cost-effectiveness of Screening and Brief Intervention (SBI) for excessive alcohol use in primary care in the Netherlands, which is targeted at early detection and treatment of 'at-risk' drinkers. The study compared several scenarios for a Dutch

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[2] Excluded SR and economic studies are described here to help put the mid-life findings into context. Theses SR and economic studies were not quality assessed, the data not extracted, and the findings not included in the evidence statements. Abstracts are included as supporting information.

population aged 18-65 years of age using the RIVM Chronic Disease model to extrapolate from decreased alcohol consumption to effects on health care costs and QALYs gained. A cost-effectiveness ratio of 5,400 Euros per QALY gained was estimated. The authors concluded that prevention of excessive alcohol use by implementing SBI for excessive alcohol use in primary care settings appears to be cost-effective.

- Mansdotter et al (2007) looked at the cost-effectiveness of alcohol prevention targeting licensed premises in Stockholm focusing on savings made as a result of fewer assaults, unlawful threats and violence towards officials, and the health gains in terms of QALYs, with data collected among victims of violence. The low response (35%) rate calls for caution when interpreting the results, but the authors nevertheless concluded that the monetary and human benefits have been considerable.

- Barrett et al (2006) investigated the cost effectiveness of screening and referral to an alcohol health worker in alcohol misusing patients attending an accident and emergency department in London using a decision-making approach. This intervention is out of scope.

- Mortimer et al (2005) compared the performance of competing and complementary interventions for prevention or treatment of problem drinking and alcohol dependence to provide an example of how (Australian) decision makers can use QALYs to help formulate an optimal package of care. They used a time-dependent state-transition model; interventions are divided into three clusters of mutually exclusive programs: (i) brief interventions for problem drinking; (ii) psychotherapy for mild to moderate dependence; (iii) drug-therapy adjuvant to counselling for detoxified patients with a history of severe physical dependence; effectiveness data comes from subjectively selected studies (for illustration purposes), with an included population ranging for 15 to 70 years old.

- Fleming et al (2002) looked at the cost-benefit of brief physician advice for problem drinkers in a population aged 18-65, building on efficacy data from the TrEAT trial conducted in the mid-90s in Wisconsin (Fleming, Lancet 1997). The long-term follow-up of Project TrEAT provides the first direct evidence that brief physician advice is associated with sustained reductions in alcohol use, health care utilisation, motor vehicle events, and associated costs. The report suggests that a patient's personal physician can successfully treat alcohol problems and endorses the implementation of alcohol screening and brief intervention in the US health care system.

Evidence statements for ALCOHOL (AL)

<u>**3.6.1AL**</u> <u>Effectiveness of Internet based interventions on uptake or maintenance of healthy drinking behaviours</u>

There is moderate evidence from two good quality RCTs [++][1,2] demonstrating that internet based interventions are effective at changing alcohol consumption in the short term; and better value for money than internet-based self-help and might therefore be considered as a treatment option [++][3].

Boon et al. [++][1] showed that Internet-based self-assessment appears to be effective at changing unhealthy drinking patterns in adult men in the short term (at one month; but not at the six month follow-up). Results from Blankers et al [++][2] support the effectiveness of Internet-based therapy and Internet-based self-help (both based on cognitive–behavioural therapy/motivational interviewing; compared to no intervention) for problematic alcohol users. At six months post-randomisation, Internet-based therapy led to better results than Internet-based self-help in terms of alcohol consumption, treatment response, and quality of life. Building on these results, Blankers et al 2011b [++][3] demonstrated that Internet based therapy offers better value for money than internet-based self-help and might therefore be considered as a treatment option.

[1] Boon et al 2011 [++]; [2] Blankers et al 2011a [++]; [3] Blankers et al 2011b [++]

- **Applicability:** Partially applicable - Both studies were conducted in the Netherlands, with one conducted only in men[1], and one in people who visited the website of a substance abuse treatment centre[2].

<u>**3.6.2AL**</u> <u>Effectiveness of nurse led interventions on uptake or maintenance of healthy drinking behaviours</u>

There is moderate evidence from one UK based high quality study [++][4] showing that a nurse-led intervention (five-ten minutes face-to-face intervention using the DrinkLess protocol) had no effect over standard advice delivered by nurses in primary health care.

[4] Lock et al 2006 [++]

- **Applicability:** Directly applicable - Study was conducted in the UK. However, the trial is underpowered and somewhat dated (published in 2006; the role of nurses in the NHS has most likely evolved since).

3.6.3AL Effectiveness of clinical reminder

There is moderate evidence from one high quality study [++][5] that availability of a system-level clinical reminder (aimed at clinical practitioners) to facilitate brief intervention did not, alone, result in substantial use of the clinical reminder nor with resolution of unhealthy drinking.

Williams et al evaluated an electronic alcohol-counseling clinical reminder at a single Veterans Affairs general medicine clinic. The systems-level intervention evaluated in this study consisted of making the clinical reminder, which facilitated medical record documentation of brief intervention among patients who screened positive for unhealthy alcohol use, available to providers on one (of two) randomly selected hallways. Secondary electronic data were extracted for all patients who visited the clinic (October 1, 2002, to September 30, 2005). The proportion of patients with clinical-reminder use was evaluated among patients who screened positive for unhealthy drinking and were assigned to intervention hallway providers ("descriptive cohort"). Adjusted logistic regression evaluated the association between the intervention and resolution of unhealthy drinking at follow-up among all screen-positive patients who completed a second Alcohol Use Disorders Identification Test Consumption questionnaire 18 months or longer after the first ("outcomes cohort"). Eligible patients (N = 22,863) included 10,392 controls and 12,471 in the intervention group. Fifteen percent (398 of 2,640) of descriptive cohort patients with unhealthy drinking had clinical-reminder use, which varied by severity (14% [n = 302 of 2,165] with mild/moderate and 20% [n = 96 of 475] with severe unhealthy drinking, p = .001). Only 39% (156 of 398) of patients with clinical-reminder use had documented brief intervention; advice to abstain was most common. Access to the clinical reminder was not significantly associated with resolution of unhealthy drinking in 1,358 patients in the outcomes cohort. Availability of a clinical reminder to facilitate brief intervention did not, alone, result in substantial use of the clinical reminder. More active implementation efforts may be needed to get brief interventions onto the agenda of busy primary care providers.

[5] Williams et al 2010 [++]

- **Applicability:** The evidence for system-wide clinical reminders is not directly applicable but may provide useful information about implementation issues.

Table 4a. Summary ALCOHOL primary intervention studies (focus on mid-life)

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Boon 2011	Netherlands	Adult men	40.4	Internet based self-assessment (Drinktest - Single 10 minute online session in which tailored feedback is delivered, with no therapist involved)	Information only	Self-report alcohol consumption (6 month)	Personalised online feedback on alcohol consumption appears to be an effective and easy way to change unhealthy drinking patterns in adult men, at least in the short-term (1 month p=0.01); findings not significant at 6 month.	++
Blankers 2011a	Netherlands	Adult population (recruited from Tx centre)	42.5	Internet-based self-help (SAO) vs Internet-based therapy (TAO)	Waiting list (WL)	i) Self-reported consumption ii) Treatment response: Alc. during last 7 days (BMA boundaries) and no more than 10% deterioration on AUDIT or QoLs or Global severity index of the Brief Symptom inventory iii) QOLs, EQ5D (6 month)	i) In all three arms, participants reported less alcohol consumption at the 3-month follow-up than at baseline (p<0.001); TAO vs WL (p=0.002), SAO vs WL (p=0.03). ii) TAO group drank significantly less compare to SAO group at 6 month post randomisation (p=0.03); the difference in treatment response was non-significant. iii) Differences between TAO and SAO were significant at 6mth for AUDI, QoLs & EQ5D.	++

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Lock 2006	UK	General practice clusters/ general population	Intervention 42.7 (15.5) Control 45.7 (14.9)	Nurse led screening and brief intervention "Drink less" protocol	Standard care (usual advice & Think about Drink leaflet)	Alcohol consumption (AUDIT & TLFB)* Quality of Life Cost (1 year)	No statistically significant differences between intervention groups in relation to any outcome measures. Significant reduction in AUDIT score for the whole sample at 1 year (p: 0.046)	++
Williams 2010	US	VA primary care clinic	58.5 (14.0)	Electronic Clinical Reminder to Facilitate Brief Alcohol-Counselling Interventions in Primary Care	No reminder	Frequency of clinical reminder, follow-up treatment or assessment re to alcohol (18 months)	Availability of a clinical reminder to facilitate brief intervention did not, alone, result in substantial use of the clinical reminder. More active implementation efforts may be needed to get brief interventions onto the agenda of busy primary care providers.	++

Table 4b. Summary ALCOHOL economic studies (focus on midlife)

Author (year)	Country	Population	Effectiveness measure	Costing	Effectiveness (discounting)	Cost (discounting)	CE / CU (ICER)	Uncertainty	Quality (-/+/0)
Blankers 2011b	Netherlands	General (recruited from treatment centre alongside a RCT) Age: 41.5 (9.83)	Treatment response based on Alcohol Consumption during last 7 days (BMA boundaries) and no more than 10% deterioration on AUDIT* or QoLs or Global severity index of the Brief Symptom inventory QALY from EQ5D & Dolan's UK tariff	Societal perspective Timeframe and all time-variant costs was **6 months** Intervention costs collected over 2004-2009 (devel. phase) Health care uptake Opportunity cost of participants' time Productivity loss	Effectiveness from Blankers 2011a (Table 4a). Based on intent to treat Treatment response (6 month): TAO: 36 / 68 = 0.53 SAO: 20 / 68 = 0.29 EQ5D: TAO: 0.89 SAO: 0.78 Incremental utility gain: 0.12 No discounting	Intervention costs (average) TAO: €283 SAO: €12 Productivity losses TAO: €1331 SAO: €886 Work absenteeism: considerable but not sign. different Total cost: TAO: €2010 SAO: €1120 Incremental: €845 (not sign.) No discounting	CE €845/0.24 = **€3521** for 1 additional treatment responder, 6 months after inclusion Median ICER €3683 (using bootstrapping) CU €845 / 0.06 = €14,083 for 1 extra QALY Median ICER: €14,710	TAO: 79% probability of leading to additional effect, at additional costs relative to SAO; 80% for QALYs 20% likelihood that TAO led to additional treatment effects and QALY at lower societal costs WTP at 50% was €3683/additional treatment responder; above that TOA more cost effective than SAO. At a WTP of €20,000/QALY, 60% probability that TAO more cost effective than SAO; at a WTP of €14,710 or more for 1 additional QALY, TAO must be considered cost effective in comparison with IS.	++

* AUDIT: Alcohol Use Disorders Identification Test; TLFB: alco

3.7 Evidence statements for WEIGHT MANAGEMENT (WI) interventions in mid-life

Characteristics of included studies for WEIGHT MANAGEMENT in mid-life

Note: The inclusion criteria for this review includes weight prevention, maintenance and management in overweight populations (to prevent obesity) at midlife but does not include management or treatment of obesity in populations with existing obesity (BMI >30). Primary studies in populations with BMI > 30 have therefore been excluded.

Two primary studies (published since 2000) and four systematic reviews (published since 2010) were included.

One included primary study in overweight participants was a randomised crossover trial in mid-life men and women of an exercise training intervention compared to a non-training control (Maiorana 2001, n=16). The other study had a pre-post-test design and evaluated a high intensity exercise training programme in Korean women (Lee 2012, n=22).

Two of the four included systematic reviews aimed to include RCT studies in both overweight and obese participants (BMI>25 kg/m^2). One included all populations and the majority of included studies were in midlife populations (Armstrong 2012). The other included non-white minority ethnic groups (Ossei-Assibey 2012). The third included systematic review evaluated a diet and physical activity training intervention delivered in real world settings for weight loss (in order to prevent diabetes) (Ali 2012). One further systematic review was excluded as all the included studies were in obese populations although the review did aim to include both overweight and obese populations (Fitzgibbon 2012). A fourth systematic review of yoga intervention trials included RCTs, controlled and uncontrolled studies with weight-related outcomes that were aimed at weight loss or weight-related risk reduction. (Rioux 2013).

Table 5 presents a summary of the data.

Evidence statements WEIGHT MANAGEMENT in mid-life

Effect of interventions on uptake and maintenance of healthy behaviours

Midlife weight management interventions

Overall summary

There is moderate evidence from two primary studies ([+][1]; [+][2]) and four systematic reviews ([+][3]; [+][4]; [+][5]; [+][6]) that a range of physical activity, dietary and lifestyle interventions are effective for weight management behaviours in midlife overweight populations:-

3.7.1WI *Exercise training*

There is weak and limited evidence from two ([+][1]; [+][2]) small primary studies (n=16, n=22) that supervised exercise training programmes of high or moderate intensity (including delivery as a group session) can improve body composition parameters such as skinfold thickness and waist to hip ratio but differences in body weight and BMI were not statistically significant.

[1] Maiorana 2001 [+]; [2]Lee et al 2012 [+]

- **Applicability**: Partially applicable. One primary study was in a midlife population of men and women in Australia and the other was conducted in middle-aged women in Korea. The training programmes were supervised so would be resource intensive.

3.7.2WI *Motivational interviewing*

There is inconsistent evidence relating to the use of motivational interviewing from one systematic review [+][3]. No significant effect was seen in any of three included studies in overweight populations but a meta-analysis in a larger sample in which studies in overweight and obese participants were included showed a significant benefit of motivational interviewing [+][3].

[3]Armstrong 2012 [+]

- **Applicability**: Partially applicable. The majority of included studies in the systematic review were in mid-life populations. The systematic review included international studies in men and women.

3.7.3WI *Dietary advice (with and without exercise)*

There is moderate evidence from one systematic review [+][4] that dietary advice based on American Heart Association step 2 diet (designed to provide 15% of calories as protein, 58% carbohydrate, 30% fat (7% saturated fat, 10% monounsaturated fat and 10% polyunsaturated fat)) plus endurance exercise or dietary advice to reduce fat intake to <20% are effective for weight loss in midlife populations [+][4].

[4] Ossei-Assibey 2010 [+]

- **Applicability**: Partially applicable. The majority of included studies in the systematic review were in midlife populations. The systematic review included only studies in ethnic minority groups and were international studies in men and women.

3.7.4WI *Lifestyle intervention*

There is moderate evidence from one systematic review [+][5] that a lifestyle intervention aimed initially at reducing total fat (which allowed participants to reduce total energy intake) and promotion of healthy eating, and the subsequent introduction of a concept of calorie balance, is effective for weight reduction in people at risk of diabetes whether delivered by clinically trained professionals or lay educators and with a range of delivery methods.

The systematic review only included studies based on the Diabetes Prevention trial (n=28 studies) that involved training people with prediabetes to achieve modest weight loss through diet and physical activity. Change in weight was similar when the intervention was delivered by clinically trained professionals or lay educators. The intervention involved additional support including clearly defined weight loss and physical activity goals, individual case managers or lifestyle coaches, intensive ongoing intervention and individualisation, materials and strategies that addressed the needs of an ethnically diverse population.

[5] Ali et al 2012 [+]

- **Applicability**: Partially applicable. The majority of included studies in the systematic review were in midlife populations. The systematic review included international studies in men and women.

3.7.5WI *Yoga*

There is moderate evidence from one systematic review [+][6] that yoga is effective for weight loss and prevention of weight gain in overweight populations. Yoga sessions were delivered in a group format.

[6] Rioux et al 2013 [+]

- **Applicability**: Partially applicable. Five of 17 included studies in the systematic review were in midlife populations but the results from primary studies included in the review support the conclusion that yoga is effective for weight management. The systematic review included international studies in men and women. Most of the relevant midlife studies were conducted in India.

Effect of midlife weight management interventions on long term dementia, disability, frailty or non-communicable diseases outcomes (in later life).

No studies found.

Effect of midlife weight management interventions on short term dementia, disability, frailty or non-communicable diseases outcomes (in midlife).

Weight outcomes reported in section 3.7.1WI

Cost-effectiveness of midlife weight management interventions

No studies found specifically in overweight populations.

Table 5. Summary WEIGHT MANAGEMENT primary intervention studies and systematic reviews

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
Primary mid-life studies									
Primary weight management studies in mid-life									
Maiorana 2001	Australia	Healthy, middle-aged people, n=16	47 (SE 2)	8 wk of supervised moderate intensity exercise - circuit training, combined aerobic and resistance exercise. Exercise bicycle, seven resistance exercises (dual seated leg press, left and right hip extension, pectoral exercises, shoulder extension, seated abdominal flexion, and dual leg flexion)	Not reported (randomised crossover trial but details of control phase not given	8 week intervention, 16 week follow up.	Body composition (16 weeks)	There were no significant differences in body weight and BMI between intervention and control groups after training, although the sum of skinfolds (144±10 vs 134±9 mm, P<0.001) and waist:hip ratio (0.92±0.02 vs 0.90±0.02, P<0.05) significantly decreased.	+
Lee 2012	Korea	Middle-aged and elderly women	Control 38.3±4.9 Low intensity exercise 41.6±4.5 High intensity exercise	Supervised exercise sessions with individual targets	Pre/post test design	8 weeks	Body weight, body mass index, body fat, and blood pressure	Study reported significant between group improvements in BMI between the high intensity exercise group (n=7) and the control group (n=7) but not between the low intensity exercise group (n=8) and control group p<0.05. BMI changed from 25.4 (2.7) to 24.3 (2.3) in the high intensity group and from 27.3 (2.3) to 27.0 (1.7) kg in the control group. There were no significant between group differences for weight (kg) although there was a	+

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
			41.7±4.3					significant pre-post test difference in the high intensity group.	
Systematic reviews									
Systematic reviews of weight maintenance or management in overweight populations									
Ossei-Assibey 2010	International	Adults from minority ethnic/non-white groups (Studies included African American, Hispanic, Japanese-American populations)	45-59 (in studies in overweight populations)	Dietary and lifestyle interventions for weight management - RCTs	Any relevant control – see results section	Intervention > 6 months	Weight	The review aimed to include studies in overweight as well as obese participants but in most of the included studies mean BMI was >30kg/m^2 so were in obese groups. Nineteen studies were included but only 2 were in overweight, BMI 25-30 kg/m^2 (rather than obese) populations: The overall conclusions of the review (narrative synthesis) and the conclusions of the individual studies in overweight people are reported below. _Overall conclusions (overweight and obese included)_ Most of the included dietary and lifestyle interventions achieved positive weight management results in people from minority ethnic groups. 1) There is some evidence that group/family based interventions are effective in African Americans compared to individual interventions; 2) that low fat diets are effective in Black and Hispanic populations 3) that nutrition education and cookery classes with provision of fruit and	+

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
								vegetables are effective in African Americans; 4) there is some evidence that web based tailored weight management programmes (healthy eating and PA) are more effective than web based information only. *Interventions in overweight people* Interventions in people with impaired glucose tolerance One study (Liao et al 2009). Significant weight loss was achieved in intervention group (-1.8 +/- 0.5 vs 0.7 +.- 0.6 kg, p= 0.002). Intervention was dietary advice based on American Heart Association (AHA) step 2 diet plus endurance exercise. Control group followed AHA step 1 diet plus stretching exercise. Low fat diet vs general dietary info One study (Hall et al 2003). Intervention group received dietary advice to reduce fat intake to < 20% E, control group received a pamphlet on general dietary guidelines. Both groups lost weight but difference between groups only statistically significant in Black participants (not sig in Hispanic participants).	
Armstrong 2011	International	Adults	41-62 years (included studies)	Motivational interviewing to improve weight loss in overweight	Any relevant control	Any follow up (included studies		The review aimed to include studies in overweight as well as obese participants but in most of the included studies mean BMI was >30kg/m^2.	++

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
				and/or obese participants.				Nineteen studies were included but only 2 were in overweight, BMI 25-30 kg/m^2 (rather than obese) populations: 12 studies met the inclusion criteria and 11 were included for meta-analysis (1 excl due to inappropriate randomisation) but only 3 were in overweight, BMI 25-30 kg/m^2 (rather than obese) populations: <u>Overall conclusions of the review</u> Motivational interviewing was associated with a significant reduction in body weight (kg) for those in the intervention group compared with those in the control group (WMD = -1.47 kg [95% CI -2.05, -0.88]). For BMI the WMD was -0.25 kg m$_{-2}$ (95% CI -0.50, 0.01), not sig . There is some evidence that motivational interviewing appears to enhance weight loss in overweight and obese patients. Note: However the 3 individual studies in overweight populations found no significant differences between MI and control groups. <u>Results of individual studies in overweight participants</u> <u>Amrit 2009 (age not reported) n=136 inactive adults:</u> Counselling for physical activity delivered as a 30-min individual counselling session followed by three 10- to 15-min phone calls over 12 weeks Those in intervention group (3 months) lost 0.1 (4.6) kg from 28.3 (4.6) to 28.2 (4.6) kg and	

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
								control group gained weight 1.8 (5.1) kg (from 27.9 (5.1) kg pre to 29.7 (5.1) kg post intervention. Elliot 2007 (mean age 41) n=599 firefighters: MI for PA and diet behaviours delivered as four face-to-face sessions. Those in intervention group (12 months) gained 0.2 (3.9) kg from 27.1 (3.9) to 27.3 (3.9) kg and control group gained 0.5 (4.2) kg (from 27.9 kg pre to 28.4 kg post intervention. Mhurchu 1998 (mean age not reported) n=97 people with hyperlipidaemia: MI for diet, 3 sessions of MI with dietary counselling. Those in intervention group (3 months) lost 0.45 (0.7) kg from and control group lost 0.44 (0.6) kg.	
Ali 2012	USA	People at high risk for diabetes	55.1 years	Lifestyle intervention aimed at weight loss (in order to prevent diabetes). Only included studies based on the Diabetes Prevention trial	Included both controlled and uncontrolled studies	(Any follow up)	Weight	Across all studies, mean weight change was −3.99%; 95%CI: −5.16, −2.83; I^2 = 52.4%) at twelve-month. Results were comparable when delivered via medical and allied health professionals (−4.27%; 95%CI: −5.85, −2.70), lay community educators (−3.15%; 95%CI: −5.46, −0.83), and those using electronic media–assisted interventions (−4.20%; 95%CI: −7.62, −0.77).s	+
Rioux 2013	International (most studies conducted in US or India)	Any	Any (including children)	Yoga as an intervention for weight loss or as a means of risk reduction for obesity	Any relevant control	Any follow up	Weight related anthropometric outcome measures	The review aimed to include randomised and non-randomised studies in all populations including children and adults and including people of normal weight, overweight or obese. Of 17 included studies, 2 were in children, 5 were specifically in midlife populations, 3 were	+

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
								in broader range adult groups e.g. 18 to 76y, 5 were in younger adults and in 2 the age was not reported.	
								Of the five studies specifically in midlife populations:-	
								Sivasankaran et al 2006 (India), Uncontrolled pre-post trial, n=33 Mean age 55, 30% of participants had coronary artery disease; 6 wk intervention on 3 d per wk. No control group. BMI change from 29 (5) to 28 (5), p<0.01.	
								McCaffrey et al, 2005 (Thailand), RCT, n=61 Mean age 56, participants with hypertension not currently on hypertensive medication; 8 wk intervention on 3 d per wk. Control group, outpatient care, no yoga or stress reduction. BMI change from 25.74 (2.87) to 25.5 (2.71) in intervention group and 25.32 (3.19) to 25.37 (3.31) in control group, p<0.05.	
								Manchanda et al 2000 (India), RCT, n=42 Mean age 51, participants with coronary artery disease; Intervention: 4 day residential program plus 1 year of home practice AND dietary modification (low fat, low cholesterol, high carb, high fibre diet). Control: Heart Association Step 1 diet (not clear if this is same diet as intervention group). Weight change from 72 (12) to 66 (8) kg in intervention group and from 73	

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
5.								(10) to 72 (9.7) in control group, p=0.005. Murugesan 2000 (India), RCT, n=33 Age 35-65y participants with hypertension, Intervention, 11 wk, 6d/wk; Control 1 (n=11) drug treatment, control 2 (n=11) therapeutic advice. Weight change from 54.75 (10.23) to 47.32 (9.5)) kg in intervention group, p<0.01 and from 57.58 (12.2) to 53.29 (10.26) in drug therapy control group 1, p<0.01; and from 47.49 (10.56) to 49.25 (11.25) in advice group control (ns), *not clear if p values for between group differences or pre-post differences.* Mahajan et al 1999 (India), RCT, n=93 Age 56-59, all male, angina patients or normal subjects with >/= 2 risk factors for CHD. Intervention 4d residential course, followed by home practice for 14 wk. Control: conventional care and lifestyle advice. Weight change in intervention group participants with angina was from 68.51 (7.06) to 67.15 (10.39) kg compared to from 74.94 (12.53) to 74.29 (12.04) in matched control (p<0.05) and in normal subjects with risk factors it was from 74.26 (11.61) kg to 70.48 (10.48) compared to from 67.15 (10.39) to 66.68 (10.07) in matched control. (p<0.05)	

3.8 Evidence for MULTIPLE COMPONENT/LIFESTYLE/BEHAVIOURAL interventions

Characteristics of included studies MULTIPLE COMPONENT LIFESTYLE

Three primary studies published since 2000 have been included (Gaston 2007, Lakerveld 2013, Lee 2012) and three systematic reviews published since 2010. These primary studies were conducted in USA, Korea and the Netherlands. All included studies used self-reported lifestyle data.

One primary study evaluated a gender-specific, culturally relevant, cognitive behavioural health intervention in mid-life African-American women (Gaston 2007). One was a mindfulness based intervention based on cognitive behavioural therapy (Lee 2012). One was a telephone delivered motivational interviewing intervention (Lakerveld 2013).

The three systematic reviews examined 1) the effect of internet-based lifestyle interventions (Aalbers 2011); 2) multiple risk factor interventions based on counselling and education (Ebrahim 2011) on lifestyle behaviours; 3) dietary and lifestyle interventions to prevent progression of people with impaired glucose tolerance to diabetes (Hopper 2011).

Evidence statements for MULTIPLE COMPONENT/LIFESTYLE/BEHAVIOURAL (MC) interventions in mid-life

Effect of midlife interventions on uptake and maintenance of healthy behaviours at mid-life

3.8.1MC Cognitive behavioural interventions

There is weak evidence from one [-][1] primary study with a pre-post test design that a cultural and gender specific cognitive behavioural intervention is effective in improving uptake of physical activity and improving diet in African American women aged >35 years.

The intervention (n=106) was based on group sessions over 10 weeks. Each group was led by a facilitator who with the exception of one, were midlife African-American women. The women were set specific goals related to nutrition, physical activity and stress management and were taught specific cognitive behavioural strategies and skills. (This study is also included in the DISADVANTAGED/MINORITY GROUPS section).

[1] Gaston et al 2007 [-]

- **Applicability**: Partially applicable. The intervention was conducted in the US among African American women. There may be some cultural differences between US African American and UK ethnic minority populations. The intervention was delivered in a group setting with a facilitator which could be applied in the UK.

3.8.2MC Motivational interviewing and problem solving

There is weak evidence from one [++][1] primary study that a telephone intervention based on motivational interviewing may have a small effect on improving diet behaviour in the short term but this was not maintained longer term (one year).

The primary study [++][1] was conducted in the Netherlands in midlife adults (n=502) with risk of type 2 diabetes or CVD and involved three monthly telephone sessions of motivational interviewing and problem solving intervention relating to diet, physical activity and smoking. An increase in fruit intake of 0.2 pieces of fruit per day in the control group was found not to be significantly different after 12 months. There was no significant difference between the groups in changes in physical activity, vegetable intake or smoking behaviour over the 12 month follow-up period.

[1] Lakerveld et al 2013 [++]

- **Applicability**: Partially applicable. The intervention was conducted in the Netherlands among midlife women. There may be some cultural differences between US African American and UK ethnic minority populations. The intervention was delivered by telephone which could be applied in the UK.

3.8.3MC Internet based lifestyle intervention

There is moderate evidence from one [+][1] systematic review that Internet based lifestyle interventions, whether based on tailored or generic information, can improve physical activity, diet and weight loss behaviours. Complex interventions (consisting of more than one component) were more effective than single component interventions.

There is also moderate evidence from one [+][1] systematic review that interventions delivered via social networking sites are not effective in people aged over 50.

The systematic review [+][1] only included studies in people aged over 50 years and examined the effect of Internet mediated lifestyle interventions on lifestyle factors. The review included

10 studies focused on physical activity, weight loss, nutrition and diabetes prevention, most of which reported a small to moderate beneficial effect size. Overall conclusions were that complex interventions were more effective than interventions with only one component. This applied whether information was tailored or generic. Studies in social networking sites were reported to be ineffective as they are less often accessed by people aged over 50 years.

[1] Aalbers et al 2011 [+]

- **Applicability**: Partially applicable. The systematic review included international studies. Internet delivered interventions could be applied in the UK.

3.8.4MC Interventions based on counselling or education and aimed at modifying more than one CVD risk factor

There is moderate evidence from one systematic review that multiple risk factor interventions based on counselling or education (usually including diet and/or physical activity are effective.

One systematic review [++][1] evaluated the effects of multiple risk factor interventions based on counselling or education and aimed at modifying more than one CVD risk factor of more than six months duration for reducing total mortality, fatal and non fatal CHD events and cardiovascular risk factors. Fourteen trials (139,256 participants) reported clinical event endpoints, the pooled ORs for total and CHD mortality were 1.00 (95% CI 0.96 to 1.05) and 0.99 (95% CI 0.92 to 1.07), respectively. The OR for reduction in smoking prevalence (20 trials) was 0.87 (95% CI 0.75 to 1.00). However, the pooled estimates should be treated with caution as there was marked unexplained heterogeneity. Interventions using counselling and education aimed at behaviour change do not reduce total or CHD mortality or clinical events in general populations but may be effective in reducing mortality in high-risk hypertensive and diabetic populations. Risk factor declines were modest but owing to marked unexplained heterogeneity between trials, the pooled estimates should be treated with caution.

[1] Ebrahim et al 2011 [++]

- **Applicability**: Partially applicable. The systematic review included international studies. Such multiple risk factor interventions could be delivered in the UK.

3.8.5MC Effect of mid-life interventions on long term dementia, disability, frailty or non-communicable diseases outcomes (in later life)

There is moderate evidence from one [+][1] systematic review of studies with mean age in midlife that lifestyle interventions (diet and/or exercise) can reduce progression of impaired glucose tolerance (IGT) to diabetes, relative risk 0.52 (95% CI 0.46-0.58).

The systematic review [+][1] included studies in both men and women, mean age in studies was 52 years. Both non-drug and drug based interventions reduced progression to overall diabetes but the beneficial effect was greater with non-drug lifestyle intervention (diet and/or exercise). However, there were no reductions in all-cause or cardiovascular mortality, or myocardial infarction. Reduction in fatal or non fatal stroke was of borderline significance.

[1] Hopper et al 2011 [+]

- **Applicability**: Partially applicable. The systematic review included international studies. Diet and/or physical activity lifestyle interventions could be delivered in the UK

3.8.6MC Effect of diet interventions on short term dementia, disability, frailty or non-communicable diseases outcomes (in mid-life)

There is weak evidence from one primary study [+][1] that mindfulness based cognitive therapy in midlife populations can have a positive effect on mental health outcomes.

One primary study [+][1] evaluated the effect of 8 weeks of mindfulness based cognitive therapy on mental health outcomes and reported significant positive effects on wellbeing, anxiety and depression in Korean women (n=60) aged 37 to 55 years.

[1] Lee et al 2012

- **Applicability**: Partially applicable. The primary study that reported a beneficial association was conducted in Korea [+][1] .

Table 6a. Summary MULTIPLE COMPONENT/LIFESTYLE/BEHAVIOURAL primary intervention studies

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Gaston 2007	USA	African-American women aged >35	54.4 (SD 9.46)	Educational workshop and a "sister-to-sister" support structure	Comparison group with educational book	Perception of overall health, self-care, Nutrition and eating patterns (1 year)	There were significant changes in physical activity from pre-test to post-test. At six months post-test, the women reported participating in aerobic exercise, on average, 2.48 days per week at six months [t(30)=2.02, p<0.05] and 3.21 days at 12 months [t(42)=3.05, p<0.01].	+
Lakerveld 2013	Netherlands	Adults with ≥10% estimated risk of T2DM and/or CVD mortality	Control 43.4 (5.5) Intervention 43.6 (5.1)	3-monthly telephone sessions of motivational interviewing and problem solving treatment	Control group received existing health brochures	Estimated diabetes risk, estimated risk for CVD mortality, diet, physical activity and smoking (1 year)	There were no significant between-group differences in either of the estimated risk scores between the intervention and the control group at either follow-up. An increase in fruit intake of 0.2 pieces of fruit per day in the control group was found not to be significantly different after 12 months. No significant difference between the groups with regard to changes in physical activity, vegetable intake or smoking behaviour over the 12 month follow-up period.	++
Lee WK 2012	Korea	Women aged 37–55	Intervention 41.46 (5.41)	Mindfulness-based cognitive therapy	Wait-list control	Psychological well-being, depression, anxiety, hostility, somatization,	There were significant time x group effects with regard to Psychological well-being [F(1, 58) = 15.38, p < 0.01], depression [F(1,58) = 15.60, p < 0.01], anxiety [F(1, 58) = 14.03, p < 0.01].	+

			Control 40.36 (6.17)			positive affect and negative affect (8 weeks)	

Table 6b. Summary MULTIPLE COMPONENT/LIFESTYLE/BEHAVIOURAL systematic reviews

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Outcomes	Results Association	Quality (-/+/0)
Effective media, internet mediated								
Aalbers 2011	International	Adults age of 50 years or older	54.9 years (±8.3)	Internet delivered social support, physical activity, weight loss and programmes	Both online and offline control groups	Body weight, BMI and physical activity (Any follow up)	The effect sizes are small to moderate-small. Average effect size for the online interventions in comparison to the offline and online control groups is 0.19 (±0.21) and 0.39 (±0.37), respectively	+
Effective face-to-face								
Ebrahim 2011	International	Adults assumed to be without prior clinical evidence CHD	50 years (35 to 75 years)	Health promotion activity, counselling and educational interventions	Control or usual care groups	Smoking prevalence, CHD, all cause mortality (>6 months duration)	All analyses showed considerable heterogeneity of effect; however studies with the highest baseline DBP, smoking prevalence and blood cholesterol levels demonstrated larger falls in risk factors at follow up. The RR for reduction in smoking prevalence (20 trials) was not significant 0.87 (95% CI 0.75 to 1.00). Blood cholesterol levels showed a small but highly significant fall (weighted mean net difference -0.07 mmol/L; 95% CI -0.08 to -0.06)	++

Hopper 2011	Internatio nal	Particip ants with impaired glucose toleranc e and impaired fasting glucose	52 years (45 to 64 years)	lifestyle intervention (diet, exercise or diet with exercise) or pharmacological intervention	Lifestyle arm, a drug arm and placebo control groups	Weight loss, prevention of diabetes, all-cause and cardiovascul ar mortality, incidence of major cardiovascul ar events (2.8 to 6 years)	The lifestyle interventions in the non-drug trials achieved greater weight loss than those in the drug trials. Diabetes was delayed or prevented by these interventions vs control (RR 0.83, 95%CI 0.80–0.86). Non-drug approaches vs drug-based approaches (0.52, 0.46–0.58 vs 0.70, 0.58–0.85, P<0.05)	+

3.9 Evidence for DISADVANTAGED AND MINORITY GROUPS

Characteristics of included studies DISADVANTAGED AND MINORITY GROUPS

Four primary studies (published since 2000) and nine systematic reviews (published since 2010) were included that were conducted in disadvantaged or minority groups.

Two primary studies were physical activity interventions. One was conducted in Pakistani men (Andersen 2013) and one in UK men from urban deprived neighbourhoods (Goyder 2014). One was a study of smoking in UK Pakistani and Bangladeshi men (Begh 2011). The other primary study was a cognitive behavioural based intervention to improve physical activity and diet behaviour in African American women (Gaston 2007).

Five systematic reviews were aimed at physical activity interventions, one in South Asian populations (Chapman 2013), one in socioeconomically disadvantaged populations in general (Cleland 2012), one in socioeconomically disadvantaged women (Cleland 2013), one in Hispanic adults (in the US; Ickes 2012) and one in healthy minority adults (Conn 2012).

One primary study and one systematic review were aimed at smoking cessation. The primary study was conducted in Pakistani and Bangladeshi men in the UK (Begh 2011), the systematic review was conducted among Hispanic populations in the US (Webb 2010). Two systematic reviews involved weight loss or weight management interventions, one in African-American women (in the US; Fitzgibbon 2012) and one in minority ethnic or non-white groups in general (Ossei-Assibey 2010). One primary study evaluated a gender-specific culturally relevant health intervention to decrease major risk factors in mid-life African-American women (Gaston 2007). One systematic review investigated community based health and health promotion for homeless people (Coles 2012).

Additionally, two systematic reviews previously described above, also incorporated both diet and physical activity lifestyle interventions, one investigated effectiveness in South Asian populations (Chapman 2013) and one examined weight management in minority ethnic groups (Ossei-Assibey 2010).

Table 7 presents a summary of the data

Evidence statements for interventions in DISADVANTAGED AND MINORITY GROUPS (DM)

Effect of interventions on uptake and maintenance of healthy behaviours

3.9.1DM Physical activity – physical activity interventions in ethnic minority groups

There is moderate evidence from two [+][1], [-][2] systematic reviews and one primary study [+][3] in ethnic minority groups that a range of lifestyle and behavioural physical activity interventions and settings to promote PA are effective in ethnic minority groups. There is some moderate and consistent evidence from one [+][3] primary study that an intervention including structured exercise, group lectures, counselling and phone calls is effective in increasing PA in Pakistani men. There is some moderate and consistent evidence from one review [+][1] that social support incorporated into interventions in ethnic minority groups is an effective strategy. There is some weak evidence from one review and meta-analysis of 21 studies that motivational and educational PA interventions are effective in increasing PA levels [-][2].

In the primary study in Pakistani men in Norway [+][3], the intervention included structured group exercise, group lectures, individual counselling sessions and phone calls. PA was measured using accelerometry and there was a 15% (95% CI 8.7-21.2) increase in PA in the intervention group.

One systematic review in Hispanic adults in the US found that community [+][1], clinical, family-based and faith-based interventions were effective in improving the level or frequency of PA participation. Not all studies reported effect on PA behaviours such as uptake or participation in PA (some just reported changes in related measures such as knowledge or attitudes) PA behaviours were self-reported. Of those measuring PA as an outcome, 72% reported an improvement in PA (13 studies). Five interventions reported an increase in minutes walking and/or associated METS, three interventions reported an increase in individuals meeting recommended PA levels, two found an increase in MVPA and one an increase in VPA. Intervention settings varied, the target populations, theoretical frameworks, and intervention strategies were very different but social support was incorporated into 65% of the interventions and 60% of those resulted in an increase in PA levels.

One systematic review [-][2] of PA interventions in a range of ethnic populations in the US found that interventions designed to motivate ethnic minority adults to increase PA significantly changed subsequent PA behaviour and anthropometric outcomes. Motivational and educational interventions designed to increase PA significantly increased PA behaviour

in meta-analysis of 21 studies with treatment versus control group comparison. Random effects analyses reported a standardised mean difference (*d*) of 0.172 (95% CI 0.023, 0.321) in subsequent physical activity behaviour. For PA motivation interventions, the typical intervention was of 10 sessions lasting 49 minutes. Thirty two studies were found of supervised exercise interventions, typically 40 minutes of verified exercise three times weekly over 11 weeks, mostly moderate intensity exercise, (n=19), low intensity (n=3) and high intensity (n=1). There was a significant increase in fitness levels (effect size: 0.172 – 0.312) in treatment versus control groups but compliance and uptake of the interventions not reported.

[1] Ickes et al 2012 [+]; [2] Conn et al 2012 [-]; [3] Andersen et al 2013 [+]

- **Applicability**: Partially applicable. The primary study in Pakistani men was conducted in Norway. The systematic reviews only included studies that were conducted in ethnic minority groups in the US. The primary study and reviews cover a wide variety of interventions, which in general could be applied in the UK. Interventions involving group exercise, counselling, phone calls, social support, motivational and educational interventions or supervised exercise interventions could be applied in the UK and the settings are mainly relevant to the UK although faith and cultural requirements may be different.

3.9.2DM Physical activity – physical activity interventions in socioeconomically disadvantaged populations

Group delivery interventions

There is moderate evidence from two [+][1], [+][2] systematic reviews that evaluated interventions to promote physical activity among socioeconomically disadvantaged populations in general and among socioeconomically disadvantaged women that programmes with a group delivery mode are effective in increasing PA in both these populations.

One systematic review found that there was sufficient evidence from 12 studies in adults to recommend that group interventions are effective to influence PA behaviour in adults [+][1]. There was some limited evidence of effectiveness of community based interventions. (Based on additional expert opinion, the authors made a recommendation that community based interventions are effective in socioeconomically disadvantaged communities). There was insufficient evidence from the same review [+][1] to assess the effectiveness of interventions

targeting individuals. One systematic review in women [+][2] from socioeconomically disadvantaged communities also found that group interventions were effective.

- **Applicability**: Partially applicable. The two systematic reviews included international studies in socioeconomically disadvantaged communities. Most studies were conducted in the US. One of the systematic reviews specifically reported studies in women. The group interventions described could be applied in the UK.

Community interventions

There is weak, limited evidence from one systematic review that community interventions are effective in promoting uptake of physical activity in socioeconomically disadvantaged populations [+][1].

See above for further information.

- **Applicability**: Partially applicable. The systematic review included international studies in socioeconomically disadvantaged communities. Most studies were conducted in the US. The group interventions described could be applied in the UK.

Booster interventions based on motivational interviews

There is moderate evidence from one primary study [++][3] that booster interventions based on motivational interviews to sustain increases in PA in middle-aged men who had previously taken part in a PA intervention are not effective in further improving PA behaviour in middle-aged men from deprived urban neighbourhoods.

The [++][3] primary study evaluated 'booster' interventions to sustain increases in PA in middle-aged men from deprived urban neighbourhoods. Participants had two sessions of motivational interviews either face to face - 'full booster' or by telephone - 'mini booster'. The control group had no further intervention. Mean difference in total energy expenditure (TEE) measured by 7-day accelerometry was not statistically significant for either intervention. Neither intervention was shown to be cost-effective.

[1] Cleland et al 2012 [+]; [2] Cleland et al 2013 [+]; [3] Goyder et al 2014 [++]

- **Applicability**: Directly applicable. The primary study was conducted in the UK (Sheffield) in men from deprived urban neighbourhoods.

3.9.3DM Smoking – smoking cessation behaviour in ethnic minority populations

There is moderate evidence from one primary study, an RCT conducted in the UK [+][1], that trained community outreach workers can be effective in promoting smoking cessation behaviour among Pakistani and Bangladeshi men. There is weak evidence from one systematic review [-][2] in healthy Hispanic adults living in the US that a range of smoking cessation programmes including telephone counselling, individual and group counselling, provision of self-help materials are effective in this population.

The systematic review included 12 intervention studies (randomised and non-randomised), five of which were RCTs that were included in a meta-analysis. The age range of included studies was 35-44 (mean 40.70 SD 3.21). Interventions consisted of self-help, nicotine replacement therapy, and community-based interventions, as well as individual, group, and telephone counselling. The five randomised studies included in the analysis were interventions based on telephone counselling, individual and group counselling, provision of self-help materials and nicotine replacement therapy. From all the five studies included in meta-analysis, there was evidence for the efficacy of smoking cessation interventions at the end of treatment (odds ratio, 1.54; 95% confidence interval, 1.09-2.16), which was attenuated in the longer term. Each of the individual studies also reported a beneficial effect of the intervention.

One primary study [+][1] evaluated a pilot cluster randomised controlled trial in Birmingham comparing the effectiveness of Pakistani and Bangladeshi smoking cessation outreach workers with standard care to improve access to and the success of English smoking cessation services. The study found that more Pakistani and Bangladeshi men made quit attempts with NHS services in intervention areas compared with control areas, rate ratio (RR) 1.32 (95%CI: 1.03-1.69). There was a small increase in the number of four-week abstinent smokers in intervention areas (RR 1.30, 95%CI: 0.82-2.06). The proportion of service users attending weekly appointments was lower in intervention areas than control areas. No difference was found between intervention and control areas in choice and adherence to treatments or patient satisfaction with the service.

[1] Begh et al 2011 [+]; [2] Webb et al 2010 [-]

- **Applicability**: Primary study: Directly applicable. The study was conducted in the UK. Trained community outreach workers could be applied in the UK amongst similar populations. SR: Partially applicable. The types of smoking cessation programmes included in the systematic review could be applied in the UK. There are likely to be cultural differences between US Hispanic populations and UK populations.

3.9.4DM Smoking – Cost effectiveness of smoking cessation behaviour in ethnic minority populations

One primary study [+][1], described above, evaluated a pilot cluster randomised controlled trial in Birmingham comparing the effectiveness of Pakistani and Bangladeshi smoking cessation outreach workers with standard care to improve access to and the success of English smoking cessation services. The total cost of the intervention was £124,000; an estimated cost per quality-adjusted life year (QALY) gained of £8,500. The authors concluded the intervention proved feasible and acceptable. The outreach worker model has the potential to increase community cessation rates and could prove cost-effective, but needs evaluating in a larger, appropriately powered, randomised controlled trial.

[1] Begh et al 2011 [+]

- **Applicability**: Directly applicable. The study was conducted in the UK. Trained community outreach workers could be applied in the UK amongst similar populations.

3.9.5DM Diet and PA interventions in ethnic minority populations

There is weak and limited evidence from one systematic review [+][1] in South Asian populations that diet and physical activity interventions can improve dietary and/or physical activity behaviour.

The review included any community or primary care based intervention study conducted in developed countries that reported data for South Asian adults. Both randomised and non-randomised controlled studies were included, including before and after study designs. Four studies met the inclusion criteria and evaluated community interventions with South Asian populations, but there was limited evidence for effects on behaviour as only two studies evaluated behavioural outcomes. Both were uncontrolled before and after studies and used self-reported measures. In one study, the intervention included individual tests and CHD/diabetes risk profile, nutritional support from dietetic clinics, optional practical activities including cookery workshops, exercise classes and awareness sessions. The intervention was delivered at the project base and community venues by health visitors and South Asian community workers with interpreter and translator services. The other study reported improved physical outcomes but no information on level and uptake of diet and physical activity behaviour.

[1] Chapman et al 2013 [+]

- **Applicability**: Partially applicable. The South Asian populations included were from developed countries. The intervention could be delivered in the UK and in UK settings.

3.9.6DM Cognitive-behavioural health interventions in ethnic minority populations

There is weak evidence from one [-][1] primary study with a pre-post test design that a cultural and gender specific cognitive behavioural intervention is effective in improving uptake of physical activity and improving diet in African American women aged >35 years.

The intervention (n=106) was based on group sessions over 10 weeks. Each group was led by a facilitator who with the exception of one, were midlife African-American women. The women were set specific goals related to nutrition, physical activity and stress management and were taught specific cognitive behavioural strategies and skills.

[1] Gaston et al 2007 [-]

- **Applicability**: Partially applicable. The intervention was conducted in the US among African American women. There may be some cultural differences between US African American and UK ethnic minority populations. The intervention was delivered in a group setting with a facilitator which could be applied in the UK.

3.9.7DM Health promotion interventions (general) in socioeconomically disadvantaged communities

There is weak evidence from one systematic review [++][1] that included that looked at health promotion in general that intervention can improve health promotion behaviours relating to smoking cessation and mental health appointments. (While the systematic review is rated good quality overall, the evidence relevant to this review is weak).

The review reported one study that found participants in a trial-based at a homeless shelter were more likely to attend appointments at a community mental health centre (64.7% vs 37.3%), one smoking cessation pilot trial based on group and individual motivational sessions had higher effectiveness when nicotine replacement therapy was combined with motivational interviewing, that included smoking, life behaviours and addiction (27.4%) than smoking behaviours alone (15.4%), and one study that demonstrated improved uptake of

dental health check-ups. All individual trials were conducted in the US.

[1] Coles et al 2012 [++]

- **Applicability**: Partially applicable. International systematic review, relevant studies conducted in US. Similar health promotion interventions could be applied in the UK among similar populations.

3.9.8DM Weight management interventions in ethnic minority groups (in people who are overweight)

There is weak evidence from one systematic review [+][1] that dietary advice, interventions delivered by peer educators and web based tailored weight management programmes may be effective interventions in ethnic minority groups to promote weight loss behaviour in ethnic minority groups.

The systematic review is a comprehensive review in minority ethnic groups. The review aimed to include studies in overweight as well as obese participants but most of the studies were in obese people. Nineteen studies were included but only three were in overweight (rather than obese) populations: only studies and conclusions based on overweight populations are considered here to meet the inclusion criteria for the review. Details of the primary studies are listed in the summary evidence table.

In one study, intervention was dietary advice based on AHA step 2 diet plus endurance exercise in Japanese Americans. The control group followed AHA step 1 diet plus stretching exercise. Significant weight loss was achieved in intervention group (-1.8 +/- 0.5 vs 0.7 +.- 0.6 kg, p= 0.002). In another study aimed at weight prevention, the intervention was nutrition education and cookery classes delivered by peer educators to African American women and provision of fruit and vegetables. Significant weight loss was reported in the intervention group compared to control (-2.0 +/-3.2 vs 1.1 +/- 2.0 kg). In the third study, aimed at weight management, web based tailored weight management programme (healthy eating and PA) vs web based information only gave significantly greater weight loss (healthy eating and PA) compared with information only group - 1.21 +/-0.1 vs -0.48 +/- 0.2 kg (p=0.007).

A further systematic review (Fitzgibbon et al 2012) was found which aimed to include both overweight and obese populations, however all included studies were in obese populations. It is included in the evidence summary tables for information but has not been included as evidence for this evidence statement.

[1] Ossei-Assibey et al 2010 [+]

- **Applicability**: Partially applicable. International systematic review, relevant studies conducted in US. Similar weight management interventions could be applied in the UK among similar populations. However there may to be cultural differences between the US African American and Japanese American populations studied and UK ethnic minority groups.

Effect of interventions in disadvantaged groups on long term dementia, disability, frailty or non-communicable diseases outcomes (in later life).

No studies found.

Effect of interventions in disadvantaged groups on short term dementia, disability, frailty or non-communicable diseases outcomes (in midlife).

No studies found.

Table 7. Summary DISADVANTAGED AND MINORITY ETHNIC GROUPS primary intervention studies and systematic reviews

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
Primary studies									
Physical activity – primary midlife studies in ethnic minority groups									
Andersen 2013	Norway	Men of Pakistani origin living in Oslo (n=150)	Intervention 35.7 (6.1); control 39.7 (9.2) years.	Physical activity intervention based on social cognitive theory with structured supervised group exercises, group lectures, individual counselling and telephone follow-up	Control gp – no intervention (offered exercise, lecture, information AFTER completion)	5 months	PA level (assessed by accelerometer)	Mean difference in PA between the 2 groups of 49 counts per min/day representing a 15% (95% CI 8.7, 21.2, p=0.01) higher increase in PA in the intervention group than the control group	+
Gaston 2007	USA	African-American women aged >35	54.4 (SD 9.46)	A curriculum-based, culture- and gender specific health intervention, aimed at assisting mid-life African-American women to decrease physical inactivity, poor nutrition and stress. Cognitive behavioural approach based on three theoretical approaches to reduce risk factors and promote positive health changes.	Comparison group with educational book	1 year	Nutrition and eating patterns, physical activity behaviour Perception of overall health, self-care	There were significant changes in physical activity from pre-test to post-test. At six months post-test, the women reported participating in aerobic exercise, on average, 2.48 days per week at six months [t(30)=2.02, p<0.05] and 3.21 days at 12 months [t(42)=3.0 A significant.10-week difference was found in the women's diet, with them reporting eating more nutritious foods, t(77)=3.32, p<0.001. The women also indicated from pretest to 10 weeks, and six and 12 months that they changed what they ate to prevent disease (40.4%, 62.8%, 97.5% and 100%, respectively). A majority of the women at 10 weeks (62.7%) and 12 months (65.9%) reported utilizing stress management strategies. There was also a 60% increase in yearly mammograms and a 54% increase in blood pressures checks. Finally, 83.7% of the women at 12 months felt that the positive changes could be maintained	-

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
								over their lifetime.5, p<0.01]	
Physical activity – primary studies in disadvantaged communities									
Goyder 2014	Deprived areas of Sheffield, UK	Previously sedentary people, aged 40–64 years, living in deprived areas of Sheffield, UK, who increased their physical activity levels after receiving a brief intervention	Mean age 54.6 (7.3)	'Booster' interventions to sustain increases in physical activity in middle-aged men from deprived urban neighbourhoods. Participants were randomised to the control group (no further intervention) or to two sessions of motivational interviews (MI),either face to face ('full booster') or by telephone ('mini booster'). Sessions were delivered 1 and 2 months post-randomisation	To determine whether objectively measured physical activity, 6 months after a brief intervention, is increased in those receiving physical activity 'booster' consultations delivered in a motivational interviewing (MI) style, either face to face or by telephone	Intervention sessions at 1 and 2 months, follow-up at 6 months	Total energy expenditure (TEE) per day in kcal from 7-day accelerometry, cost-effectiveness	The mean difference in TEE per day between baseline and 3 months favoured the control arm over the combined booster arm but this was not statistically significant (–39 kcal, 95% confidence interval −173 to 95, p = 0.57). The autonomy-enabled MI communication style was generally acceptable, although some participants wanted a more paternalistic approach and most expressed enthusiasm for monitoring and feedback components of the intervention and research. Full boosters were more popular than mini boosters Cost-effectiveness Two alternative modelling approaches both suggested that neither intervention was likely to be cost-effective	++
Smoking – Primary studies in ethnic minority groups									
Begh (2011)	UK	Pakistani and Bangladeshi men	36 (34-58)	Four male, community based, stop smoking advisors of Bangladeshi and Pakistani origin delivering	NHS smoking cessation support as normal	6 months	Quit attempts, abstinence (6 month)	More Pakistani and Bangladeshi men made quit attempts with NHS services in intervention areas compared with control areas, rate ratio (RR) 1.32 (95%CI: 1.03 1.69). There was a small increase in the number of 4-week abstinent smokers in intervention areas (RR 1.30, 95%CI: 0.82-	+

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
				behavioural support and medication management for smoking cessation, general health promotion, communication skills, and the cultural specific norms of Pakistani and Bangladeshi smokers				2.06)	
Systematic reviews									
Systematic reviews of physical activity interventions in ethnic minority groups									
Ickes 2012	US	> 35% Hispanic adults, male and female, age >18 (age range 18-95)	Age range 18 - 95	Intervention settings of included studies varied, but included community, clinical, family and faith-based interventions. A range of theoretical frameworks, and intervention strategies were used. 45% if the interventions used walking groups, 30% group aerobics, dance or structured activities, 45% used culturally appropriate activities and	Any comparison group	Any follow-up	90% (n=18) of included studies measured behaviour change relating to PA, in 15 outcomes were self-reported, one used a pedometer and 2 used accelerometers	Community, clinical, family-based and faith-based interventions were effective in improving the level or frequency of PA participation. Of those studies measuring PA as an outcome, 72% reported an improvement in PA (13 studies). Five interventions reported an increase in minutes walking and/or associated METS, three interventions reported an increase in individuals meeting recommended PA levels, 2 found an increase in MVPA and one an increase in VPA. Social support was incorporated into 65% of the interventions and 60% of those resulted in an increase in PA levels	+

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
				materials, 30% used bilingual instructors, 30% used self-management strategies including goal setting and problem solving in 30%, 15% used behavioural counselling					
Conn 2012	US	African American, Hispanic, Native American and Native Hawaiian, adults > 18 years	Not reported	PA motivation interventions, the typical intervention was of 10 sessions lasting 49 minutes. Supervised exercise interventions, typically 40 minutes of verified exercise 3 times weekly over 11 weeks, mostly moderate intensity exercise, (n=19), low intensity (n=3) and high intensity (n=1)	Any control group	Any follow up	PA behaviour (also fitness, anthropometric outcomes, lipids, diabetes risk, mood, QoL)	PA motivation interventions Motivational and educational interventions designed to increase PA significantly increased PA behaviour in meta-analysis of 21 studies with treatment versus control group comparison. Effect size reported (units?) as 0.172 (95% CI 0.023 Supervised exercise interventions, Typically 40 minutes of verified exercise 3 times weekly over 11 weeks, mostly moderate intensity exercise, (n=19), low intensity (n=3) and high intensity (n=1) There was a significant increase in fitness levels in treatment versus control groups but compliance and uptake of the interventions not reported	-
Systematic reviews of physical activity interventions in disadvantaged communities									
Cleland 2012	International Mainly US (20/27), also UK (2/27) studies)	Socioeconomically disadvantaged communities (adults and children but reported	Adults and children: but reported separately	Interventions aiming to promote PA Interventions included education, organised exercise classes, information distribution, exercise consultation, fitness	Any relevant control	Any follow up	Measures of PA behaviour measures included self-report, pedometers, accelerometers	In adults, 4 studies targeted individuals, 12 were group interventions and 5 were community interventions. No meta-analysis Group interventions: There was sufficient evidence to recommend that group interventions are effective to influence PA behaviour in adults. Community interventions: There was	+

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
		separately) (measured by low education, low income, unemployed, low status occupation or living in low SES area)		assessment, lifestyle advice, including individually targeted and group interventions				sufficient but limited evidence of effectiveness. (Based on additional expert opinion, the authors made a recommendation that community based interventions are effective in socioeconomically disadvantaged communities) Individual interventions There was insufficient evidence to assess the effectiveness of interventions targeting individuals	
Cleland 2013	International (10 of 19 studies from US, no UK studies)	Socioeconomically disadvantaged women (measured by low education, low income, unemployed, low status occupation or living in low SES area)	Women aged 18-64 years	Any intervention focused on increasing PA in any setting. Included: education, organised exercise classes, information distribution, exercise consultation, fitness assessment, lifestyle advice, including individually targeted and group interventions	Any relevant control	Any follow up	Measures of PA behaviour	Nineteen studies were included. No pooled effect because of heterogeneity. In sub-group analyses, studies with a group delivery mode had a significantly greater effect on PA than either individual or community based delivery	+
Coles 2012	International (but all 7 included intervention studies were conducte	Homeless people		Community based health and health promotion for homeless people Relevant studies were: an oral health Promotion intervention	Any relevant control	Any follow up	Various – see results section	In the shelter-based trial participants were more likely to attend subsequent appointments at a community mental health centre (64.7% versus 37.3%, P<0.006 The smoking cessation pilot clinical trial, which provided six group sessions and	++

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
	d in the UK)			consisting of three elements: dental health education, smoking cessation trials, shelter based interventions to promote engagement with psychiatric services. Other less relevant studies were the promotion of sexual health, and comparison of health and housing initiatives				five individual motivational sessions to participants showed that the quit rate at 26 weeks was higher in the group receiving NRT in combination with MI which included smoking behaviours, addiction behaviours and life events (26.7% of participants), than controls who received NRT and MI which focused only on smoking (15.4%). For non-quitters, the mean change in the numbers of cigarettes smoked daily from baseline to week 26 was 10.2 (SD¼9.3) and 6.5 (SD 6.4) in the intervention and control groups respectively (P<0.512)	
Systematic reviews of physical activity and diet interventions in ethnic minority groups									
Chapman (2013)	International (developed countries)	South Asian populations	Adults	Community or primary care based intervention studies (randomised and non-randomised designs included) Four studies were included in the review. Only 2 studies were found that reported outcomes related to dietary behaviours. Both were before and after studies (no control group) with self reported	Any relevant control	Any follow up	Behavioural (e.g. dietary intake, physical activity participation), physical (weight, BP, lipids)	In one study, the intervention included individual tests and CHD/diabetes risk profile, nutritional support from dietetic clinics, optional practical activities including cookery workshops, exercise classes and awareness sessions. The intervention was delivered at the project base and community venues by health visitors, South Asian community workers with interpreter and translator services. Significant improvements in salt intake and consumption of fried meat snacks was reported. For physical activity, an average of 49% of participants reported taking more moderate exercise (defined as 'physical activity that makes one out of breath but not sweaty') 6–12 months after intervention. Weight change in males was -2.1kg (from mean 71.8kg at baseline)	

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
				changes in dietary behaviour				and in females was -1.9 kg (63.3kg) at baseline). Error limits not reported in review

The other study involved community based PA and diet group education sessions, with food guides, healthy lifestyle hand-outs, pedometers waist measurements, pedometer diary and 3 monthly follow up sessions. No outcome data relating to behavioural changes was reported only physical data e.g. anthropometric, blood pressure, lipids and other biochemistry. Weight change was -0.9 kg (from 30.8 kg) and BMI change -1.1kg/m2 (from mean of 28.6 at baseline). Error limits not reported in review | |
| **Systematic reviews of weight management interventions in ethnic minority groups** | | | | | | | | | |
| Ossei-Assibey 2010 | International | Adults from minority ethnic/non-white groups (Studies included African American, Hispanic, Japanese-American populations) | 45-59 (in studies in overweight populations) | Dietary and lifestyle interventions for weight management - RCTs | Any relevant control – see results section | Intervention > 6 months | Weight | The review aimed to include studies in overweight as well as obese participants but most of the studies were in obese people

Nineteen studies were included but only 3 were in overweight (rather than obese) populations: Only studies and conclusions based on overweight populations are reported here.

<u>Interventions in people with pre-diabetes or diabetes</u>
One study (Liao et al 2009) . Significant weight loss was achieved in intervention group (-1.8 +/- 0.5 vs 0.7 +.- 0.6 kg, p= 0.002). Intervention was dietary advice based on AHA step 2 diet plus endurance exercise. Control group followed AHA step 1 diet plus stretching exercise.
<u>Low fat diet vs general dietary info</u> | + |

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
								One study (Hall et al 2003). Intervention group received dietary advice to reduce fat intake to < 20% E, control group received a pamphlet on general dietary guidelines. Both groups lost weight but difference between groups not stat sig. Peer educator intervention One study aimed at weight prevention (mean BMI 33, but prevention intervention) (Kennedy et al 2009). Nutrition education and cookery classes delivered by peer educators to African American women and provision of fruit and veg. Significant weight loss in the intervention group compared to control (-2.0 +/-3.2 vs 1.1 +/- 2.0 kg). Web based tailored weight management programme vs web based information only One study (Rothert et al, mean BMI 32 but prevention/management intervention). Significantly greater weight loss in web based weight management programme (healthy eating and PA) compared with information only group - -1.21 +/-0.1 vs -0.48 +/- 0.2 kg (p=0.007).	
Fitzgibb on 2012	US	African-American women	>/= 18 years	Behavioural weight loss interventions	Any relevant control	Any follow up	Weight	The review aimed to include randomised and non-randomised studies in overweight or obese people but all included studies were in obese populations Four included studies focused on diet, nutrition and behavioural components, Seventeen included PA, diet and	-

Author (year)	Country	Population	Mean age (range)	Intervention	Comparison	Follow-up	Outcomes	Results Association	Quality (-/+/0)
								behavioural components, two PA alone, one nutrition and PA alone and one on nutrition and behavioural components. Settings for the trials were community clinics, universities and clinics	
								Intervention participants in all trials lost weight (though sample sizes mainly not sufficient for statistical significance). There is some evidence that more intensive behavioural weight loss trials with medically at-risk populations are effective although based on selected studies. Note: conclusion is based on obese populations only	

4. DISCUSSION

A comprehensive search of the academic literature was undertaken to identify primary prevention approaches to be adopted in mid-life that are effective and cost-effective to prevent and delay the onset of disability, dementia, frailty, and other non-communicable chronic conditions in later life. We found a broad range of interventions targeting health behaviours in midlife that are associated with uptake of behaviours in mid-life and few studies assessing the longer term impact on successful ageing or the primary prevention or delay of ill health in later life. So this review contains many small sized randomised and non-randomised trials mostly with short follow-up, with the exception of two studies which followed individual for 24 years (e.g. Hjerkinn 2004; Bos 2011). As studies did not follow participants into old age the observed significant effects are applicable for shorter-term outcomes, and cannot be assumed to be maintained in the medium- and long-term. We found no evidence describing adverse events associated with these interventions.

Gaps and limitations in the data

There is limited but good quality evidence from intervention studies conducted exclusively in the UK health care context (10 primary studies and 2 economic evaluations), yet few large scale experimental or population based studies seeking to develop and evaluate the effect and costs of midlife interventions on late life outcomes. Nevertheless, a number of good quality economic evaluations based on primary data and Markov or decision analytic models (directly and partially applicable to the UK because conducted in OECD countries) suggest that interventions targeting behavioural risk factors are likely to be cost-effective from a societal perspective - with the caveat that findings are sensitive to effectiveness and maintenance assumptions in the long term (mainly due to the lack of evidence based for some risk factors). Also, different sociocultural, environmental and economic factors may influence the success or failure of interventions if implemented in the UK context or sub-populations.

While evidence was found for men and women at midlife and for some minority and disadvantaged groups, there is a paucity of research in midlife for LGBT groups and other groups protected under the equality and diversity legislation; or vulnerable groups including migrants, asylum seekers, refugees, prisoners and Roma. This has implications for the generalizability of our findings to whole populations because contextual factors that may have favoured intervention efficacy may differ between and within communities.

Limitations of this review

Similar to Review 1 and Review 2, the main limitation of this review relates to the search strategies, which were focused on studies with midlife-related terms in the title, abstract or

related MeSH indexing to identify interventions studies specifically delivered in midlife. The result is that intervention studies that have recruited only/mainly individuals in mid-life without specifying midlife terms in the title or abstract were not identified by the searches. This might explain some of the gaps in evidence and further work is ongoing (though beyond the scope of this report) to address this limitation.

In addition to the short follow-up period (i.e. weeks or months rather than years), the findings are limited by the small samples recruited into the trials, which compromises the power to detect significant associations namely where small effects are expected. Furthermore, within all the papers (experimental studies, systematic reviews and economic evaluations) included in this review behavioural risk factors and their associated health outcomes have been defined and operationalised differently, making comparison between studies (pooling effect estimates) problematic. The modifiable risk behaviours targeted by the intervention (alcohol consumption, smoking, physical activity and lifestyle conditions) are usually self-reported - few studies adopted objective measures. This may result in biased differences in reported behaviours before and after the intervention, for example quantity of alcohol or tobacco consumed.

Another source of heterogeneity across studies relates to the different choices of control groups. These varied from no intervention to usual care, educational sessions, combined education and information groups. Finally, while a plurality of approaches may be required to accommodate different types of interventions and settings, there is limited evidence on the comparative effectiveness and cost-effectiveness of competing and/or complementary delivery modalities.

5. CONCLUSIONS AND RECOMMENDATIONS

This review found evidence for a number of interventions that have been shown to be effective to promote the uptake and maintenance of healthy behaviours in midlife. Effective interventions were found for promotion of positive physical activity and diet behaviours; reduction or cessation of smoking and alcohol behaviour; weight prevention, weight maintenance and weight loss (in those overweight) in midlife; and interventions addressing combinations of multiple health behaviours. No evidence from intervention studies specifically conducted in midlife was found that met the review inclusion criteria for social, leisure and cognitive interventions or programmes to address hearing or sight behaviours. While healthier behaviours earlier in life will reduce risks and need for intervention, the evidence suggests that some modification of health behavioural risks can occur in mid-life. However, only limited evidence was found relating to the effectiveness of midlife

interventions on long term successful ageing and dementia, disability and frailty or outcomes related to non-communicable chronic diseases.

The evidence found is quite diverse and covers a range of health behaviours or combinations of behaviours, components and delivery of interventions. Some evidence was also found relevant to health inequalities with interventions conducted in some ethnic minority groups, socioeconomically disadvantaged groups, homeless populations and for men and women - also successful in changing some health behaviours.

Summary of findings and recommendations

Physical activity

28. **Structured physical activity programmes**. Evidence suggests provision of a structured exercise programme can influence decisions to start and maintain PA. Programmes included stretching, aerobic exercise, walking, weight training, cycling, yoga and tai chi. A wide choice of exercise programmes could be made available so that there are programmes of interest to a broad population.

29. **Provision of tailored individual and group support for changing physical activity levels:** Evidence suggests that PA individual and group support interventions produce moderate but statistically significant increases in PA behaviour, in particular when participants were involved with behavioural interventions. Interventions were multimodal and ranged from a single motivational education session (although these were less effective) to extensive supervised exercise sessions. Intervention components such as support, self-monitoring, stimuli to increase PA, self-regulation techniques, rewards, behavioural goal setting, personalised activity goals, provision of information about local opportunities and modelling PA behaviour produced better health and behavioural outcomes; however due to the lack of longitudinal data the impact beyond 12 months is unclear. Evidence from economic papers suggests that the least cost-effective categories were the high-intensity "individually adapted behaviour change" and "social support" programmes yet these programmes also had the largest effect on PA behaviour. Overall physical activity interventions were shown to be cost effective from societal perspective in a majority of studies (but the findings are sensitive to long-term effectiveness and maintenance assumptions).

30. **Provision of combined diet and exercise interventions:** Evidence suggests that combined diet and exercise modification can have significant improvements in nutrition and PA behaviour; in particular these interventions can improve dietary and/or PA

behaviour in South Asian populations. Components included exercise and nutrition information, and support and were usually delivered by a PA specialist and registered dietician. Due to short duration of studies the long-term impact is uncertain.

31. **Internet and telephone support:** Evidence suggests that Internet and telephone services are beneficial when attempting to produce positive changes in PA. Telephone contact to provide feedback and to support also appeared to positively change PA levels. Educational components in the intervention significantly increased effectiveness. There could be an increase in the provision of Internet and telephone-based physical activity programmes. However effect sizes were small and some evidence suggested that technological solutions are no more effective than print materials, face-to-face programmes and other health promotion methods. There is insufficient evidence to assess whether face-to-face interventions or remote approaches are more effective at promoting PA. Internet and telephone technologies should therefore be considered as an addition to other delivery methods and not seen or used as a replacement for services. The ability of Internet and telephone delivered interventions to produce change in long-term PA remains unclear.

32. **Raise awareness in mass media:** Evidence suggests that mass media campaigns increase awareness in the population. However, there is limited evidence of campaign effects on increasing PA. Campaigns that promoted PA as a 'social norm' seemed to be more effective in reducing sedentary behaviour; however effect sizes were small**.**

33. **Combined physical activity, support and awareness raising:** Consideration could be given to an approach which combines the provision of support and exercise programmes; awareness raising would be more beneficial to population-level health as it may both provide the context in which behaviours can be adopted and maintained into old age. Although due to limited evidence the long-term effects of each component is unknown.

Diet
34. **Dietary advice can be effective in improving dietary behaviour:** There is some limited evidence that individually tailored advice is effective and that group programmes or printed individual dietary advice can be effective.

35. **Reduction of fat/saturated fat intake as part of dietary advice/recommendations**: Reduction of fat/saturated fat intake as part of dietary advice/recommendations. However

consideration should also be given to the balance of foods required for prevention of osteoporosis.

Smoking

36. **Increase provision of reduction interventions:** Evidence suggests reduction interventions can be carried out using self-help materials or aided by behavioural support, and can be carried out with the aid of pre-quit NRT (studies suggest that pre-quit NRT does not increase adverse events). Reducing cigarettes smoked is an important contribution to prevention of non-communicable chronic diseases. Patients can be given the choice of a variety of strategies (before quit day and quitting abruptly, with no prior reduction) to assist in behavioural change**.**

37. **Increase provision of cessation interventions:** Evidence suggests that interventions consisting of self-help, NRT, and community-based, individual based, group, and telephone counselling can promote smoking cessation; however effects were attenuated in the longer term. Where evidence exist telephone care intervention versus usual care using the provider's perspective was more cost-effective. There is a paucity of evidence from a societal perspective**.**

38. **Increase provision of culturally sensitive interventions:** Evidence suggests smoking cessation outreach workers who are members of BME and other minority groups can more effectively improve access to and the success of smoking cessation services compared with standard care. Evidence however was primarily on Pakistani and Bangladeshi men. Costs of these interventions per quality-adjusted life year proved feasible and acceptable.

39. **Increase provision of quitting intention interventions:** Evidence suggests that the intention to quit was a strong predictor of smoking reduction or cessation. Interventions often combined behavioural, counselling, and educational components to impact on smoking attitudes. There were a variety of methods used to deliver the interventions such as information leaflets, practice nurses, outreach workers, the Internet and telephone. Programs could be designed to address contextual factors, which may change attitudes and increase the efficacy of reduction and cessation interventions.

Alcohol

40. **Limiting licensed premises:** Evidence suggests that the availability of alcohol does have an impact on consumption (review 1 and 3). Alcohol prevention targeting licensed premises resulted in fewer assaults, unlawful threats and violence towards officials. Economic analysis shows that the monetary and human benefits may be considerable. It may therefore be necessary to reduce alcohol outlet density, defined as shops, bars and restaurants in communities.

41. **Improve availability of behavioural, counselling and therapy programs:** Evidence suggests that behavioural counselling and therapy have positive impacts on excessive alcohol use; however effect sizes vary. Interventions can include provision of brief information for minor problem drinking, psychotherapy for mild to moderate dependence and drug-therapy adjuvant to counselling for detoxified patients with a history of severe physical dependence. Internet-based interventions are effective at changing alcohol consumption, treatment response, and quality of life in the short term; however long-term data is unavailable. Internet-based therapy may therefore offer better value for money as an adjunct to existing service provision, and be considered as an additional treatment option.

Weight management

1. **Programmes involving promotion of healthy balanced diet and exercise**; or dietary advice to reduce total fat intake could be recommended for midlife populations, including ethnic minority groups.

2. **Delivery of programmes**: There is some limited evidence that diet programmes can be delivered effectively by clinically trained professionals or lay educators and with a range of delivery methods.

3. **Programmes involving yoga** may be effective for weight management in midlife, particularly for those for whom more intensive exercise programmes may be unsuitable.

Multiple component/lifestyle/behavioural

42. **Lifestyle interventions targeting more than one health behaviour** can be effective in improving health behaviour.

43. **A range of type of intervention** (e.g. cognitive behavioural therapy, motivational interviewing and problems solving or educational and counselling interventions) can be effective in delivering lifestyle interventions targeting more than one health behaviour.

44. **Internet based interventions can be effective** for delivering lifestyle interventions targeting more than one health behaviour.

45. **Social networking sites are not recommended** for delivery of lifestyle interventions to people in midlife.

Disadvantaged or minority groups

46. **Provision of supporting PA interventions:** The findings on PA suggest that support, provided by instructors, facilitators, family and friends is important for supporting individual efforts to increase PA. Evidence suggests those interventions focused on improving the PA in ethnic minority and disadvantaged groups have greater success if they incorporate social support, group delivery and motivational components.

47. **Provision of community level PA interventions:** Evidence suggests that community-based interventions can be more effective, than individual focused interventions, in socioeconomically disadvantaged communities.

48. **Provision of community outreach workers from ethnic minorities for changing smoking behaviours:** Evidence suggests trained culturally sensitive community outreach workers can be effective in promoting smoking cessation behaviour among Pakistani and Bangladeshi men. Smoking cessation outreach workers compared with standard care were able to improve rates of access to smoking cessation services. Trained community outreach workers could be applied in the UK amongst similar populations. If rolled out to other communities such a program would require recruitment and training of individuals from diverse ethnic groups. Economic evaluation demonstrated the intervention proved feasible and acceptable.

49. **Increase provision of culturally sensitive smoking cessation/reduction programs:** Evidence suggests culturally sensitive interventions can help improve smoking reduction, cessation rates and improved uptake of dental health check-ups. Interventions consisted of self-help, NRT, and community-based interventions, as well as individual, group, and telephone counselling. Due to the lack of longitudinal research the long-term impact is unclear.

50. **Increase provision of cultural and gender sensitive diet and/or physical activity interventions:** Evidence suggests these interventions can improve dietary and/or physical activity behaviour in BME communities, in particular the South Asian population. Interventions were delivered at community-level or in primary care. Components included individual tests and CHD/diabetes risk profile, nutritional support from dietetic clinics, optional practical activities including cookery workshops, exercise classes and awareness sessions. Delivered at into the community by health visitors and South Asian community workers with interpreter and translator services.

51. **Increase provision of health promotion interventions in homeless shelters:** Evidence suggests that homeless individuals are at high risk of a number of and non-communicable chronic diseases. Interventions delivered directly into a homeless shelter setting were more likely to increase attendance at community mental health centres.

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