National Clinical Guideline Centre

Draft for consultation

Obesity

Identification, assessment and management of overweight and obesity in children, young people and adults

Update of CG43

Appendix L

July 2014

Draft for Consultation

Commissioned by the National Institute for Health and Care Excellence

Royal College of Physicians

The Royal College of Surgeons of England

RCGP Royal College of General Practitioners

Royal College of Nursing

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Appendix L: Research recommendations

L.1 Research question: Do post-operative lifestyle intervention programmes (exercise, behavioural or dietary) improve weight-loss and weight-loss maintenance following bariatric surgery?

Why this is important: Lifestyle interventions are targeted pre-operatively with formalised recommendations to prepare patients for surgery. In contrast, post-surgery there are no lifestyle intervention programmes to help patients adapt. Limited evidence suggests that exercise and behavioural input improve weight loss outcomes but high quality research is needed to assess the impact of these interventions.

Criteria for selecting high-priority research recommendations:

Importance to patients or the population	Provide information on the impact of lifestyle interventions on post-operative weight loss and weight-loss maintenance following bariatric surgery.
Relevance to NICE guidance	Developing research on the effectiveness of post-operative lifestyle intervention programme would help strengthen recommendations on the impact and costs of structured lifestyle intervention programmes on post-operative weight loss.
Relevance to the NHS	Despite well documented effects of bariatric surgery, current provision of lifestyle interventions post operatively is variable. Further evidence in this area would help to inform providers about the best post-operative pathways that should be offered and ensure that long term, positive outcomes are achieved.
National priorities	Whilst bariatric surgery aids weight loss, some patients may not lose the expected amount of weight or may have difficulty in maintaining lower weight. This may result in the return of comorbidities and lead to some patients or their health professionals requesting revisional surgery. It is essential to make sure that the optimum outcomes are achieved in relation to weight loss and weight maintenance so that the benefits of bariatric surgery are fully realised.
Current evidence base	Limited evidence relating to the effectiveness of post bariatric surgery care packages was identified by current guideline and this evidence was considered of limited applicability to the current clinical practice, often focusing on specific populations of people with severe obesity or comparing the care package against non-standard care.
Equality	There is prejudice against people with obesity and many patients with morbid obesity are from lower socioeconomic groups. This recommendation is for all groups and would help to identify the best follow up interventions and care for patients who have undergone bariatric surgery.
Study design	The study would take the form of an RCT of current, standard care, versus a lifestyle intervention programme (6 month minimum duration), with a minimum follow up of 2 years. The study should consider the benefits of post-operative lifestyle interventions, including exercise, behavioural and dietary interventions on weight loss, quality of life, and physical activity level and eating behaviour, post bariatric surgery. The study should focus on people over the age of 18 who have had surgery within the last 12 months and whom have no other medical or psychological comorbidities.
Feasibility	The study would be undertaken by primary bariatric surgical providers or tier 3

	services
Other comments	None.
Importance	High: the research is essential to inform future updates of key recommendations in the guideline

L.2 Research question: What is the long-term effect of bariatric surgery on diabetes-related complications and quality of life in people with type 2 diabetes compared to optimal medical treatment?

Why this is important: Short-term studies (1-2 years) show that patients with type 2 diabetes who undergo bariatric surgery lose more weight and have better blood glucose control than those treated with conventional diabetes management. There are no long-term data (over 3 years) to show whether this results in reduced development of diabetes complications and improved quality of life compared to standard care.

Criteria for selecting high-priority research recommendations:

Importance to patients or the population	**There is an important balance between quality of life improvements from better controlled diabetes and reduced medication use that results from surgery when compared to the potential risks of surgery. Lifestyle intervention and medication are a less invasive option than bariatric surgery but may be less effective at weight loss and at improving diabetes control. This has been considered in recent guidelines, but if one approach was shown to be superior to the other in terms of reducing long-term complications this would have a profound effect on the way the condition is treated.**
Relevance to NICE guidance	At present guidance recommends consideration of surgery for patients with recent onset diabetes; if surgery was more (or less) effective at reducing complications than conventional management, this would allow for a much clearer recommendation in a future version of the guideline as to whether bariatric surgery was an appropriate treatment for type 2 diabetes.
Relevance to the NHS	A clear result from such a trial would enable the NHS to make a decision based on effects on morbidity, quality of life and cost-effectiveness rather than surrogate markers.
National priorities	Type 2 diabetes is a significant part of the National Service Framework for Diabetes and is a major clinical problem, affecting over 5% of the population and currently accounting for at least 10% of the NHS budget, mostly as a result of complications. A clear outcome to this research question could lead to a fundamental change in the way the condition is treated.
Current evidence base	The current evidence base is mainly based on observational studies and a few very small clinical trials with surrogate outcomes (See CG43 update page xx)
Equality	The research question is inclusive of all people with type 2 diabetes, irrespective of gender, ethnicity or disability. A detailed clinical trial design would need to take into consideration ethnic differences in diabetes risk as some groups are prone to diabetes at a lower BMI.
Study design	The study should take the form of primary research as a randomised clinical trial. The study should focus on people with type 2 diabetes and a BMI of at least 30kg/m2, with risk factors for the development of complications, randomised to groups given bariatric surgery (RYGB or sleeve gastrectomy) versus optimal diabetes care (lifestyle, glucose lowering therapy plus other risk factor management (e.g. for blood pressure and lipids) as needed). The study should focus on the impact of the interventions on complications of diabetes, quality of life and healthcare costs.

Feasibility	The research would require an appropriate size clinical trial, which will take 5 years or more to complete. Whilst this is likely to be expensive this would help answer a clinical question of critical importance to the care of people with type 2 diabetes. Such trials are a regulatory requirement for new drug treatments for diabetes, and there is no reason why a surgical treatment should not be tested to the same standard. Ethically, it is firstly needed to conduct such research given the uncertainties about the long-term efficacy of the surgical approach, compared to standard care. Secondly, if bariatric surgery is an appropriate intervention it is currently accessed by less than 1% of eligible population and guidance may need to be changed.
Other comments	It may be necessary to consider recruiting a relatively high risk population (for example, those with microalbuminuria or more than 1 cardiovascular risk factor) to ensure likelihood of observing significant differences in micro- and macrovascular complications within a reasonable timescale. This is usual in such trials using medication.
Importance	High: the research is essential to inform future updates of key recommendations in the guideline

L.3 Research question: What are the long-term outcomes of bariatric surgery in children and young people with obesity?

Why this is important: Monitoring of obesity co-morbidities (respiratory problems, atherosclerosis, insulin resistance, Type 2 diabetes, dyslipidaemia, fatty liver disease, psychological sequelae) in children and young people with complex obesity is limited due to the paucity of Tier 3 / 4 dedicated paediatric obesity services in the UK. Centralised collection of cohort data is lacking in the UK when compared to Europe[2] and the United States.[4] Current data on longer term outcomes (>5 years) in young people undergoing bariatric surgery is also sparse[1,3] demonstrating a need for research in this area.

Criteria for selecting high-priority research recommendations:

Importance to patients or the population	**Cohort studies would inform on trends and longer term implications of obesity related co-morbidities in young people into adulthood and the therapeutic impact of bariatric surgery in younger populations on morbidity and mortality prevention.**
Relevance to NICE guidance	Long term outcome data would help inform NICE about the impact of obesity related comorbidities on young people and the effect of bariatric interventions in young people and disease modification into adulthood.
Relevance to the NHS	Inform the NHS regarding the complete costs of treating obesity and obesity related co-morbidities in the young people with predictive costings for long term care. These data will also outline disease remission / prevention and inform cost effectiveness of bariatric surgery versus lifestyle interventions for the longer term in younger populations.
National priorities	Department of Health. The NHS Outcomes Framework 2011/12. London. Department of Health, 2010. (domain 2). Available from: http://www.gov.uk/government/publications/nhs-outcomes-framework-2011-to-2012 Department of Health (2012) Better Health, Better Care, Better Value- Equality objectives 2012-2016. www.gov.uk/government/publications/department-of-health-equality-objectives-2012-to-2016

Importance to patients or the population	**Cohort studies would inform on trends and longer term implications of obesity related co-morbidities in young people into adulthood and the therapeutic impact of bariatric surgery in younger populations on morbidity and mortality prevention.**
Current evidence base	During this review process, it was established there was no available long term data on obesity related comorbidities in young people, particularly those undergoing bariatric surgery. No long term RCTs were found comparing outcomes in these areas between life-style interventions and bariatric surgery.
Equality	Monitoring and establishment of centralised registries will enable monitoring of population data from across the UK, ensuring varied ethnic and socioeconomic population data capture. Data however would be dependent on cohorts that are referred into Tier 3 / 4 services and therefore may exclude those with severe learning difficulties or patients that fail to engage with local services.
Study design	Primary research is needed. Cohort studies in young people monitoring obesity related comorbidities against lifestyle interventions and compulsory registries to monitor bariatric surgical patients including obesity related comorbidities in cohorts of young people are required. Comorbidities to include: respiratory problems, atherosclerosis, insulin resistance, Type 2 diabetes, dyslipidaemia, fatty liver disease, psychological sequelae and quality of life.
Feasibility	This would be possible within Tier 3 / 4 weight management services and cohort data would be collected rigorously in tandem with clinical monitoring of patients over 5 to 10 years.
Other comments	The paediatric database should be funded as an extension of the National Bariatric Surgery Registry. Obesity related co-morbidity data should be funded through CCG commissioning of Tier 3 paediatric obesity services and research into outcomes of interventions and management strategies.
Importance	This research is of High importance: the research is essential to inform future updates of key recommendations in the guideline

L.4 Research question: How best to deliver obesity management interventions to people with particular conditions associated with increased risk of obesity (e.g., people with a learning disability or enduring mental health difficulties)?

Why this is important: Across the lifespan, individuals living with learning disabilities or enduring mental health difficulties have been found to experience higher rates of obesity compared to individuals who do not have these conditions.

It is estimated that around 23% of children with obesity have learning disabilities and studies to report rates of obesity in adults with learning disabilities of 50%.

Among adults with serious and persistent mental illness the prevalence of obesity has been reported to be as high as 55%. Physical inactivity, unhealthy diets, and weight gain from psychotropic medication are all factors that contribute to this. People with serious mental illness have mortality rates 2-3 times as high as the general population; the primary cause of death being cardiovascular disease which is strongly associated with the incidence of obesity.

There is minimal evidence from controlled studies on which obesity interventions are effective for individuals with learning disabilities or with enduring mental health difficulties. This lack of evidence

contributes to the inequalities around outcomes and accessing services experienced by individuals with these conditions.

Criteria for selecting high-priority research recommendations:

Importance to patients or the population	**Identifying how best healthcare professionals should deliver obesity management interventions to adults with learning disabilities or those with mental health difficulties may result in significant improvement in quality of life, a reduced prevalence of secondary disabilities associated with obesity and improved mortality. It may also result in an improvement in access to services.**
Relevance to NICE guidance	It is currently not feasible to provide guidance on effective weight management interventions for people with learning disabilities or serious and persistent mental illness. Therefore, examining this question would inform future guidance on effective weight management services for individuals with learning disabilities or serious and persistent mental illness.
Relevance to the NHS	Reduced cost to the NHS in managing health problems associated with obesity, equitable service provision
National priorities	Department of Health (2012) Better Health, Better Care, Better Value- Equality objectives 2012-2016. www.gov.uk/government/publications/department-of-health-equality-objectives-2012-to-2016 Department of Health (2012). The Mandate. A Mandate from the Government to the NHS Commissioning Board: April 2013 to March 2015. www.gov.uk/government/publications/the-nhs-mandate Scottish Government (2013) The Keys to Life- improving quality of life for people with learning disabilities http://www.scotland.gov.uk/Publications/2013/06/1123 Public Health England (2013) Obesity and disability-Adults. Implications of rising obesity and disability for health and social care service in England.
Current evidence base	The current guideline recommends multi-component interventions (CG43: 1.2.4.1) as the treatment of choice for children and adults with obesity. There are currently no published RCTs involving patients with learning disabilities or serious mental illness focus examining the effectiveness and acceptability of multi-component weight management interventions that meet NICE guidance. The majority of published learning disabilities studies have used a health education approach without any focus on reducing energy intake. This has been repeatedly shown to be ineffective in supporting individuals with learning disabilities and obesity to manage their weight.
Equality	Individuals with serious mental illness or learning disabilities currently experience higher rates of obesity, inequitable access to weight management services and poorer outcomes. Evidence from studies examining this research question would inform strategic planning and service provision to reduce these heath inequalities.
Study design	Primary research. Interventions should have a clear focus on reducing energy intake. This should be randomised controlled trials with a minimum follow up of 12 months. Studies should include an additional qualitative interview study of a sub-group of patients from each group to understand the experience of the participants. Patient representatives should be involved in designing the interview guide. Population: children and adults with obesity and learning disabilities or serious and persistent mental illness Intervention: Multi-component weight management interventions Comparison: Treatment as usual or comparator interventions Outcomes: Weight loss; weight loss maintenance; quality of life
Feasibility	Pilot studies have shown it is possible to recruit and retain participants with

Importance to patients or the population	**Identifying how best healthcare professionals should deliver obesity management interventions to adults with learning disabilities or those with mental health difficulties may result in significant improvement in quality of life, a reduced prevalence of secondary disabilities associated with obesity and improved mortality. It may also result in an improvement in access to services.**
	learning disabilities and serious mental illness in trials of multi-component weight management interventions.
Other comments	NIHR Evaluation, Trials and Studies (NETS) funding is a possible funding stream for this research. Public Health England highlighted the importance of investigating barriers that people with disabilities and obesity may face in access to health and preventative services and make efforts to address them. Capacity to make informed decisions is an important ethical issue that is often discussed in relation to weight management interventions for adults with learning disabilities. UK capacity legislation provides a framework for health professionals, family members and other appointees to consider this in circumstances where an individual lacks capacity. Previous UK weight management studies have received ethical approval to include adults with learning disabilities who lack capacity.
Importance	High: the research is essential to inform future updates of key recommendations in the guideline Individuals with learning disabilities or serious mental illness have been shown to experience significant health inequalities related to weight management. It is not possible to make recommendations in guidance at present so examining this research question would inform future updates.

L.5 Research question: What are the long term effects of using very low calorie diets (VLCD) versus low calorie diet (LCD) on weight and quality of life in patients with a BMI of 40kg/m2 or more, including the impact on weight cycling?

Why this is important: There was little information found in the literature search on the use of VLCDs in patients with a BMI above 40 kg/m2 although there are increasingly used in this group of patients. The lack of quality of life data was also striking. The GDG group was concerned about the possibility of VLCDs encouraging disordered eating or weight cycling which is detrimental to both physical and psychological health. It would also be useful to differentiate between liquid VLCDs and those VLCDs which incorporated solid food products to identify whether the liquid formulation or the energy reduction alone affected weight loss, quality of life, and subsequent disordered eating.

Criteria for selecting high-priority research recommendations:

Importance to patients or the population	**Identifying the possible long term impact on using a very low calorie diet would help people decide whether VCLD was a suitable intervention for their long term aims, and clarify the risk of developing subsequent disordered eating.**
Relevance to NICE guidance	This would help strengthen recommendations developed on the quality of life for people using VLCDs, and improve the data on cost-effectiveness, long-term efficacy and effect on subsequent eating patterns.
Relevance to the NHS	The results might influence the use of VLCDs in this population in either direction. The weight cycling data might influence the use of VLCD in particular patient groups.

Importance to patients or the population	**Identifying the possible long term impact on using a very low calorie diet would help people decide whether VCLD was a suitable intervention for their long term aims, and clarify the risk of developing subsequent disordered eating.**
National priorities	Department for Innovation, Universities and Skills; 2007. Foresight project. Tackling obesities: Future choices. URL http://www.bis.gov.uk/foresight/our-work/projects/published-projects/tackling-obesities Healthy Lives, Healthy People: A call to action on Obesity in England Department of Health 2011 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213720/dh_130487.pdf
Current evidence base	The current guidelines recommends multi-component interventions (CG43:1.2.4.1) and accepts the effectiveness of VLCDs for short term rapid weight loss. This evidence review in this guideline on VLCDs identified a lack of RCT evidence on long term weight maintenance, quality of life, psychological effects and eating disorders. There are no existing studies giving this QoL information, long term weight maintenance information, psychological effects and disordered eating in this group.
Equality	There is some evidence of stigma being attached to very obese patients which might bias clinicians against intensive intervention. If the VLCD product is funded by the participant and not the NHS the expense of the preparations might be a barrier to uptake by lower socio-economic groups.
Study design	The study should take the form of primary research involving people over the age of 18 with no medical or psychological contraindications for VLCD, who have a BMI of 40kg/m2 or more. Exclusion criteria to include pregnancy and people with an active eating disorder. The study should be a randomised controlled trial, with groups allocated to very low calorie diets and low calorie diets in matched patient groups, with each group being offered the same number of visits and provided with identical psychological and activity interventions. The VLCD group should contain sub groups with either liquid or mixed solid and liquid formulations but with identical nutritional quality, to investigate the independent effect of withdrawing solid foods from the diet on both weight loss, and the development of disordered eating. Baseline observation should be carried forward on weight data to account for missing values. At every 3 month point, the study should consider weight in kg, BMI kg/m2, % weight loss in kg, Quality of life using EQ 5D 5L (and possibly obesity related quality of life score), eating disorder score, depression score, and consider also using scores to assess diet (2 item food frequency questionnaire) and activity. Follow-up for a minimum of 2 years (5 would be better) The study should include an additional qualitative interview study of a sub-group of patients from each group to understand the experience of the participants, and identify themes (grounded theory). Patient representatives should be involved in designing the interview guide.
Feasibility	This would be possible within Tier 3 weight management services. It would be important that patients who were suitable for bariatric surgery did not have their surgery delayed by taking part in this study. The qualitative interviews could include vulnerable groups such as patients with learning difficulties
Other comments	None.
Importance	This research is of High importance: the research is essential to inform future updates of key recommendations in the guideline

1 Black JA, White B, Viner RM, Simmons RK. Bariatric surgery for obese children and adolescents: a systematic review and meta-analysis. Obesity Reviews. 2013; 14(8):634-644

2 Flechtner-Mors M, Wiegand S, Gellhaus I, Siefken-Kaletka H, Widhalm K, Reinehr T et al. Screening for co-morbidity in 65,397 obese pediatric patients from Germany, Austria and Switzerland: adherence to guidelines improved from the year 2000 to 2010. Obesity Facts. 2013; 6(4):360-368

3 Lennerz BS, Wabitsch M, Lippert H, Wolff S, Knoll C, Weiner R et al. Bariatric surgery in adolescents and young adults--safety and effectiveness in a cohort of 345 patients. International Journal of Obesity (2005). 2014; 38(3):334-340

4 Must A, Phillips SM, Naumova EN. Occurrence and timing of childhood overweight and mortality: findings from the Third Harvard Growth Study. Journal of Pediatrics. 2012; 160(5):743-750