Interventions to help overweight and obese adults to maintain weight loss

Introduction

The aim of the HTA programme is to ensure that high quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage, provide care in or develop policy for the NHS. Topics for research are identified and prioritised to meet the needs of the NHS. Health technology assessment forms the largest portfolio of work in the NHS Research and Development Programme and each year about fifty new studies are commissioned to help answer questions of direct importance to the NHS. The studies include both primary research and evidence synthesis.

Question

What is the clinical and cost-effectiveness of long-term interventions with tailored support which aim to maintain weight loss in overweight and/or obese adults who have already attained a degree of weight loss through a pharmacological, lifestyle and/or behavioural intervention, compared to brief interventions and/or no intervention?

1 **Technology:** A precisely defined intervention or package of interventions with tailored support (up to 1 year), based on a sound and evidence based model of effectiveness. Interventions could include: health education or behaviour change programmes to modify dietary habits or to change levels of physical activity or both. Consideration will also be given to a phase 2 or 'exploratory' trials as described in the MRC guidance on complex interventions.[1]

2 **Patient group:** Adults with a current or previous BMI of over 30 who have already attained at least a 5% weight loss through a pharmacological, lifestyle and/or behavioural intervention estimated against their weight at the start of weight reduction.

3 **Setting*:*** Interventions may be undertaken in 'every day', routine clinical and non-clinical UK settings. Applicants should be clear about how the setting, mode and source of delivery may influence effectiveness. Settings will include primary care and the community.

4 **Control or comparator treatment:** Specified by researcher but comparing at least 1 evidence based "brief intervention(s)" and/or no specific intervention.

5 **Design**: The design is likely to be a 3 arm randomised controlled trial although other study types will be considered if justified by the researcher. Depending on the intervention(s), and setting(s) the design may need individual and/or cluster randomisation and outcomes should, if appropriate, be stratified by age, sex, ethnic group and other socio demographic characteristics. The generalisability, practicality and affordability of the intervention or package when applied in a wider population setting are important considerations. Note that this research is focused on the maintenance of weight loss, not its achievement. Patients who are recruited to the trial should already have achieved the weight loss specified above; the HTA programme is not interested in funding the intervention to achieve the initial weight loss.

6 **Primary outcomes:** Trend and changes in body mass index (BMI, kg/m2) and other suitable measures of obesity/overweight (justified by researcher) and durability of weight loss during the follow up period. The cost effectiveness of the intervention(s) should be estimated from modelling of the 'real' benefits likely to result from the impact of the intervention on different levels of obesity. Secondary outcomes will include: duration of participation; drop out rates; resource use; (i) waist circumference (cm), (ii) physical activity level and (iii)

[1] "A Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health."

dietary intake, based on validated measures collected before and during the intervention and follow up.

7 **Minimum duration of follow-up:** 2 years

Summary of research need:

In adults, body mass index (BMI, kg/m2) is frequently used as a measure of overweight and obesity. Overweight is defined as a BMI 25–29.9 kg/m2 and obesity as a BMI equal to or greater than 30 kg/m2. Epidemiological surveys of England indicate that the prevalence of overweight and obesity in adults has trebled during the past 25 years.

In 1980, 8% of adult women and 6% of adult men were classified as obese; by 2004 this had increased to approximately 24% of men and women, with a further 46% of men and 35% of women being overweight. Therefore by 2004, around two thirds of men and women, almost 24 million adults, were either overweight or obese with 0.9% of men and 2.6% of women having a BMI over 40 kg/m2 classified as morbidly obese.

The prevalence of obesity increases with age, is more prevalent among lower socioeconomic and lower-income groups, with a particularly strong social class gradient among women. It is more prevalent among certain ethnic groups and is a problem across all regions in the UK but shows some important regional variations.

In adults, obesity is associated with an increased risk of diseases that are a major cause of morbidity and mortality, notably type 2 diabetes, coronary heart disease (CHD), hypertension, many cancers and osteoarthritis. It is estimated that the cost resulting from obesity in England is between £3.3 and £3.7 billion per year.

Despite the high prevalence of overweight and obesity in the UK, there is a paucity of UK-based evidence on the effectiveness of multi-component interventions to support the maintenance of weight loss in adults. Published interventions to manage obesity are often of short duration, with little or no post-intervention follow-up, conducted in non-UK settings and are poorly reported. Potentially relevant interventions that have previously been shown to be effective in the US or other developed countries have seldom been repeated in the UK to assess transferability.

Research is required into the effective use of multi-component interventions in the maintenance of weight loss in overweight and obese adults in the UK who have lost at least 5% of their body weight. Understanding of the costs, benefits and resources required will help inform the NHS and other public agencies about the most appropriate methods to help adults maintain or increase weight loss.

Proposers should consider the guidance published by NICE; "Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children".

Notes to Applicants

For many of the questions posed by the HTA programme, a randomised controlled trial is likely to be the most appropriate method of providing an answer. However, there may be practical or ethical reasons why this might not be possible. Applicants proposing other research methods are invited to justify these choices.

Applicants are asked to:

1. Follow the Medical Research Council's Good Clinical Practice guidelines (http://www.mrc.ac.uk/pdf-ctg.pdf) when planning how studies, particularly RCTs, will be

supervised. Further advice specific to each topic will be given by the HTA programme at full proposal and contract stages.

2. Consider the guidance given in the MRC guidance: "A framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health."

3. Note that trials involving medicinal products must comply with "The Medicines for Human Use (Clinical Trials) Regulations 2004". In the case of such trials, the DH expects the employing institution of the chief investigator to be nominated as the sponsor. Other institutions may wish to take on this responsibility or agree co-sponsorship with the employing institution. The DH is prepared to accept the nomination of multiple sponsors. Applicants who are asked to submit a full proposal will need to obtain confirmation of a sponsor(s) to complete their application. The DH reserve the right to withdraw from funding the project if they are not satisfied with the arrangements put in place to conduct the trial.

The MHRA (info@mhra.gsi.gov.uk, http://www.mhra.gov.uk) can provide guidance as to whether your trial would be covered by the regulations. The DH/MRC website (http://www.ct-toolkit.ac.uk/) also contains the latest information about Clinical Trials regulations and a helpful FAQ page.

Making an application

If you wish to submit an outline proposal on this topic, complete the electronic application form and submit it to htaprop@soton.ac.uk or by post to HTA Standard Commissioning, at the NCCHTA, Alpha House, Enterprise Road, Southampton Science Park, Chilworth, Southampton, SO16 7NS by **1pm on 30 July 2008.** Outline applications will be considered by the HTA Commissioning Board at its meeting in **November 2008**. If they are acceptable, investigators will be given a minimum of eight weeks to submit a full proposal.

Please note that while previous applications to *Interventions to help overweight and obese adults to maintain weight loss (06/86)* should not be resubmitted, previous applicants can reapply.

Applications received after 1300 hours on the due date will not be considered.

Please see GUIDANCE ON APPLICATIONS overleaf.

Guidance on applications

Required expertise

HTA is a multidisciplinary enterprise. It needs to draw on the expertise and knowledge of clinicians and of those trained in health service research methodologies such as health economics, medical statistics, study design and qualitative approaches. HTA expects applicants to engage a qualified Trial Manager for appropriate projects. Applicants will need to show a commitment to team working and may wish to consider a collaborative approach between several institutions. It is expected that the research will be undertaken only following a thorough literature review.

Research Networks

The HTA Programme expects, where appropriate, that applicants will work with the relevant research networks.

Public involvement in research

The HTA programme recognises the increasing active involvement of members of the public in research and would like to support research projects appropriately. The HTA programme encourages applicants to consider *how* the scientific quality, feasibility or practicality of their proposal *might* be improved by involving members of the public. Research teams wishing to involve members of the public should include in their application: the aims of active involvement in this project; a description of the members of the public (to be) involved; a description of the methods of involvement; and an appropriate budget. Applications that involve members of the public will not, for that reason alone, be favoured over proposals that do not but it is hoped that the involvement of members of the public will improve the quality of the application.

Outcomes

Wherever possible, the results of HTA should provide information about the effectiveness and cost-effectiveness of care provided in its usual clinical setting and for the diverse subjects who would be eligible for the interventions under study. The endpoints of interest will in most cases include disease specific measures, health related quality of life and costs (directly and indirectly related to patient management). Wherever possible, these measurements should be made by individuals who are unaware of the treatment allocation of the subjects they are assessing. We encourage applicants to involve users of health care in the preparation of their proposal, for instance in selecting patient-oriented outcomes. A period of follow up should be undertaken which is sufficient to ensure that a wider range of effects are identified other than those which are evident immediately after treatment. These factors should guide applicants in their choice of subjects, settings and measurements made.

Sample size

A formal estimate should be made of the number of subjects required to show important differences in the chosen primary outcome measure. Justification of this estimate will be expected in the application.

Communication

Communication of the results of research to decision makers in the NHS is central to the HTA Programme. Successful applicants will be required to submit a single final report for publication by the HTA programme. They are also required to seek peer-reviewed publication of their results elsewhere and may also be asked to support the NCCHTA in further efforts to ensure that results are readily available to all relevant parties in the NHS. Where findings demonstrate continuing uncertainty, these should be highlighted as areas for further research.

Timescale

There are no fixed limits on the duration of projects or funding and proposals should be tailored to fully address the problem (including long-term follow-up if necessary). Applicants should consider however that there is a pressing need within the NHS for this research, and so the duration of the research needs to be timely.