The value of 'booster' physical activity advice

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 different kinds of 'booster' sessions in maintaining physical activity in the longer term?

1 **Technology:** 'Booster' sessions. Researchers to specify and justify the content and timing of the booster approach they intend to use. The HTA programme's initial view is that these 'booster' sessions should be at 3 months but the programme is open to other, well-justified suggestions from applicants.

2 **Patient group:** Less active middle-aged adults, who have already succeeded in achieving some increase in their exercise levels. 'Less active' is defined as adults not reaching the Chief Medical Officer's recommendation of a total of at least 30 minutes a day of at least moderate intensity physical activity on 5 or more days of the week. Researchers should consider what stratification would be appropriate and/or pre-planned subgroup analyses they will undertake (e.g. by factors such as age, gender, ethnic group).

3 **Setting:** Primary care within a deprived area. Researchers should justify their definition of 'deprived'.

4 **Control or comparator treatment:** A single session of brief advice following the recommendation in the 2006 NICE physical activity guideline: that primary care practitioners should take the opportunity, whenever possible, to identify inactive adults and advise them to aim for 30 minutes of moderate activity on 5 days of the week (or more); that they should also provide written information about the benefits of activity and the local opportunities to be active; and that they should follow them up at appropriate intervals over a 3 to 6 month period.

5 **Design:** Randomised controlled trial, with three arms comparing i) no booster (control); with ii) a mini 'booster' session; and iii) a full 'booster' session. Applicants should consider how to deal with participants accessing community-based resources in response to brief advice. Variations in local provision and quality of the community-based resources will need to be taken into account within the study design, since this may also have an important impact on the effectiveness of the brief advice.

6 **Primary outcomes:** Increased physical activity at 6 months, measured in a simple but validated way; quality of life and cost-effectiveness. Process evaluation is also required.

7 **Minimum duration of follow-up:** 1 year after the initial brief advice.

Background to commissioning brief:

According to current recommendations, adults should be at least moderately active for at least 30 minutes, at least 5 days a week. However, recent estimates suggest that around 6 out of 10 men and 7 out of 10 women are not active enough to benefit their health.

NICE Public Health Intervention Guidance on physical activity (2006) has recommended that primary care practitioners should take the opportunity, whenever possible, to identify inactive adults and advise them to aim for 30 minutes of moderate activity on 5 days of the week (or more). However, during the preparation of this guidance a number of gaps in the evidence base relating to physical activity were identified. There was a general lack of evidence on effectiveness and cost-effectiveness; long term outcomes; the differential effect of interventions according to the target group's age, gender, socioeconomic position and ethnicity; and the impact of interventions on intermediate outcomes such as knowledge, awareness, attitudes and skills in relation to physical activity.

The long-term effects of advice are of particular interest to the HTA programme. Research is therefore needed to investigate the clinical and cost-effectiveness of a 'booster' physical advice session in improving the maintenance of physical activity in the long term.

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. 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 return it to the HTA Commissioning Manager at the National Coordinating Centre for Health Technology Assessment, Mailpoint 728 Boldrewood, University of Southampton, Southampton SO16 7PX by *Wednesday 25 April.* Outline applications will be considered by the HTA Commissioning Board at its meeting in *July 2007.* If they are acceptable, investigators will be given a minimum of eight weeks to submit a full proposal.

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

Please see GUIDANCE ON APPLICATIONS overleaf.

The HTA programme expects, where appropriate, that applicants will work with the relevant research network.

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.

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.