Psychological therapies for depression among patients with advanced cancer (no longer amenable to curative treatment)

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 a substantial portfolio of work within the National Institute for Health Research 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 effectiveness and cost-effectiveness of psychological therapies compared to normal care in treating depression for adults who have cancer that is no longer amenable to curative treatment?

1 **Technology:** A psychological therapy, such as cognitive behaviour therapy (CBT), adapted for use in this specific patient group, to be specified and justified by the researcher (for example a modified CBT package), in addition to normal care. Therapist and model/method of delivery to be specified by the researcher.
2 **Patient group:** Adults (18 years or older) with incurable cancer. The intention is for the patient group to comprise those patients with a diagnosis of cancer which is not amenable to curative treatment but not those in the terminal phase of their condition.
3 **Setting:** Primary care, community or palliative care settings.
4 **Control or comparator treatment:** Normal care, which would include antidepressant medication (usually SSRIs).
5 **Design:** A two-arm randomised controlled trial comparing normal care with a psychological therapy, adapted for use in this patient group (researcher to justify specific package or psychological therapy) in addition to SSRIs in treating depression in patients with incurable cancer, to incorporate effectiveness and cost-effectiveness measures. Researchers need to clarify how the diagnosis of depression is made and measured, anticipated life expectancy, and how patients will be reassessed for depression and response to treatment.
6 **Primary outcomes:** Severity of depression, acceptability of treatment, and quality of life. Cost-effectiveness and mortality measures.
7 **Minimum duration of follow-up:** Researcher to justify.

Background to commissioning brief:

Depression is one of the most widely recognised psychiatric disorders in cancer patients. Approximately 58% of cancer patients have depressive symptoms and up to 38% have major depression. Depression worsens quality of life, can reduce compliance with medication, is a psychological burden on carers, and can prolong hospitalisation. Thus, the appropriate management of depression in cancer patients is an important aspect of comprehensive patient care.

Studies investigating the effectiveness of psychosocial treatment for depression among cancer patients have been conducted. However, the findings of these reports are conflicting and further evidence is needed. Availability and cost for psychologist-delivered CBT in the NHS may make the delivery of CBT difficult in this patient group. Consideration should therefore be given to the feasibility of training other staff to deliver this intervention.

Notes to Applicants

The NIHR Health Technology Assessment programme is funded by the NIHR, with contributions from the CSO in Scotland and WORD in Wales.

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.

Research networks

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

Making an application

If you wish to submit an outline proposal on this topic, complete the on-line application form at http://www.hta.ac.uk/funding/standardcalls/index.shtml and submit it on line by **23rd June 09.** Applications will be considered by the HTA Commissioning Board at its meeting in September/October 09. For outline applications, if shortlisted, investigators will be given a minimum of eight weeks to submit a full proposal.

Applications received electronically 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. The HTA programme expects teams proposing randomised controlled trials to include input from an accredited clinical trials unit, or one with equivalent experience. Applicants are also expected to engage a qualified Trial Manager for appropriate projects. A commitment to team working must be shown and applicants may wish to consider a collaborative approach between several institutions.

Public involvement in research

The HTA programme recognises the benefit of 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 *could* be improved by involving members of the public. Examples of how this has been done for health technology assessment projects can be found at http://www.hta.ac.uk/PPIguidance/. 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.