Psychological interventions for the treatment of moderate and severe depression in children and young people

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 the following psychological interventions: cognitive behavioural psychotherapy or psychodynamic psychotherapy, compared to each other and treatment as usual, in children and young people with moderate or severe depressive disorder, in achieving remission from the disorder?

1 **Technology:** The technologies are individual cognitive behavioural psychotherapy, and individual psychodynamic psychotherapy, compared with each other and treatment as usual. They are briefly described below: Individual cognitive behavioural therapy (CBT) requires the patient to work collaboratively with a therapist using a shared formulation to achieve specific treatment goals. These include recognising the impact of behavioural and/or thinking patterns on feeling states, and encouraging alternative cognitive and/or behavioural coping skills to reduce the severity of target symptoms and problems. Psychodynamic psychotherapy (PP) entails the therapist and patient exploring personal conflicts and problem behaviours, modes of thought and relating as these manifest both in the young person's life and the therapy relationship. The therapy is generally non-directive and is focused on the young person's thoughts and feelings.

2 **Patient group:** The target group is children (<12 years) and young people (12-17 years) (and, as appropriate, their families/carers) diagnosed with moderate to severe depression against recognised diagnostic criteria.

3 **Setting:** NHS secondary care specialist (Tier 3) Child and Adolescent Mental Health Services (CAMHS).

4 **Control or comparator treatment:** The comparator would be the technologies described above along with treatment as usual (TAU) in CAMHS. For the purposes of the trial, usual treatment needs to be defined in the proposal.

5 **Design:** A randomised controlled trial, with a follow up of at least one year. This should be conducted with the help of the Mental Health Research Network. Given the common co-morbidity of depression with both anxiety and conduct problems, the proposal should consider the use of minimization methods to avoid study arm imbalance for co-morbidity, gender and minority ethnic status.

6 **Primary outcomes:** The primary outcome for the trial should be recurrence or persistence of symptoms by 52 weeks and cost effectiveness.

Background to commissioning brief:

Depression will shortly be the second greatest cause of disability and lost productivity in the developed economies. A significant proportion of depression, perhaps 30% or more of adult depression, starts in childhood and adolescence. It is a major factor in suicide which is the largest cause of mortality in young men.

Recent systematic reviews and advice from the MHRA have suggested only a limited role for antidepressant medication for children and adolescents. This is in contrast to adults where evidence supports the use of antidepressants as a first line treatment for moderate and severe depression. It is therefore essential that effective psychological treatments are developed and implemented in the NHS for the treatment of depression in children and adolescents.

Currently two individual psychological treatments (cognitive behavioural and psychodynamic therapy) have evidence for their use in the treatment of depression but the limited research base means it is possible to identify which of the two is the more effective and cost effective. A trial, comparing these two treatments against standard would be vital in informing the NHS on the effective use of resources in treating this serious disorder.

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, with the HTA programme acting as their agent, is prepared, in principle, to be nominated as the sponsor. The responsibilities of the sponsor will then be agreed amongst the HTA programme, the host institution and the successful applicant. The DH reserve the right to withdraw from the role of sponsor if they are not satisfied with the arrangements put in place to conduct the trial. Experience shows that some host institutions prefer to assume the role of sponsor for purposes of the clinical trials regulations. This is consistent with their duties and responsibilities under the Research Governance Framework and the HTA programme would support this approach.

The MHRA (info@mhra.gsi.gov.uk, http://www.mhra.gov.uk) can provide guidance as to whether your trial is 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 Commissioning Manager at the National Coordinating Centre for Health Technology Assessment, Mailpoint 728 Boldrewood, University of Southampton, Southampton SO16 7PX **by 29 March 2006.** Outline applications will be considered by the HTA Commissioning Board at its meeting in **June 2006**. 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.

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.