Psychological interventions in irritable bowel syndrome

Introduction

The aim of the HTA programme is to ensure that high quality research information on the effectiveness, costs 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.

Research Question*:*

What is the clinical and cost-effectiveness of psychological interventions for patients with refractory irritable bowel syndrome?

1 **Intervention:** Two psychological therapies: i) therapist-delivered cognitive behavioural therapy (CBT) and ii) a low intensity behaviour therapy. Applicants to define and justify the low-intensity therapy (e.g. internet-delivered CBT) which should be easily deliverable within the NHS.
2 **Patient group:** Adults with refractory irritable bowel syndrome (IBS) - defined by NICE as people with IBS who do not respond to first line therapies after 12 months and who develop a continuing symptom profile.
3 **Setting:** Any, but most will have been seen by a gastroenterologist.
4 **Control or comparator:** Treatment as usual, to be specified by the researchers.
5 **Study Design:** A 3-arm randomised controlled trial of therapist-delivered CBT and a low intensity behaviour therapy against usual care. Patients need to have been offered appropriate pharmacotherapy (e.g. antispasmodics and antidepressants) as recommended by NICE. Patients may still be taking IBS prescribed drugs but these should be maintained on a stable dose throughout the study. Account should be taken of the duration of the IBS condition as well as any current or previous psychiatric diagnosis. Treatment effects in different patient groups should be investigated.
6 **Important outcomes:** IBS-symptom severity; global improvement of IBS symptoms.
Other outcomes: Quality of life; comparative effectiveness; psychological distress; coping; compliance; patient satisfaction; health care utilization; adverse events; abdominal pain; stool consistency and frequency, cost-effectiveness.
7 **Minimum duration of follow-up:** 1 year.

Background information for potential applicants:

Most people with IBS experience symptoms that are relatively short-lived or that only trouble them on an intermittent basis. Some people, however, develop chronic and severe symptoms that are difficult to treat. NICE (clinical guideline 61, 2008) recommends that people with refractory IBS be referred for complex psychological interventions such as CBT. However, a recent Cochrane review found that such treatments may be slightly superior to usual care but that there was a lack of high quality evidence. They concluded that a well-designed RCT was needed investigating the role of psychological therapies in management of IBS. Complex psychological interventions are time consuming to provide, require specialist input and availability varies widely across the UK. If a low intensity behaviour therapy was found to be an effective intervention for refractory IBS this could have a positive impact on patients' access to the intervention, IBS symptoms and quality of life as well as reducing NHS costs.

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. Researchers from Northern Ireland should contact NETSCC to discuss their eligibility to apply.

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/Utilities/Documentrecord/index.htm?d=MRC002416) 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.

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information on the transparency agenda is at: http://transparency.number10.gov.uk/#

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 **6th October 2011.** Applications will be considered by the HTA Commissioning Board at its meeting in January 2012. 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 NETSCC, HTA 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.

Feasibility and Pilot studies

We expect that when pilot or feasibility studies are proposed by applicants, or specified in commissioning briefs, a clear route to the substantive study will be described. This applies whether the brief or proposal describes just the preliminary study or both together. Whether preliminary and main studies are funded together or separately may be decided on practical grounds.

Feasibility Studies are pieces of research done before a main study. They are used to estimate important parameters that are needed to design the main study. Feasibility studies for randomised controlled trials may not themselves be randomised. Crucially, feasibility studies do not evaluate the outcome of interest; that is left to the main study. If a feasibility study is a small randomised controlled trial, it need not have a primary outcome and the usual sort of power calculation is not normally undertaken. Instead the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.

Pilot studies are a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It will therefore resemble the main study in many respects. In some cases this will be the first phase of the substantive study and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Or at the end of the pilot study the data may be analysed and set aside, a so-called external pilot.

For a full definition of the terms 'feasibility study' and 'pilot study' visit the NETSCC website glossary page http://www.netscc.ac.uk/glossary/