Group exercise for depression in older people in residential care

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 group exercise for mild to moderate depression in older people in residential and nursing homes?
 - 1. **Technology:** Group exercise. Researchers to define package used
 - 2. **Patient group:** People aged over 65 with mild to moderate depression, researchers to define the diagnostic methods used.
 - 3. **Setting:** Nursing homes and residential homes.
 - 4. Control or comparator treatment: Usual care
 - 5. **Design:** Cluster randomised controlled trial with economic modelling of a programme of group exercise. The researchers should specify the instructor-participant ratio. The unit of randomisation should be the residential home.
 - 6. **Primary outcomes:** Symptom reduction; remission from depression. Secondary outcomes to be considered: well-being; quality of life; mobility; exercise tolerance; falls. Costeffectiveness.
 - 7. **Minimum duration of follow-up:** 1 year.

Background to commissioning brief:

There is a high prevalence of depression among older people living in nursing homes and residential care. Mild and moderate depression are associated with high levels of morbidity, falls, primary and secondary service use, increased mortality and the development of major depressive disorder. Interventions to reduce depressive symptoms would be beneficial in improving mobility, functional ability, reducing care needs, and improving mood and quality of life in older people living in care homes

Primary research is required in the form of a cluster randomised controlled trial with economic modelling, to compare group exercise with usual care for older people in nursing homes and residential care, in order to establish the effect of exercise on mood in older people with depression, and to explore the cost effectiveness of exercise in this setting.

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 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.

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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 costeffectiveness 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 patientoriented 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.

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