Health Technology Assessment Programme

National Institute for Health Research

HTA no 13/18

Peer support for breastfeeding maintenance

Introduction

The aim of the HTA Programme is to ensure that high quality research information on the effectiveness, costs and broader impact of health technology is produced in the most efficient way for those who use, manage, provide care in or develop policy for the NHS. Topics for research 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:

Can peer support for breastfeeding in the UK contribute to the maintenance of breastfeeding, particularly in groups of the population who are less likely to breastfeed?

1. **Intervention:** Peer support for breastfeeding; nature, intensity, timing and frequency of support to be defined.
2. **Target Group:** Women who have initiated breastfeeding, but may not continue without additional support. Different ethnic, socio-economic and age groups may need to be considered separately and research should particularly focus on groups who are less likely to continue breastfeeding.
3. **Setting:** Community and maternity services – particularly in areas with low breastfeeding prevalence at 8 weeks.
4. **Comparator treatment:** Usual care.
5. **Study design:** Primary research in the form of a feasibility study: i) Rapid review of evidence relevant to UK context, including grey literature and information from current service providers to identify the range of current practice; ii) Development of breastfeeding peer support intervention, specifying training required for peer supporters and critical components of the intervention; iii) Testing of proposed intervention to examine feasibility and acceptability, considering impact in different population groups; iv) If appropriate, recommendations for a full trial. Qualitative work with the selected groups and with providers will be necessary to support development of the intervention. This should also consider the place of peer support interventions alongside other approaches.
   The methodology used for adaptation of existing interventions or for developing population specific interventions should be clearly described and justified with reference to an appropriate theoretical framework, prior experience and evidence from the literature.
6. **Important outcomes:** Recommendations for peer support intervention, including intensity, duration and content of peer support; acceptability and uptake in different groups of women; feasibility of trial; recommendations for trial design including appropriate outcomes; cost.

Background information for potential applicants:

There is a need to identify interventions to increase breastfeeding uptake and continuation in the UK as this offers important preventative health benefits to both mother and baby.

The median duration of breastfeeding in the UK is around one month. Rates are significantly lower in the UK than other European Union countries. Breastfeeding maintenance is monitored in the NHS at 6-8 weeks post-natally and continuation rates are lowest among lower socio-economic groups and teenagers, contributing to inequalities in health. There is a lack of evidence on the effectiveness of interventions targeting specific socio-economic, ethnic, low-income or vulnerable groups.

Breastfeeding peer support usually focuses more on maintenance than initiation of breastfeeding, although it may also be helpful in initiation. It is usually provided by mothers who have received brief training and may be volunteers. If it is successful in supporting mothers to continue breastfeeding it is likely to be a valuable intervention alongside other approaches such as counselling which focuses more on breastfeeding initiation.

The HTA programme is inviting applications to carry out the research as outlined above.

Notes to Applicants

The NIHR Health Technology Assessment Programme is funded by the NIHR, with contributions from the CSO in Scotland, NISCHR in Wales, and the Public Health Agency in Northern Ireland. Researchers from Northern Ireland and Scotland for certain NICE related calls 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/#

Applicants are recommended to seek advice from suitable methodological support services, at an appropriate stage in the development of their research idea and application. It is advisable to make contact at an early a stage as possible to allow sufficient time for discussion and a considered response.

The NIHR Research Design Service (http://www.nihr.ac.uk/infrastructure/Pages/infrastructure_research_design_services.aspx) can advise on appropriate NIHR Programme choice, and developing and designing high quality research grant applications.

Clinical Trials Toolkit
Researchers designing or undertaking clinical trials are encouraged to consult the Clinical Trials Toolkit (www.ct-toolkit.ac.uk). This NIHR resource is an innovative website designed to help researchers navigate through the complex landscape of setting up and managing clinical trials in line with regulatory requirements. Although primarily aimed at those involved in publicly funded Clinical Trials of Investigational Medicinal Products (CTIMPs), the Toolkit will also benefit researchers and R&D staff working on trials in other areas, who will find useful information and guidance of relevance to the wider trials environment.

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 **29th August 2013**. Applications will be considered by the HTA Commissioning Board at its meeting in **November**. 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. Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at www.comet-initiative.org to identify whether Core Outcomes have been established. 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/

Diagnostics and Imaging

In evaluating diagnostic and imaging techniques, the emphasis of the HTA Programme is to assess the effect on patient management and outcomes (particularly where changes in management can be shown to have patient benefits). Improvements in diagnostic accuracy, whilst relevant, are not the primary interest of this commissioned research programme. Applicants should justify where they consider improvements in diagnostic accuracy to be relevant to these objectives. Where there is poor evidence to link diagnostic improvements to patient benefits, part of the primary research may be to assess the effects of such changes on patient outcome.

An assessment should also be made of changes in other resources (particularly other subsequent therapies) used as a result of changes in diagnostic methods.