Health Technology Assessment Programme

National Institute for Health Research

HTA no 16/11

Treating mental health problems associated with a history of complex traumatic events

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 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 effectiveness of interventions to treat mental health problems associated with a history of complex traumatic events such as abuse?

1. **Interventions:** Any pharmacological and non-pharmacological first and second-line interventions relevant to the NHS that are used to treat the patient group - applicants to define and justify the inclusion criteria.
2. **Patient group:** Adults presenting with mental health problems associated with a history of complex traumatic events - applicants should provide a definition of complex traumatic events for the review and justify the inclusion criteria.
3. **Setting:** Any.
4. **Control:** Any.
5. **Study design:** A systematic review to identify the effectiveness of the broad range of interventions for adults with complex traumatic event profiles. Non-randomised evidence should be included as appropriate. Where data are available, important subgroups should be identified, for example, type of intervention, type and duration of traumatic event, exposure to trauma as a child or adult, intra/extra-familial traumatic event, co-morbid mental health diagnoses.
6. **Important outcomes:** To be defined and justified by applicants – but should include measures of mental health and illness, and global functioning.

   Other outcomes: Suicidal behaviour; depression and anxiety; dissociation; adverse effects of treatment; substance abuse; engagement with treatment; health related quality of life; identification of the most promising interventions for further primary research.

NHS decision problem to be addressed by this research:

People who experience complex traumatic events such as childhood maltreatment, prolonged family or community violence, or exploitation are at risk not only for PTSD but also other psychiatric disorders including personality disorders. The term "complex PTSD" may be used for this group but terminology in clinical practice varies. The World Health Organization (WHO) Working Group on the Classification of Disorders Specifically Associated with Stress defines "complex PTSD" as an extensive reaction typically arising from severe and prolonged stressors such as repeated child sexual abuse, severe domestic violence, torture, or slavery. However defined, a distinction between PTSD arising from a single traumatic event and the psychological problems arising due to complex traumatic events that are persistent and prolonged is relevant for treatment and outcome purposes.

Evidence-based treatments for psychological problems associated with complex traumatic events are scarce; such people are usually excluded from clinical trials. Consequently, it is still unclear for clinicians whether patients who have suffered complex traumatic events are generally able to tolerate, and benefit from, commonly available psychological and pharmacological treatments aimed at single event PTSD. This is an under-served group who are not catered for by improving access to psychological therapies (IAPT) services. A broad evidence synthesis is needed that builds on and extends previous reviews to reflect the patient group as seen in clinical practice and to include pharmacological as well as non-pharmacological interventions. The review should aim to identify the most promising front runners that the HTA programme could then consider for future primary research in the area as part of a separate call.

Making an application

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.

If you wish to submit a proposal on this topic, complete the on-line application form at www.nets.nihr.ac.uk/funding/hta-commissioned and submit it on line by **19 May 2016.**

Your full proposal will be assessed by designated board members, alongside other applications submitted in the same topic area. A maximum of three proposals will be taken forward for peer review by external referees, and subsequent consideration by the HTA Funding Board at its meeting in **September 2016**.

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.rds.nihr.ac.uk/) 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 a 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.

Applications received electronically after 1300 hours on the due date will not be considered.

Please see GUIDANCE ON APPLICATIONS below.

Guidance on applications

Methods

Applicants should demonstrate knowledge of current research in the field and of systematic review methods and state how these would apply to the question posed. Valid and reliable methods should be proposed for identifying and selecting relevant material, assessing its quality and synthesising the results. Guidance on choice of appropriate methods is contained in NHS CRD Report *Systematic Reviews: CRD's guidance for undertaking reviews in health care (third edition)* (www.york.ac.uk/inst/crd/index_guidance.htm). 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. Where policy implications are considered, the emphasis should be on assessing the likely effects of a range of policy options open to decision makers rather than a judgement on any single strategy. Where epidemiological modelling or economic evaluation is required, the range of uncertainty associated with the results should be assessed. In the assessment of cost-effectiveness, further data collection may be required to estimate resource use and costs. If there is evidence that the ratio of costs and benefits may differ between readily identifiable groups, applicants are encouraged to state how they will identify these differences. Where relevant, researchers should explore the effect of the intervention in relation to health inequalities.

Cochrane

Applicants wishing to produce and maintain a Cochrane systematic review from a HTA commissioned systematic review should make the case in their proposal. This will need to include the approval of the relevant Cochrane Review Group (www.cochrane.org). Any additional costs associated with the initial preparation of a Cochrane review should be included in your project proposal. Maintenance costs cannot be met.

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 research may be to assess the effects of such changes on patient outcome.

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 www.nets.nihr.ac.uk/ppi. 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.

Updating

It is the policy of NETSCC, HTA that all search strategies undertaken as part of evidence synthesis/secondary research projects must not be more than 12 months out of date when the draft final report is submitted. We expect that most projects will manage to bring their searches up to date prior to analysis and writing up. As research funders we are aware that exceptional circumstances can apply that would not allow this to be case but this must be the exception rather than the rule and will be assessed on a case by case basis. The expectation is that projects funded by the HTA Programme will deliver information that is both relevant and timely.

In addition, in order to inform decisions on whether and when to update the review, researchers will be expected to give some indication of how fast the evidence base is changing in the field concerned, based on the nature and volume of on-going work known at the time the review is completed. Applicants should note that they will not be expected to carry out any future updating as part of the contract to complete the review.

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 communicate their work through peer-reviewed journals 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. However, there is a pressing need within the NHS for the information and so the research would normally be expected to be completed as soon as possible – however it is for applicants to justify the duration and costs proposed.