TECHNOLOGY ASSESSMENT REPORT COMMISSIONED BY THE NETSCC HTA PROGRAMME

HTA 09/145

Plain English Summary

In the UK women aged 50 to 70 years old are invited to come for mammography screening every 3 years. About 5% of these are recalled for further investigation. After follow-up it is found that about 82% of recalled women had nothing wrong with them (false-positives). However, the experience of being unnecessarily recalled can be distressing, not just in the short-term but may lead to enduring anxiety and affect attendance at future routine mammography screening. The purpose of this systematic review is to find out what the research evidence is for medium and long-term effects of having a false-positive mammogram on mental health and behaviour, whether some groups of women are more likely to be adversely affected than others and if there are ways of reducing the negative effects of being recalled when you are in fact well.

Decision problem

The purpose of this technology assessment is to conduct a systematic review, to identify the psychological and behavioural consequences following false-positive screening mammogram results that affect women and any evidence for the effectiveness of interventions designed to reduce these. In particular we will be looking at whether the psychological and behavioural consequences or the effectiveness of specific interventions differ in different groups of women.

This research is necessary because of the large number of false-positive results that come from routine mammography screening. In the UK women aged 50-70 years, on population registers, are invited for mammography every 3 years through the NHS Breast Screening Programme (NHSBSP). Around two million women were screened by the NHSBSP in 2007/8 and of these 95,006 (5%) were recalled for further investigation; 16,735 cancers were detected leaving 78,271(82%) false-positive recalls.[2]

Quantitative observational studies looking at the psychological and behavioural consequences of false-positive mammograms show conflicting results. Some studies indicate that, while women show increased distress between receiving the information about the need for a follow-up appointment and receiving the all-clear, in the longer term their anxieties about breast cancer and mammography are not increased.[53–55] Other studies report that there are long-term adverse psychological consequences to receiving a false-positive mammogram.[56,57,59,103] The outcomes of studies looking at whether having false-positive results affects future attendance at breast screening appointments is similarly conflicted.[58–61]

A quantitative systematic review in 2007 by Brewer and colleagues found that the impact of a false-positive mammogram on subsequent screening attendance varied with nationality; although, the reasons for this were unclear. They also reported a varying impact on long-term psychological distress, anxiety and depression, and other behaviours such as frequency of breast self-examination.[62] However, their review did not report the reasons for this variation in response. Furthermore, Brewer and colleague's review found no statistically sound studies that investigated whether anxiety over a false-positive mammogram directly affects whether women return for routine screening or increase breast self-examination. There was little evidence about the effects on quality of life or trust of healthcare services and no evidence about whether

women who felt anxious after a false-positive screening result replaced routine screening attendance with breast self-examination.[62] We also do not know what meanings women attribute to a false-positive mammogram or how these may determine their behaviour when invited for further routine mammogram screening as qualitative evidence is lacking.

Therefore, there is uncertainty about the psychological impact of false-positive mammograms on women. We do not know what the mediators are of negative psychological and behavioural outcomes which may affect attendance at future mammography screening. There is a need to answer these questions to identify and evaluate studies of interventions to treat the effect of false-positive results, and identify whether these effects differ in women from different backgrounds. The answers will have important policy implications for the NHS in the provision of breast cancer screening services.

The questions that this systematic review will answer are:

1. What evidence is there for medium or long-term adverse psychological consequences of false-positive screening mammograms?
   (a) Do the types of psychological consequences differ between different groups of women?
2. Are there interventions that reduce adverse psychological consequences?

For question one the population will be women who have received a false-positive result from routine mammogram screening in the UK and invited for further assessment. Where studies include a comparator this will be women who had a routine screening mammogram but who had a normal mammogram and were not invited for further assessment. A range of outcomes, including qualitative, will be considered that report psychological and behavioural measures over the medium and long-term. Where data permit, subgroup analyses will be conducted of different groups of women (including socio-economic status and ethnic group).

For question two the population and the outcomes will be the same as question one. The interventions will be those delivered to individuals to address the adverse psychological consequences of a false-positive mammogram result, including attendance at future routine breast screening. Where there are comparators this will be an absence of an individualized intervention in the same population. Where data permit, subgroup analyses will be conducted of different groups of women (including socio-economic status and ethnic group).

It is intended that this should be a wide systematic review considering a range of study types including uncontrolled studies and qualitative research but excluding individual case studies. Recommendations will be made for future primary research.

Methods for selection of evidence of clinical effectiveness

A systematic review will be conducted using the principles of the NHS Centre for Reviews and Dissemination[77] including those for non-randomized and qualitative studies.[123]

Inclusion criteria

Question	Criteria	Specification	Notes
1 and 2	Population	Women who have received a positive result from routine mammogram screening in the UK and have been invited for further assessment which shows that they do not have breast cancer	Where data permit we will look at sub groups including socio-economic status, and ethnic group
2	Intervention	Those interventions delivered to individuals to address the adverse psychological and behavioural consequences of a false-positive mammogram result.	These are individual interventions not group ones
1	Comparator	Women who have received a negative (normal) result from routine mammogram screening in the UK.	
2	Comparator	An absence of an individual intervention in the same population	
1 and 2	Outcomes	Psychological and behavioural outcomes and those from qualitative studies	Including subsequent attendance at routine mammography screening and quality of life
1 and 2	Setting	UK	Secondary care
1 and 2	Study design	Systematic reviews, randomized, non-randomized, observational and qualitative studies	We will not consider individual case studies
1 and 2	Length of follow-up	At least one month from the 'all-clear'	Measured over the medium to long-term, i.e. not the immediate response to receiving a false-positive result
1 and 2	Language	English language only	Non English language papers will be included in the searches and screened, so that the number of potentially includable foreign language papers is known

Exclusion criteria

The following types of studies will be excluded: narrative reviews, editorials, opinion pieces, non-English language papers, individual case studies, and studies only reported as posters or by abstract where there is insufficient information to assess the quality of the study.

Search strategy

Refer to Appendix 1 for the draft search strategy for MEDLINE.

The search strategy will comprise the following main elements:

- Searching of electronic bibliographic databases.
- Internet searches.
- Scrutiny of references of included studies.
- Contacting experts in the field.

Databases will include:

MEDLINE, EMBASE, The Cochrane Library, PsychLIT, CINAHL EBSCO, Web of Science, Science Citation Index Expanded, Conference Proceedings Citation Index, Sociological Abstracts, Applied Social Sciences Index, Sociological Abstracts, Applied Social Sciences Index and International Bibliography of the Social Sciences.

Study selection

Based on the above inclusion/exclusion criteria, papers will be selected for review from the titles and abstracts generated by the search strategy. This will be done independently by two reviewers; discrepancies will be resolved by discussion, with the involvement of a third reviewer if necessary. Although non-English language papers will not be included in the systematic review due to resource limitations, they will be identified and any that meet the other inclusion criteria will be recorded with their language noted as the reason for their exclusion. Retrieved papers will again be reviewed and selected against the inclusion criteria by the same independent process.

Data extraction

Data will be extracted from included studies by one reviewer using a standardised data extraction form and checked by another reviewer. Authors of studies will be contacted to provide missing information, as necessary.

Quality assessment

Quantitative studies will be assessed for internal and external validity according to criteria suggested by the updated NHS CRD Report No.4, according to study type.[77,78] Qualitative studies will have their quality assessed using a standard assessment tool, e.g. Mays and Pope 1995[124] and Popay and colleagues 1998,[125] a number of these will be piloted to assess their suitability for the task.

Methods for analysis and synthesis of evidence of clinical effectiveness

Quantitative analysis and synthesis

Studies were assessed for internal and external validity according to criteria suggested by the updated NHS CRD Report No.4, according to study type.[77,78] The quality of systematic reviews was evaluated using the PRISMA statement.[79] Individual RCTs were appraised with the CONSORT statement[80] and individual observational studies with STROBE guidelines.[81]

Qualitative analysis and synthesis

These studies will be analysed using meta-ethnography[126–128] supported by Atlas.ti6 software. Here the included studies' results are translated into one another, while preserving their original meaning, with an inductive and interpretive approach to allow comparison between them. Authors' interpretation of the primary study findings become the data, which are translated across studies by the reviewers to produce a synthesis of meaning allowing the production of higher order concepts.

Combined synthesis of quantitative and qualitative evidence

The results of the quantitative and qualitative analyses will undergo narrative synthesis to construct an explanatory framework.[129,130] In this method both types of data analysis undergo a further narrative synthesis of their combined data through a process of developing an explanatory theory, undertaking a preliminary synthesis, looking at the relationships between and within studies and evaluating the robustness of the synthesis.

Expertise in this TAR team

People

Name	Institution	Expertise
Mrs Mary Bond	PenTAG, University of Exeter	Systematic reviewing, psychology and project management
Dr Toby Pavey	PenTAG, University of Exeter	Systematic reviewing
Mrs Karen Welch	Karen Welch Information Consultancy	Information Specialist
Mr Chris Cooper	PenTAG, University of Exeter	Information Specialist
Dr Ruth Garside	PenTAG, University of Exeter	Qualitative evidence synthesis
Prof. Chris Hyde	PenTAG, University of Exeter	Diagnostics and public health

In addition to the research team, we will be receiving expert clinical advice from Dr Russell Davies Consultant Breast Radiologist (Royal Devon and Exeter Foundation Trust), Gillian Gray (Breast Care nurse Royal Devon and Exeter Foundation Trust), Dr Jim Steel Consultant Breast Radiologist and Prof Carl Roobottom, Consultant Radiologist (both at Derriford Hospital, Plymouth), Jenny Hewison Professor of the Psychology of Healthcare, from the University of Leeds. We have two patient representatives, Kate Blackmore and Sue Milward who have both had experience of having a false-positive mammogram to advise us on the patient perspective.

TAR centre – PenTAG

This project is being conducted by The Peninsula Technology Assessment Group (PenTAG), which is part of the Institute of Health Service Research at the Peninsula Medical School, University of Exeter. PenTAG was established in 2000 and carries out independent Health Technology Assessments for the UK HTA Programme and other local and national decision-makers including NICE. The group is multi-disciplinary and draws on individuals' backgrounds in public health, health services research, computing and decision analysis, systematic reviewing, psychology, statistics and health economics. The Institute of Health Service Research is made up of discrete but methodologically related research groups, among which Health Technology Assessment is a strong and recurring theme.

Contributions of team members

Name	Job title	Contribution
Mary Bond	Research Fellow in Health Technology Assessment	Providing project management. Writing the protocol. Conducting the systematic review. Writing and editing the report.
Toby Pavey	Research Fellow in Health Technology Assessment	Second reviewing the titles, abstracts and papers for the systematic review.
Karen Welch	Information Specialist	Writing and running the search strategies for the systematic review
Chris Cooper	Information Specialist	Writing and running the search strategies for the systematic review
Ruth Garside	Senior Research Fellow	Overseeing qualitative evidence synthesis
Chris Hyde	Professor of Public Health and Clinical Epidemiology	Director of the project and guarantor of the report. Contributing to editing the report.

Competing interests of authors

None.

Timetable and project milestones

Milestones	November	December	January	February	March	April	May	June	July	August	September	October
Conduct searches												
Select studies												
Analysis												
Writing up												