DOES A DETAILED INFORMATION SHEET REDUCE THE PSYCHOLOGICAL IMPACT OF RECALL AFTER SCREENING MAMMOGRAPHY? - PROPOSAL FOR A RANDOMISED TRIAL

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Abstract

False-positive mammography raises anxiety and reduces attendance for subsequent screens. Clear and concise information may allay this anxiety. We propose to test this hypothesis in a randomised trial.

After approval from the ethics committee and the national advisory committee for screening, randomly selected half of 4000 first screening mammography invitations will be accompanied by a field-tested one-page information sheet. This will clarify the exact benefit of screening mammography. It will alert the woman about the chance of her being recalled for further tests but also reassure her that cancer will be found in only 1 out of 10 cases recalled.

All women will receive a short questionnaire to assess their knowledge and attitude. Anxiety will be measured with a HAD score in the estimated 280 women who will be recalled. These women will also fill in a one-page questionnaire to assess confounding factors.

Half these women would have received the information sheet. Attendance rates and anxiety scores of those who received the information sheet will be compared with those who didn't.
This pilot project can be completed within the budget of a CR UK pilot award and would lay the foundations of an important national issue – improving knowledge about cancer screening and management.

Nature of the Collaboration

This project is a collaboration between the departments of Surgery and Molecular Oncology (those treating breast cancers), Radiology (those involved in diagnosis of both symptomatic and screening services), Medical Education (those involved with teaching how to communicate with patients) and the East of Scotland screening service (those involved with the local implementation of the NHS Screening programme).

Such a broad range of expertise will facilitate the multidisciplinary approach that this project requires. Success of this application will increase the networking within these departments and result in smoother running of services with a higher level of satisfaction for women.

Background

The psychological impact of mammographic screening has always been thought to be considerable and a recent systematic review (Brett J, et al, 2005) suggests that this is particularly true for women who are recalled for further tests. These women experience significant anxiety in the short term and possibly in the long term. Among the factors associated with higher anxiety were young age, lower education, manual occupation, and dissatisfaction with information and communication about the screening process.

As many as 46% of women who were recalled experienced significant anxiety. This is particularly disturbing because over 90% of patients who are recalled are found to be normal. These false positive results - causing false alarm have more effects than inducing anxiety per se.

Women undergoing false-positive mammography at first screen are more anxious and are less likely to re-attend for subsequent screens than non-assessed women, yet they are more likely to develop interval cancers or have cancers at the second screen, and their cancers are larger (McCannan J et al, 2002).

Hypothesis

Better information may allay this anxiety. This has been tested in a randomised trial in the USA (Barton et al, 2004). The trial aimed to reduce anxiety by either immediate reading of mammograms or educational intervention. Only the former was found to have any beneficial effect. The educational intervention however was very extensive - a 9-minute videotape and a 10-page, two-colour pamphlet that were designed to reduce anxiety among women who had undergone screening mammography by capitalizing on the "teachable moment" provided by the mammogram. In their paper, the authors admit that the educational intervention itself may have increased anxiety and this may have nullified its effect. Furthermore, the study was conducted in New England, an area where arguably the awareness about screening mammography is already high and is distinct from the UK.

We postulate that **a clear and concise information leaflet** (1 side of A-4 page) that explains in lay terms the benefits and fallacies of screening mammography may achieve what an extensive educational course could not. We propose to test this hypothesis in a randomised trial. Since the negative psychological impact of screening is minimal in those who are given a clear result after the initial visit, we shall concentrate on those women who are recalled.

As mammographic screening exposes well women to potential harms for an overall population benefit, it is difficult to ensure 'informed choice' and yet women appreciate participating in making this very complex decision (Davey C, et al 2005). A recently published model of outcomes of screening may **allow information to be given in a lucid manner and support informed choices (**Barratt A et al, 2005). This project could start the process of making mammographic screening a more informed decision for women.

Experimental Design

A randomly selected half of **4000** first screening mammography invitations in the East of Scotland area over the next 9 months will be accompanied by a one-page information sheet (appendix A) that we have prepared and piloted amongst 20 women who had normal assessments at recall.

The **main outcome measure will be a change in knowledge, attitude and behaviour.** The secondary outcome measure will be attendance rates and overall satisfaction with the screening process.

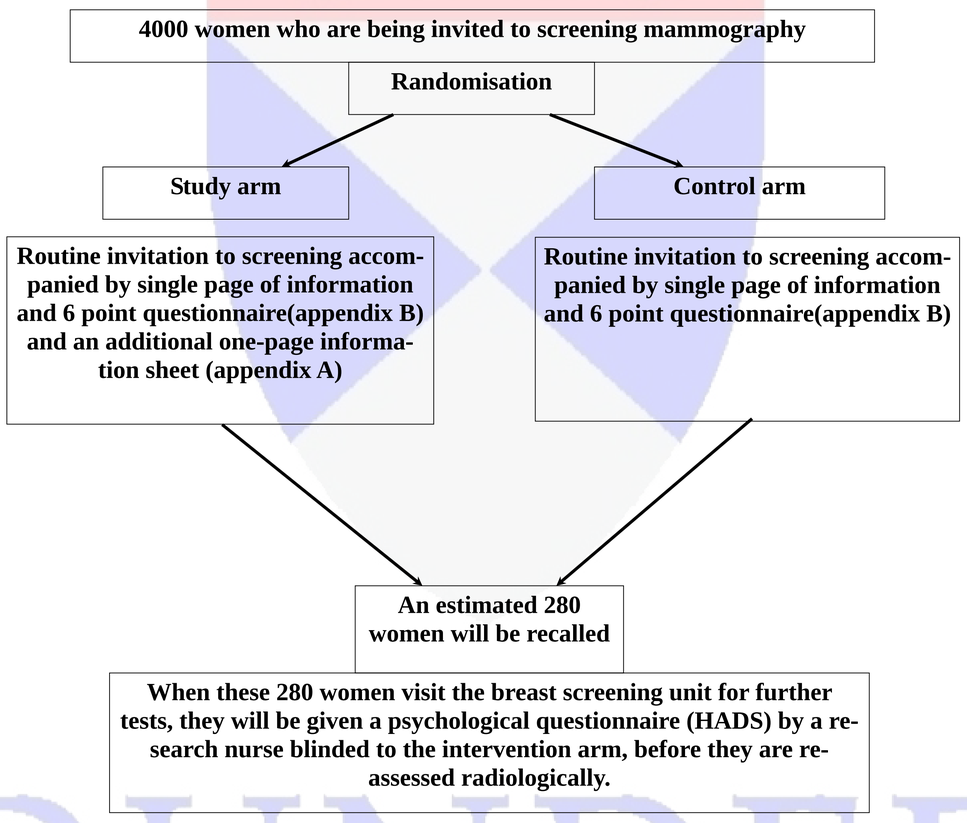
The **knowledge and attitude** of all the women returning the first questionnaire (appendix B) will be compared between those given and not given the information sheet.

Behaviour: We expect that 280 of these women will be recalled for further tests. At this time, they will be approached, consented and requested to complete the Hospital Anxiety and Depression Score (HADS) sheet (Zigmond and Snaith, 1983). This is a 14 point scale 7 items for anxiety and 7 for depression, 4 point scale measure (0-3) . Values can range from 0-21 and higher values indicate greater anxiety or depression. It has been used as a categorical measure and we shall use a the commonly used cut-off points, viz., at 8+ for borderline anxiety or depression and 11+ for significant anxiety or depression.

We shall collect data about the **known factors** that are know to be associated with adverse psychological impact of screening mammography (Brett J et al, 2005): occupation, education, deprivation (Carstair's index), marital status, number of children, family history of breast cancer and fear of cancer. We will also record the dates of the first mammogram, the receipt of the recall letter and the recall appointment. The Data will be collated in a secure database and analysed using a standard statistical package (SPSS). For analysis of data, we shall dichotomise the data into no anxiety vs. borderline or significant anxiety or depression. Half of the 280 women would have had the information sheet. Dichotomised HADS score of those who received the information sheet will be compared with those who didn't.

Power calculations based on incidence of anxiety in other studies (Brett J, et al, 2005). Let us estimate that the anxiety score is high in 50% of those not given the sheet and in 30% in those given the information sheet. The sample size required to detect this difference is 206. We expect to recruit at least 206 out of the 280 recalled patients.

Trial Schema



Justification of requested support

We have asked support for a research nurse who can identify the 4000 women participants, perform randomisation, send out the information sheets, consent and administer the 280 questionnaires; and for the stationary and data processing. The detail costs (in pound sterling (£) are as follows:

Research Nurse (0.5WTE)	15059
Stationary (6560 pages)	75
Printing	300
Postage (second class)	1690
Data Processing	824
TOTAL	17948

Timescale and potential problems

We expect to accrue **4000 patients over 1 year** during the screening programme in the East of Scotland.
We have already had informal discussions with the regional screening unit and they are very supportive and will be advocating our case. Once the information sheets have been sent with the invitations, we expect few problems in collecting the information from women coming for recall.
We may have some drop outs amongst the 4000 women sent the postal questionnaire, but we expect that this will be equal amongst the two randomised groups and the comparison will still be valid for knowledge and attitude.

Follow up work

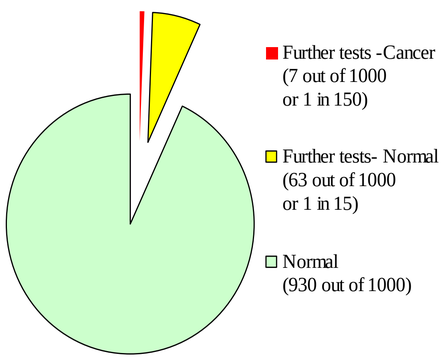
As a follow up, we shall monitor the attendance rates of those women with a negative recall at the next screening round. We expect this to be higher in the experimental arm.
With our simple intervention, we hope to make a significant difference in the experience of women undergoing screening mammography.
This could have a significant impact on women in the UK participating in the NHS breast screening programme and if the study yields a positive result, a cheap and useful intervention will have been created.
This project could start the process of making mammographic screening a more informed decision for women.

Appendix A (Information Sheet)

Understanding Mammograms

We have prepared this leaflet to help you understand mammograms better. Mammograms are used to pick up breast cancer at an early stage.
What is my chance of getting breast cancer? Between the ages of 50 and 60 the chance of getting breast cancer is about 1 in 36 and of dying from breast cancer about 1 in 200.
Does screening mammography save lives? Yes it does. Mammography can pick up cancers before they can be felt. Logically, finding cancer earlier means more chance of being cured. If 1324 women have mammograms from the age of 50 to 64, one life is saved. That one life is of course priceless but we need to recognise that the screening process itself may cause unnecessary anxiety.
What should I know about mammograms? Although mammograms can detect most cancers, they may miss a few. On the other hand they could also raise a false alarm. We tend to err on the side of safety and would rather not miss a cancer. So we often order more tests.

Every time you have a mammogram, you have a 1 in 15 chance of being called back for further tests.
The picture to the right shows the chance of being called back for further tests every time you have a screening mammogram.



The important thing to remember is that you may be called back for further tests. It just means we are being very cautious. Most likely (in over 90% of cases) these tests will be normal.
So what should I do? You are being invited for screening because you fall into the group where we know screening saves lives.
Having read this leaflet, we hope that you will be less anxious if you are recalled for further tests.

Appendix B (knowledge and attitude)

This will test knowledge with 6 questions: about the chances of getting breast cancer in the next 10 years, recall after a screening mammogram, diagnosis of breast cancer after a recall and secondly, whether they feel well prepared for screening mammography, anxious about the results of screening mammography and if she has a fear of cancer. These will be arranged in the standard easy-to-read format with the usual choices for answers for each question.

Relevant publications from our group

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Davey C, White V, Gattellari M, Ward JE. Reconciling population benefits and women's individual autonomy in mammographic screening: in-depth interviews to explore women's views about 'informed choice'. Aust N Z J Public Health. 2005 Feb;29(1):69-77.
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