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How should benign results be communicated in breast screening: in-person or by telephone?

Submission date
12/12/2017

Recruitment status
No longer recruiting

Registration date
14/02/2018

Overall study status
Completed

Last Edited
03/06/2021

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims

The National Health Service Breast Screening Programme (NHSBSP) was started to help detect breast cancer earlier in the population, in order for treatment to be more successful. All women between the ages of 43-73 are invited to breast screening once every three years. These women have no symptoms of breast cancer. At her first screening appointment, the woman will have a mammogram (an x-ray image of each breast). If anything suspicious is found in the mammogram, the woman will be asked to come back for further tests, which can include a biopsy. This is where a needle is inserted into the breast in order to remove sections from the suspicious area. These results are given to the woman within a week. Most women who have these tests will be told that their biopsy result was benign, which means that they do not have cancer. A woman with a benign result will have been identified as having a suspicious mammogram, but further tests show that this is not cancer. In 2014-15, around 69,000 women were given a benign result and had this experience. One of the main harms of breast screening is the anxiety that receiving a benign result can cause. Women who are invited to be screened have no symptoms of breast cancer at the time of their first appointment. Being told that something has been found in the mammogram and that further tests are needed can make women feel very anxious and believe that they might have cancer. This is an issue, as the NHSBSP has a duty to minimize the harm caused by screening. Anxiety for women is at its highest when a women receives her result, which means this is an important moment to make women feel less anxious and more reassured. 2014-15 NHSBSP guidelines for communicating results state they should always be given to the woman in-person. However, most breast screening centres in the UK deliver benign results to the woman over the telephone. Telephone results may be more difficult to understand, missing out important body language. This may make the woman feel more anxious than reassured. However, telephone results mean a woman doesn't have to wait in a stressful hospital environment, and may even receive her results quicker. Currently there is no research focusing on how the communication method used to deliver a screening result may impact on the woman involved. Furthermore, no research has considered how women themselves may prefer to receive their result. The aim of this project is to explore anxiety, patient understanding and preferences to see if there are any differences for women who receive their results in-person and women who receive their results over the telephone.

Who can participate?
Women aged 47-73 who are attending asymptomatic breast screening.

What does the study involve?
Centres are randomly allocated to one of two groups. Those in the first group receive four weeks of delivering benign results in-person, followed by four weeks of delivering benign results over the telephone. Those in the second group provide benign results over telephone for four weeks and provide results by four weeks of delivering benign results in-person. Those sequences are repeated for the duration of the study. All women participating during in-person months at their relevant centre will be given a scheduled appointment to re-attend to receive their results from screening in-person. All women participating during telephone months at their relevant centre will be given a scheduled appointment to re-attend to receive their results in-person, but will be contacted by telephone ahead of this appointment instead. For women not involved in the study, they will receive their results based on the centres current practice (this varies by centre). Participants are followed up at three and six months to measured anxiety and understanding of their results.

What are the possible benefits and risks of participating?
There is no direct benefit to the women involved in the study. The findings from the study will be used to ensure that the communication of benign results minimises anxiety and is more patient-centred. However, this will be a more generalised benefit, than individual patient benefit. By measuring anxiety, this may prompt further anxiety in women involved. However, as this study is being delivered by and in the presence of Breast Care Nurses, we feel that they will be able to provide women with the advice and support they need. In all surveys, at all time points, women are reassured that, if they require any further advice about their anxiety or any other screening related problems, they can contact the Breast Care Nurses at their local centre. Furthermore, we have engaged extensively with PPI for this project, involving the group Independent Cancer Patient Voices. Women who have received a benign result previously did not believe that measuring anxiety would cause them any extra harm – measuring anxiety is fairly common in standard practice for monitoring at breast screening centres.

Where is the study run from?
Macclesfield District General Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2015 to February 2019

Who is funding the study?
1. Economic and Social Research Council (UK)
2. Public Health England (UK)

Who is the main contact?
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Contact information

Type(s)
Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number
212999

ClinicalTrials.gov number

Secondary identifying numbers
REC:17/WM/0313 IRAS ID: 212999 Internal sponsorship number: SC.68/16-17

Study information

Scientific Title
The communication of benign biopsy results in the NHS Breast Screening Programme: A comparison of telephone and in-person results on patient anxiety, understanding and preferences

Study objectives
In the NHS Breast Screening Programme, policy guidelines recommend that results are given in-person. However, a large percentage of breast screening centres in the UK already deliver benign results over the telephone. There is concern about what impact this might have on patient anxiety, particularly as previous research has shown that women with a benign result frequently experience ongoing anxiety. Therefore, this research aims to address whether how results are communicated (either by telephone or in-person) has an impact on patient outcomes. This includes anxiety, which is the main concern. This also involves measuring whether patients understand their results better in-person or over the telephone, as communication research suggests key cues might be missed in a telephone interaction. How patients would prefer their results to be delivered will also be considered.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NHS HRA Ethics, 18/10/2017, 17/WM/0313
2. Breast Advisory Group, 04/08/2017, ref: BSPRAC_0013 (ODR1718_040)

Study design
Multi-centre cluster cross-over trial using a longitudinal survey design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format. Please use contact details to request.

Health condition(s) or problem(s) studied
Breast cancer screening - focusing on women with a benign/false-positive outcome.

Interventions
The two study arms are as follows:
1. Four weeks of delivering benign results in-person, followed by 4 weeks of delivering benign results over the telephone (with this sequence repeated for the duration of the study)
2. Four weeks of delivering benign results over the telephone, followed by 4 weeks of delivering benign results in-person (with this sequence repeated for the duration of the study)
The study arms will be randomised at the centre level – randomised by chance (drawing from a hat).

All women participating during in-person months at their relevant centre will be given a scheduled appointment to reattend to receive their results from screening in-person. All women participating during telephone months at their relevant centre will be given a scheduled appointment to reattend to receive their results in-person, but will be contacted by telephone ahead of this appointment instead.

For women not involved in the study, they will receive their results based on the centres current practice (this varies by centre).

Duration of 'treatment': both a telephone call and in-person results appointments last approximately 15 minutes.

The follow-up duration is 6 months post-results.

Intervention Type
Other

Primary outcome measure
Anxiety is measured using the Psychological Consequences Questionniare, PCQ, at baseline, after results have been delivered, three months and six months.

Secondary outcome measures

Understanding is measured using a two-question measure in the survey at time point, developed by the lead researcher, is a basic two question measure of objective and subjective understanding at baseline, after results have been delivered, three months and six months..

Overall study start date
01/10/2015

Completion date
20/02/2019

Eligibility

Key inclusion criteria
1. Women who are attending asymptomatic breast screening as part of the NHSBSP
2. Women of recommended screening age (47-73)
3. Women must receive a biopsy test as part of their assessment clinic
4. Only women who receive a benign (B2) result will be included from time 2 onwards
5. Women who have English as a first or second language

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
702 at time point one, divided between 4 clusters/centres.

Total final enrolment
104

Key exclusion criteria
1. Women presenting symptomatically to the breast screening clinic
2. Women outside of the recommended screening age
3. Women who are diagnosed with any result other than benign (e.g. cancer, inconclusive)
4. Women who not receive a biopsy test
5. Women who do not have English as a first or second language
6. Women who do not have the capacity to consent

Date of first enrolment
01/02/2018

Date of final enrolment
01/04/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Macclesfield District General Hospital
Victoria Centre
New Alderley House Building
Macclesfield
United Kingdom
SK10 3BL

Sponsor information

Organisation
Warwick Medical School Sponsorship

Sponsor details
University of Warwick, Research & Impact Services
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Sponsor type
University/education

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Public Health England

Alternative Name(s)
PHE

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
I intend to publish the results from the study in several publications.
This will likely be publications focusing on:
The impact of communication method on short-term anxiety and understanding
The impact of communication method on long-term anxiety
How would women prefer their results to be delivered and what are the reasons for these preferences? (Mixed methods paper)

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
As the trial is part of a PhD project, the data will be held in accordance with the University of Warwick PhD guidelines. Data will be stored securely for 10 years post-publication. However, this data will not be made available.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/08/2019	02/09/2020	Yes	No
HRA research summary			28/06/2023	No	No