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A brief TELephone intervention to increase uptake of BREast Cancer Screening (TELBRECS)

Submission date 02/12/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 16/01/2014	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 05/10/2018	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-breast-cancer-screening-scotland-telbrecs

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of a brief telephone reminder and support intervention to increase the uptake of breast cancer screening in women from socially deprived areas in Scotland

Acronym
TELBRECS

Study objectives
Our aim is to elicit and address barriers and facilitators to breast screening attendance in women from lower socioeconomic areas via a brief, personalised, telephone intervention, aimed at increasing screening uptake. We will also test whether asking questions about anticipated regret (AR) leads to additional increases in screening uptake, and examine whether this brief intervention is feasible and acceptable to low-income women.

Our research questions are:
1. Is a simple, telephone reminder intervention, aimed at eliciting and addressing the barriers and concerns of women in socially deprived areas regarding attending screening at the East of Scotland Breast Screening Service, feasible and acceptable to participants?
2. Can this brief, telephone intervention increase uptake in non-attenders from socially deprived areas?
3. Does adding anticipated regret to the telephone intervention have any additional benefit in terms of increasing uptake of screening in non-attenders?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Tayside, East of Scotland Research Ethics Service REC1, 04/11/2013, Ref: 13/ES/0128

Study design
Simple between groups four-arm prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Breast cancer screening.

Interventions

Participants will be randomised to one of the four treatment groups:
1. Letter reminder (i.e., treatment as usual: Control)
2. Telephone reminder (TEL)
3. Telephone reminder plus telephone support (TEL-SUPP)
4. Telephone reminder plus support plus anticipated regret (TEL-SUPP-AR)

Letter reminder group (Control)
Participants randomised to the control group will receive the reminder letter only, as current practice.

All telephone groups (TEL, TEL-SUPP, TEL-SUPP-AR)
All telephone groups will receive the standard reminder letter in the same manner as the control group. Participants in each of the three telephone groups will also be telephoned by the Research Fellow from the University of Stirling.

Telephone reminder group (TEL)
The telephone reminder (TEL) will be a simple telephone call to remind non-attenders that they did not attend their scheduled appointment and provide information on how they can rearrange this appointment. Women wishing to rearrange their appointment will be given the option of being transferred directly to the appointments service at the Breast Screening Centre in Dundee.

Telephone support groups (TEL-SUPP and TEL-SUPP-AR)
Participants who are allocated to the telephone support intervention arms (TEL-SUPP and TEL-SUPP-AR) will be told that we are trying to understand why some women do not take up their invitation to attend for breast screening when invited and asked whether they would be prepared to answer some questions about breast screening. Those declining at this point would be assumed to have not given consent and would not be contacted further. The Patient Information Sheet would then be read out to prospective participants. This explains the nature and purpose of this research and reassures participants about the confidentiality and anonymity of their responses. They will also be given the option of being able to talk to a Health Psychologist, who is independent of this research. They will be asked whether they agree to take part now (Yes/No), or whether they would prefer to be phoned back later.

In both telephone support arms (TEL-SUPP and TEL-SUPP-AR), consenting patients will be asked to describe any reasons they had for not taking up the invitation to attend their appointment, and where appropriate, any barriers they mention will be addressed using a pre-specified list of responses, which will be generated from previous research. Any patient queries or concerns about the process of breast screening will also be addressed, using responses from existing materials. Whether or not specific barriers are mentioned by individuals will be recorded on a check-list of barriers generated from the existing research and previous telephone interviews. Any additional barriers mentioned will be added to this check-list.

Participants in the TEL-SUPP and TEL-SUPP-AR groups would also be asked to say whether they now intended to make an appointment to attend for breast screening.

Participants will be reassured throughout that it is their choice whether or not to take up their invitation to attend breast screening, but that the researcher is there to seek their views on attending and to provide them with additional help and information, should they wish to make another appointment to attend.

In order to check the acceptability and feasibility of the telephone support intervention, participants will be asked whether they minded being phoned up about breast screening, and also whether they found the telephone call helpful in addressing any concerns, queries or issues they might have regarding attending breast screening.

It is envisaged each phone call would last 5-10 minutes, although some may take longer, if a participant has a lot of issues she wants to discuss, and some would be shorter, if the participant does not mention any barriers or does not wish to take part. Women who express a desire to rearrange their appointment will be given the option of being transferred directly to the appointments service at the Breast Screening Centre in Dundee at the end of the telephone intervention.

Telephone support plus anticipated regret only (TEL-SUPP-AR)
In the TEL-SUPP-AR group, participants will receive exactly the same intervention as the TEL-SUPP condition, with the addition of two questions relating to Anticipated Regret, If you didnt make another appointment to attend for breast cancer screening, would you later wish you had? ; If you didnt attend for breast screening, would you later regret it?.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Attendance at the breast screening service within 3 months of the reminder letter being sent out

Secondary outcome measures
1. Intention to make another appointment
2. Anticipated regret
3. Number of barriers to breast screening mentioned by participants
4. Specific barriers reported
5. To determine the likely effect size of the intervention

All of the secondary outcome measures are recorded at interview

Overall study start date
01/12/2013

Completion date
30/04/2015

Eligibility

Key inclusion criteria
1. Female members of the Scottish general public who are invited to participate in the national breast screening programme and who do not attend their screening appointment
2. Aged between 50 and 70 years
3. The intervention will be targeted at lower income women; thus, only those from Scottish Index of Multiple Deprivation vigintiles 1-12 (representing the highest 60% of areas of deprivation) will be included

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
We will target 600 individuals (150 in each arm)

Key exclusion criteria
1. Participants who have already telephoned to cancel or rebook their appointment for breast screening
2. Participants who, when telephoned, appear to have difficulty in understanding the intervention and/or appear unable to give verbal informed consent
3. Participants who have a medical reason for not attending breast screening (e.g., current breast cancer diagnosis)

Date of first enrolment
01/12/2013

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Psychology, School of Natural Sciences
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Tayside (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/08/2014		Yes	No
Results article	results	01/09/2016		Yes	No
HRA research summary			28/06/2023	No	No