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A clinical trial to investigate the effect of psychological support for women called back for assessment following breast cancer screening: The TLC study

Submission date
22/10/2009

Registration date
11/11/2009

Last Edited
21/06/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

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 to investigate the effect of psychological support for women called back for assessment following breast cancer screening: The TLC study

Acronym
The TLC study

Study objectives
Compared with care as usual, a self-help psychological support package (TLC) for women recalled for assessment following an abnormality on breast screening will result in significantly reduced scores on the Psychological Consequences Questionnaire (PCQ) at six week follow up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dyfed Powys Research Ethics Committee, Carmarthen, Wales SA31 3YH (ref: 05/WMWO1/45)

Study design
Multicentre single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Depression and anxiety in women recalled for assessment following an abnormality on breast screening

Interventions
Some women invited for breast screening are then asked to attend for further tests. This study looks at a relaxation and self help package known as "Travel Lightly Companion" (TLC) to see if it reduces any distress linked to recall. The TLC pack consists of guided self help presented as a

Compact Disc of relaxation music with relaxation exercises including breathing and guided imagery exercises. Women agreeing to take part will get either the TLC package or care as usual. Participants fill out some questionnaires at the start, 6 weeks, 6 months and 1 year later.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Score on the negative sub scale of the Psychological Consequences Questionnaire

All primary and secondary outcomes will be assessed at baseline, 6 weeks, 6 months and 1 year.

Secondary outcome measures
1. SF-36® Health Survey
2. Hospital Anxiety and Depression Scale
3. Euroquol EQ-5D
4. Short Explanatory Model Interview for patient experiences

All primary and secondary outcomes will be assessed at baseline, 6 weeks, 6 months and 1 year.

Overall study start date
01/07/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Females, age 50-64
2. Those attending a Breast Test Wales Centre for a recall visit following initial breast screening
3. Participant should be willing to give verbal and written consent for the study
4. Participant should be willing to complete a questionnaire prior to assessment at baseline, within 1 month, 6 months and 12 months post assessment

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
300

Key exclusion criteria
1. Those who are recalled for technical reasons (technical recall)
2. Women who have had a previous recall within the last three years
3. Women who have any hearing, visual or learning impairment which would not allow them to complete the questionnaires or listen to the support package
4. Women who themselves have identified breast problems (clinical override)
5. Women who cannot answer questionnaires in English or Welsh

Date of first enrolment
01/07/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
School of Medicine
Swansea
United Kingdom
SA2 8PP

Sponsor information

Organisation
Breast Test Wales

Sponsor details
18 Cathedral Road
Cardiff
United Kingdom
CF11 9LJ

Sponsor type
Government

Website
http://www.screeningservices.org.uk/btw/index_eng.asp

ROR

https://ror.org/00265c946

Funder(s)

Funder type
Government

Funder Name
Breast Test Wales

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