

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	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 11/11/2009	Overall study status Completed	☐ Protocol
Last Edited 21/06/2016	Condition category Mental and Behavioural Disorders	☐ 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

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)

Primary study design

Interventional

Study design

Multicentre single-blind randomised controlled trial

Study type(s)

Screening

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

ROR
<https://ror.org/00265c946>

Funder(s)

Funder type
Government

Funder Name
Breast Test Wales

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration