# 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	Recruitment status	<ul><li>Prospectively registered</li></ul>
22/10/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
11/11/2009	Completed	Results
Last Edited	Condition category	Individual participant data
21/06/2016	Mental and Behavioural Disorders	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Keith Lloyd

#### Contact details

School of Medicine Swansea University Swansea United Kingdom SA2 8PP

# 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**

# 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