

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

<b>Submission date</b> 22/10/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/11/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/06/2016	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Protocol serial number**  
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

### **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