

Ongoing trials search: the psychological consequences of false-positive mammograms.

Sources searched for ongoing trials: UKCRN, ControlledTrials.com, ClinicalTrials.gov, WHO ICTRP, www.nhs.uk/Conditions/Clinical-trials/Pages/clinical-trial.aspx, DUETs.

Searches found one UK ongoing study, which is probably outside this scope:

<http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=8080>
Predicting Risk Of Cancer At Screening (PROCAS).
Breast cancer risk assessment and validation in the National Breast Screening Programme.
Topic.
Cancer (co-adopted by Congenital Disorders).
Portfolio eligibility.
Funded by UK Cancer Research Campaign (CRC), CRC partner.
Current status: open.
Closure date: 1 June 2012.
Not many details – probably not relevant.

Four other non-UK studies were found, which may be of general interest:

<http://clinicaltrials.gov/show/NCT00742755>
No specific mention of false-positive.
Increasing Adherence to Follow-up of Breast Abnormalities in Low-Income Korean American Women.
This study has been completed.
Study type: interventional.
Study design: allocation, randomised.
End point classification: safety/efficacy study.
Intervention model: parallel assignment.
Masking: single blind (subject).
Primary purpose: screening.
Enrolment: 160.
Study start date: September 2003.
Study completion date: September 2009.
The purpose of this study is to design an intervention to assist Korean American women who have been identified with a *potential breast abnormality* through the Breast Cancer Early Detection Program and who have missed their first follow-up appointment (at risk women). Intervention activities will include reminder telephone calls or home visits by a trained peer navigator to explain the importance of follow-up procedures, emotional support, help with transportation to follow-up appointments, translations, organising care for children or grandchildren during medical appointments, and other assistance to overcome barriers to follow-up identified during the initial phase of the study. The investigators will collect extensive process measures including number and type of intervention activities requested and delivered in order to estimate the feasibility for institutionalising intervention activities. The investigators will conduct chart reviews and a follow-up survey to evaluate the effectiveness of the intervention in increasing adherence to follow-up procedures.
Included as it said 'Potential breast abnormality' – so could result in a false-positive on re-examination.

<http://clinicaltrials.gov/ct2/show/NCT00247442>
Australian Screening Mammography Decision Aid Trial (ASMDAT).

Not specifically false-positive but interventions might be of interest.

<http://clinicaltrials.gov/ct2/show/NCT01267110> – USA study.

Not false-positive – included only for educational to ethnic intervention information.

Engaging Diverse Underserved Communities to Bridge the Mammography Divide.

Estimated enrolment: 242.

Study start date: September 2010.

Estimated study completion date: June 2015.

<http://clinicaltrials.gov/show/NCT01261520>

Not false-positive – routine mammography – video intervention.

Chinese Women and Mammography Screening.

Enrolment: 671.

Study start date: July 2005.

Primary completion date: August 2009 (final data collection date for primary outcome measure).

Publications:

Wang JH, Mandelblatt JS, Liang W, Yi B, Ma JJ, Schwartz MD. Knowledge, cultural, and attitudinal barriers to mammography screening among nonadherent immigrant Chinese women: ever versus never screened status. *Cancer* 2009;**115**:4828–38.

Sources searched for ongoing trials 26 March 2012: UKCRN, ControlledTrials.com, clinicaltrials.gov, WHO ICTRP.

www.controlled-trials.com/ISRCTN89206644

A clinical trial to investigate the effect of psychological support for women called back for assessment following breast cancer screening: the TLC study is a randomised controlled trial to investigate the effect of psychological support for women called back for assessment following breast cancer screening: the TLC study. Latest information loaded on 21 February 2012.

Primary sponsor: Breast Test Wales (UK).

Date of first enrolment: 1 July 2007.

Target sample size: 300.

Recruitment status: completed/not recruiting.

URL: <http://isrctn.org/ISRCTN89206644>.

Inclusion criteria: (1) females, aged 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; and (4) participant should be willing to complete a questionnaire prior to assessment at baseline, within 1 month, 6 months and 12 months post assessment.

Exclusion criteria: (1) those who are recalled for technical reasons (technical recall); (2) women who have had a previous recall within the last 3 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); and (5) women who cannot answer questionnaires in English or Welsh.

Outcomes:

Primary: score on the negative subscale of the PCQ. All primary and secondary outcomes will be assessed at baseline, 6 weeks, 6 months and 1 year.

Secondary: (1) SF-36 Health Survey; (2) HADS; (3) Euroquol EQ-5D; and (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.

Intervention: 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 CD 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.

Conference searches:

7th European Breast Cancer Conference (EBCC-7).
Barcelona, Spain, 24–27 March 2010 – nothing relevant.

First British Breast Cancer Research Conference.
East Midlands Conference Centre, Nottingham, UK.
15–17 September 2010 (planned to be held biennially).
www.bbrc.org.uk/bbx/contact.asp
No abstracts online only programme.

15th Annual Mammography Update for Physicists (2011).
www.mtmi.net/seminars/mam_phys_update.php

American Society of Clinical Oncology (ASCO) Breast Cancer Symposium 2010 – nothing relevant.

11th St. Gallen International Breast Cancer Conference – nothing relevant.

Society of Radiographers.
www.sor.org/

Radiological Society of North America (RSNA) 2010 – nothing relevant for conference.
www.rsna.org/media/pressreleases/pr_target.cfm?ID=475
www.rsna.org/Publications/rsnanews/oct05/digitalmammography.cfm