

# ActWELL - working together to support active living and well-being in the health-promoting health service

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| <b>Submission date</b><br>19/03/2014   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>07/04/2014 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>19/01/2015       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Breast cancer is diagnosed in over 4,500 women in Scotland each year and this number is rising (13.7% increase between 2001 and 2011). We know that around 40% of post-menopausal breast cancers could be prevented by following dietary (including alcohol consumption), weight management and physical activity guidelines for cancer prevention. There is some evidence that women attending breast cancer screening are interested in receiving lifestyle advice although neither this or the response to this approach has been formally assessed. This study aims to assess the response of women to lifestyle advice as part of breast cancer screening.

### Who can participate?

Women attending NHS breast screening clinics who have a BMI greater than 20kg/m<sup>2</sup> and no contraindication to physical activity or weight loss.

### What does the study involve?

At the start of the study and after 3 months, height, weight and waist circumference will be recorded, sitting blood pressure measured, a 24 hour dietary recall and questionnaires on health behaviours, diet (including alcohol consumption) and physical activity will be completed. Based on the initial measures, women will be randomly allocated to one of two groups: ActWELL group (advice) or usual care (booklet only). The advice will be delivered via a one hour counselling session (face to face) with a lifestyle coach and fortnightly telephone consultations for 3 months. It will focus on body weight, diet and physical activity. The face to face session will be interactive and include a 10 minute walk and talk session, self-identification of BMI from standard coloured charts and measurement of one standard unit of alcohol using a wine coloured liquid. Behavioural techniques will be used including goal setting, action plans, implementation intentions, coping planning and self-monitoring.

### What are the possible benefits and risks of participating?

Possible benefits include weight loss, a healthier lifestyle, fewer risks of all obesity related chronic diseases which are major causes of death in the UK. No risks are foreseen from participation.

Where is the study run from?  
University of Dundee (UK)

When is the study starting and how long is it expected to run for?  
The study started on 1st Dec 2012, recruitment started on 7th June 2013 and ended on 28th February 2013 and a final report will be available on April 30th 2014.

Who is funding the study?  
Chief Scientist Office (UK)

Who is the main contact?  
Prof Annie Anderson  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Annie Anderson

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
13811

## Study information

**Scientific Title**  
ActWELL - working together to support ACTive living and WELLbeing in the health-promoting health service - a feasibility trial to reduce breast cancer risk factors

## **Acronym**

ActWELL

## **Study objectives**

It is feasible to deliver a minimal contact behaviour change intervention (ActWELL) initiated within the breast cancer screening setting and achieve significant improvement in lifestyle behaviours over a 3-month period.

More details can be found here: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=13811>

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

East of Scotland Research Ethics Service, 09/10/2012, REC ref: 12/ES/0087.

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Other

## **Study type(s)**

Prevention

## **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**

Breast cancer/cancer screening/cancer prevention

## **Interventions**

Participants were randomised (1:1) to either the ActWELL intervention or usual care (booklet only).

The ActWELL intervention consisted of a 1-hour counselling session (face to face) with a lifestyle coach and fortnightly follow-up telephone consultations for 3 months with access to written /online support materials. The face-to-face session was designed to be interactive and included a 10-minute walk and talk session, self-identification of Body Mass Index from standard coloured charts and measurement of one standard unit of alcohol using a wine-coloured liquid. Behavioural techniques were used including goal setting, action plans, implementation intentions, coping planning and self-monitoring.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Feasibility outcomes - programme implementation, fidelity to protocol, achieved measurements, recruitment, response, early retention and reported adherence. Acceptability measures of recruitment, implementation and exit strategy (i.e., signposting to further support)
2. Indicative findings - primary outcome was weight change, measured at baseline and follow up (after 3 months)

**Secondary outcome measures**

1. Indicative findings measured at baseline and follow up (after 3 months):
  - 1.1. Changes in waist circumference
  - 1.2. Changes in blood pressure
  - 1.3. Changes in physical activity (International Physical Activity Questionnaire Short form)
  - 1.4. Changes in diet and alcohol habits (dietary instrument for nutrition education, 24 h diet recall, 7-day alcohol record)

**Overall study start date**

01/04/2013

**Completion date**

30/04/2014

**Eligibility****Key inclusion criteria**

Participation in the NHS breast cancer screening programme (age range 50-75 years)

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Female

**Target number of participants**

80

**Key exclusion criteria**

1. Breast cancer diagnosis
2. BMI < 20 kg/m<sup>2</sup>
3. Any known contra-indicators to physical activity or weight management

**Date of first enrolment**

01/04/2013

**Date of final enrolment**

30/04/2014

## **Locations**

**Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**Centre for Research into Cancer Prevention and Screening**

Dundee

United Kingdom

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## **Sponsor information**

**Organisation**

Tayside Medical Science Centre (UK)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.tahsc.org/>

**ROR**

<https://ror.org/000ywep40>

# Funder(s)

## Funder type

Government

## Funder Name

Chief Scientist Office (UK) (CHZ/4/745)

## Alternative Name(s)

CSO

## Funding Body Type

Government organisation

## Funding Body Subtype

Local government

## Location

United Kingdom

# 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

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 17/12/2014   |            | Yes            | No              |