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

Submission date
19/03/2014

Recruitment status
No longer recruiting

Registration date
07/04/2014

Overall study status
Completed

Last Edited
19/01/2015

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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/m2 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
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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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(s)
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)

Key secondary outcome(s))

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)

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

Healthy volunteers allowed
No

Age group
Other

Sex
Female

Key exclusion criteria
1. Breast cancer diagnosis
2. BMI < 20 kg/m2
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
United Kingdom

Scotland

Study participating centre
Centre for Research into Cancer Prevention and Screening
Dundee

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Sponsor information

Organisation
Tayside Medical Science Centre (UK)

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

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?
	results				

Results article		17/12/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes