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A randomised controlled trial to assess the impact of a lifestyle intervention (ActWELL) in women invited to NHS breast screening

Submission date
15/02/2017

Recruitment status
No longer recruiting

Registration date
21/07/2017

Overall study status
Completed

Last Edited
05/08/2024

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is estimated that 38% of breast cancer could be prevented by increasing physical activity, decreasing alcohol intake and losing weight. It is notable that weight gain in adult life is associated with a greater risk of the disease (e.g., an increase of 2-10 kg after age 50 is associated with a 30% increased risk). The aim of this study is to assess the impact of a lifestyle intervention (ActWELL) on body weight and physical activity in women attending NHS breast screening clinics.

Who can participate?
Women aged 50-70 who are overweight and attending routine breast screening in four Scottish breast screening service centres

What does the study involve?
Participants are randomly allocated to either the intervention group or the control group. Participants in the intervention group have two face-to-face visits with a lifestyle coach and a further nine phone calls over 12 months. They are given a diet and physical activity programme with the aim of weight management and change in physical activity. This is delivered in the community by Breast Cancer Now volunteer lifestyle coaches. Participants in the control group continue with usual care. After the study is completed they are offered a one-off session with a lifestyle coach if they wish. All participants attend measurement visits with a research nurse at the start of the study and at 12 months follow up and have one phone call at 3 months. This involves recording demographic details, physiological measures such as weight, waist circumference and blood pressure, one blood sample and health questions.

What are the possible benefits and risks of participating?
Possible benefits are weight loss and a healthier lifestyle which may lead to a reduced risk of obesity-related chronic (long-term) conditions which are a major cause of death in the UK. There are considered to be no risks of taking part.

Where is the study run from?
1. NHS Tayside (UK)
2. NHS Grampian (UK)
3. NHS Lothian (UK)
4. NHS Greater Glasgow and Clyde (UK)

When is the study starting and how long is it expected to run for?
January 2017 to December 2019

Who is funding the study?
Scottish Government (UK)

Who is the main contact?
Ms Stephanie Gallant
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Contact information

Type(s)
Public

Contact name
Ms Stephanie Gallant

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol V1.1, 22/06/2017

Study information

Scientific Title

A randomised controlled trial to assess the impact of a lifestyle intervention (ActWELL) in women invited to NHS breast screening

Acronym
ActWELL

Study objectives
In Scotland, the incidence of breast cancer is predicted to rise by 27% by 2030 and whilst there are measures to support reductions in morbidity and mortality, the breast cancer community is now turning to support weight management programmes in post-menopausal women. In Scotland, 72% of women aged 55 to 74 years have a BMI >25 kg/m2. A recent feasibility study of a lifestyle intervention initiated in the NHS breast screening sites and delivered in the community reported significant findings in weight loss and increased activity after 12 weeks in intervention versus control groups.

The aim of this study is to assess the impact of a lifestyle intervention (ActWELL) on body weight and physical activity in women invited to NHS breast screening clinics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Committee, 28/06/2017, ref: 17/ES/0073

Study design
Four-centre 1:1 parallel-group randomized 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Body weight and physical activity

Interventions
This study is a minimal contact, weight management and physical activity intervention initiated within the breast cancer screening setting.

Actwell is a randomised controlled trial of a lifestyle intervention and is 26 months in duration. Randomisation is via the online TRuST system provided by Tayside Clinical Trials Unit (TCTU):
1. Those in the intervention group will have 2 face to face visits with a lifestyle coach and a further 9 phone calls over 12 months. They will be given a diet and physical activity programme with the aim of weight management and change in physical activity. This will be delivered in the community by Breast Cancer Now volunteer Lifestyle Coaches.
2. The control group continue with usual care. After the study is completed they are offered a one of session with a lifestyle coach if they wish.

Participants will attend for baseline and 12 month follow-up measurement visits with a research nurse and have one phone call at 3 months. This will involve recording of demographic details, physiological measures e.g. weight, waist circumference, blood pressure, heart rate, one blood sample and health questions.

Intervention Type
Behavioural

Primary outcome measure
1. Physical activity, measured using Scottish Physical Activity Questionnaire (SPAQ) and ActivPAL activity monitors
2. Weight loss, measured by research nurses (locally provided and calibrated by clinical research centres)

All outcomes are measured at two measurement visits at baseline and 12 months. At 3 months there is a telephone call to assess self-reported weight, SPAQ and EQ5D along with three food questions.

Secondary outcome measures
1. HbA1C, non-fasting lipids and non-fasting insulin, measured using a blood test analysed at University of Glasgow
2. Sedentary behaviour and modes of physical activity, measured using SPAQ
3. Eating habits, measured using modified questionnaire from the Scottish Health Survey
4. Alcohol intake, measured using Audit C
5. Psycho-social variables, measured using Modified Illness Perception Questionnaire and various questions
6. Economic outcomes, measured using EQ5D- L and health resource usage questions
7. Blood pressure, measured using blood pressure monitor
All outcomes are measured at two measurement visits at baseline and 12 months. At 3 months there is a telephone call to assess self-reported weight, SPAQ and EQ5D along with three food questions.

Overall study start date
01/01/2017

Completion date
31/12/2019

Eligibility

Key inclusion criteria

1. Invited to attend, or attended, routine breast screening clinics (not recall clinics)
2. Measured BMI >25 kg/m2
3. Women aged 50-70 years

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
50 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
552

Total final enrolment
560

Key exclusion criteria
1. Currently undergoing treatment for any malignant condition
2. Reported contra-indication to physical activity (e.g. recent surgery)
3. Reported contra-indication to weight management (e.g. currently following a recovery programme for weight gain)
4. Diagnosis of Type 1 diabetes
5. No telephone contact
6. Current use of insulin
7. Unable to consent
8. On a special or prescribed diet e.g. gluten free

Date of first enrolment
05/09/2017

Date of final enrolment
14/08/2018

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NHS Tayside
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Study participating centre
NHS Grampian
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
NHS Lothian
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
NHS Greater Glasgow and Clyde
United Kingdom
G12 0XH

Sponsor information

Organisation
University of Dundee

Sponsor details
Tayside Medical Science Centre
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Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Organisation
NHS Tayside

Sponsor details
Tayside Medical Science Centre
Ninewells Hospital & Medical School
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Sponsor type
Hospital/treatment centre

Website
http://www.nhstayside.scot.nhs.uk/index.htm

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Government

Funder Name
Scottish Government

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
Access to collated participant data will be restricted to the CI and appropriate study staff. Data will be held on university secure servers.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/11/2018		Yes	No
Results article	feasibility and optimisation results	05/06/2020	08/06/2020	Yes	No
Results article		06/03/2021	18/06/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Letter	05/06/2021	05/08/2024	Yes	No
Other publications	SWAT 76 evaluation	08/02/2021	05/08/2024	Yes	No