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A weight loss trial of Weight Watchers groups with additional dietetic support compared to regular Weight Watchers groups only in women treated for breast cancer

Submission date
07/10/2013

Recruitment status
No longer recruiting

Registration date
12/11/2013

Overall study status
Completed

Last Edited
27/02/2019

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
There is some evidence that women who have undergone treatment for breast cancer are vulnerable to weight gain but less information on whether weight loss or prevention of weight gain could help improve health after treatment. Therefore to design a suitable weight loss programme for this group, we explored the opinions of women who had completed their initial treatment (chemotherapy, surgery and/or radiotherapy) for breast cancer. The aim is to help to provide a healthy body weight programme in the future for women treated for breast cancer. However, it is very important to investigate the suitability of the designed weight loss programme before a full-scale study.

Who can participate?
Women at least 18 years of age who have completed initial treatment (surgery, chemotherapy and/or radiotherapy) for breast cancer, and have a body mass index greater than or equal to 25.

What does the study involve?
We are contacting women attending a follow-up appointment at the outpatient breast clinic at Aberdeen Royal Infirmary (ARI) who have been treated for breast cancer. If they are interested in taking part, they will be contacted to attend a meeting with the researcher at ARI or a local cancer charity where we will provide information and will answer any questions they may have about the study. Then if they decide to take part, they will be asked to sign the study consent form. We will measure their height and weight and they will also be asked to complete a quality of life questionnaire. Then they will be randomly allocated to one of the study groups: Group A, Group B or Group C, and contacted by the researcher to inform them about their allocated group and arrange future meetings. Group A will attend the regular Weight Watchers (WW) programme plus five additional breast cancer tailored group (BCTG) meetings led by a dietitian. Group B will attend the regular WW programme. Group C will have no additional contact following random allocation until they are invited to attend a final visit, when they will receive 12 weeks free WW vouchers.

What are the possible benefits and risks of participating?
The participant will have the potential to learn more about healthy eating and healthy lifestyle and in some cases may lose weight. The free vouchers will exempt them from payments for the first 12 weeks of the Weight Watchers programme attended at their suitable time and location. We do not anticipate any disadvantages or risks in taking part.

Where is the study run from?
This study is being carried out by staff from Aberdeen Royal Infirmary (NHS Grampian) and the University of Aberdeen (UK).

When is the study starting and how long is it expected to run for?
We will start recruiting participants in October 2013 and the study will end by May 2014.

Who is funding the study?
It is being funded by Fraserburgh Moonlight Prowl, Cancer Research Aberdeen and North East Scotland (CRANES) and Weight Watchers.

Who is the main contact?
Mrs Rumana Newlands

Contact information

Type(s)
Scientific

Contact name
Prof Steven Heys

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Additional identifiers

Protocol serial number
version 1.1

Study information

Scientific Title
A randomised feasibility trial of Weight Watchers groups with additional dietetic support compared to Weight Watchers groups only in women treated for breast cancer: The BReast cancer healthy weIGHT (BRIGHT) study

Acronym
BRIGHT

Study objectives
Research Questions:
1. Whether additional dietitian-led group sessions with regular Weight Watchers programme will be feasible and more effective for the purpose of weight loss in women treated for breast cancer than a regular Weight Watchers programme or a wait-list control group?
2. What are the opportunities and barriers of delivering the intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee, 20/09/2013, ref: 13/NS/0060

Study design
Single centre 12 week randomised feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity and breast cancer

Interventions
A mixed method randomised feasibility intervention study for a proposed 12 week randomised controlled trial. A total of 90 participants (30 per group) will be allocated to one of three groups:
1. Weight Watchers with additional breast cancer tailored dietitian-led group
2. Regular Weight Watchers group and
3. Wait- list control group.
The baseline meeting will be one-to-one with the participant and a member of the research team. The participants will be randomised based on their age and body mass index (BMI) to any of the three groups.
The Weight Watchers (WW) intervention will be provided in accordance with the usual WW guidance and the group leader will be trained by the WW organisation. The participants will be provided with three months free WW vouchers which will exempt them from payments for the first 12 weeks of the programme.
Group A: The participants will attend the regular WW programme plus five additional breast cancer tailored group (BCTG) meetings led by a dietitian.
Group B: The participants will attend the regular WW programme.
Group C: The participants will have no additional contact following randomisation until they are invited to attend an end-point visit when they will receive 12 weeks free WW vouchers.

Total duration of follow-up will be 12 weeks

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The feasibility and acceptability of the intervention will be measured from the beginning till trial exit and evaluated by examining data on recruitment rate, attendance at intervention sessions, drop-out rates, completion rates and participant feedback from semi-structured interviews.

Key secondary outcome(s))
1. Changes in body weight. It will be measured at the baseline visit and trial end-point visit
2. Quality of life (QoL). Participants will complete this questionnaire at the baseline visit and trial end-point visit

Completion date
30/05/2014

Eligibility

Key inclusion criteria
1. Women who have completed initial treatment (surgery, chemotherapy and/or radiotherapy) for breast cancer
2. Age at least 18 years
3. Body mass index greater than or equal to 25

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Known distant metastasis prior to study entry
2. Currently participating in any supervised weight loss programmes
3. Participated in Weight Watchers programme within the previous three months
4. Pregnant women
5. Diagnosed eating disorder
6. Need interpreter to understand English

Date of first enrolment
10/10/2013

Date of final enrolment
30/05/2014

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
3rd Floor, Polwarth Building
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Charity

Funder Name
Fraserburgh Moonlight prowl

Funder Name
Cancer Research Aberdeen and North-East of Scotland (CRANES)

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 article	results	13/02/2019		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes