

Breast activity and healthy eating after diagnosis - 2 During chemotherapy for early breast cancer

Submission date 19/11/2012	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 19/11/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/02/2023	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-healthy-eating-exercise-women-having-chemotherapy-breast-cancer-b-ahead-2>

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

13255

Study information

Scientific Title

Breast activity and healthy eating after diagnosis - 2 During chemotherapy for early breast cancer

Acronym

B-AHEAD 2

Study objectives

Excess weight at the time of breast cancer diagnosis and weight gain during adjuvant chemotherapy increases the risk of breast cancer recurrence and death. We and others have demonstrated that continuous energy restriction (CER) and exercise is only partially effective at limiting the 2.5-3kg weight gain which occurs during chemotherapy, and for promoting weight loss for overweight women. Our other studies in non cancer patients have shown intermittent energy restriction (IER) is equivalent or superior to continuous restriction for weight control, and our pilot studies indicate that IER could be useful amongst chemotherapy patients because the days after chemotherapy administration can be avoided.

The purpose of this study is to formally assess the feasibility and effectiveness of IER to prevent chemotherapy induced weight gain and promote weight loss for overweight women compared with continuous energy restriction in a randomised trial (n=170). This study will re test whether continuous energy restriction can be effective, and whether the novel IER is better. The trial aims to identify a much needed regimen for weight control and toxicity reduction for breast cancer patients receiving chemotherapy. If either of our test regimes are succesful, this would then be tested in a larger phase III trial to evaluate its effects on relapse free and overall survival.

More details can be found at: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=13255>

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North West - Greater Manchester West, 04 April 2012, ref: 12/NW/0230

Primary study design

Interventional

Study design

Randomized interventional and observational trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions

Comparison group (n = 85)

Continuous energy restricted Mediterranean diet plus an exercise intervention (2.5 hours/ moderate activity week)

Intervention group (n = 85)

2 consecutive days / week of energy restriction with an intermittent low energy diet (<50g

carbohydrate / day and ad lib protein diet [self limits to approximately 800-1000 kcal/day]), and a Mediterranean diet for 5 days/week, plus an exercise intervention (2.5 hours/ moderate activity week).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Weight, body fat (DXA, impedance), waist and hips measured twice at baseline and post chemotherapy appointments

Key secondary outcome(s)

1. Blood markers of chemotherapy associated toxicity measured twice at the first and final chemotherapy cycles
2. Examining the effects of the restricted and normal intake phases measured once at the final chemotherapy cycles
2. Quality of life and fatigue (functional assessment of cancer therapy; FACT-B, FACT-ES and FACT-F; measured twice at baseline and post chemotherapy appointments;
3. Serum markers of breast cancer risk prognosis measured twice at baseline and post chemotherapy appointments
4. Serum markers of cardiovascular disease measured twice at baseline and post chemotherapy appointments
5. Fitness measured twice at baseline and post chemotherapy appointments
6. Blood markers of oxidative stress measured twice at baseline and post chemotherapy appointments
7. Motivational, stage of behaviour change, health beliefs, and self-efficacy scales measured twice at baseline and post chemotherapy appointments
8. Dietary intake (7 day food diary), accelerometer and physical activity questionnaire measured at three times at baseline, post chemotherapy appointments, and half way through chemotherapy
9. Differences in self reported chemotherapy toxicity measured at each chemotherapy cycle

Completion date

20/11/2017

Eligibility

Key inclusion criteria

1. Scheduled to have standard adjuvant or neoadjuvant chemotherapy
2. Breast cancer stage I to III
3. Any age >18 years: weight affects prognosis amongst preand post menopausal women
4. BMI>19 Kg / m² (Using IER and exercise we aim to avoid weight gain in all patients; this may lead to some weight loss in normal weight individuals).
5. Ability to understand written instructions and have completed baseline 7 day diet and exercise diaries.
6. Resident within Greater Manchester or Cheshire area only in order to maximise uptake and

retention to interventions and study.

7. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

172

Key exclusion criteria

1. Metastatic disease
2. Previously had chemotherapy for breast or any cancer within the last 2 years.
3. Physical/or psychiatric conditions which may impair compliance to the diet or physical activity interventions assessed from medical history by recruitment nurse/ clinician i.e. Serious digestive and/or absorptive problems, including inflammatory bowel disease. Cardiovascular, respiratory (determined from recent preoperative ECG, chest Xray, and verified from baseline fitness assessment by the trial exercise specialist (DM) Musculoskeletal disease or joint problems. Psychiatric disorders or conditions, e.g. untreated major depression, psychosis, substance abuse, severe personality disorder.
4. Medications affecting weight e.g. metformin or continuous daily steroids (23 days with chemotherapy allowed)
5. Insulin requiring diabetes, as diet and physical activity changes would require close coordination with the diabetiologist. Non-insulin requiring diabetics are eligible for the study.
6. Already commenced chemotherapy.
7. Scheduled to have weekly paclitaxel

Date of first enrolment

26/11/2012

Date of final enrolment

26/03/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Wythenshawe Hospital

Manchester

United Kingdom

M23 9LT

Sponsor information

Organisation

University Hospital of South Manchester (UK)

ROR

<https://ror.org/00he80998>

Funder(s)

Funder type

Charity

Funder Name

Breast Cancer Research Trust (UK)

Alternative Name(s)

BCRT

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	version 9	15/12/2021	17/12/2021	Yes	No
Plain English results				No	Yes
Protocol file		04/08/2017	28/02/2023	No	No