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

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomized interventional and observational trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

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

Secondary outcome measures
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

Overall study start date
26/11/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 170

Total final enrolment
172

Key exclusion criteria
1. Metastatic disease
2. Previouly 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
England

United Kingdom

Study participating centre
Wythenshawe Hospital
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University Hospital of South Manchester (UK)

Sponsor details
Genesis Prevention Centre
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England
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Sponsor type
Hospital/treatment centre

Website
http://www.uhsm.nhs.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

Publication and dissemination plan
2016 results presented at Obesity, Physical Activity & Cancer: Life course influences and mechanisms 2016 https://www.wcrf.org/int/news-events/conferences/presentations-conferences/obesity-physical-activity-cancer-life-course.

Intention to publish date
31/03/2019

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?
Plain English results				No	Yes

Results article	version 9	15/12/2021	17/12/2021	Yes	No
Protocol file		04/08/2017	28/02/2023	No	No