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Randomised comparison of three weight control programmes during adjuvant treatment for early breast cancer (Breast - Activity and Healthy Eating After Diagnosis)

Submission date
31/03/2010

Recruitment status
No longer recruiting

Registration date
31/03/2010

Overall study status
Completed

Last Edited
21/09/2021

Condition category
Cancer

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-exercise-and-healthy-eating-for-women-with-breast-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00869466

Secondary identifying numbers
5102

Study information

Scientific Title
Randomised comparison of three weight control programmes during adjuvant treatment for early breast cancer (Breast - Activity and Healthy Eating After Diagnosis)

Acronym
B- AHEAD

Study objectives
To determine whether individualised weight control programmes are better than standard written advice for existing weight and preventing weight gain in first year after breast cancer treatment for women with early breast cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 09/07/2008 (ref: 08/H1013/45)

Study design
Randomised interventional multicentre process of care trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions
Current interventions as of 30/04/2015:
Group 1 (Control): Standard written advice
This group will receive standard written diet and exercise advice.

Group 2 (Intervention): Individualised home-based intervention
Each woman receives individualised diet and exercise advice from the study dietitian (40

minutes) and exercise referral officer (40 minutes). This advice will be reinforced with bi-weekly phone calls (study dietitian) and mailed information during the first 12 weeks, and booster phone calls during the 12-month study.

Group 3 (Intervention): Supervised group community-based weight control programme
Each woman received individualised diet and exercise advice from the study dietitian (40 minutes) and exercise referral officer (40 minutes). They are then asked to attend weekly group classes for the first 12 weeks which comprise an exercise class followed by a diet and behaviour change educational component with handouts, and booster phone calls during the 12-month study.

Previous interventions:
Group 1 (Control): Standard written advice -
This group will receive standard written diet and exercise advice.

Group 2 (Intervention): Individualised home based intervention:
Each woman receives individualised diet and exercise advice from the study dietitian (40 minutes) and exercise referral officer (40 minutes). This advice will be reinforced with bi-weekly phone calls (study dietitian) and mailed information during the first 12 weeks, and booster phone calls during the 12-month study.

Follow Up Length: 12 month(s)
Study Entry: Single Randomisation only

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Changes in body weight and composition (body fat, fat free mass DXA, bioelectrical impedance)

Secondary outcome measures
Uptake and retention to the programmes and any adverse effects of the programmes.

Overall study start date
11/08/2008

Completion date
02/02/2012

Eligibility

Key inclusion criteria
1. Within 10 weeks of primary surgery for primary breast cancer (invasive or in-situ)
2. Pre and postmenopausal women of any age able to undertake interventions
3. Any weight, as programmes aim to tackle existing weight problems and prevent weight gain in healthy weight women
4. Receiving/due to start adjuvant chemotherapy, radiotherapy or endocrine therapy or no adjuvant treatment

5. Early breast cancer stages I - III
6. Ability to understand written instructions and have completed baseline 7 day diet and exercise diaries
7. Resident within Greater Manchester only in order to maximise uptake and retention to interventions and study
8. Written informed consent
9. Females, no specified age limit

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 480; UK Sample Size: 480

Key exclusion criteria
1. Metastatic or inoperable disease
2. Physical/psychiatric condition which impairs compliance or mobility assessed from medical history by recruitment nurse or verified from baseline fitness assessment by the trial physiotherapist, i.e.:
2.1. Insulin requiring diabetes, as diet and physical activity changes would require close coordination with the treating physician. Non-insulin requiring diabetics are eligible for the study.
2.2. Serious digestive and/or absorptive problems, including inflammatory bowel disease
2.3. Cardiovascular, respiratory (determined from recent pre-operative electrocardiogram [ECG], chest X-ray) disease
2.4. Musculoskeletal disease or joint problems
2.5. Psychiatric disorders or conditions, e.g., untreated major depression, psychosis, substance abuse, severe personality disorder
3. Women who regularly take daily medication known to effect body composition, e.g., corticosteroids (women receiving 2 - 3 days steroids with chemotherapy may be included)
4. Patients with metal implants, ie hip prosthesis are excluded from the study as this precludes DXA measurement of body fat (breast implants, pacemakers are not excluded)
5. Women who have received neoadjuvant chemotherapy or endocrine
6. Patients considering reconstruction surgery in the next 12 months

Date of first enrolment
11/08/2008

Date of final enrolment
02/02/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University Hospital of South Manchester NHS Foundation Trust
United Kingdom
M23 9LT

Study participating centre
The Christie Hospital NHS Trust
United Kingdom
M20 4BX

Study participating centre
Mid Cheshire NHS Foundation Trust
United Kingdom
CW1 4QJ

Study participating centre
East Cheshire NHS Trust
United Kingdom
SK10 3BL

Study participating centre
Pennine Acute Hospitals NHS Trust
United Kingdom
M8 5RB

Study participating centre
Salford Royal NHS Foundation Trust
United Kingdom
M6 8HD

Study participating centre

Stockport NHS Foundation Trust
United Kingdom
SK2 7JE

Study participating centre
Tameside Hospital NHS Foundation Trust
United Kingdom
OL6 9RW

Sponsor information

Organisation
South Manchester University Hospital (UK)

Sponsor details
Wythenshawe Hospital
Southmoor Road
Manchester
England
United Kingdom
M23 9LT

Sponsor type
Hospital/treatment centre

Website
http://www.uhsm.nhs.uk/Pages/default.aspx

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2018		Yes	No
Plain English results			10/09/2019	No	Yes
Results article	results	01/09/2019	28/05/2020	Yes	No