ISRCTN08045231 https://doi.org/10.1186/ISRCTN08045231

The effect of a lifestyle intervention on body weight, psychological health status and risk factors associated with disease recurrence in women recovering from breast cancer treatment

Submission date
24/08/2005

Recruitment status
No longer recruiting

Registration date
25/10/2005

Overall study status
Completed

Last Edited
24/01/2022

Condition category
Cancer

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

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-the-effect-of-exercise-and-dietary-changes-for-women-recovering-from-breast-cancer-treatment

Contact information

Type(s)
Scientific

Contact name
Dr John Saxton

Contact details
Centre for Sport and Exercise Science
Sheffield Hallam University
Collegiate Crescent Campus
Sheffield
United Kingdom
S10 2BP
+44 (0)114 225 4414
j.m.saxton@shu.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00689975

Secondary identifying numbers
05A008

Study information

Scientific Title
The effect of a lifestyle intervention on body weight, psychological health status and risk factors associated with disease recurrence in women recovering from breast cancer treatment

Study objectives
1. A dietary and exercise intervention will evoke a reduction in body weight in overweight or obese women who have undergone breast cancer treatment
2. A dietary and exercise intervention will evoke positive changes in indices of psychological health status and biomarkers associated with disease recurrence in overweight or obese women who have undergone breast cancer treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Breast cancer

Interventions

Exercise and dietary intervention versus no intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Body weight; body composition.

Secondary outcome measures
Psychological health status; biomarkers associated with disease recurrence (including stress hormones, immune function, inflammatory mediators); quality of life; cardiovascular fitness.

Overall study start date
01/10/2005

Completion date
30/09/2007

Eligibility

Key inclusion criteria
1. Women who have undergone appropriate treatment for operable breast cancer within the past 3-18 months and are no longer undergoing chemotherapy or radiation therapy, will be recruited from the Cancer Research Centre, Weston Park Hospital, Sheffield University Hospitals NHS Trust
2. Postmenopausal women (confirmed by plasma estradiol and gonadotrophin measures in all women aged <55) with a body mass index (BMI) >25 and classified as disease stage I-III
3. Patients must have completed some form of breast cancer treatment at least three months, and not more than 18 months ago
4. Patients on Tamoxifen and other endocrine treatments but not hormone replacement therapy (HRT) will be included
5. Patients must be willing and able to attend supervised exercise sessions at least 3 times per week for a period of 24 weeks, with the intention of achieving an 80% minimum compliance target for attendance
6. Patients must be an exercise pre-contemplator, contemplator or preparer as defined by the Transtheoretical Model

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Female

Target number of participants
100

Key exclusion criteria
1. Metastatic breast cancer patients and patients with inoperable or active loco-regional disease
2. Patients following alternative/complementary diets or taking high dose antioxidant supplements
3. Patients with a physical/psychiatric impairment that would seriously impair their physical mobility
4. Patients who are currently suffering from severe nausea, anorexia or other diseases affecting health (e.g. arthritis and multiple sclerosis)
5. HRT is not commonly prescribed in women who are recovering from breast cancer treatment, but use of HRT or oral contraceptives within the past four months is an exclusion criteria
6. Patients who are currently engaged in exercise (two or more times per week for at least 30 min per session during the previous 3 months)

Date of first enrolment
01/10/2005

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Sport and Exercise Science
Sheffield
United Kingdom
S10 2BP

Sponsor information

Organisation
Sheffield Hallam University (UK)

Sponsor details
City Campus
Howard Street

Sheffield
England
United Kingdom
S1 1WB
+44 (0)114 225 5555
liaison@shu.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/019wt1929

Funder(s)

Funder type
Research organisation

Funder Name
American Institute for Cancer Research (USA) (ref: 05A008)

Alternative Name(s)
American Institute for Cancer Research, Inc., AICR

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	09/02/2006		Yes	No
Results article	results	01/01/2013		Yes	No
Results article	results	14/04/2014		Yes	No
Plain English results			24/01/2022	No	Yes