

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/01/2022	Condition category Cancer	<input type="checkbox"/> 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

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00689975

Protocol serial number

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

Intentional

Study type(s)

Treatment

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(s)

Body weight; body composition.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

United Kingdom

England

Study participating centre

Centre for Sport and Exercise Science

Sheffield

United Kingdom

S10 2BP

Sponsor information

Organisation

Sheffield Hallam University (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

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