

# 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

<b>Submission date</b> 24/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/01/2022	<b>Condition category</b> 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

### Contact name

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### Contact details

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## 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?
<a href="#">Protocol article</a>	protocol	09/02/2006		Yes	No
<a href="#">Results article</a>	results	01/01/2013		Yes	No
<a href="#">Results article</a>	results	14/04/2014		Yes	No
<a href="#">Plain English results</a>			24/01/2022	No	Yes