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Promoting weight loss through diet and exercise in overweight women with breast cancer

Submission date
29/09/2015

Recruitment status
No longer recruiting

Registration date
16/10/2015

Overall study status
Completed

Last Edited
29/10/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Being overweight or obese puts you at a higher risk for health problems such as heart disease, stroke, high blood pressure and diabetes, and is also associated with an increased risk of developing many forms of cancer, including breast cancer. There is also evidence that being overweight increases the risk of recurrence and death in patients diagnosed with breast cancer. We think that diet and/or exercise counseling could help overweight or obese breast cancer patients to lose weight, which could in turn improve their quality of life and general health status, and in the long term reduce the risk of breast cancer recurrence. We aim to find out about the effects of 6 months of counseling focused on weight loss in a group of overweight or obese women previously treated for early breast cancer. The counseling is designed to promote a healthy diet or/and to increase exercise and decrease sedentary (sitting) time.

Who can participate?
Breast cancer patients aged 18 or older who are overweight or obese.

What does the study involve?
Participant are randomly allocated to one of four groups: diet counseling, exercise counseling, both diet and exercise counseling, or minimal counseling. Women allocated to the diet and/or exercise counseling groups are offered individual counseling consisting of face-to face contact, group meetings, motivational phone calls and information pamphlets. Participants are given a pedometer device (wrist band) in order to monitor their physical activity and sedentary time. Diet, quality of life, health status and participants' anxiety are assessed with questionnaires. Blood samples are collected at the start of the study and follow-up visits.

What are the possible benefits and risks of participating?
The expected result is weight loss in any of the diet or physical activity groups. Other expected long-term results include long-term weight control, increased physical fitness, increased physical activity, reduced sedentary time, healthier diet, improved health status and quality of life. We do not foresee any serious side effects. However, if participants will experience side effects, this will be reported immediately to the attention of the clinical staff. All participants will be

monitored to prevent any possible deficiency or inadequate nutrient and/or calorie intake by evaluating their dietary intake. Participants will also be monitored for injuries or problems associated with the increased physical activity.

Where is the study run from?
European Institute of Oncology (IEO), Milan, Italy

When is the study starting and how long is it expected to run for?
March 2014 to June 2019

Who is funding the study?
The Italian Association for Cancer Research (Associazione Italiana per la Ricerca sul Cancro [AIRC]) (Italy)

Who is the main contact?
1. Patrick Maisonnevue (public)
2. Patrizia Gnagnarella (scientific)

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

Protocol serial number
IEO-0244

Study information

Scientific Title
Promoting weight loss through diet and exercise in overweight women with breast cancer: a four-arm randomized trial - InForma study

Acronym
InForma

Study objectives
We hypothesized that individual dietary and/or exercise counseling could help overweight or obese breast cancer patients to lose weight, which could in turn improve their hormonal status, quality of life and general health status, and at long term limit their risk of developing breast cancer recurrence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the European Institute of Oncology, 01/04/2015 , ref: n. R233/15 –IEO 244

Study design
Mono-institutional randomized controlled four-arm parallel-group trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Overweight or obese breast cancer patients

Interventions
We will randomize overweight or obese patients into four intervention arms:
1. Dietary Intervention (DI)
2. Physical Activity Intervention (PAI)
3. Physical Activity And Dietary Intervention (PADI)
4. Less Intensive Intervention (LII)

Women allocated to the dietary intervention and/or physical activity intervention arms will be offered an individualized dietary and/or physical activity counseling consisting of face-to face contacts, group meetings, motivational phone calls and information pamphlets. All participants will be given a pedometer device (wrist band) in order to monitor (in the two physical activity arms) participants' physical activity and sedentary time. Dietary intake for all participants will be

repeatedly assessed with validated food frequency questionnaires. Quality of life, health status and participants' anxiety will be assessed with self-administered questionnaires including FACT-B and the State-Trait Anxiety Inventory (STAI) questionnaires. Blood samples will be collected at baseline and follow-up visit to assess glucose, insulin, lipid and hormone profile. Women allocated to the less intensive intervention (or minimal counseling) arm will be considered as control group.

Participants will be followed up for a further 18 months and outcome assessments will be made at 12 and 24 months.

Intervention Type
Behavioural

Primary outcome(s)
Change in body weight (weight loss ≥5% of the baseline body weight) at the end of the 6-month intervention

Key secondary outcome(s))
The secondary outcome measures will be assessed along intervention including:
1. Maintain long-term weight control, measured at baseline, 6 months, 12 months and 24 months
2. Increase physical activity levels and reduce physical inactivity from baseline, measured at baseline, 6 months, 12 months and 24 months
3. Change in dietary intake (increase adherence to healthy diet from baseline), measured at baseline, 6 months and 24 months
4. Evaluate the effect of intervention on long-term breast cancer recurrence
5. Change in health status and quality of life, measured at baseline, 6 months, 12 months and 24 months
6. Evaluate the effect of intervention on blood lipid profile (total cholesterol, LDL and HDL cholesterol, triglycerides), measured at baseline, 6 months and 24 months
7. Evaluate the effect of intervention on biomarkers (estradiol, C-reactive protein (CRP), insulin, glucose), measured at baseline, 6 months and 24 months

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Women aged 18 or older
2. Written informed consent obtained
3. Willing to be randomized to either group
4. Histological breast cancer diagnosis
5. BMI comprised between 25 and 40 kg/m2
6. Within one year/6 months of completion of main cancer treatment
7. Willing to wear the wrist-based activity monitor during the 6-month study period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
266

Key exclusion criteria
1. Unable to find transportation to the study location over the study period
2. Plan to move away from Lombardy or to be out of town for more than 3 weeks during the study period
3. Investigator does not approve participation in the study in case of:
3.1. History of heart condition, stroke, chest pain during activity or rest
3.2. Severe hypertension
3.3. Patient is unable to walk for exercise (self-report)
3.4. Symptoms of alcohol or substance dependence
3.5. Recent hip fracture, hip or knee replacement, spinal surgery or other orthopedic complications that would prevent optimal participation in the physical activities prescribed
4. Any other severe medical condition or advanced age impeding the patient to adhere at the planned study follow-up period
5. Participant already participates to a physical activity or diet intervention trial
6. Participant currently uses an activity monitor device

Date of first enrolment
01/10/2015

Date of final enrolment
01/10/2016

Locations

Countries of recruitment
Italy

Study participating centre
European Institute of Oncology
Via Ripamonti, 435
Milan
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Sponsor information

Organisation
European Institute of Oncology (Italy)

ROR
https://ror.org/02vr0ne26

Funder(s)

Funder type
Research organisation

Funder Name
Associazione Italiana per la Ricerca sul Cancro

Alternative Name(s)
Italian Association for Cancer Research, The Italian Association for Cancer Research, AIRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Italy

Results and Publications

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		16/10/2025	29/10/2025	Yes	No
Protocol article	protocol	28/07/2016		Yes	No
Basic results		19/02/2020	19/02/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes