

# 1-year at home diet and exercise interventions in ER+ breast cancer patients

<b>Submission date</b> 03/07/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/01/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Background and study aims:

Its common for women having chemotherapy and antiestrogenic treatment for breast cancer to gain weight. This can increase the risk of the cancer coming back and death due to the fact that they can aggravate insulin and leptin (a hormone produced by the body's fat cells) resistance, , as well as dysbiosis (a term used to describe microbial imbalance in the gut) and dyslipidemia (increase through osteosarcopenia. Also, the emotional impact of either conservative surgery or mastectomy can theoretically influence these patients' eating behavior and willingness to exercise in order to reverse this weight gain. This home-based study aims to answer three questions:

1. Is a high protein diet effective for fat loss in ER+ breast cancer patients on antiestrogenic medication?
2. Is the addition of only 4 minutes of daily isometric exercises to this high protein diet more effective to improve their body composition?
3. How does the surgery, chemotherapy and antiestrogenic medication type influences the effects of these interventions?

Who can participate?

Overweight women with breast cancer who are currently being treated with antiestrogenic treatment after surgery and chemotherapy

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 follow an at home diet based on food rich in protein, calcium, omega-3 fatty acids, probiotics and prebiotics for one year. Those in group 2 follow the same diet but also do 4' isometric exercises for one year. All participants have their total body weight, body fat and visceral fat (belly fat) six months into the study and again at the end of the study (one year).

What are the possible benefits and risks of participating?

The diet was made up of easily affordable foods and the exercises were highly accepted. It is hoped that these will led to an improvement in body composition and general wellbeing. All participants were closely supervised for the first two months of the study so that any associated risk of taking part would be reduced to minimum.

Where is the study run from?

"Prof. Dr. Al. Trestioreanu" Institute of Oncology (Romania)

When is the study starting and how long is it expected to run for?

February 2015 to April 2016

Who is funding the study?

European Social Fund

Who is the main contact?

Mrs Diana Viorela Arterne

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Diana Viorela Artene

### ORCID ID

<https://orcid.org/0000-0002-7910-9572>

### Contact details

Ficusului street no. 1

vila 80

Balotesti

Romania

077010

## Additional identifiers

### Protocol serial number

1

## Study information

### Scientific Title

Comparative results of 1-year at home diet and exercise interventions in ER+ breast cancer patients correlated with treatment type

### Study objectives

This home-based study aims to answer three questions:

1. Is a high protein diet effective for fat loss in ER+ breast cancer patients on antiestrogenic medication?
2. Is the addition of only 4 minutes of daily isometric exercises to this high protein diet more effective to improve their body composition?
3. How does the surgery, chemotherapy and antiestrogenic medication type influences the effects of these interventions?

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics Committee of the "Prof. Dr. Al. Trestioreanu" Institute of Oncology, Bucharest, Romania, ref: 4555/18.03.2016.

## **Study design**

Single center interventional randomised parallel trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

ER+/PR±/HER2- breast cancer

## **Interventions**

Overweight patients with ER+/PR±/HER2- luminal A and B breast cancer, currently under antiestrogenic treatment after surgery and chemotherapy - without diabetes, thyroid or renal disease, eating disorders, depression and osteoporosis were selected for this study. They were randomly allocated into one of two groups.

1. Participants follow an at home diet based on food high in proteins, calcium, omega-3 fatty acids, probiotics and prebiotics (D) for one year
2. Participants follow the same diet as those in group 1 in combination with 4' isometric exercises (D+Ex) for one year

Total body weight, body and and visceral fat were measured for all participants using a multi-frequency bioelectrical impedance scale after 6 months and after 12 months. The results were then correlated with the study intervention and with the type of antiestrogenic medication, surgery and chemotherapy.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Total body weight, body and and visceral fat using a multi-frequency bioelectrical impedance scale at 6 months and 12 months

## **Key secondary outcome(s)**

N/A

## **Completion date**

01/04/2016

## **Eligibility**

### **Key inclusion criteria**

1. Overweight patients with ER+/PR±/HER2- luminal A and B breast cancer
2. Currently under antiestrogenic treatment after surgery and chemotherapy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

1. Diabetes
2. Thyroid or renal disease
3. Eating disorders
4. Depression
5. Osteoporosis

**Date of first enrolment**

01/02/2015

**Date of final enrolment**

15/02/2015

**Locations****Countries of recruitment**

Romania

**Study participating centre**

**"Prof. Dr. Al. Trestioreanu" Institute of Oncology**

Şoseaua Fundeni 252

Bucharest

Romania

022328

**Sponsor information****Organisation**

Carol Davila Medicine University

ROR

<https://ror.org/04fm87419>

## Funder(s)

### Funder type

Government

### Funder Name

European Social Fund

### Alternative Name(s)

European Social Fund, Европейският социален фонд, Европейският социален фонд плюс, Fondo Social Europeo, Fondo Social Europeo Plus, Ευρωπαϊκό Κοινωνικό Ταμείο, Ευρωπαϊκό Κοινωνικό Ταμείο+, Ciste Sóisialta na hEorpa Plus, Ciste Sóisialta na hEorpa, ESF, ESF+, ЕСФ, ЕСФ+, FSE, FSE+, EKT, EKT+, CSE, CSE+

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Available on request

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2017	24/01/2019	Yes	No