

# Personalised nutrition intervention for breast cancer survivors based on individual molecular analyses (nutrigenetics, lipidomics and microbiomics)

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| <b>Submission date</b><br>05/08/2021   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>19/10/2021 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>02/11/2023       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input type="checkbox"/> Results                     |
|  |  | <input type="checkbox"/> Individual participant data |
|  |  | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

It is well known that cancer survivors have an increased risk of suffering from other chronic diseases, such as diabetes and cardiovascular diseases, as well as increased risk of recurrence and second malignancies. In an effort to prevent, or at least reduce, the severity of many of these diseases, a healthy and balanced diet is currently promoted by numerous cancer organizations to ensure optimal health status.

A clinical nutritional trial will be carried out with 50 breast cancer survivors, to evaluate the benefit of personalized nutritional advice on their metabolic and nutritional status. Nutritional advice will be based on individual metabolic and genetic profiles determined at the beginning of the intervention, as well as from food frequency questionnaires to determine habitual dietary intake. Intestinal microbiota will be measured throughout the intervention to assess the impact of the personalized nutritional advice on gut health. Efficacy of the nutritional advice will be determined by whether individual metabolic profiles can reach an optimal metabolic state.

### Who can participate?

Breast cancer survivors.

### What does the study involve?

The study involves a few hospital visits in 1 year, where blood samples will be taken from participants and they will personally meet the nutritionist.

### What are the possible benefits and risks of participating?

The participants will benefit from a personalised diet (intervention group) or healthy general diet (control group). There are no other risks than the ones associated with the blood extraction procedures.

### Where is the study run from?

AZTI (Spain)

When is the study starting and how long is it expected to run for?  
December 2020 to May 2024

Who is funding the study?  
Spanish Association Against Cancer (AECC)

Who is the main contact?  
Itziar Tueros PhD, [itueros@azti.es](mailto:itueros@azti.es)

## Contact information

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## Additional identifiers

EudraCT/CTIS number

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

TUE-SUR-2018-01

## Study information

### Scientific Title

Precision nutrition for breast cancer survivors based on molecular tools: nutrigenetics, lipidomics and microbiomics

### Acronym

SUMA

### Study objectives

The understanding of the interactions among diet and metabolism is necessary to formulate the best nutritional recommendations and thus help people achieve their health goals.

Consequently, through a methodology that integrates different omic tools, it is feasible to evaluate each patient individually, and based on their molecular characteristics, it is possible to design a personalized nutritional monitoring strategy considering diet and supplementation adapted to their nutritional requirements. This strategy would work as a guide for the control and care of the survivors' health, not only at the time of the check-up but also in the future

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 20/07/2021, Research Ethics Committee of the Health Area from Gipuzkoa (P<sup>o</sup>Doctor Beguiristains/n. 20014 Donostia-San Sebastian, Spain; +34 943007402; mjose.velazquezzubicoa@osakidetza.eus), ref: TUE-SUR-2018-01

### Study design

Prospective interventional randomized controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Prevention

## **Participant information sheet**

Not available in web format, please, use contact details to request a participant information sheet (available in spanish only)

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

Nutritional and metabolic status, and well being of breast cancer survivors

## **Interventions**

Prospective randomized controlled clinical trial with nutritional intervention for a year with a total of 50 breast cancer survivors. Participants will be randomly divided into two equal size groups: control (C) and personalized diet (D).

At the beginning of the study, blood samples will be obtained for the analysis of membrane lipidomic, nutrigenetic and epigenetic and biochemical parameters. Stool samples will be also collected to analyse gut microbiome. The anthropometric parameters will be also measured, and all patients will complete a validated quality of life (QoL) questionnaire and food frequency questionnaire (FFQ).

The Diet Group (D) participants will be provided with a personalized nutritional strategy (diet + supplementation) based on the erythrocyte membrane lipid profile and genetic profile, that will last 12 months.

The control group (C) will not receive personalized nutritional advice but they will have a general recommendation based on the Mediterranean diet and a placebo supplement. Follow-up questionnaires and analyses will be done at 6 and 12 months.

## **Randomisation:**

Oxmar software will be used. Groups will be distributed according to a random assignment sequence. In this way, we increase the probability that the two groups (control and intervention) are comparable with respect to age and pre- and post-menopause. In addition, the OxMaR system allows the concealment of the randomization sequence (OSA), as required by the CONSORT directive, since an SSL security and encryption system will be used, and a password access system to keep the randomization sequence hidden.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Metabolic status will be measured as the rebalance of the lipidomic analyses and other biochemical parameters (standard biochemistry parameters: blood cholesterol, TG.) together with anthropometric parameters at 6 and 12 months.
2. Well-being will be measured using validated questionnaires (EORTC QLQ-30 or similar) at 6 and 12 months.
3. Improvements of dietary habits will be assessed by validated food frequency questionnaire (FFQ from predimed) at 6 and 12 months.

## **Secondary outcome measures**

Cancer recurrence: relapses will be measured at 12 months using patient records

## **Overall study start date**

01/12/2020

**Completion date**

30/05/2024

## Eligibility

**Key inclusion criteria**

Breast cancer survivors (at least 6 months after treatment), with hormonal treatment

**Participant type(s)**

Other

**Age group**

Mixed

**Sex**

Female

**Target number of participants**

50

**Total final enrolment**

50

**Key exclusion criteria**

1. Metastasis
2. Severe malnutrition
3. Allergy to fish
4. Any difficulty to take supplements
5. Without gallbladder

**Date of first enrolment**

01/09/2021

**Date of final enrolment**

20/09/2022

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

Fundación Onkologikoa Fundazioa. Unidad de Gestión Clínica de Cáncer, Osakidetza

P. Dr Beguiristain 121.

Donostia- San Sebastian

Spain

20014

# Sponsor information

## Organisation

AZTI - Member of the Basque Research & Technology Alliance

## Sponsor details

Parque tecnologico bizkaia

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## Sponsor type

Research organisation

## Website

<http://www.azti.es>

# Funder(s)

## Funder type

Charity

## Funder Name

Fundación Científica Asociación Española Contra el Cáncer

## Alternative Name(s)

Fundación Científica de la Asociación Española Contra el Cáncer, Fundación Científica AECC, Scientific Foundation, Spanish Association Against Cancer, AECC

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

Spain

# Results and Publications

**Publication and dissemination plan**

Results will be disseminated in conferences and specialized scientific journals on nutrition and oncology. Also at university level, as participant researchers are lecturers in nutrition and health topic. Moreover, dissemination of results will be done for general public, in conferences in informative format, but also by publications in digital media.

**Intention to publish date**

30/05/2024

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available

**IPD sharing plan summary**

Not expected to be made available