INFORMATION SHEET AND CONSENT FORM
Adult patient

This document contains essential information about the clinical study in which you are being asked to participate. You will receive it well in advance of your final decision. It is important that you read this information and discuss it with the study clinician/researcher before signing the consent form to participate in the study.
Only patients who agree to participate in the study will be enrolled.
You may withdraw your consent at any time.

Study identification code at the Fondazione: INT 240/23

Patient identification number:

Title of the study: European Linkage of Initiative from Science to Action in Health (ELISAH)

Version 01 dated 14 September 2023

Study promoter: Fondazione IRCCS - Istituto Nazionale dei Tumori di Milano (INT)

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Introduction

Dear Ms/Mrs,

We invite you to participate in an observational study, which we outline below.

Before deciding whether or not to take part, it is important that you are informed about the reasons why the study is being conducted and what participating in it will mean for you. Take the time to read this information carefully and, if you wish, discuss it with friends, relatives and your family doctor.

Do not hesitate to ask questions if anything (for example, medical terms or expressions) is not clear to you or if you would like more information.

The observational study we are proposing to you has been reviewed and approved by the pertinent Ethics Committee.

What is an observational clinical study?

An observational study is a study in which a patient is treated for his or her disease according to routine medical practice. From the available diagnostic pathways and therapies the doctor freely chooses the ones most suitable for the treatment of the patient's disease, regardless of their participation in the observational study. The information and data from the procedures and examinations performed during the study are collected and analysed to answer the research question. In this study not only breast cancer patients but also women without breast cancer and women having a high genetic risk of breast cancer (women carrying BRCA gene mutations) will be enrolled and observed. In addition, study participants will be asked to provide personal data including body weight, height, waist circumference and lifestyle information such as smoking status (active or passive, past and current), dietary habits and physical activity. Participants will receive web-based information about a healthy lifestyle as well as information related to cancer risk factors and new researches on them and treatments.
Women carrying BRCA mutations will also be asked to download an app (equipped with smart consent) allowing them to participate in a web-based intervention regarding the Mediterranean diet and physical activity. This intervention lasts 6 months and favours the adoption of a healthy lifestyle and body weight. Participants will be randomly assigned to an intervention group or a control group. Women in the intervention group will receive dietary guidance, physical activity recommendations, exercise videos, weekly recipes, lectures and themed online cooking classes. Women in the control group will receive online information about BRCA-related cancer (new research, policies, etc.), a monthly recipe and general recommendations on prevention.

What is the objective of this study? How many participants and centres will take part?

[Present and explain the design and objectives of the study, specify the duration of patient participation, how many centres it will take place in and the total number of patients]

The objective of this study is to create an innovative European web-based cohort of 3000 women with breast cancer (in clinical follow-up) and without breast cancer, including at least 600 women with BRCA gene mutations. The study aims to promote web-based lifestyle interventions and smoking cessation, and to inform women about the cancer risks related to exposure to environmental carcinogens. The ultimate aim of the study is to reduce the risk of developing breast cancer by acting on modifiable risk factor. The study will last three years but the web cohort this web-based cohort represents the starting point for a potentially larger "open" platform to be implemented with additional women, data and contents. The best way to implement prevention is to develop strategies that integrate interventions for public and individual health promotion and that take into account the molteplicity of risk factors and their interaction.

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What are my responsibilities?
As this is an observational study, you will be requested to provide us with data on the exposures that are being studied (for example, by answering ad hoc questionnaires) and with permission to use these data for research purposes.

What are the possible risks and drawbacks?
There are no medical risks associated with participation in the study.
Given the observational nature of the study the insurance policy taken out by Fondazione IRCCS Istituto Nazionale dei Tumori guarantees adequate coverage in accordance with current legislation.

Can I interrupt my participation in the study?
Participation in the study is voluntary. You may leave the study at any time without giving any reason and your decision will not affect any medical treatment you may otherwise receive.
You may also continue your participation in the study by informing the study clinician/researcher that you withdraw the consent for processing your clinical data for research purposes.

How will my data and samples be processed?
Your clinical data, collected to the extent that they are essential for the study objective, will be processed in accordance with EU Regulation 2016/679 known as GDPR (General Data Protection Regulation). This means that the data and samples will be kept securely and will not bear your name in plain text but an identification code known only to your doctor and to the clinical staff. You can find all details on the processing of your data in the privacy policy, which you should read carefully before deciding whether to give your consent. Without consent to the processing of your personal data you will not be able to participate in the study.

Will I be paid for my participation in this study?
You will receive no payment for your participation in this study.

Will I have access to the results of the study?
Once the study is completed, the collected data and information will be analysed to draw conclusions. The promoter and investigators undertake to make these available to the scientific community. You can therefore ask to the study clinician/researcher how you can access the results.

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INFORMED CONSENT FOR PARTICIPATION IN THE STUDY

You should sign this consent form only if you wish to participate in the study. It is important that, before signing the form, you discuss your participation with the study clinician/researcher*, also on the basis of the information provided in the Information Sheet. Only participants who agree to participate will be enrolled in the study. Patients may withdraw their consent at any time.*

I, the undersigned,

1) **declare that I have been fully informed about the clinical study in question and that I have read the Information Sheet,**

2) **declare that I have received a copy of the consent form for safekeeping,**

The consent form will be signed electronically, by accepting the digital consent presented during the registration phase in ELISAH app.

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