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The DAMA25 study: A physical activity and dietary intervention in young women with breast cancer family history

Submission date
25/01/2017

Recruitment status
No longer recruiting

Registration date
18/05/2017

Overall study status
Completed

Last Edited
10/10/2022

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Studies have shown that around 20% of all breast cancer cases occur in women who have a family history of breast cancer (BC), suggesting a strong genetic link. Around 10% of these women have mutations (errors) in the genes BRCA1 or BRCA2. Women who carry these mutations may have up to a 60% lifetime risk of developing BC and up to a 30% risk of developing ovarian cancer. Clinical services for women with a family history of breast cancer or ovarian cancer usually include a risk assessment and regular monitoring using standardized methods. Genetic testing is offered to families where their family history suggests that there may be a mutation in BRCA genes or one of the other major genes involved in the development of BC, and preventative surgery may be recommended. It has been suggested that, in the general population, BC risk could be reduced through specific dietary and physical activity programs, as these changeable lifestyle factors may interact with genetic risk. The aim of this study is to investigate the effectiveness of a combined dietary and physical activity program in healthy women with a family history of breast cancer.

Who can participate?
Healthy pre-menopausal women aged 25-49 years who live in the metropolitan Florence area and have a family history of cancer.

What does the study involve?
All participants are invited for a visit where they are weighted and measured as well as having blood samples taken and providing information about their diet and exercise habits. Participants then start the diet program, which involves eating a diet made up of mainly plant-based food, which is low in fats and alcohol. They are also invited to take part in two group sessions and up to six practical cooking sessions, led by a professional cook and a study dietitian, in an appropriate facility. Dishes are prepared according to specifically designed recipes and then eaten at the end of session. Participants also take part in a physical activity program, designed to increase moderate daily activities (such as walking, biking, swimming, ballroom dancing), to be combined with a more strenuous activity. The program is based on individual and group training, including practical sessions, with an aim of reaching at least one hour/day of a moderate activity

plus one hour/week of a more strenuous activities. Activities can be split in two daily sessions (e. g. 30 minutes walking at moderate pace and 30 minutes fast dancing). They are also invited to take part in two group sessions where the benefits of physical activity are presented and discussed, and two collective walks supported by physical activity study specialists. Throughout the study, participants are asked to keep a written food diary and a physical activity diary which is regularly reviewed by the researchers. After 12 months, participants are invited to a follow up visit where they are weighted and measured as well as having blood samples taken and providing information about their diet and exercise habits.

What are the possible benefits and risks of participating?
Healthy dietary and physical activity patterns are recognized to be relevant for primary prevention of a wide spectrum of chronic diseases, moreover the dietary and physical activity intervention are explained and gradually adapted to each participant. Minimal risk could be related to the blood drawing at the first and final visits, performed by trained nurses in an appropriate setting. Possible risks related to the increased physical activity level are minimal, since the level of exercise foreseen in the intervention is mostly moderate and the more intense component is carried out with the supervision of experts in the field and gradually applied, taking into account individual characteristics.

Where is the study run from?
Cancer Research an Prevention Institute (ISPO) (Italy)

When is study starting and how long is it expected to run for?
July 2015 to November 2017

Who is funding the study?
Corri La Vita ONLUS (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The DAMA25 study: A non-randomized behavioural intervention to modify physical activity and dietary habits in healthy young women with breast cancer family history with a pre-post evaluation

Acronym
DAMA25

Study objectives
The aim of this study is to evaluate:
1. The efficacy of a 1-year structured behavioural intervention including individual counselling and group educational and practical activities to induce modification of dietary habits and to increase physical activity level in healthy women aged 25-49 years with a relevant BC family history
2. The effect on anthropometric indices and body composition
3. The adherence overall and for each type of activity proposed

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Local Health Authority, Florence, 30/11/2015.

Study design
Non-randomised interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Prevention

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
After a baseline visit in which blood samples, anthropometric measurements, dietary and lifestyle information are collected, participants begin dietary and physical activity interventions for 12 months.
Dietary Intervention: Participant are asked to consume a diet mainly based on plant food, with a low glycaemic load, low in saturated and trans-fats and alcohol, and rich in antioxidants. The requested dietary changes are individually discussed. An integrated approach includes individual and group sessions and cooking classes. Study participants are invited to participate to 2 group sessions about: diet, lifestyle and disease prevention; nutritional value of foods; energy balance, readiness to change. Participant are also invited to 6 practical cooking sessions, led by a professional cook and by a study dietician, in an appropriate facility. Dishes are prepared according to specifically designed recipes and then consumed at the end of session. Participants are encouraged to use study recipes as frequently as possible.

Physical activity (PA) intervention: Participants aim to increase moderate daily activities, accounting for 3-5.9 metabolic equivalent (MET) hours/day, such as walking, biking, swimming, ballroom dancing, to be combined with a more strenuous activity. The intervention is based on individual and group training, including practical sessions. The goal is to reach at least 1hour/day of a moderate plus at least 1 hour/week of a more strenuous activity. These aims are discussed and specifically adapted to each participant's lifestyle. Activities can be split in two daily sessions (e.g. 30 minutes walking at moderate pace +30 minutes fast dancing).
Study participants are invited to participate to 2 group sessions where the benefits of physical activity are presented and discussed, and to 2 collective walks supported by PA study specialists. Moreover, study participants will be motivated to organize autonomously collective walks. Participants are also trained in measuring their own improvement in physical fitness by pedometers. A more specific and intensive counselling for weight loss is offered to overweight /obese participants.

Participants are also supplied with printed material to provide them with more detailed information and insights on the different components of the program.

Throughout the study, participants are asked to keep a written food diary and a physical activity diary, which is periodically reviewed by study operators to assess compliance and to inform periodic telephone contacts. Participants are also periodically contacted (by telephone, e-mail etc.) to monitor the adherence to the intervention program and to discuss about any problems arising during the study.

After the 12 month interventions, participants are invited to a follow up visit where blood samples, anthropometric measurements, dietary and lifestyle information are collected.

Intervention Type

Behavioural

Primary outcome measure
1. Consumption of a series of foods (g/day) will be assessed by means of the FFQ specifically developed for the Italian component of the European Prospective Investigation into Cancer and nutrition (EPIC) study at baseline and 12 months
2. Reported physical activity in leisure time both in household and recreational activities (hours /week) is assessed using a lifestyle questionnaire developed for the purpose of this study at baseline and 12 months
3. Weight, waist and hip circumference and body composition (fat mass and fat- free mass) will be measured by trained personnel using a standard protocol at baseline and 12 months

Secondary outcome measures
No secondary outcome measures

Overall study start date
31/07/2015

Completion date
17/11/2017

Eligibility

Key inclusion criteria
1. Healthy pre-menopausal women aged 25-49 years
2. Residing in the metropolitan Florence area
3. Positive cancer family history assessed in the frame of the Genetic Counselling Service of ISPO (Cancer Research and Prevention Institute)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
100

Key exclusion criteria
1. Post-menopausal status
2. Diabetes and/or other major co-morbidities that could affect the possibility to follow the intervention protocol (major cardiovascular disease, severe hip or knee osteoarthritis)
3. Previous diagnosis of breast cancer or other malignancies

Date of first enrolment
20/01/2016

Date of final enrolment
21/03/2016

Locations

Countries of recruitment
Italy

Study participating centre
Cancer Research an Prevention Institute (ISPO)
Cancer Risk Factors and Lifestyle Epidemiology Unit
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Sponsor information

Organisation
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Sponsor type
Research organisation

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ROR
https://ror.org/007wes890

Funder(s)

Funder type
Research organisation

Funder Name
Corri La Vita ONLUS

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
17/11/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request depending on the evaluation of the PI and the local Ethics Committee clearance from g.masala@ispo.toscana.it.

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/11/2021	10/10/2022	Yes	No