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The DAMA - Diet Exercise and Mammography (Dieta Attività fisica e MAmmografia) Trial: a physical activity and diet intervention trial to reduce mammographic breast density, a strong risk factor for breast cancer, in postmenopausal women

Submission date	Recruitment status	[_] Prospectively registered
22/03/2012	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
17/05/2012	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
04/08/2025	Cancer	

Plain English summary of protocol

Background and study aims
Most of the major factors affecting breast cancer risk cannot be changed. However, potentially modifiable lifestyle and dietary factors have been identified, suggesting that breast cancer incidence could be reduced through intervention programs. There is increasing evidence that moderate intensity physical activity reduces the risk of breast cancer. Concerning diet, high intake of fats, mainly animal fats, and high consumption of foods rich in fats such as meat, have been proposed as risk factors for breast cancer. High consumption of vegetables and high intake of antioxidants have been suggested to be protective in studies carried out in Mediterranean countries. Breast density is influenced by well-known breast cancer risk factors and by potentially modifiable factors such as diet and physical activity, and high breast density is associated with an increased breast cancer risk. The aim of this study is to find out whether a specific dietary and physical activity intervention program can reduce breast density in women with high breast density.

Who can participate?
Participants are healthy postmenopausal women (aged 50-69) at increased breast cancer risk because of high-density mammographic patterns as routinely assessed in the local screening program carried out in the city of Florence.

What does the study involve?
All participants are invited for a visit where we will measure their weight, height, hip and waist circumferences, collect blood and urine samples, and collect information on dietary and lifestyle habits. Then participants are randomly allocated to one of four groups. Women in group 1 are asked to consume a diet mainly based on plant food rich in fiber and low in added sugar, animal

fat and alcohol, and rich in antioxidants. An integrated approach includes individual sessions with trained dieticians, six group sessions and eight cooking classes with a professional cook. Dishes are prepared according to specifically designed recipes and then consumed at the end of the session. Study recipes are developed and distributed to participants. Women in group 2 are asked to increase moderate daily activities, such as walking, biking, swimming, stretching and ballroom dancing, to be combined with a more strenuous activity, and are offered a one-hour session per week of scheduled activity in a fitness facility where the exercise program can be carried out with the support of specifically trained personnel. Women in group 3 are asked to change both their diet and physical activity as outlined above. Participants are requested to keep a written food diary (group 1), a physical activity diary (group 2) and food and physical activity diary (group 3). Overall, subjects will be contacted by telephone at least once a month: in that occasion they can ask questions and discuss about problems arising during the study. Women in group 4 receive general advice on healthy dietary and physical activity patterns. A group meeting is organized to discuss healthy diet and physical activity and to distribute printed material specifically developed for the trial. After the 24-month intervention all participants will be invited to undergo a mammographic examination to measure breast density and to repeat the other measurements carried out at the beginning of the study.

What are the possible benefits and risks of participating?
All participants will receive general advice on healthy dietary and physical activity patterns that are relevant for prevention of a wide spectrum of chronic diseases. 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?
The study is run from ISPO Cancer Research and Prevention Institute (Italy).

When is the study starting and how long is it expected to run for?
The study ran from January 2009 to December 2012.

Who is funding the study?
This study is being funded by the Istituto Toscano Tumori Tuscany Region and by the Ministry of Health, 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 DAMA Trial: a physical activity and diet intervention trial to reduce mammographic breast density, a strong risk factor for breast cancer, in postmenopausal women - a factorial randomized trial

Acronym
DAMA

Study objectives
Mammographic breast density is a strong risk factor for breast cancer and can be modulated by established breast cancer risk factors and by potentially modifiable factors such as diet and physical activity. Breast density has been proposed as a possible intermediate endpoint in randomized trials aimed to evaluate the efficacy of specific interventions in reducing breast cancer risk.

The hypothesis tested in this study is that breast density, a strong risk factor for breast cancer risk, can be reduced by a structured protocol of modifications of dietary and physical activity habits in post-menopausal women with high mammographic breast density (percent density >50).

The adopted design, a factorial randomized trial, will allow to evaluate in an efficient way :
1. The ability of a dietary intervention to reduce breast density. The 24-month dietary intervention will be aimed at changing diet towards a pattern rich in plant-based food, with a low glycemic load, low in saturated and trans fats and alcohol, and rich in antioxidants. This pattern is based on guidelines provided by World Cancer Research Fund Report 2007 and by National Institutions.
2. The ability of a 24-month physical activity intervention to reduce breast density. The physical

activity intervention will be aimed at increasing physical activity levels from a mainly sedentary to a moderate physical activity pattern, according to national and international guidelines.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Local Health Authority in Florence, Italy approved on 11/07/2007 and subsequent amendment was approved on 27/10/2008

Study design
Single-centre factorial randomized intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Change in mammographic breast density

Interventions
After a baseline visit in which blood and urine samples, anthropometric measurements, dietary and lifestyle information are collected, subjects are randomized to one of the treatment arms (dietary intervention, physical activity intervention, dietary + physical activity intervention) or to the control arm, by age- and body mass index (BMI) stratified blocks.

1. Dietary intervention DI (arm 1):
Participants assigned to the dietary intervention are asked to consume a diet mainly based on plant food, with a low glycemic load, low in saturated and trans fats and alcohol, and rich in antioxidants. The requested dietary changes are individually discussed.

An integrated approach include individual and group sessions and cooking classes. Study participants are invited to participate to six group sessions about: diet, lifestyle and disease prevention; nutritional value of foods; energy balance; readiness to change. Participants are also invited to eight practical cooking sessions, led by a professional cook and by a study dietitian, in an appropriate facility. Dishes are prepared according to specifically designed recipes and then consumed at the end of the session. Participants are encouraged to use study recipes as frequently as possible.

2. Physical activity intervention - PA (arm 2):
The aim is to increase moderate daily activities, accounting for three metabolic equivalent (MET) hr/day, such as walking, biking, swimming, stretching and ballroom dancing, to be combined with a more strenuous activity (accounting for 6-10 MET hr/week). The intervention is based on individual and group training, including practical sessions.

Daily routines: engage in 1 hour/day of a moderate activity. This is discussed and specifically adapted to each participants lifestyle and daily schedule. Activities can be split in two daily sessions (e.g., 30 minutes walking at moderate pace + 20 minutes fast dancing).

Weekly routines: engage in at least one session per week of a 6-10 MET/hrs activity scheduled in a fitness facility, where trained instructors, paid by the project, provide support and guidance to trial participants. Study participants are invited to participate in six group sessions where the benefits of physical activity are presented and discussed, and to six collective walks. Subjects are also trained in measuring their own improvement in physical fitness by pedometers.

3. Dietary + physical activity intervention DI+PA (arm 3):
Participants randomized into the DI+PA arm are asked to change both their diet and physical activity, using the combination of arm 1 and arm 2 protocols. Study participants are invited to participate in 12 group sessions (6 physical activity and 6 dietary sessions for approximately 25 women). Sessions have the exact same program as described for arm 1 and arm 2. Participants are also invited to participate in 14 practical sessions (cooking classes and collective walks), as described above for arm 1 and arm 2.

Periodically, participants are requested to keep a written food diary (arm 1), a physical activity diary (arm 2) and food + physical activity diary (arm 3), reviewed by study operators and subsequently analyzed to assess compliance. Overall, subjects will be contacted by telephone at least once a month: in that occasion they can ask questions and discuss about problems arising during the trial.

4. Control group
After the baseline visit, women randomized to the control group receive general advice on healthy dietary and physical activity patterns according to the World Cancer Research Fund Report 2007. A brief version of the guidelines has been translated into Italian. One group meeting (approximately 50 women/group) is organized at the beginning of the study to discuss healthy diet and physical activity.

After the 24-month intervention participants will be invited:
1. To undergo, in the frame of the local screening programme, a mammographic examination
2. At the follow-up visit the same information and the biological samples collected at the beginning of the study will be obtained

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Absolute change in percent breast density, calculated as the difference between end of study and baseline percent density values, as assessed on the cranio-caudal view of the right breast of the baseline and follow-up mammograms of each participant.

Follow-up mammograms will be performed in a specific time-window (24+3 months after randomization) in the intervention and control groups. All mammograms will be performed in the frame of the local screening program with the same digital mammography equipment. MBD will be assessed on each mammogram using a previously validated computer-assisted technique (Boyd et al., JNCI, 1995) by a study radiologist .Measurements will be done in batches including 80-100 matched mammograms randomly selected from the baseline and follow-up mammograms. Radiologists will be blind to the treatment status and to the sequence of the mammograms.

Secondary outcome measures
1. Absolute change in area of dense tissue and area of non-dense tissue. These measurements are derived through the same procedures described for the primary outcome
2. Biological samples collected at the first and at the last visit, aliquoted (serum, plasma, buffy coat) and stored in the biological bank of the project will be used to monitor dietary compliance (biomarkers of intake) and to study the effect of the intervention on other outcomes related to breast cancer risk [i.e. plasma levels of sexual hormones, growth factors as insulin-like growth factor 1 (IGF-I) and its binding proteins, urine biomarkers] according also to specific genetic polymorphisms. Biomarkers will be measured depending on the availability of additional funding and, when appropriate, after a specific evaluation by the local Ethics Committee that have already approved the overall project.

Overall study start date
01/01/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Postmenopausal women aged 50-69 years, with a high-density mammographic pattern as routinely assessed in the local screening program by a semi-quantitative method (> 50% high-density area)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
300

Total final enrolment
234

Key exclusion criteria
1. Pre- or peri-menopausal status
2. Current or recent (last 12 months) hormone replacement therapy
3. Current smokers
4. Diabetes and/or other major co-morbidities that could affect the possibility to follow the intervention protocol (major cardiovascular diseases, severe hip or knee osteoarthritis)
5. Previous diagnosis of breast cancer or other malignancies

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Italy

Study participating centre
Molecular and Nutritional Epidemiology Unit
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Sponsor information

Organisation
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Sponsor type
Research organisation

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ROR
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Funder(s)

Funder type
Government

Funder Name
Tumour Institute of Tuscany (Istituto Toscano Tumori), Tuscany Region (Italy) ref: ITT Grant Proposal 2007 (DD n 6888 28- 12-2007)

Funder Name
Ministry of Health, Tuscany Region (Italy)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		01/07/2014		Yes	No
Results article		01/01/2019	16/12/2020	Yes	No
Other publications		01/12/2022	02/12/2022	Yes	No
Results article		31/07/2025	04/08/2025	Yes	No