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Does a new leaflet with information about the breast cancer screening program, its benefits and risks, affect participation in the screening program?

Submission date
22/04/2021

Recruitment status
No longer recruiting

Registration date
06/05/2021

Overall study status
Completed

Last Edited
05/07/2021

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
In Catalonia, Spain, a new leaflet was designed with information about the breast cancer screening program. To our knowledge, it is not known whether the leaflet has any effect on women's attendance. Therefore, the aim of this study was to evaluate the impact on participation of this new leaflet targeting women invited to the breast cancer screening program.

Who can participate?
The study included women aged 50 - 69 years invited to the breast cancer screening program in the catchment area of the Parc the Salut Mar in Barcelona, Spain.

What does the study involve?
This study follows the usual screening program protocol, in which invitations to participate in the screening program are sent by surface mail. Two groups were created, one group received an information leaflet on the benefits and harms of mammography screening. The other group received the usual invitation letter. We compared participation in the screening program between groups.

What are the possible benefits and risks of participating?
The possible benefit of participating is having more information about the breast cancer screening program, its benefits and risks. A possible risks of participating in the study is deciding not to participate in the screening program.

Where is the study run from?
Department of Epidemiology and Evaluation of the Hospital del Mar and IMIM (Hospital del Mar Medical Research Institute) (Spain.)

When is the study starting and how long is it expected to run for?
September 2019 to March 2020

Who is funding the study?
This work was supported by a grant from Instituto de Salud Carlos III (grant number: PI19 /00007), and by the Research Network on Health Services in Chronic Diseases (RD12/0001/0015) (Spain)

Who is the main contact?
Margarita Posso, mposso@parcdesalutmar.cat

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Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2019/8898/I

Study information

Scientific Title
Effect of an information leaflet on breast cancer screening participation. A cluster randomized controlled trial

Study objectives
A new leaflet containing information about the breast cancer screening program modifies the participation rate of women invited to participate in at least three percentual points.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/10/2019, Clinical Research Ethics Committee of the PSMAR (CEIm – Parc de Salut MAR; Dr Aiguader, 88; 08003, Barcelona, Spain; +34 93 316 06 77; ceic-psmar@imim.es), ref: 2019/8898/I

Study design
Single-center interventional cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Breast cancer screening program

Interventions
-Control group: women received the usual invitation letter, that offers an appointment date to undergo mammography as part of the breast cancer screening program, without informing about the benefits and risks of participating in the screening program.

-Intervention group: received an information leaflet in addition to the invitation letter. This information leaflet describes the breast cancer screening program, and how it is implemented in the region. It contains qualitative and quantitative information on breast cancer, mortality reduction due to mammography screening, the possibility and advantages of detecting early-stage cancer in participants, and explaining the mammogram. The leaflet also provides information on the potential risks of screening, overdiagnosis and overtreatment, and false positives and false negatives.

The randomization unit was the processing day of the letter of invitation, and was performed as a blind random assignment using the RANDOM excel function.

The follow-up period was initially set to be 90 days, but due to the COVID-19 pandemic we had to deviate from the protocol and shorten it to 30 days.

Intervention Type
Behavioural

Primary outcome(s)
Participation in the breast cancer screening program measured as a dichotomous variable (yes /no) and is automatically registered in an informatic application at the moment that the woman undergoes screening mammography

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
08/03/2020

Eligibility

Key inclusion criteria
1. Women aged 50 to 69 years
2. Invited to participate to the Breast Cancer Screening Program between 30th September 2019 and 17th January 2020
3. Residents of six catchment areas of Barcelona

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
11119

Key exclusion criteria
1. Women who had moved residence outside the PSMAR catchment area
2. Census errors

Date of first enrolment
30/09/2019

Date of final enrolment
17/01/2020

Locations

Countries of recruitment
Spain

Study participating centre
Parc de Salut Mar
Carrer Dr. Aiguader, 88
Barcelona
Spain
08003

Sponsor information

Organisation
Parc de Salut

ROR
https://ror.org/032exky44

Funder(s)

Funder type
Government

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Funder Name
Research Network on Health Services in Chronic Diseases

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Margarita Posso (mposso@parcdesalutmar.cat) upon reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/07/2021	05/07/2021	Yes	No
Participant information sheet	Participant information sheet version v1	11/11/2025	11/11/2025	No	Yes
Protocol file		27/09/2019	06/05/2021	No	No