

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

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<b>Registration date</b> 06/05/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/07/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

## Contact information

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Scientific

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

2019/8898/1

## 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: 2019/8898/1

**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)**

SaludISCI, 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 (ISCI), ISCI

**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?
<a href="#">Results article</a>		03/07/2021	05/07/2021	Yes	No
<a href="#">Protocol file</a>	version v1	27/09/2019	06/05/2021	No	No