

Testing an online tool to help women decide whether to have breast cancer screening with mammography

Submission date 22/10/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/10/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 22/10/2026	Condition category Cancer	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Mammography screening can reduce deaths from breast cancer, but it can also cause harms, such as false alarms that lead to extra tests, and overdiagnosis, which is the detection and treatment of cancers that would never have caused health problems. Because of this balance, guidelines recommend that women make an informed decision together with their doctor. In 2019 the researchers developed a free online decision aid in Spanish that explains the benefits and harms of screening mammography. This study aimed to find out whether using this tool during routine medical consultations helps women make an informed choice about screening.

Who can participate?

Women aged 40 to 69 years at average risk of breast cancer who are members of the Hospital Italiano de Buenos Aires health plan and have not had a mammogram in the previous 12 months, and physicians from the family medicine, internal medicine and gynaecology services of the hospital.

What does the study involve?

Physicians watch a short video tutorial on how to use the decision aid. Women answer a questionnaire about their knowledge and views on breast cancer screening before a routine consultation. During the consultation, the physician spends 15 to 20 minutes going through the decision aid with them. Afterwards, women answer a second questionnaire sent by email or instant messaging. Physicians answer questionnaires at the start and end of the study.

What are the possible benefits and risks of participating?

Participants may gain a better understanding of the benefits and harms of mammography screening and feel more involved in the decision. There are no known physical risks. Some women may find information about the harms of screening unexpected or worrying.

Where is the study run from?

Hospital Italiano de Buenos Aires, Argentina

When is the study starting and how long is it expected to run for?
June to October 2021.

Who is funding the study?
Ministry of Health of Argentina (Salud Investiga Fellowship)
Asociación Mutual de Profesionales del Hospital Italiano (AMPHI), Argentina

Who is the main contact?
Juan Franco (juan.franco@med.uni-duesseldorf.de)

Contact information

Type(s)

Principal investigator, Public, Scientific

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Additional identifiers

Computerized Registry Platform for Health Research in the City of Buenos Aires (Plataforma de Registro Informatizado de Investigaciones en Salud de la Ciudad de Buenos Aires, PRIISA.BA)
3399

Study information

Scientific Title

Effect of a web-based patient decision aid used during routine primary care consultations on informed choice about breast cancer screening in average-risk women aged 40–69 years: a single-arm pre–post implementation study

Study objectives

Primary objective:

1. To evaluate whether the use of a web-based patient decision aid (PtDA) during routine consultations increases the proportion of women aged 40–69 years at average risk of breast cancer who make an informed choice about screening mammography

Secondary objectives:

2. To assess changes in women's knowledge of the benefits and harms of screening mammography, including false-positive results and overdiagnosis
3. To describe changes in women's attitudes towards screening and their intention to undergo screening mammography
4. To assess shared decision making as perceived by women and physicians, and women's decisional conflict after the consultation
5. To assess the acceptability of the PtDA among women and physicians
6. To assess changes in physicians' knowledge of breast cancer screening

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 17/12/2020, Research Protocols Ethics Committee of Hospital Italiano de Buenos Aires (Comité de Ética de Protocolos de Investigación, CEPI) (Tte. Gral. Juan Domingo Perón 4190 - 4192, Buenos Aires, C1199ABB, Argentina; +54 114959-0200 (interno 8425); cepi@hospitalitaliano.org.ar), ref: 5861

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Single

Purpose

Health services research, Screening

Study type(s)

Health condition(s) or problem(s) studied

Breast cancer screening decision-making in women at average risk of breast cancer

Interventions

Participating physicians from the family medicine, internal medicine and gynaecology services complete a baseline questionnaire on their knowledge of breast cancer screening. They are then trained in the use of a Spanish-language web-based patient decision aid (PtDA) about screening mammography (<https://decidirmamografia.com.ar/>) through a video tutorial, with an optional follow-up session.

Eligible women complete a baseline questionnaire on knowledge, attitudes and intention regarding screening mammography. They then attend their already-scheduled routine consultation with a participating physician, during which 15 to 20 minutes are devoted to presenting and discussing the PtDA. No dedicated or extended appointment slots are provided.

After the consultation, women receive a second questionnaire by email or instant messaging, which reassesses knowledge, attitudes and intention and also assesses shared decision making, decisional conflict and acceptability of the PtDA. Physicians complete a final questionnaire at the end of the study.

This is a single-arm study with no control group and no randomisation. Each woman's participation consists of one consultation, from the baseline questionnaire to completion of the post-consultation questionnaire.

Intervention Type

Behavioural

Primary outcome(s)

1. Informed choice about screening mammography (adequate knowledge combined with an attitude towards screening consistent with the intention to be screened) measured using self-administered questionnaire adapted from Pérez-Lacasta et al. (InforMa trial) at baseline (before the consultation) and after the consultation

Key secondary outcome(s)

1. Knowledge of the benefits and harms of screening (15 items covering benefits, false-positive results and overdiagnosis) measured using self-administered questionnaire at baseline (before the consultation) and after the consultation

2. Attitudes towards screening measured using 5-item attitude scale (each item scored 1–5) at baseline (before the consultation) and after the consultation

3. Intention to undergo screening mammography measured using single item with five response options at baseline (before the consultation) and after the consultation

4. Perceived shared decision making measured using Spanish version of the Ask 3 Questions questionnaire at after the consultation (women) and at the end of the study (physicians)

5. Decisional conflict measured using Spanish version of the 10-item low-literacy Decisional Conflict Scale at after the consultation

6. Acceptability of the PtDA (length, clarity, balance and usefulness) measured using four questionnaire items at after the consultation (women) and at the end of the study (physicians)

7. Physicians' knowledge of breast cancer screening measured using self-administered questionnaire at baseline and end of the study

Completion date

31/10/2021

Eligibility

Key inclusion criteria

Women:

1. Aged 40 to 69 years
2. Affiliated to the Hospital Italiano de Buenos Aires prepaid health plan
3. At least two consultations with a participating physician during the previous two years
4. No screening mammography in the previous 12 months
5. A consultation already scheduled with a participating physician during the following month

Physicians:

1. Physicians from the family medicine, internal medicine or gynaecology services of Hospital Italiano de Buenos Aires
2. Did not take part in the development of the patient decision aid

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

40 Years

Upper age limit

69 Years

Sex

All

Total final enrolment

111

Key exclusion criteria

1. Previous use of the patient decision aid
2. Increased risk of breast cancer
3. Cognitive impairment
4. Inability to understand Spanish or the information provided by the tool

Date of first enrolment

01/06/2021

Date of final enrolment

31/10/2021

Locations**Countries of recruitment**

Argentina

Study participating centre

Hospital Italiano de Buenos Aires
Tte. Gral. Juan Domingo Perón 4190
Buenos Aires
Argentina
C1199ABB

Sponsor information

Organisation
Hospital Italiano de Buenos Aires

ROR
<https://ror.org/00bq4rw46>

Funder(s)

Funder type

Funder Name
Ministerio de Salud de la Nación (Ministry of Health of Argentina)

Funder Name
Asociación Mutual de Profesionales del Hospital Italiano (AMPHI)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study are not expected to be made publicly available because the small sample size and the single-centre setting create a risk of participant re-identification. De-identified data will be available from Dr Juan Víctor Ariel Franco (juan.franco@med.uni-duesseldorf.de) on reasonable request.

IPD sharing plan summary

Available on request