

# THE LANCET

## **Supplementary appendix**

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Hersch J, Barratt A, Jansen J, et al. Use of a decision aid including information on overdetected to support informed choice before breast cancer screening: a randomised controlled trial. *Lancet* 2015; published online Feb 18. [http://dx.doi.org/10.1016/S0140-6736\(15\)60123-4](http://dx.doi.org/10.1016/S0140-6736(15)60123-4).

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# Breast cancer screening: It's your choice

New information to help women aged  
about 50 to make a decision



# Introduction

## Why is there a decision to make about having breast cancer screening?

Many people think screening for early signs of **breast cancer** is always a good thing. But **breast screening** has advantages and disadvantages. This booklet is designed to help you make an informed choice about whether you would prefer to have screening or not.

Remember, there is no right or wrong answer about whether to have breast screening. It is a matter of what you believe is the right choice for you.

## What is the purpose of this booklet?

You may have seen the BreastScreen leaflet which gives a basic introduction to breast screening. The booklet you are now reading contains extra information★ you can consider to help you decide whether or not you want to start screening. It was developed at The University of Sydney by gathering together the best available scientific evidence.

Whenever you see a word in **this colour**, you can find its meaning on page 11.

## What is breast cancer screening?

Cancer screening is testing people who are well and do not have any **symptoms**, to look for early signs of cancer. Screening cannot stop people from getting cancer, but aims to find those people who have cancer so they receive a diagnosis and can start treatment.

The best available method of screening women for breast cancer is using a test called a **screening mammogram**. This test uses x-rays to make images of the breasts.

Screening is for women without any breast symptoms (such as a lump, pain, or nipple discharge). **If you do have any unusual changes in your breasts, see your doctor.**

## Making my choice about screening: Is this information relevant for me?

This booklet is for women who are 50 years old or will be 50 in the next few years, who have no symptoms and are thinking about whether to start breast screening.

If you have had breast cancer, or if you have been told that you are at very high risk for breast cancer or that you are likely to have a breast cancer **gene mutation**, this booklet is not for you. Ask your doctor about breast screening.

## What can I consider to help me make my decision?

The next few pages of the booklet contain some diagrams showing different things that may happen to women who have breast screening. Each diagram shows 1000 women who have a screening mammogram every 2 years for a period of 20 years, starting when they are 50 years old.



### There are 3 important things to know:

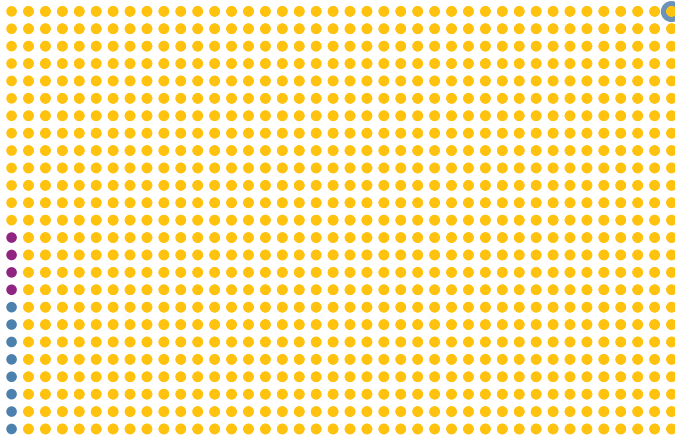
- (1) Screening leads to fewer women dying from breast cancer
- (2) Screening leads to finding some breast cancers that are not harmful (**over-detection**)
- (3) Screening leads to some **false positive** results and extra testing

The numbers presented are the best available estimates based on the latest research. They may need to be reviewed in the future when new information becomes available.

# 1. Screening leads to fewer women dying from breast cancer

The aim of breast screening is to lower the number of women who die of breast cancer.

## Breast cancer deaths avoided over 20 years of screening



1 dot = 1 woman

- woman who avoids dying from breast cancer because of screening
- woman who still dies from breast cancer, in spite of screening
- woman who would not die from breast cancer anyway

Out of 1000 women who have breast screening for 20 years,

- **4 women avoid dying from breast cancer** because of screening and
- **8 women still die** from breast cancer.

## 2. Screening leads to finding some breast cancers that are not harmful (over-detection)<sup>★</sup>

The cancers found by screening are treated to try and prevent problems later. But some cancers found by screening would never cause problems anyway. Cancers like this may grow very slowly or just stay the same. Without screening, they would never be noticed or cause any trouble. **Finding these cancers through screening is called over-detection (or over-diagnosis).**

**Even after further checks and examination, doctors cannot be sure which cancers will be harmless.** Therefore, treatment is recommended. So, across all the women who have screening, some end up having treatment they do not need.

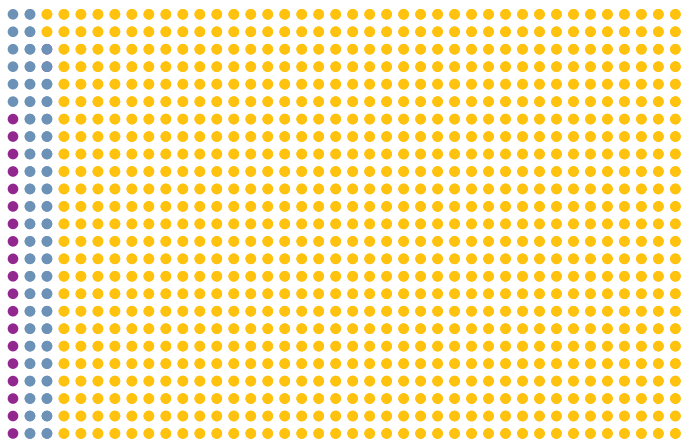
Breast cancer treatments include **surgery, radiotherapy, hormone therapy,** and **chemotherapy.** There are important side effects to these treatments which are described on page 8.

### Over-detection over 20 years of screening

Out of 1000 women who have breast screening for 20 years, **73** women are diagnosed with breast cancer.

Of these,

- **19 women experience over-detection:** they are diagnosed and treated for a cancer that would not have caused any trouble and
- **54** women are diagnosed with breast cancer that is not over-detection.

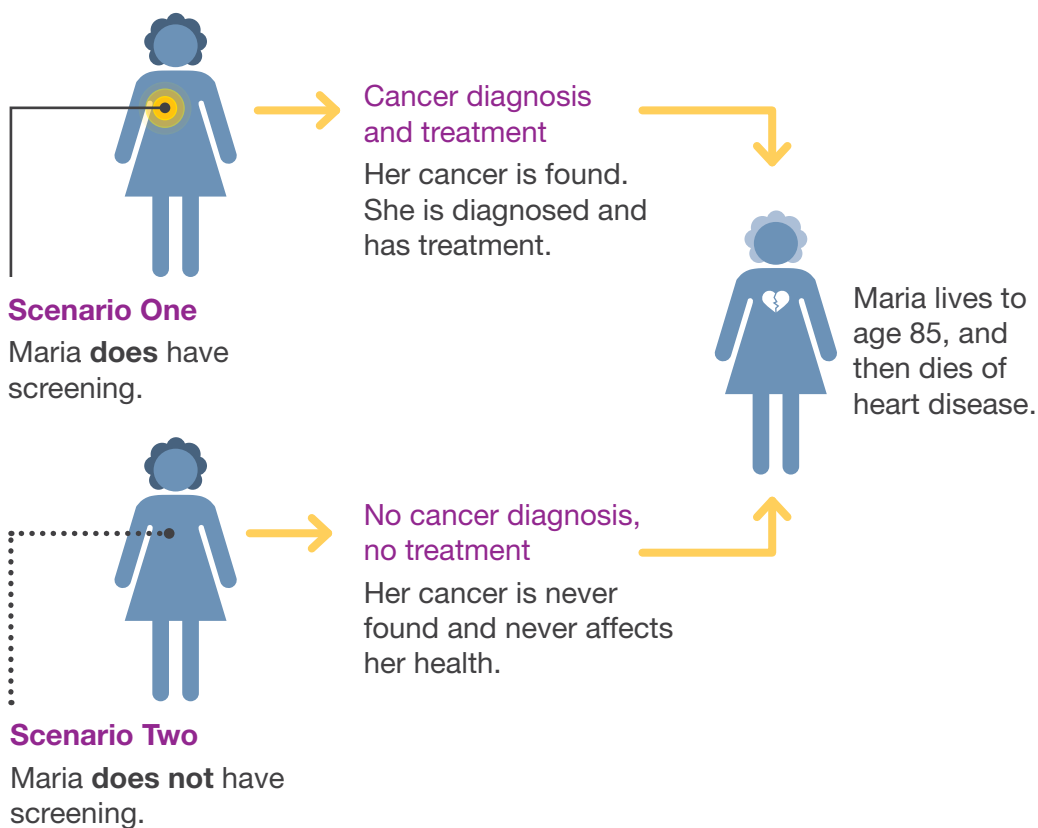


- extra woman diagnosed with breast cancer due to over-detection
- woman diagnosed with breast cancer that is not over-detection
- woman not diagnosed with breast cancer

As this information is new, there is an example of over-detection on the next page.

## Over-detection: an example

Imagine a woman called Maria who develops a small, slow-growing breast cancer in her 50s or 60s. The picture below shows two possible scenarios that could happen to Maria: Scenario 1 (top) is with screening, and Scenario 2 (bottom) is without screening.



Maria's life span is the same, whether or not she has screening. So if she has screening, she experiences over-detection (a diagnosis and treatment she does not need).

### Putting it together ★

For women in Australia who have breast screening over 20 years:

4 out of 1000 women avoid dying from breast cancer, and 19 out of 1000 women experience over-detection.

So that means **more women experience over-detection than avoid dying** from breast cancer.



### 3. Screening leads to some false positive results and extra testing

Like any other screening test, a mammogram is not perfect. Sometimes the result looks **abnormal** and the woman is recalled for extra tests, but it turns out that there is **no cancer** so it was a false alarm. **These false alarms from screening are called false positive results.**

Women often feel anxious while they are having the extra tests and waiting for their results, and then feel relieved when they are told there is no cancer after all. However, some women find that they keep worrying about breast cancer for a while afterwards.

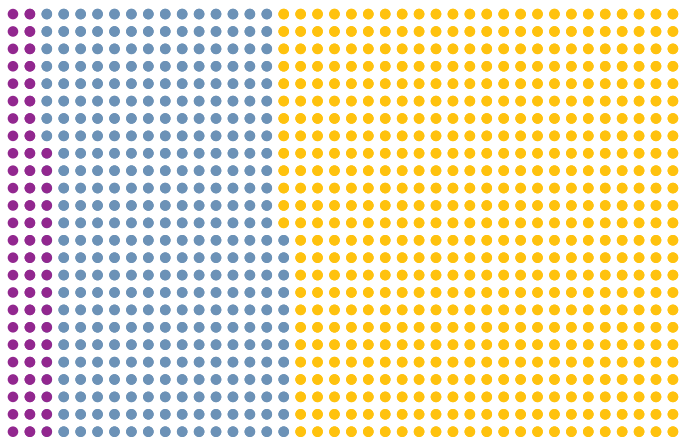
#### False positives over 20 years of screening

Out of 1000 women who have breast screening for 20 years,

**412 women experience a false positive result:** they have an abnormal mammogram followed by extra tests but they do not have cancer.

Of these,

- **67** women have a **biopsy** and
- **345** women have other extra tests but no biopsy.



- woman who has a false positive with a biopsy
- woman who has a false positive with other tests
- woman who does not have a false positive

## Some questions you may have



### 1. What happens after an abnormal screening result?

If her screening mammogram result is abnormal, the woman is called to a clinic for extra tests to check whether she has cancer or not. The extra tests may include more mammograms, **ultrasound scans**, **clinical examination**, and a biopsy (taking a sample of breast **cells**, usually with a needle).

### 2. How is over-detection different from false positives?

False positives occur in women who do not have breast cancer. These women have an abnormal screening result, but then extra tests (see above) show they **do not** have cancer. By contrast, in cases of over-detection the women **do** have breast cancer confirmed by further tests, so they get a cancer diagnosis and treatment (see below).

### 3. How is breast cancer treated?

As part of their treatment, nearly all women with breast cancer have surgery. Most also have radiotherapy or hormone therapy, and some have chemotherapy. For more information on breast cancer treatments, see below.



Nearly all breast cancer patients have **surgery** to either remove the cancer and a bit of surrounding tissue or to remove the whole breast. In addition, one or more of the other treatments described here may be recommended.



**Hormone therapy** blocks certain hormones in the body that may be contributing to tumour growth. Common side effects include hot flushes, vaginal dryness, and reduced libido (sex drive).



**Radiotherapy** uses X-rays to destroy cancer cells in the breast or stop them from growing. Common side effects include tiredness, and the skin of the breast becoming dry and red or darker in colour.



Some breast cancer patients have **chemotherapy**, which uses drugs to destroy cancer cells. Common side effects include nausea and vomiting, tiredness, hair loss, and diarrhoea or constipation.

**4. If I am diagnosed with breast cancer, can I just wait and see if it is growing fast or not before I decide about treatment, or maybe try alternative therapies instead?**

Once a breast cancer is found, doctors cannot be sure whether it can safely be left alone. This is why they recommend treatment.

**5. Can I screen using ultrasound or some other test instead, or combine multiple tests?**

Mammograms are the only tool scientifically shown to work for breast cancer screening in the general population. Having other tests instead of mammograms, or as well, cannot avoid over-detection and has not been shown to have any health benefits.

**6. How do we know that over-detection exists?**

Over-detection research compares groups (populations) with and without screening. For example, there have been big studies that randomly allocated women to be invited to screening or not. This made two groups that were the same in every way; the only difference between them was whether or not they were offered screening. When researchers followed these groups over many years, they found that more women in the screened group were diagnosed with breast cancer. The reason is that some of the cancers found by screening would never cause symptoms; otherwise the unscreened group of women would have just as many cancers diagnosed.

## Making a choice: summary over 20 years with and without screening

Key questions	Screening (over 20 years, from age 50)	No screening (over 20 years, from age 50)
<b>1. What are the chances of dying from breast cancer?</b>	8 out of 1000 women die from breast cancer.	12 out of 1000 women die from breast cancer.
<b>2. What are the chances of being diagnosed and treated for a breast cancer that is not harmful?</b>	19 out of 1000 women are diagnosed and treated for a breast cancer that is not harmful (over-detection).	Women who do not have screening will not experience over-detection caused by screening.
<b>3. What are the chances of having a false positive screening result that leads to extra testing?</b>	412 out of 1000 women have a false positive result and extra testing, when they do not have cancer.	Women who do not have screening will not experience a false positive screening result.
<b>4. What would I need to do?</b>	<p>If you decide to start screening, you will be invited to have another mammogram every 2 years.</p> <p>If you have any breast symptoms, see your doctor.</p>	<p>If you decide not to start screening now, you can always reconsider in the future.</p> <p>If you have any breast symptoms, see your doctor.</p>

**Key scientific articles:** (1) Barratt A, Howard K, Irwig L, Salkeld G, Houssami N. Model of outcomes of screening mammography: information to support informed choices. *British Medical Journal* 2005; 330: 936. (2) Independent UK Panel on Breast Cancer Screening. The benefits and harms of breast cancer screening: an independent review. *Lancet* 2012; 380: 1778.

## List of medical terms and what they mean

**abnormal** not normal

**biopsy** taking a small sample of tissue or cells from the body, mostly with a needle

**breast cancer** collection of cells in the breast that grow and multiply abnormally, which in some cases can spread (metastasise) to other areas of the body

**breast screening** having mammograms to look for early signs of breast cancer

**cells** the basic units of living things such as plants, animals and people

**chemotherapy** drug treatment to kill cancer cells or stop them growing so fast

**clinical examination** examination by a doctor to look and feel for signs of illness

**false positive** abnormal test result in a person who does not have the illness

**gene mutation** problem in a gene that may increase the risk of certain diseases

**hormone therapy** drug treatment to stop cancer responding to certain hormones

**over-detection / over-diagnosis** finding a hidden illness through screening that would otherwise never cause any symptoms or health problems in the person's life

**radiotherapy** treatment using strong x-rays to kill cancer cells or stop their growth

**screening mammogram** test using x-rays to make images of the breasts to look for early signs of cancer in women who have not noticed any breast symptoms

**surgery** operation, for example to remove a part of the body affected by illness

**symptoms** changes in the body, like pain or a lump, that may be due to illness

**ultrasound scan** test using sound waves to make images of a part of the body

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If you want to know more about breast cancer risk, you may find this website useful: [www.canceraustralia.gov.au/affected-cancer/cancer-types/breast-cancer/your-risk/calculate](http://www.canceraustralia.gov.au/affected-cancer/cancer-types/breast-cancer/your-risk/calculate)

This booklet was developed in 2013 by members of the Screening and Test Evaluation Program at The University of Sydney, Australia.

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THE UNIVERSITY OF  
SYDNEY



# Breast cancer screening: It's your choice

New information to help women aged  
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# Introduction

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The next few pages of the booklet contain some diagrams showing different things that may happen to women who have breast screening. Each diagram shows 1000 women who have a screening mammogram every 2 years for a period of 20 years, starting when they are 50 years old.



### **There are 2 important things to know:**

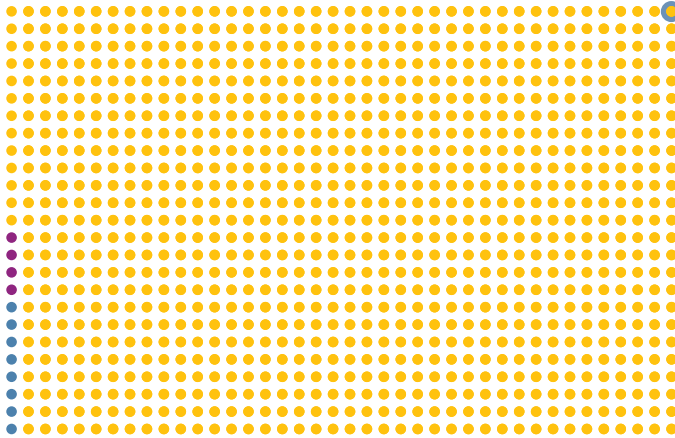
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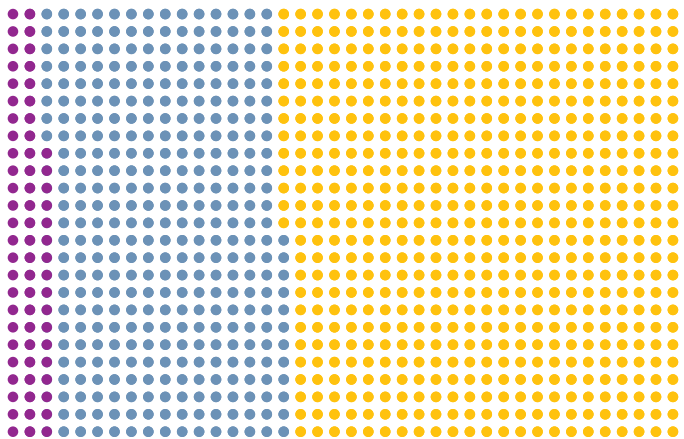
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<b>3. What would I need to do?</b>	<p>If you decide to start screening, you will be invited to have another mammogram every 2 years.</p> <p>If you have any breast symptoms, see your doctor.</p>	<p>If you decide not to start screening now, you can always reconsider in the future.</p> <p>If you have any breast symptoms, see your doctor.</p>

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## Knowledge questions

QK1. What is a SCREENING mammogram?

- # 1. A mammogram you have when you're healthy
- 2. A mammogram you have if you notice a change or lump in your breast

BC2. Do you think a screening mammogram will find every breast cancer?

- # 1. YES
- 2. NO

FC1. Do all women with an abnormal screening mammogram result have breast cancer?

- # 1. YES
- 2. NO

BC1. Who do you think is more likely to die from breast cancer?

- # 1. Women who have screening mammograms
- 2. Women who do not have screening mammograms

OC1. Who do you think is more likely to be diagnosed with breast cancer?

- # 1. Women who have screening mammograms
- 2. Women who do not have screening mammograms

I'll now read some statements about breast screening and ask you to tell me whether each one is true or false.

OC2. All breast cancers will eventually cause illness and death if they are not found and treated.

- # 1. TRUE
- 2. FALSE

OC3. When screening finds cancer, doctors can reliably predict whether it will ever cause harm.

- # 1. TRUE
- 2. FALSE

OC4. Even breast cancers that may not cause any health problems are likely to be treated.

- # 1. TRUE
- 2. FALSE

OC5. Screening leads some women with a harmless cancer to get treatment they do not need.

- # 1. TRUE
- 2. FALSE

OC6. Screening finds harmless cancers more often than it prevents death from breast cancer.

- # 1. TRUE
- 2. FALSE

OC7. Which of these 2 statements best describes over-detection?

- # 1. Screening finds a cancer that would never have caused trouble
- 2. Screening finds an abnormality but extra tests show it is not cancer

For the next few questions, I would like you to imagine 1000 ordinary women who are 50 years old.

BN1. If these 1,000 women have breast screening every 2 years for 20 years, in that time about how many women do you think will avoid dying from breast cancer because of screening?

BN2. If these 1,000 women have breast screening every 2 years for 20 years, about how many do you think will STILL die from breast cancer in that time?

ON1. If these 1,000 women have screening every 2 years for 20 years, in that time about how many will be diagnosed and treated for a breast cancer that is not harmful?

FN1. If these 1,000 women have breast screening every 2 years for 20 years, about how many women will have a false positive; that is, have an abnormal mammogram result, go for extra testing and find out they do NOT have cancer?



Knowledge marking scheme

Topic	CONCEPTUAL KNOWLEDGE	NUMERIC KNOWLEDGE		Total
	multiple choice items: marks for right answers	free response items: marks for absolute values	eXtra marks for relative values about right	
<b>Benefit including false negatives</b>	BC1. Screened women less likely to die of BC 2 marks if correct	BN1. Reduction in risk of BC death if screened 2 marks if 2-8; 1 mark if 1 or 9-12	BX. Relationship: deaths to deaths avoided 1 mark if $BN2 \geq BN1$	<b>8</b>
	BC2. Screening will not find every BC 1 mark if correct	BN2. Remaining risk of BC death if screened 2 marks if 4-16; 1 mark if 3 or 17-24		
<b>False positives</b>	FC1. Not all with abnormal result have BC 1 mark if correct	FN1. Risk of false positive due to screening 2 marks if 287-537; 1 mark if 162-286 or 538-662	FX. Relationship: FPs to deaths avoided 1 mark if $FN1 \geq 10x BN1$	<b>4</b>
<b>Over-detection</b>	OC1. Screened women more likely diagnosed 1 mark if correct	ON1. Risk of over-detection due to screening 2 marks if 10-38; 1 mark if 6-9 or 39-57	OX. Relationship: ODx to deaths avoided 1 mark if $ON1 > BN1$	<b>10</b>
	OC2. Not all BCs would cause illness and death 1 mark if correct			
	OC3. Can't predict whether BC will cause harm 1 mark if correct			
	OC4. BC that may not cause problems is treated 1 mark if correct			
	OC5. Some get treatment they don't need 1 mark if correct			
	OC6. Find harmless C more than prevent death 1 mark if correct			
	OC7. Over-detection v. false positive distinction 1 mark if correct			
<b>Total</b>	<b>11 marks in total for conceptual knowledge</b>	8 marks for numeric knowledge (absolute)	3 marks for numeric knowledge (relative)	<b>22</b>

To demonstrate adequate knowledge, the respondent must **meet the threshold for all 3 screening outcome scales** (benefit, false positives, and over-detection).

To meet the threshold for each of the 3 scales, the respondent must score at least **50% of the total marks available, including at least 1 numeric mark.**

## Sensitivity analysis for primary outcome using alternative criteria to define adequate knowledge

Outcome	Intervention DA (n=419)	Control DA (n=419)	Difference (95% CI)	p value
Knowledge (conceptual only)	<i>no. meeting threshold (%)</i>			
Breast cancer mortality benefit: 100% correct	370 (88)	382 (91)	-2.9 (-7.0 to 1.2)	.17
False positives: 100% correct	415 (99)	418 (99.8)	-0.7 (-1.8 to 0.3)	.18
Overdetection: 70% correct	279 (67)	93 (22)	44.4 (38.4 to 50.4)	<.0001
Adequate conceptual knowledge overall	248 (59)	87 (21)	38.4 (32.3 to 44.5)	<.0001
Attitudes towards having breast screening *	<i>n (%)</i>			
Positive attitudes (scores $\geq 24$ )	282 (69)	340 (83)	-14.4 (-20.1 to -8.6)	<.0001
Intentions about having breast screening	<i>n (%)</i>			
Intending to have screening	308 (74)	363 (87)	-13.1 (-18.5 to -7.8)	<.0001
Informed choice (conceptual knowledge only) †	<i>n (%)</i>			
Made an informed choice	203 (50)	79 (19)	30.3 (24.1 to 36.4)	<.0001

For some variables a small proportion of data was missing (maximum 21 cases).

\* Scores could range from 6 to 30, higher scores being more positive attitudes. A small proportion of data was missing (21 cases).

† Adequate knowledge and intentions consistent with attitudes. Participants missing attitudes data were excluded from analysis.