PSYCHOSOCIAL AND DECISION PROCESS EFFECTS OF INFORMATION ABOUT OVERDETECTION IN A BREAST SCREENING DECISION AID

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STEP SCREENING & TEST EVALUATION PROGRAM

BACKGROUND AND RATIONALE

- Breast screening can lead to overdetection / overdiagnosis and overtreatment of inconsequential breast cancers
  - Harm to emotional wellbeing, physical health in short/long term

- Women unaware of risk of overdetection
  - Prevents them being able to make informed decisions about participation in screening
- Lack of evidence regarding effects of giving women information about overdetection

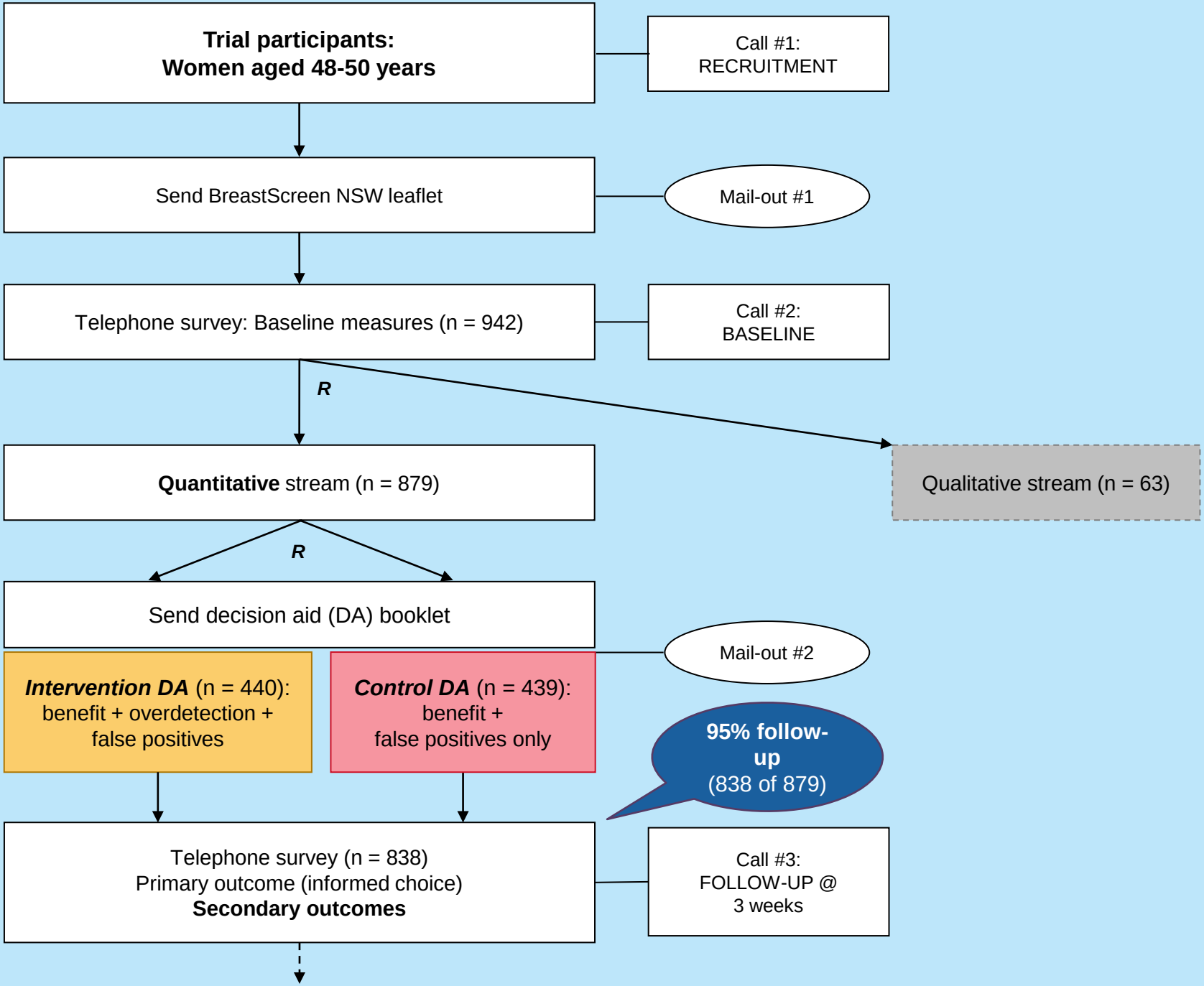
RESEARCH QUESTIONS

› What are the consequences of providing **written information about overdetection of breast cancer** to women approaching the age of invitation to breast screening?

- Can overdetection information (in a decision aid) improve informed choice about breast screening?

- How does information affect decision process (decisional conflict, confidence) and psychosocial outcomes (anxiety, perceived risk, breast cancer worry, anticipated regret)?

- How do women evaluate the decision aid?


Trial participants:
Women aged 48-50 years
Call #1:
RECRUITMENT
Send BreastScreen NSW leaflet
Mail-out #1
Telephone survey: Baseline measures (n = 942)
Call #2:
BASELINE
R
Quantitative stream (n = 879)
Qualitative stream (n = 63)
R
Send decision aid (DA) booklet
Mail-out #2
Intervention DA (n = 440):
benefit + overdetection +
false positives
Control DA (n = 439):
benefit +
false positives only
95% follow-up
(838 of 879)
Telephone survey (n = 838)
Primary outcome (informed choice)
Secondary outcomes
Call #3:
FOLLOW-UP @
3 weeks

2. Screening leads to finding some breast cancers that are not harmful (over-detection)*

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,

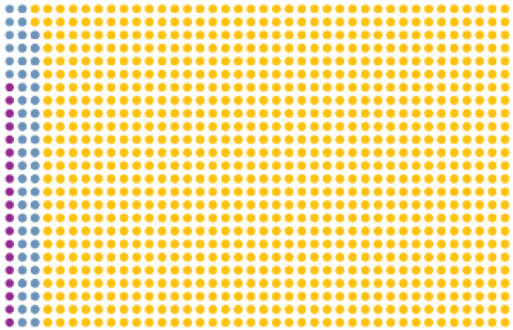
73 women are diagnosed with breast cancer.

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.

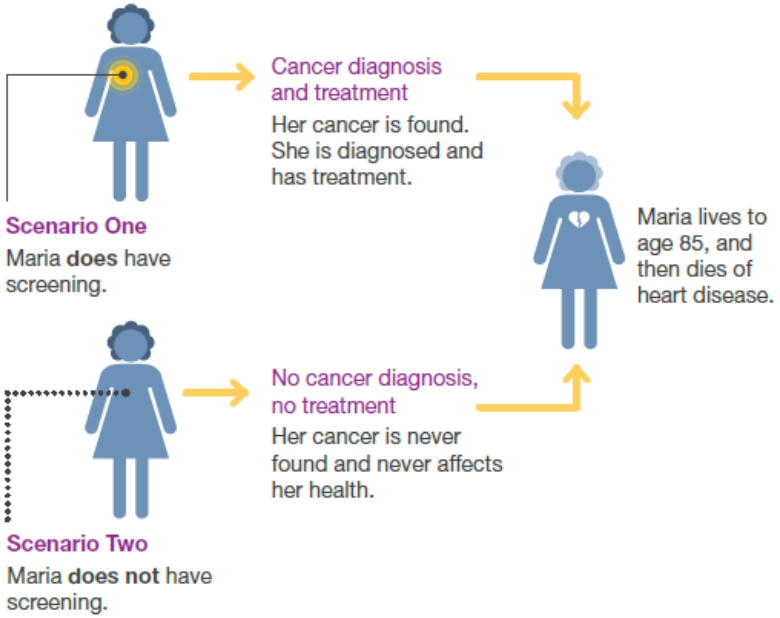


- extra woman diagnosed with breast cancer due to over-detection
- woman diagnosed with breast cancer that is not over-detection
- woman not diagnosed with breast cancer

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.



Scenario One

Maria **does** have screening.

Scenario Two

Maria **does not** have 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.

RESULTS: PSYCHOSOCIAL

Outcome	Intervention Group	Control Group	P value
Anxiety *(STAI-short 20-80)*	29.7	29.6	.9
Perceived risk *(absolute)* No chance Low chance Medium / high chance	 5% 60% 35%	 5% 54% 41%	.2
Perceived risk *(relative)* Much / a bit lower About the same A bit / much higher	 37% 55% 8%	 33% 58% 9%	.8

RESULTS: PSYCHOSOCIAL

Outcome	Intervention Group	Control Group	P value
Worry about breast cancer			<.01
Not worried at all	42%	32%	
A bit / quite / very worried	58%	68%	
Anticipated regret *(not screen)*			<.01
Strongly agree	36%	49%	
Agree	38%	35%	
(Strongly) disagree / neither	26%	16%	
Anticipated regret *(do screen)*			<.01
(Strongly) agree / neither	26%	13%	
Disagree	44%	42%	
Strongly disagree	29%	44%	

RESULTS: DECISION PROCESS

Outcome	Intervention Group	Control Group	P value
Decisional conflict *(DCS 0-100)* 0 1-24 ≥25	12.6 49% 29% 22%	12.2 50% 30% 20%	.8
Confidence in decision making *(scale 1-5)*	4.35	4.53	<.01

RESULTS: ACCEPTABILITY

Outcome	Intervention Group	Control Group	P value
DA clear & easy to understand			<.01
Strongly agree	35%	52%	
Agree	51%	42%	
(Strongly) disagree / neither	14%	6%	
Would recommend DA			<.01
Strongly agree	34%	50%	
Agree	49%	39%	
(Strongly) disagree / neither	17%	11%	
How balanced did you find DA			<.01
Slanted towards screening	21%	31%	
Completely balanced	43%	52%	
Slanted away from screening	36%	17%	

CONCLUSIONS

- Including information on overdetection in a decision aid
  - (Increased knowledge and informed choice)
  - Reduced breast cancer worry
  - Did not raise anxiety or decisional conflict
  - Slightly reduced confidence in decision making
  - Made decision aid slightly less ‘clear and easy to understand’
  - Affected perceptions of balance of decision aid

- This information challenged women’s expectations
  - Need to ensure women are supported in making their decisions

Use of a decision aid including information on overdetection to support informed choice about breast cancer screening: a randomised controlled trial

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Lancet 2015; 385: 1642–52

Published Online
February 18, 2015
http://dx.doi.org/10.1016/S0140-6736(15)60123-4

This online publication has been corrected. The corrected version first appeared at thelancet.com on March 26, 2015

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Summary

Background Mammography screening can reduce breast cancer mortality. However, most women are unaware that inconsequential disease can also be detected by screening, leading to overdiagnosis and overtreatment. We aimed to investigate whether including information about overdetection of breast cancer in a decision aid would help women aged around 50 years to make an informed choice about breast screening.

Methods We did a community-based, parallel-group, randomised controlled trial in New South Wales, Australia, using a random cohort of women aged 48–50 years. Recruitment to the study was done by telephone; women were eligible if they had not had mammography in the past 2 years and did not have a personal or strong family history of breast cancer. With a computer program, we randomly assigned 879 participants to either the intervention decision aid (comprising evidence-based explanatory and quantitative information on overdetection, breast cancer mortality reduction, and false positives) or a control decision aid (including information on breast cancer mortality reduction and false positives). Participants and interviewers were masked to group assignment. The primary outcome was informed choice (defined as adequate knowledge and consistency between attitudes and screening intentions), which we assessed by telephone interview about 3 weeks after random allocation. The primary outcome was analysed in all women who completed the relevant follow-up interview questions fully. This trial is registered with the Australian New Zealand Clinical Trials Registry, number ACTRN12613001035718.

Findings Between January, 2014, and July, 2014, 440 women were allocated to the intervention group and 439 were assigned to the control group. 21 women in the intervention group and 20 controls were lost to follow-up; a further ten women assigned to the intervention and 11 controls did not answer all questions on attitudes. Therefore, 409 women in the intervention group and 408 controls were analysed for the primary outcome. 99 (24%) of 409 women in the intervention group made an informed choice compared with 63 (15%) of 408 in the control group (difference 9%, 95% CI 3–14; p=0·0017). Compared with controls, more women in the intervention group met the threshold for adequate overall knowledge (122/419 [29%] *vs* 71/419 [17%]; difference 12%, 95% CI 6–18; p<0·0001), fewer women expressed positive attitudes towards screening (282/409 [69%] *vs* 340/408 [83%]; 14%, 9–20; p<0·0001), and fewer women intended to be screened (308/419 [74%] *vs* 363/419 [87%]; 13%, 8–19; p<0·0001). When conceptual knowledge alone was considered, 203 (50%) of 409 women in the intervention group made an informed choice compared with 79 (19%) of 408 in the control group (p<0·0001).

Interpretation Information on overdetection of breast cancer provided within a decision aid increased the number of women making an informed choice about breast screening. Becoming better informed might mean women are less likely to choose screening.

Funding Australian National Health and Medical Research Council.

ACKNOWLEDGEMENTS

- Kirsten McCaffery, Jesse Jansen, Les Irwig, Alex Barratt
- Nehmat Houssami, Kevin McGeechan, Haryana Dhillon
- Gemma Jacklyn, Hazel Thornton, Jenn Kidd

  - National Health and Medical Research Council
    - Screening and Test Evaluation Program

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