SUPPLEMENTARY MATERIAL FOR THE ARTICLE ENTITLED:

Informing women about overdetection in breast cancer screening: Two-year outcomes from a randomized trial

Supplementary Methods

Measurement of outcomes

The study follow-up questionnaire was administered during a structured, computer-assisted telephone interview.

Anxiety

Short-form state scale of Spielberger State-Trait Anxiety Inventory – Marteau & Bekker, Br J Clin Psychol 1992.

For each statement describe how you feel right now, at this moment.

You feel calm
You are tense
You feel upset
You are relaxed
You feel content
You are worried

- Not at all / Somewhat / Moderately / Very much

Attitudes to breast screening

Adapted from Dormandy et al, Patient Educ Couns 2012.

I'll now read you some statements. Please tell me how strongly you agree or disagree.

For you, having breast screening is: Beneficial
For you, having breast screening is: A good thing
For you, having breast screening is: Harmful
For you, having breast screening is: Worthwhile
For you, having breast screening is: Important
For you, having breast screening is: A bad thing

- Strongly agree / Agree / Neither agree nor disagree / Disagree / Strongly disagree

Screening participation

Since we last interviewed you for this study, have you had a mammogram at all for any reason? If so…

There are different places where you might have had that mammogram [explanation provided].
Did you have your mammogram as part of the BreastScreen program or in the private system?

When you had your mammogram, was it because you already thought you might have had some problems with your breasts?

Decision regret

Measured using the Decision Regret Scale – Brehaut et al, Med Decis Making 2003.

Please reflect on the decision you made recently about whether or not to have breast screening in the next few years. Please tell me how strongly you agree or disagree with these statements regarding that decision.

It was the right decision.
You regret the choice that was made.
You would go for the same choice if you had to do it over again.
The choice did you a lot of harm.
The decision was a wise one.

- Strongly agree / Agree / Neither agree nor disagree / Disagree / Strongly disagree

Quality of life

Consequences of Screening in Breast Cancer (COS-BC) – Brodersen & Thorsen, Scand J Prim Hlth Care 2008.

Sometimes, after women have had screening or just considered it, they find themselves thinking about breast cancer a lot. The next few questions all ask whether thoughts about breast cancer have affected you in everyday life. I'll now read you some statements. For each statement, please tell me to what extent, over the last week, you have felt this because of thoughts about breast cancer.

You have felt scared.
You have slept badly.
You have felt sad.
You have been worried.
You have been irritable.
You have felt terrified.
You have been quieter than normal.
You have kept busy to take your mind off things.
You have found it hard to concentrate.
You have felt time passed slowly.
Your appetite has changed.
You have been worried about your future.
You have been upset.
You have examined your breasts.
You have felt restless.
You have been nervous.
You have been uneasy.
It has taken you a long time to fall asleep.
You have examined your breasts in the mirror.
You have withdrawn into yourself.
You have felt unable to cope.
You have been depressed.
You have had difficulty dealing with your work or other commitments.
You have woken up far too early in the morning.
You have had difficulty doing everyday things around the house.
You have been awake most of the night.
You have felt less attractive.

- Not at all / A bit / Quite a bit / A lot

These items may seem a bit personal but we ask because some women are affected in these ways. Again, these questions refer to thoughts about breast cancer over the last week.

You have felt less interest in sex.
You have not felt like having your breast touched.

- Not at all / A bit / Quite a bit / A lot

Intentions about breast screening

At the moment, which of the following best describes your intentions about having breast screening within the next 2-3 years?

- You definitely will have breast screening
- You are likely to have breast screening
- You are unsure
- You are not likely to have breast screening
- You definitely will not have breast screening

Knowledge

Conceptual items

BC2. Do you think a screening mammogram will find every breast cancer?
- YES [0]
- NO [1]

FC1. Do all women with an abnormal screening mammogram result have breast cancer?
- YES [0]
- NO [1]

BC1. Who do you think is more likely to die from breast cancer?
- Women who have screening mammograms [0]
- Women who do not have screening mammograms [2]

OC1. Who do you think is more likely to be diagnosed with breast cancer?
- Women who have screening mammograms [1]
- Women who do not have screening mammograms [0]

OC2. All breast cancers will eventually cause illness and death if they are not found and treated.
- TRUE [0]
- FALSE [1]

OC3. When screening finds cancer, doctors can reliably predict whether it will ever cause harm.
- TRUE [0]
- FALSE [1]

OC4. Even breast cancers that may not cause any health problems are likely to be treated.
- TRUE [1]
- FALSE [0]

OC5. Screening leads some women with a harmless cancer to get treatment they do not need.
- TRUE [1]
- FALSE [0]

OC6. Screening finds harmless cancers more often than it prevents death from breast cancer.
- TRUE [1]
- FALSE [0]

OC7. Which of these two statements best describes over-detection?
- Screening finds a cancer that would never have caused trouble [1]
- Screening finds an abnormality but extra tests show it is not cancer [0]

Numerical items

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?

For the full marking scheme and details of thresholds used, please see Hersch et al, Lancet 2015.

Anticipated regret

Adapted from Sandberg & Conner, Br J Soc Psychol 2009.

If you do NOT have breast screening in the next few years, you may later wish you DID.
If you DO have breast screening in the next few years, you may later wish you did NOT.

- Strongly agree / Agree / Neither agree nor disagree / Disagree / Strongly disagree

Worry about breast cancer

Adapted from Sutton et al, J Epidemiol Community Health 1994.

How worried are you about developing breast cancer?

- Not worried at all / A bit worried / Quite worried / Very worried

Perceived risk of breast cancer

Adapted from Ziarnowski et al, Prev Med 2009 and Lipkus et al, J Risk Res 2005.

How likely do you think it is that you will develop breast cancer in your lifetime?

- No chance / Low chance / Medium chance / High chance

Compared with the average woman your age, how would you rate your chances of developing breast cancer sometime in your life?

- Much lower / A bit lower / About the same / A bit higher / Much higher

Consent for access to screening data

Participants were invited to consent for their screening records (BreastScreen and/or Medicare data) to be checked for the period 1 January 2014 to 31 December 2016. We posted an information statement, consent form, and prepaid return envelope. The statement explained the request, information to be checked, data storage and destruction procedures, and contact details for queries. We made clear that if the woman chose not to return the consent form, her data would not be accessed. Women consenting for linkage were more likely to have been born in Australia or New Zealand, be married or living with a partner, have positive baseline screening intentions, be in the control group, and report having had a mammogram during trial follow-up (**Supplementary Table 5**).

Data linkage

Data matching for the BreastScreen and Medicare data was conducted by the Centre for Health Record Linkage (CHeReL) and the Department of Human Services, respectively. Personal identifiers used for matching included name, date of birth, address, country of birth, and Medicare number. The time frame was from randomisation (in 2014) until December 2016.

To assess the agreement between women's self-reported attendance and externally documented attendance, we cross-tabulated the proportions of women who did and did not report having a mammogram according to each data source (**Supplementary Table 6**).

Analysis of linked screening data

We compared the time from receipt of the decision aid to screening attendance for women in the intervention versus control groups using survival models. These models adjusted for characteristics collected at baseline that were likely to be associated with attendance (e.g., education level, remoteness of residence, and screening attitudes and intentions prior to intervention). To accommodate any time-varying effect of the intervention, we included in the survival model an interaction term between study group and time. We compared the proportion of women in the intervention and control groups who had a mammogram between January 2014 and December 2016. We performed sensitivity analyses (i) excluding women who reported symptoms at the time of BreastScreen attendance (because the program is intended for asymptomatic women) and (ii) using booking date instead of attendance date (because making an appointment represents the woman's first step to enacting her decision to screen); neither of these sensitivity analyses changed results. We used multiple imputation models to explore the impact of including trial participants who did not give consent to have their screening data linked (for whom the outcome is missing).

Supplementary Tables

Supplementary Table 1: Baseline characteristics of participants completing 2-year follow-up vs not, among all those randomised (n=879)[a]

	Followed up at 2 years (n=712)		Not followed up at 2 years (n=167)		p value
Age					
48-49 years	504	(71%)	119	(72%)	0.84
50 years	207	(29%)	47	(28%)	
Education					
School only / trade certificate	390	(55%)	93	(56%)	0.71
Diploma /university degree	322	(45%)	72	(44%)	
Employment					
In paid work	592	(83%)	139	(84%)	0.86
Not in paid work	120	(17%)	27	(16%)	
Country of birth					
Australia / New Zealand	587	(82%)	127	(76%)	0.06
Other	125	(18%)	40	(24%)	
Marital status					
Married / living with partner	569	(80%)	129	(77%)	0.44
Not married / living with partner	143	(20%)	38	(23%)	
Residence					
Major cities	456	(64%)	113	(68%)	0.38
Regional / remote	256	(36%)	54	(32%)	
Attitudes to breast screening					
Scores 24-30 (‘positive attitudes’)	619	(87%)	146	(88%)	0.76
Scores 6-23	92	(13%)	20	(12%)	
Intentions about breast screening					
Intending to be screened	645	(91%)	147	(88%)	0.32
Not intending to be screened / unsure	67	(9%)	20	(12%)	
Study group					
Intervention	358	(50%)	82	(49%)	0.78
Control	354	(50%)	85	(51%)	

[a]Data are number of participants (%). For some variables, data are missing for one or two women. Additional details about baseline characteristics have been published previously (Hersch et al, Lancet 2015).

Supplementary Table 2: Additional outcomes, mean scores[a]

	Possible range	<1 month		6 months		1 year		2 years		$P_{interaction}$[b]
		Int (n=419)	Con (n=419)	Int (n=396)	Con (n=394)	Int (n=371)	Con (n=375)	Int (n=358)	Con (n=354)	
All knowledge subscales										
Conceptual	0–11	8.85 [c]	7.33 [c]	--	--	8.03 [c]	7.31 [c]	7.91 [c]	7.31 [c]	<0.001
Numerical	0–11	4.64	4.50	--	--	1.70	1.58	1.66	1.58	0.94
Total	0–22	13.49 [c]	11.84 [c]	--	--	9.73 [c]	8.89 [c]	9.57 [c]	8.89 [c]	0.004
Mortality benefit subscale										
Conceptual	0–3	2.81	2.86	--	--	2.78	2.76	2.72	2.71	0.33
Numerical	0–5	2.19	2.37	--	--	0.60	0.54	0.54	0.49	0.28
Total	0–8	5.00	5.22	--	--	3.38	3.30	3.27	3.20	0.14
False positives subscale										
Conceptual	0–1	0.99	1.00	--	--	1.00	0.99	0.98	0.99	0.10
Numerical	0–3	1.31 [c]	1.57 [c]	--	--	0.62	0.68	0.66	0.71	0.13
Total	0–4	2.30 [c]	2.56 [c]	--	--	1.62	1.67	1.64	1.70	0.11
Overdetection subscale										
Conceptual	0–7	5.05 [c]	3.48 [c]	--	--	4.26 [c]	3.56 [c]	4.20 [c]	3.61 [c]	<0.001
Numerical	0–3	1.14 [c]	0.57 [c]	--	--	0.48 [c]	0.37 [c]	0.46	0.38	<0.001
Total	0–10	6.19 [c]	4.05 [c]	--	--	4.74 [c]	3.92 [c]	4.66 [c]	3.99 [c]	<0.001
Intentions about screening	1–5	4.09 [c]	4.42 [c]	--	--	--	--	4.30	4.43	0.002
Anxiety	20–80	29.71	29.64	32.45	32.73	31.74	32.17	31.76	32.98	0.62
Breast cancer worry	1–4	1.67 [c]	1.84 [c]	1.60 [c]	1.72 [c]	1.58 [c]	1.70 [c]	1.63	1.68	0.09
Anticipated regret										
Regret if do not screen	1–5	3.94 [c]	4.22 [c]	--	--	--	--	4.05 [c]	4.19 [c]	0.07
Regret if do screen	1–5	2.09 [c]	1.81 [c]	--	--	--	--	2.01 [c]	1.82 [c]	0.20
Perceived risk of breast cancer										
Risk in absolute terms	1–4	2.31	2.39	2.30	2.37	2.33	2.36	2.21	2.26	0.60
Relative to average woman	1–5	2.62	2.68	2.67	2.73	2.63	2.70	2.55	2.61	0.99
Decision regret[d]	0–100	--	--	17.83 [c]	15.56 [c]	18.28	16.60	--	--	0.67

[a]For some variables, data are missing (max. 23 cases in one round). Int=Intervention group. Con=Control group.

[b]P values are for the group x time interaction.

[c]This symbol indicates a significant group difference at that time point.

[d]Decision regret was not assessed at 2-year follow-up (programming error).

Supplementary Table 3: Model-estimated group differences by time[a]

	<1 month		**6 months**		**1 year**		**2 years**		$P_{interaction}$[b]
	Difference	95% CI	Difference	95% CI	Difference	95% CI	Difference	95% CI	
All knowledge subscales									
Conceptual	1.52	1.30, 1.73	--	--	0.70	0.47, 0.93	0.60	0.36, 0.84	<0.001
Numerical	0.14	-0.32, 0.60	--	--	0.12	-0.14, 0.38	0.07	-0.18, 0.33	0.94
Total	1.66	1.11, 2.21	--	--	0.83	0.45, 1.21	0.68	0.30, 1.05	0.004
Mortality benefit subscale									
Conceptual	-0.05	-0.12, 0.02	--	--	0.02	-0.07, 0.10	0.01	-0.09, 0.12	0.33
Numerical	-0.17	-0.45, 0.11	--	--	0.06	-0.09, 0.21	0.05	-0.09, 0.19	0.28
Total	-0.22	-0.52, 0.07	--	--	0.07	-0.10, 0.25	0.06	-0.10, 0.23	0.14
False positives subscale									
Conceptual	-0.01	-0.02, 0.00	--	--	0.01	-0.01, 0.02	-0.01	-0.02, 0.01	0.10
Numerical	-0.25	-0.42, -0.08	--	--	-0.05	-0.18, 0.07	-0.06	-0.19, 0.07	0.14
Total	-0.26	-0.43, -0.09	--	--	-0.05	-0.18, 0.08	-0.07	-0.20, 0.06	0.11
Overdetection subscale									
Conceptual	1.58	1.38, 1.78	--	--	0.68	0.47, 0.89	0.60	0.38, 0.81	<0.001
Numerical	0.56	0.43, 0.70	--	--	0.11	0.00, 0.22	0.08	-0.03, 0.19	<0.001
Total	2.14	1.88, 2.40	--	--	0.79	0.54, 1.04	0.68	0.42, 0.93	<0.001
Attitudes to breast screening[c]	-1.30	-1.78, -0.82	--	--	-0.77	-1.24, -0.30	-0.49	-0.98, -0.00	0.008
Intentions about screening[c]	-0.29	-0.40, -0.18	--	--	--	--	-0.09	-0.20, 0.03	0.002
Anxiety	0.07	-1.43, 1.57	-0.28	-2.09, 1.52	-0.23	-1.89, 1.42	-1.16	-2.89, 0.57	0.62
Breast cancer worry	-0.17	-0.27, -0.08	-0.11	-0.20, -0.03	-0.11	-0.20, -0.03	-0.05	-0.14, 0.04	0.09
Anticipated regret, do not screen	-0.27	-0.41, -0.13	--	--	--	--	-0.14	-0.27, -0.01	0.07
Anticipated regret, do screen	0.28	0.15, 0.42	--	--	--	--	0.19	0.07, 0.32	0.20
Perceived risk of breast cancer	-0.08	-0.16, 0.00	-0.07	-0.15, 0.01	-0.03	-0.11, 0.05	-0.06	-0.13, 0.02	0.60
Perceived risk, in relative terms	-0.07	-0.17, 0.04	-0.06	-0.17, 0.05	-0.08	-0.19, 0.04	-0.06	-0.18, 0.05	0.99
Decision regret	--	--	2.23	0.37, 4.09	1.77	-0.28, 3.81	--	--	0.67
Quality of life	--	--	-0.69	-1.40, 0.01	-0.35	-1.10, 0.40	0.00	-0.53, 0.52	0.10

[a]Model-estimated differences in means (intervention – control), with confidence intervals.
[b]P value for group-by-time interaction.
[c]Model includes baseline scores.

Supplementary Table 4: Model-estimated group odds ratios by time[a]

	<1 month		**6 months**		**1 year**		**2 years**		$P_{interaction}$[b]
	Odds ratio	95% CI	Odds ratio	95% CI	Odds ratio	95% CI	Odds ratio	95% CI	
Adequate knowledge (conceptual only)									
Breast cancer mortality benefit	0.73	0.47, 1.15	--	--	1.23	0.82, 1.83	1.11	0.81, 1.53	0.12
False positives	0.25	0.03, 2.23	--	--	2.85	0.59, 13.66	1.00	0.67, 1.52	0.10
Overdetection	6.99	5.14, 9.50	--	--	2.54	1.86, 3.47	2.08	1.52, 2.84	<0.001
Across all subscales	5.53	4.08, 7.52	--	--	2.62	1.89, 3.63	2.04	1.46, 2.85	<0.001
Adequate knowledge (incl. numerical)									
Breast cancer mortality benefit	1.18	0.89, 1.56	--	--	1.29	0.93, 1.78	1.17	0.84, 1.62	0.86
False positives	0.71	0.53, 0.94	--	--	0.95	0.71, 1.28	0.93	0.70, 1.23	0.27
Overdetection	3.34	2.50, 4.46	--	--	1.66	1.16, 2.37	1.59	1.12, 2.26	<0.001
Across all subscales	2.01	1.45, 2.80	--	--	1.33	0.69, 2.55	1.17	0.62, 2.21	0.28
Positive attitude to screening (score≥24)	0.42	0.29, 0.61	--	--	0.53	0.36, 0.79	0.89	0.59, 1.34	0.004
Intending to screen (definitely/likely)	0.39	0.26, 0.58	--	--	--	--	0.81	0.52, 1.26	<0.001
Heightened decision regret[c] (score >25)	--	--	1.14	0.77, 1.69	1.21	0.82, 1.79	--	--	0.81
Had a mammogram (self-reported)	--	--	0.72	0.50, 1.04	1.03	0.76, 1.40	0.97	0.73, 1.29	0.03

[a]Model-estimated odds ratios for group proportions (intervention versus control), with confidence intervals.

[b]P value for group-by-time interaction.

[c]Decision regret was not assessed at 2-year follow-up due to programming error.

Supplementary Table 5: Baseline characteristics and screening behaviour during trial follow-up of participants giving consent for data linkage vs not, among all those followed up at 2 years (n=712)[a]

	Consented to data linkage (n=418)		Did not consent to linkage (n=294)		p value
Age					
48-49 years	299	(72%)	205	(70%)	0.65
50 years	119	(28%)	88	(30%)	
Education					
School only / trade certificate	223	(53%)	167	(57%)	0.36
Diploma /university degree	195	(47%)	127	(43%)	
Employment					
In paid work	357	(85%)	235	(80%)	0.06
Not in paid work	61	(15%)	59	(20%)	
Country of birth					
Australia / New Zealand	356	(85%)	231	(79%)	0.02
Other	62	(15%)	63	(21%)	
Marital status					
Married / living with partner	351	(84%)	218	(74%)	0.001
Not married / living with partner	67	(16%)	76	(26%)	
Residence					
Major cities	264	(84%)	192	(65%)	0.56
Regional / remote	154	(16%)	102	(35%)	
Attitudes to breast screening					
Scores 24-30 (‘positive attitudes’)	370	(89%)	249	(85%)	0.17
Scores 6-23	48	(11%)	44	(15%)	
Intentions about breast screening					
Intending to be screened	392	(94%)	253	(86%)	0.001
Not intending to be screened / unsure	26	(6%)	41	(14%)	
Study group					
Intervention	196	(47%)	162	(55%)	0.03
Control	222	(53%)	132	(45%)	
Reported a mammogram at 6 months					
Yes	97	(23%)	31	(11%)	<0.001
No	316	(77%)	253	(89%)	
Reported a mammogram by 1 year					
Yes	164	(40%)	51	(18%)	<0.001
No	246	(60%)	226	(82%)	
Reported a mammogram by 2 years					
Yes	285	(68%)	102	(35%)	<0.001
No	132	(32%)	191	(65%)	

[a]Data are number of participants (%). For some variables, data are missing for one woman.

Supplementary Table 6: Agreement between self-reported mammography and screening records[a]

		Mammogram recorded by BreastScreen / Medicare Benefits Schedule					
		6 months		1 year		2 years	
		No	**Yes**	**No**	**Yes**	**No**	**Yes**
Mammogram self-reported	No	310	6	237	9	120	12
	Yes	6	91	8	156	7	278

[a]Not all women consenting to linkage completed the survey (and answered this question) at every time point.

Supplementary Table 7: Proportions of women who had a mammogram, by group and method, including imputation[a]

		6 months		1 year		2 years	
		Int	**Con**	**Int**	**Con**	**Int**	**Con**
	Self-report data from all study participants						
	N	396	394	373	381	363	364
Self-reported screen (any)	n (%)	60 (15%)	80 (20%)	116 (31%)	116 (30%)	200 (55%)	204 (56%)
Self-reported screen (BreastScreen)	n (%)	52 (13%)	70 (18%)	101 (27%)	100 (26%)	175 (48%)	179 (49%)
	Self-report data from participants consenting to the data linkage component						
	N	195	218	194	216	196	221
Self-reported screen (any)	n (%)	41 (21%)	56 (26%)	81 (42%)	83 (38%)	135 (69%)	150 (68%)
Self-reported screen (BreastScreen)	n (%)	36 (18%)	50 (23%)	74 (38%)	71 (33%)	132 (67%)	144 (65%)
	Linked data from all participants consenting to the data linkage component						
	N	196	222	196	222	196	222
Screen recorded in BreastScreen/Medicare	n (%)	43 (22%)	54 (25%)	85 (44%)	80 (37%)	137 (70%)	154 (70%)
Screen recorded in BreastScreen	n (%)	39 (20%)	48 (22%)	78 (40%)	70 (32%)	127 (65%)	139 (63%)
	Imputed overall screening rates, including those not consenting to linkage						
Imputed screen (BreastScreen/Medicare)	%	16%	20%	30%	28%	52%	54%
Imputed screen (BreastScreen)	%	15%	18%	28%	26%	50%	51%

[a]Int=Intervention group. Con=Control group.

Supplementary Figure

Supplementary Figure 1: Cumulative risk plot of attending screening through either BreastScreen or Medicare (intervention vs control groups). There is no difference in the curves, Wilcoxon p = 0.39 (note: does not assume proportional hazards). The hazard ratio comparing the "hazard" of attending screening among the intervention group compared to the control group is 1.14 (95% CI: 0.90, 1.44; p = 0.29) adjusted for age, education, employment, country of birth, marital status, remoteness, and attitudes and intentions at baseline.