

APPENDIX 1

Search criteria for Decision Aids on breast cancer screening

1. In MEDLINE:

“breast cancer”[tiab] (decision[tiab] OR choice[tiab]) AND (aid[tiab] OR informed[tiab]) AND (mammography[tiab] OR mammogram[tiab]) NOT protocol[ti]

2. Adapting it to SCOPUS:

(TITLE-ABS-KEY (“breast cancer”) AND (TITLE-ABS-KEY (decision) OR TITLE-ABS-KEY (choice)) AND(TITLE-ABS-KEY (aid) OR TITLE-ABS-KEY (informed)) AND (TITLE-ABS-KEY (mammography) OR TITLE-ABS-KEY (mammogram)) AND NOT TITLE (protocol))

3. And, equivalently for EMBASE, CINAHL, PsycInfo, and the Cochrane Library Plus.

APPENDIX 2

Table A2. 1: Excluded studies after full text assessment

Study	Reason of exclusion
Lawrence 2000	No adequate evaluation of the decision aid (DA), only acceptability is assessed.
Webster 2007	No adequate evaluation of the DA, no DA but a leaflet is assessed.
Bodurtha 2009	No adequate evaluation of the DA, no decision is assessed.
Pasternack 2011	No adequate evaluation of the DA, only acceptability is assessed.
Waller 2013	No adequate evaluation of the DA, only the design is described, no assessment is reported.
Hersch 2014	Pilot study of a main study already included.
Waller 2014	No adequate evaluation of the DA, three formats of reporting information are compared.
Berens 2015	No adequate evaluation of the DA, no DA but a leaflet is assessed.
Petrova 2015	The DA is not assessed in a real context.
Bourmaud 2016	No adequate evaluation of the DA. Informed choice is assessed only by participation rate. The overdiagnosis harm is not mentioned.

Characteristics of the included studies

Table A2.2. Study Characteristics

Mathieu 2010		
<i>Methods</i>	Online randomised controlled study of decision aid (DA) vs usual care (UC).	
<i>Setting</i>	Australia, where biennial mammography screening is offered free of charge for all women over the age of 40, through a national population screening program. Women aged 50–69 years are invited by personal letter, and, women turning 40 are eligible for screening if they wish to start earlier.	
<i>Participants</i>	189 + 223 women, aged 38-45 years, who accessed the web site. Eligible if they were considering whether to (a) start screening in their 40s (ie before the recommended age of 50) or (b) wait until they were 50.	
<i>Interventions</i>	DA: explained the benefits and harms, included a values clarification exercise and a worksheet to support decision making. UC: delayed intervention	
<i>Outcomes</i>	Primary outcome: knowledge of benefits and harms of screening. Secondary outcomes: informed choice (composite of knowledge, values and intention), anxiety, acceptability of the DA, and intention regarding screening.	
Risk of bias		
<i>Bias</i>	<i>Authors' judgement</i>	<i>Support for judgement</i>
Random sequence generation (Selection bias)	Low risk	Pg. 66 (randomization and baseline questions section): "computer generated simple randomization schedule".
Allocation concealment (Selection bias)	Unclear risk	Pg. 66 "randomization was conducted in a concealed manner." The method of allocation concealment was not stated.
Blinding of participants and personnel (Performance bias)	Unclear risk	Not reported
Blinding of outcome assessment (Detection bias)	Low risk	Unclear blinding but outcomes were not subjective to interpretation.
Incomplete outcomes' data. All outcomes (Attrition bias)	Low risk	Table 2: all outcomes mentioned in the paper were reported in the Results section. Table 3: outcomes of anxiety and acceptability can be found. Page 69 explains missing data. Figures 1 and 2 provide the reasons for the exclusions in each group.
Selective reporting (Reporting bias)	Unclear risk	No mention of protocol.
Other bias (Sampling and other)	Low risk	Pg. 65: "To proceed, women were required to click in a box on the computer screen to indicate they had read the study information and were eligible to participate." The trial was advertised on various websites and in a radio program.

Table A2.3. Study Characteristics

Eden 2015	
<i>Methods</i>	Observational study. Women were assessed before and after the decision aid (DA).
<i>Setting</i>	Three clinics in the Oregon Rural Practice-Based Research Network (ORPRN), USA.
<i>Participants</i>	75 women aged 40-49 years with no known risk factors associated with high or moderate risks for breast cancer and no mammography during the previous year.
<i>Interventions</i>	The decision aid (Mammopad) included modules on breast cancer, mammography, risk assessment, and priority setting about screening.
<i>Outcomes</i>	Primary outcome: decisional conflict measured before and after using DA. Secondary outcomes: decision self-efficacy and intention to begin or continue mammography screening.

Criteria	Yes/No	Other (CD, NR, NA)*
1. Was the study question or objective clearly stated?	Yes	
2. Were eligibility/selection criteria for the study population prespecified and clearly described?	Yes	
3. Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?	No	
4. Were all eligible participants that met the prespecified entry criteria enrolled?	No	
5. Was the sample size sufficiently large to provide confidence in the findings?	Yes	
6. Was the test/service/intervention clearly described and delivered consistently across the study population?	Yes	
7. Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?	Yes	
8. Were the people assessing the outcomes blinded to the participants' exposures/interventions?	No	
9. Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?	Yes	
10. Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?	Yes	
11. Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?	No	
12. If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?		NA

*CD, cannot determine; NA, not applicable; NR, not reported

National Institutes of Health. Quality Assessment Tool for before-after (pre-post) studies with no control group. Study Quality Assessment Tools. <https://www.nhlbi.nih.gov/health->

Table A2.4. Study Characteristics

Gummersbach 2015		
<i>Methods</i>	Randomised to two decision aids (DA) with different information.	
<i>Setting</i>	Family practices in the German federal state of North Rhine–Westphalia. In Germany, screening is recommended biennially for all women aged 50 to 69.	
<i>Participants</i>	353 women, aged 48-49 years, about to receive the first invitation to screening.	
<i>Interventions</i>	Intervention: DA with detailed information on screening harms. Control: standard DA.	
<i>Outcomes</i>	Primary outcome: willingness to participate in screening. Secondary outcomes: knowledge, decisional confidence, determinants of the screening decision.	
Risk of bias		
<i>Bias</i>	<i>Authors' judgement</i>	<i>Support for judgement</i>
Random sequence generation (Selection bias)	Low risk	Pg. 62: "The 24 participants from each practice were selected by a computer-assisted random procedure."
Allocation concealment (Selection bias)	Low risk	Pg. 62: the group allotment process was also random.
Blinding of participants and personnel (Performance bias)	Low risk	Pg. 62: "The participants and their family physicians were blinded with respect to group allotment, but the study team was not".
Blinding of outcome assessment (Detection bias)	Low risk	Pg. 62: "The participants were asked by letter to fill out the questionnaire after reading the leaflet and to send it back in an envelope that was also enclosed in the mailing".
Incomplete outcomes' data. All outcomes (Attrition bias)	High risk	46.7% non-response.
Selective reporting (Reporting bias)	Low risk	Pg. 63. Primary outcome was assessed in accordance with the protocol.
Other bias (sampling bias)	Low risk	Participants recruited from family practices.

Table A2.5. Study Characteristics

Hersch 2015		
<i>Methods</i>	Randomised to two decision aids (DA) with different information.	
<i>Setting</i>	Community-based sample of women around the target age for starting breast screening, in New South Wales, Australia.	
<i>Participants</i>	879 women, aged 48-50 years, about to receive the first invitation to screening.	
<i>Interventions</i>	Intervention: comprising evidence-based explanatory and quantitative information on overdetected, breast cancer mortality reduction, and false positives. Control: decision aid including information on breast cancer mortality reduction and false positives.	
<i>Outcomes</i>	Primary outcome: informed choice defined as adequate knowledge and consistency between attitudes and screening intentions. Secondary outcomes: screening attitudes, decisional conflict, worry about breast cancer, intention about undergoing screening, and opinions about the decision aid.	
Risk of bias		
<i>Bias</i>	<i>Authors' judgement</i>	<i>Support for judgement</i>
Random sequence generation (Selection bias)	Low risk	Pg. 1644: "A programmer who had no contact with participants generated the randomisation sequence using a computer system that was inaccessible until after recruitment... We assigned participants to either the intervention or control group in a 1:1 ratio with permuted block sizes of four and eight."
Allocation concealment (Selection bias)	Low risk	Pg. 1645: "Interviewers were unaware of the materials that women would receive (ensuring allocation concealment)."
Blinding of participants and personnel (Performance bias)	Low risk	Pg. 1645: "Double blinded. Women knew they would receive one of two versions of an information booklet but did not know how these differed or which one was the intervention. We designed the follow-up interview to ensure the group assignment was unclear to the interviewer until the final question."
Blinding of outcome assessment (Detection bias)	Low risk	Pg. 1645: "Researchers who analysed data were unaware of the random allocation."
Incomplete outcomes' data. All outcomes (Attrition bias)	Low risk	Both groups have similar dropout rates.
Selective reporting (Reporting bias)	Low risk	Pg. 5. Primary outcome was assessed in accordance with the protocol.
Other bias	Low risk	It seems free of other biases.

APPENDIX 3

Table A3.1. Mean differences for the quantitative outcome decisional confidence. Meta-analysis of the RCTs.

Outcome	Study	Group	N	Mean (SD)	Difference, p-value
Decisional confidence	Gummersbach 2015 ^a	Intervention	178	5.15 (1.36)	-0.37, p=0.017
		Control	182	5.52 (0.93)	
	Hersch 2015 ^b	Intervention	419	4.35 (0.74)	-0.18, p=0.0003
		Control	419	4.53 (0.67)	
Summary					-0.42 [-0.64, -0.21] ^c

Heterogeneity measures: $I^2=21.7\%$, Q test $p=0.26$.

^a Confidence scale, range 0- 6.

^b Confidence scale, range 0- 5 (mean of 3 subscales).

^c Once re-scaled to a maximum score of 10.

Table A3.2. Risk differences for the dichotomous outcome screening intentions. Meta-analysis of the RCTs.

Outcome	Study	Group	Assessed	n (%)	Difference, p-value ^a
Decided to be screened	Mathieu 2010	Intervention	117	50 (42.7%)	3.0% ^a , p=0.64
		Control	209	83 (39.7%)	
	Gummersbach 2015	Intervention	178	145 (81.5%)	-7.1%, p=0.06
		Control	175	155 (88.6%)	
	Hersch 2015	Intervention	419	308 (73.5%)	-13.1%, p<0.001
		Control	419	363 (86.6%)	
Summary					-7% [-15%, -2%]

^a Fisher's exact test. Heterogeneity measures: $I^2=73.7\%$, Q test $p=0.030$.