

## REVIEW

# Use of patient decision aids increased younger women's reluctance to begin screening mammography: a systematic review and meta-analysis

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**BACKGROUND:** As breast cancer screening guidelines have changed recently, additional investigation is needed to understand changes in women's behavior after using breast cancer screening patient decision aids (BCS-PtDAs) and the potential effect on mammography utilization. This systematic review and meta-analysis sought to evaluate the effect of BCS-PtDAs on changes in women's intentions to undergo screening mammography and whether women deciding to begin or discontinue screening mammography displayed similar changes in screening intentions after using a BCS-PtDA.

**METHODS:** We searched Medline, Scopus, PsycINFO, CENTRAL, Health and Psychosocial Instruments, Health Technology Assessment Database, PsycARTICLES, and cited references in eligible papers for randomized controlled trials (RCTs) and observational studies, published through August 24, 2016. The proportions of women who did and not intend to undergo screening and who were uncertain about undergoing screening mammography were pooled, using risk ratios (RR) and random effects. According to the protocol, RCTs or observational studies and any language were considered eligible for systematic review if they included data about women for which shared decision making is recommended.

**RESULTS:** We ultimately included six studies with screening intention data for 2040 women. Compared to usual care, the use of BCS-PtDAs in three RCTs resulted in significantly more women deciding not to undergo screening mammography (RR 1.48 [95% CI 1.04–2.13];  $P=0.03$ ), particularly for younger (38–50 years) women (1.77 [1.34–2.34];  $P<0.001$ ). The use of BCS-PtDAs had a non-significant effect on the intentions of older women (69–89 years) to discontinue screening.

**CONCLUSIONS:** The use of BCS-PtDAs increased younger women's reluctance to undergo screening for breast cancer. The implementation of such BCS-PtDAs in clinical practice would be expected to result in a 77% increase in the number of younger women (aged 38–50) who do not intend to be screened, and as a consequence, may reduce utilization of screening mammography.

**REGISTRATION:** The protocol of this review is registered in the PROSPERO database, #CRD42016036695.

**KEY WORDS:** breast cancer screening; mammography; decision support techniques; patient decision aid; intention; utilization of screening mammography.

## Abbreviations

BCS-PtDA	breast cancer screening patient decision aid
CENTRAL	Cochrane Central Register of Controlled Trials
IPDAS	International Patient Decision Aid Standards
KQ	key question
PtDA	patient decision aid
RCT	randomized controlled trial
RR	risk ratio

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## INTRODUCTION

According to the World Health Organization (WHO), breast cancer is the most common cancer among women in 140 countries and is the leading cause of cancer mortality in 101 countries.<sup>1</sup> The American Cancer Society estimates<sup>2</sup> that in 2017, approximately 252,710 women in the United States (U.S.) will be diagnosed with invasive breast cancer, and about 40,610 women will die from breast cancer. Because of the disease's asymptomatic phase, mammography is recommended as a primary screening procedure for early diagnosis.<sup>3</sup> However, it is expected that if 1000 U.S. women in their 40s with an average population risk for breast cancer undergo screening mammography today, then 125 of those women would be called back for additional testing.<sup>4</sup> False-positive results elicit fear and distress in women and can lead to further imaging tests and/or biopsy. Criticism based on frequent false-positive findings, which occur at an even higher rate with annual screening than biennial screening,<sup>5,6</sup> are reinforced by a lack of evidence that screening mammography significantly reduces breast cancer mortality among women in their 40s and 70s.<sup>7</sup> Older women whose life expectancy is less than 10 years might not benefit from screening mammography.<sup>6</sup> Another drawback of screening mammography is the high number needed to screen to prevent one death—in the case of biennial

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screening, equal to 1034 for women in their 40s, 426 for women in their 70s, and 1339 for women in their 80s.<sup>8</sup> Additionally, a recent cohort study<sup>9</sup> reported that screening mammography can result in overdiagnosis.

Due to the different interpretations of evidence around potential benefits and harms of screening mammography, current breast cancer screening recommendations are not uniform across countries<sup>10–12</sup> and professional organizations (Fig. 1) including the WHO,<sup>3</sup> American Cancer Society,<sup>6</sup> United States Preventive Services Task Force,<sup>13</sup> and Canadian Cancer Society.<sup>14</sup> Nevertheless, recent recommendations<sup>3,6,12,13</sup> do converge on the view that any decision regarding mammography screening for women at average risk of breast cancer should be based on age, knowledge of risks, personal values, and concerns (Fig. 1). Evidence-based patient decision aids (PtDAs)<sup>15–20</sup> are currently utilized to facilitate shared decision making. The Cochrane Collaboration reports<sup>21</sup> that PtDAs support shared decision making by increasing patients' knowledge, enhancing the accuracy of risk perception, reducing patient decisional conflict, increasing patient satisfaction with a choice, and engaging patients in the decision-making process.

It is not known whether the implementation of the recommendations for shared decision making and the use of PtDAs in clinical practice at the national level will affect the rates of screening mammography utilization. The present paper seeks to understand the influence of breast cancer patient decision aids (BCS-PtDAs) on changes in women's intentions to undergo screening mammography in age groups where shared decision making is recommended. The purpose of this systematic review was to answer the following key questions (KQs; Fig. 2):

KQ1: What effect do BCS-PtDAs have on changing younger and older women's intentions to undergo screening mammography?

KQ2a: What effect do BCS-PtDAs have on changing younger women's intentions to begin screening mammography (women in their 40s)?

KQ2b: What effect do BCS-PtDAs have on changing older women's intentions to continue screening mammography (women in their 70s)?

## METHODS

The protocol of this systematic review was registered in the PROSPERO database, #CRD42016036695.<sup>22</sup>

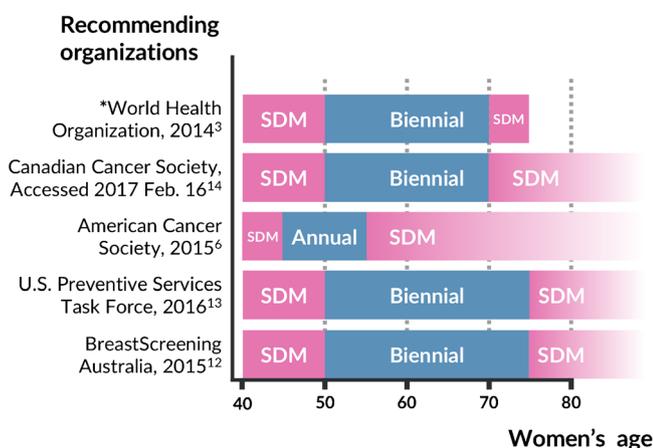
### Eligibility Criteria, Information Sources, and Search Strategy

The present study employed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations for systematic reviews and meta-analyses.<sup>23</sup> Studies were considered eligible for systematic review if they (i) reported data from primary studies; (ii) included data about women aged 38–50 and 69–89 who had not been diagnosed with breast cancer prior to using a PtDA; (iii) contained an intervention that was a PtDA; and (iv) were randomized controlled trials (RCTs), non-randomized studies, cohort studies, case-control studies, or before-after studies. The exclusion and inclusion criteria are presented in Online Appendix 1.

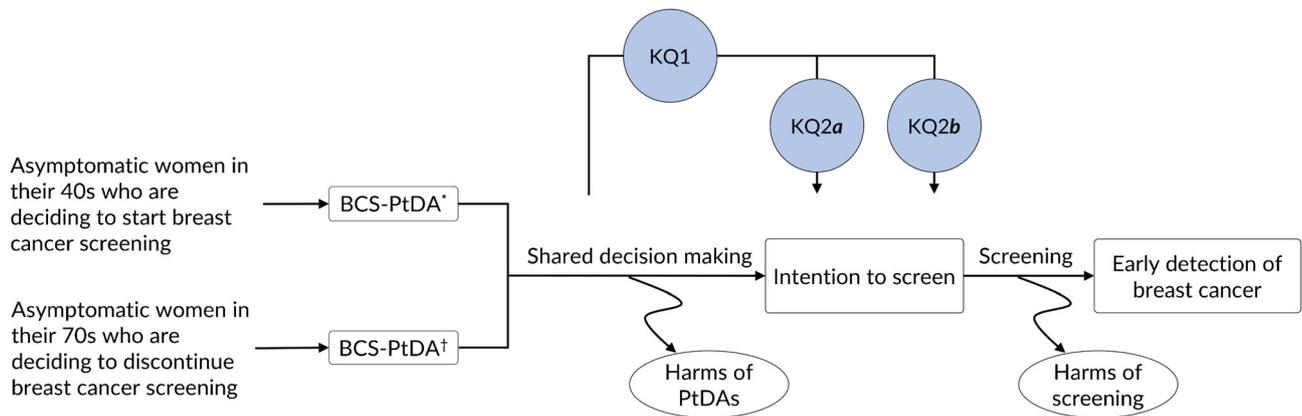
A search was conducted and updated using the following databases: Scopus (through August 24, 2016), MEDLINE Epub Ahead of Print (OvidSP), MEDLINE In-Process & Other Non-Indexed Citations (OvidSP), MEDLINE® Daily (OvidSP), and MEDLINE (OvidSP; 1946 to August 16, 2016), Cochrane Central Register of Controlled Trials [(CENTRAL) OvidSP; 1991 to July 2016], PsycINFO (OvidSP; 1806 to July [week 4] 2016), Health and Psychosocial Instruments (OvidSP; 1985 to July 2016), Health Technology Assessment (OvidSP; 2001 to third quarter 2016), PsycARTICLES Full Text (OvidSP; through August 16, 2016) (Online Appendix 2). In addition, we reviewed cited references in eligible studies.

### Study Selection

All potentially eligible articles were independently screened by two reviewers (II, EH), who coded each article as “eligible,” “potentially eligible,” or “not eligible.” All papers classified as eligible with appropriate risk of evidence were included in the subsequent analysis. Articles ranked as “potentially eligible” or “not eligible” by at least one reviewer were examined again by both reviewers together and were then either classified as “eligible” or disqualified on the basis of consensus. If the two investigators could not reach consensus, an intermediary (KE) was consulted for final judgment. The same procedure was adopted for full-text papers of all potentially eligible studies. A list of included and excluded



**Figure 1** Comparison of current breast cancer screening recommendations. \*Recommendation applies in well-resourced settings. SDM: shared decision making is recommended. Biennial: biennial mammography is recommended. Annual: annual mammography is recommended.



**Key Questions (KQ):**

- KQ1** What effect do BCS-PtDAs have on changing younger and older women's intention to undergo screening mammography?
- KQ2**
  - a. What effect do BCS-PtDAs have on changing younger women's intention to begin screening mammography (women in their 40s)?
  - b. What effect do BCS-PtDAs have on changing older women's intention to continue screening mammography (women in their 70s)?

\*† Different BCS-PtDAs

**Figure 2 Analytic framework.**

papers may be found in Online Appendix 3. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach<sup>24</sup> was used to assess evidence quality.

**Data Collection and Risk of Bias**

Based on the Cochrane Consumers and Communication Review Group's Data Extraction Template, a Microsoft Excel data extraction sheet was developed. The two reviewers (II, EH) extracted and assessed the following data for accuracy and completeness: author; year of publication; country; type of study; data collection period; number and age of patients; type of intervention; and proportion of women who were undecided, who intended to undergo mammography, and who did not wish to undergo mammography (Table 1). For RCTs, data were obtained for control and intervention groups. For before–after studies, data were abstracted pre/post-intervention. Two papers<sup>16,20</sup> did not contain the requisite information about women's screening intentions; the corresponding authors were contacted to obtain the required data in these cases. One study<sup>19</sup> did not differentiate between the women who were unsure and the women who did not intend to undergo screening mammography. The corresponding author of that paper<sup>19</sup> (Mara A. Schonberg, MD, MPH) was successfully contacted by email to identify the boundaries between groups of patients who were unsure and those who did not plan to continue with screening mammography. The results of the individual studies are presented in Table 1. The two investigators (II, EH) assessed the strengths and weaknesses of each eligible study.

For studies that did not randomize patients, the National Institutes of Health Quality Assessment Tool for before–after (pre–post) studies with no control group was used.<sup>25</sup> For randomized trials, the Cochrane Collaboration tool for assessing risk of bias was used.<sup>26</sup>

**Synthesis of Results**

Studies with an acceptable risk of bias (i.e., they did not meet more than three criteria) that were similar in clinical and methodological aspects were combined for meta-analysis. A random effects model<sup>27</sup> was used to process the risk ratio (RR). Heterogeneity testing was conducted to establish the degree of inconsistency among studies and subgroups of studies, and an *I*<sup>2</sup> statistic was calculated.

The number of women who planned to undergo screening mammography was calculated as being equal to the total number of women minus the sum of unsure women and women who did not wish to undergo screening. The number of women who did not want to undergo screening mammography was defined as the total number of women minus the sum of women in the intended and undecided groups. The number of women who were undecided about undergoing screening mammography equaled the total number of women minus the sum of intended women and women who did not wish to undergo screening.

Neither funnel plots nor the Egger test<sup>28</sup> was used to examine the effect of publication bias, since only six studies were ultimately included in the analysis.<sup>29</sup> We did identify protocols for new or ongoing studies on the effects of BCS-PtDAs,

Table 1 The Main Characteristics of the Included Studies

Study, design, country	Data collection period	Patients			Intervention		Outcome		Total results
		No. of interventions, age in years, mean, range	No. of controls, average age	No. at baseline (in before–after)	Assessed breast cancer risk	After intervention	Control, or pretest for before–after		
Hersch et al. <sup>15</sup> 2015 RCT Australia	1/2014–7/2014	419, 49.7 median, 48–50 range	419, 49.7 median, 48–50 range	N/A	Yes, average risk	“Decision aid contained evidence-based information about important outcomes of breast screening over the past 20 years.”	69 unsure 350 decided: 308 plan to start 42 do not plan to start	30 unsure 389 decided: 363 intended to start 26 do not plan to start	“Fewer women in the intervention group than in the control group intended to be screened (308/419 [74%] vs. 363/419 [87%]; $P < 0.001$ ).”
Mathieu et al. <sup>17</sup> 2010 RCT Australia	9/2005–6/2007	117, 41.9 mean, 38–45 range	209, 41.8 mean, 38–45 range	N/A	Yes*	“PDA to identify women's knowledge of the benefits and harms of screening for breast cancer”	21 unsure 96 decided: 50 plan to start 46 do not plan to start	82 unsure 127 decided: 83 plan to start 44 do not plan to start	“Women in the intervention group... were more likely to have made a decision (82% vs. 61% $P < 0.001$ ).” “Of those who made a decision, women in the intervention group were less likely to start screening now (52% vs. 65% $P = 0.05$ ).” “Women in the intervention group were less likely to be undecided (odds ratio, 0.32 [95% confidence interval, 0.17–0.63]; $P = 0.001$ ). Among those women who had a decision regarding screening, the decision aid did not alter the odds of intending to stop screening (odds ratio, 1.28 [95% confidence interval, 0.63–2.61]; $P = 0.50$ ).” “However, these women reported no change in screening intention ( $Z = -1.5$ , $P = 0.132$ ).”
Mathieu et al. <sup>18</sup> 2007 RCT Australia	8/2005–6/2006	349, 70.4 (SD = 0.7)	356, 70.3 (SD = 0.6)	N/A	Yes*	“PDA to assess the effect of a decision aid on whether to continue or stop mammography screening for women aged 70 years”	17 unsure 332 decided: 33 plan to stop screening 299 plan to continue screening	36 unsure 320 decided: 33 plan to stop screening 287 plan to continue screening	“Most women reported that they intended to have a mammogram before age 50, both before and after using Mammopad, and there was no significant change over time ( $Z = 1.543$ , $P = 0.123$ ).” “After reading the DA, fewer participants intended to be screened” ( $P = 0.04$ ).
Scariati et al. <sup>20</sup> 2015 Before–after USA	7/14/00–4/10/12	51, mean not reported 38–48 range	N/A	51	Yes, average risk	“Screening mammography decision aid”	2 unsure 49 decided: 5 will stop screening 44 will continue screening	4 unsure 47 decided: 5 will stop screening 42 will continue screening	“Most women reported that they intended to have a mammogram before age 50, both before and after using Mammopad, and there was no significant change over time ( $Z = 1.543$ , $P = 0.123$ ).” “After reading the DA, fewer participants intended to be screened” ( $P = 0.04$ ).
Eden et al. <sup>16</sup> 2015 Before–after USA	2/2014–7/2014	75, 45 mean, 40–49 range	N/A	75	Yes, average risk	“Mammography decision aid as a web-based application”	9 unsure 66 decided: 59 plan to start 7 do not plan to start	11 unsure 64 decided: 54 plan to start 10 do not plan to start	“Most women reported that they intended to have a mammogram before age 50, both before and after using Mammopad, and there was no significant change over time ( $Z = 1.543$ , $P = 0.123$ ).” “After reading the DA, fewer participants intended to be screened” ( $P = 0.04$ ).
Schonberg et al. <sup>19</sup> 2014 Before–after USA	2010–2011	45, 79 median, 75–89 range	N/A	45	Yes*	“Mammography screening decision aid”	13 unsure 32 decided: 25 plan to start 7 do not plan to start	5 unsure 40 decided: 37 plan to start 3 do not plan to start	“Most women reported that they intended to have a mammogram before age 50, both before and after using Mammopad, and there was no significant change over time ( $Z = 1.543$ , $P = 0.123$ ).” “After reading the DA, fewer participants intended to be screened” ( $P = 0.04$ ).

\* Women were eligible for the study if they were not previously diagnosed with breast cancer. However, neither family history of breast cancer nor BRCA1/2 gene mutations were used as exclusion criteria. DA decision aid

however, and a future update of the current review will include more studies and will test for funnel plot asymmetry.

Sensitivity analyses were pre-specified. We examined the influence of (i) the chosen effects model, (ii) quasi-experimental studies, (iii) major outliers (i.e., those with the largest and lowest RR in analyses involving more than two studies were excluded in turn), and (iv) study quality and methodological diversity.

Data concerning women's intentions were stored using Review Manager (RevMan) 5.3.5<sup>30</sup> software; the same software was used for the meta-analysis. For statistically significant results, we calculated the number required to be treated from the results of a meta-analysis of RR.<sup>31</sup> The primary investigator (II) conducted the data synthesis, and its accuracy was verified by the collaborators (EH, KE, MM).

## RESULTS

### Study Selection

The search identified 422 potentially eligible records, of which six<sup>15–20</sup> met the inclusion criteria (Online Appendix 1); 44 were duplicates, and 372 did not meet the inclusion criteria and thus were excluded (Fig. 3 and Online Appendix 3). Of the 372 excluded records, 363 were excluded after evaluation of the titles and abstracts. Nine articles were excluded after accessing full texts: two articles<sup>32,33</sup> reported outcomes that were not relevant to the present review; two studies<sup>34,35</sup> lacked any PtDA intervention; one article<sup>36</sup> appeared in the wrong type of publication (study protocol); and four studies<sup>37–40</sup> were based on unsuitable study designs.

### Study Characteristics

Data were extracted from all six selected studies<sup>15–20</sup> (Table 1). Of these, three were randomized controlled trials,<sup>15,17,18</sup> while the other three were uncontrolled before–after studies.<sup>16,19,20</sup> All six studies<sup>15–20</sup> measured the

proportion of women who (i) did not wish to start (aged 38–50)<sup>15–17,20</sup> or continue (aged 69–89)<sup>18,19</sup> screening mammography, (ii) intended to start (aged 38–50)<sup>15–17,20</sup> or continue (aged 69–89)<sup>18,19</sup> screening mammography, and (iii) were unsure about starting<sup>15–17,20</sup> or continuing<sup>18,19</sup> screening mammography. These data were available for all trials,<sup>15,17,18</sup> which randomized 2025 patients and reported data regarding intention for 1869 women. Data on intention for 171 women from before–after studies<sup>16,19,20</sup> were included; the meta-analysis included a total of 2040 women from six studies.

### Breast Cancer Screening Patient Decision Aids

Three BCS-PtDAs<sup>16,17,20</sup> were computerized and presented screening information as text and diagrams. Only one of these three<sup>16</sup> used animation to provide information to women. The other three BCS-PtDAs were booklets<sup>15,18</sup> or a pamphlet.<sup>19</sup> The authors of four studies<sup>15,16,19,20</sup> reported using International Patient Decision Aid Standards (IPDAS) when creating a BCS-PtDA; however, the level of IPDAS implementation differed among the BCS-PtDAs. Two BCS-PtDAs were developed using a decision support framework<sup>41</sup> and were not guided by the IPDAS. Four BCS-PtDAs<sup>16,17,19,20</sup> contained an algorithm that assessed the risk of breast cancer in users. Five of six BCS-PtDAs<sup>16–20</sup> given to women described risk factors that could lead to breast cancer. Two BCS-PtDAs<sup>15,16</sup> included an extensive list of medical terms that patients might be unfamiliar with; the other two BCS-PtDAs<sup>17,18</sup> contained an explanation of one or two terms; one BCS-PtDA<sup>19</sup> did not have an explanation of medical terms, and another BCS-PtDA<sup>20</sup> was not available for this assessment. The level of personalization differed among BCS-PtDAs. Five BCS-PtDAs<sup>16–20</sup> provided personalization, as they included interactive exercises to identify the patients' values, critical factors for their decisions, and their expectations. All six BCS-PtDAs had some level of patient, caregiver, or stakeholder engagement in the development process. A detailed comparison of analyzed BCS-PtDAs is described in Online Appendix 4.

### Risk of Bias Within Studies

The risk of bias was also assessed for each study, and all six studies were considered to have a low or moderate risk of bias (Online Appendix 5). The before–after studies recruited specific populations—for example, rural women<sup>16</sup> and women who used social media<sup>20</sup>—thus limiting generalizability (the women in the articles were not typical of those among the general population who would be eligible for the intervention). The risk of performance bias for two RCTs<sup>17,18</sup> was unclear. One study<sup>17</sup> did not report on the allocation and did not provide a link to its protocol (Online Appendix 6).

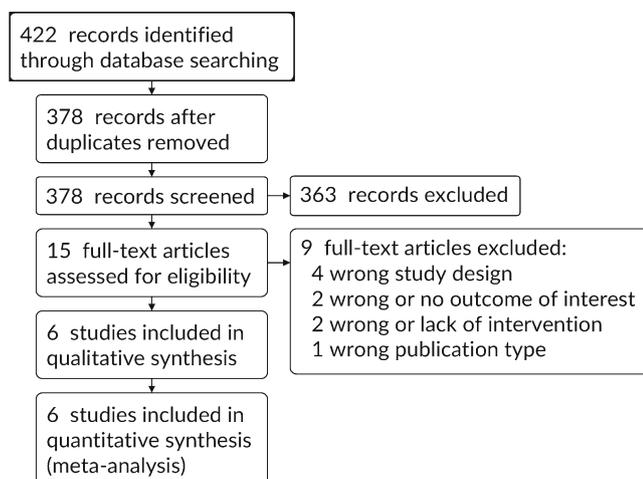


Figure 3 PRISMA flow diagram of study selection.

## Results of Individual Studies

Three studies<sup>17–19</sup> examined the effect of PtDAs on women's knowledge. All three studies reported a statistically significant improvement in knowledge after use of the BCS-PtDAs ( $P < 0.001$ ). Five of the studies<sup>16–20</sup> assessed the clarity of values; three papers<sup>15,17,18</sup> used Dormandy's multidimensional measure of informed choice<sup>42</sup> to evaluate the clarity of values; two studies<sup>16,19</sup> used values clarity subscale scores;<sup>43</sup> and two studies<sup>16,18</sup> indicated that the use of PtDAs significantly reduced women's uncertainty about their values ( $P < 0.001$  and  $P = 0.02$ ). The other two studies<sup>17,19</sup> were unable to identify statistically significant differences in clarity of values ( $P = 0.14$  and  $P = 0.89$ ). Two RCTs<sup>15,18</sup> reported that a significantly greater number of women ( $P < 0.01$ ) in the intervention group made an informed choice (choices were made among women with similar attitudes and values based on an adequate level of knowledge). Two before–after studies<sup>16,20</sup> reported that women, after using a BCS-PtDAs, felt significantly more informed when making a decision on when they should begin screening mammography. One RCT<sup>17</sup> and one before–after study<sup>19</sup> did not indicate a significant change in the number of women who felt informed or were more likely to make an informed decision.

## Synthesis of Results

Analysis of the overall effect of RCTs<sup>15,17,18</sup> indicated that, compared to usual care interventions, BCS-PtDAs resulted in a statistically significant increase in the proportion of women (aged 38–50 and 69–71) who decided not to undergo screening following the use of a BCS-PtDA (RR 1.48; 95% CI 1.04–2.13;  $P = 0.03$ ;  $n = 3$ ; [ $I^2 = 54%$ ;  $P = 0.11$ ]; Fig. 4a, subgroup 1.1.1). The meta-analysis of the RCTs showed that in the usual care group, 105 of 1000 women decided not to be screened, compared to 155 (95% CI 109–223) of 1000 for the BCS-PtDA group. This suggests that an additional 50 women out of 1000 would not plan to be screened after using a BCS-PtDA (Table 2 and Online Appendix 7). Using a number-needed-to-treat approach, 20 women aged 38–50 and 69–71 (95% CI 9–239) would need to use a BCS-PtDA in order for one woman to decide not to undergo screening mammography. In contrast, the analysis of the before–after studies showed no statistically significant difference (RR 1.05; 95% CI 0.54–2.05;  $P = 0.89$ ; Fig. 4a, subgroup 1.1.2). The three observational studies<sup>16,19,20</sup> were all significantly smaller in size (one-way ANOVA  $F[1,4] = 13.57$ ;  $P = 0.02$ ), however, and were not powered to evaluate change in intention. The RCTs and before–after studies suggest that a higher proportion of women would not want to undergo screening mammography after using a BCS-PtDA (Table 2).

When different age categories were considered, the proportion of women in the younger age group (38–50) who decided not to begin screening increased (RR 1.77; 95% CI 1.34–2.34;  $P < 0.001$ ;  $n = 2$ ; [ $I^2 = 0%$ ;  $P = 0.62$ ] Fig. 4b, subgroup 1.2.1) after using a BCS-PtDA. Analysis of intentions among these women revealed that in the usual care group, 111/1000 would not plan to be screened, compared to 197/1000 (95% CI 149–261) for the PtDA group. This suggests that after using the BCS-PtDA, an additional 85/1000 women would change their initial plans and would decide not to begin screening (Table 2 and Online Appendix 8). This means that 12 women (95% CI 7–27) aged 38–50 years must use a BCS-PtDA for one woman to decide not to begin screening mammography. The before–after studies (Fig. 4b, subgroup 1.2.2) showed no change in intention after using the BCS-PtDA and were not evaluated with a number-needed screening approach.

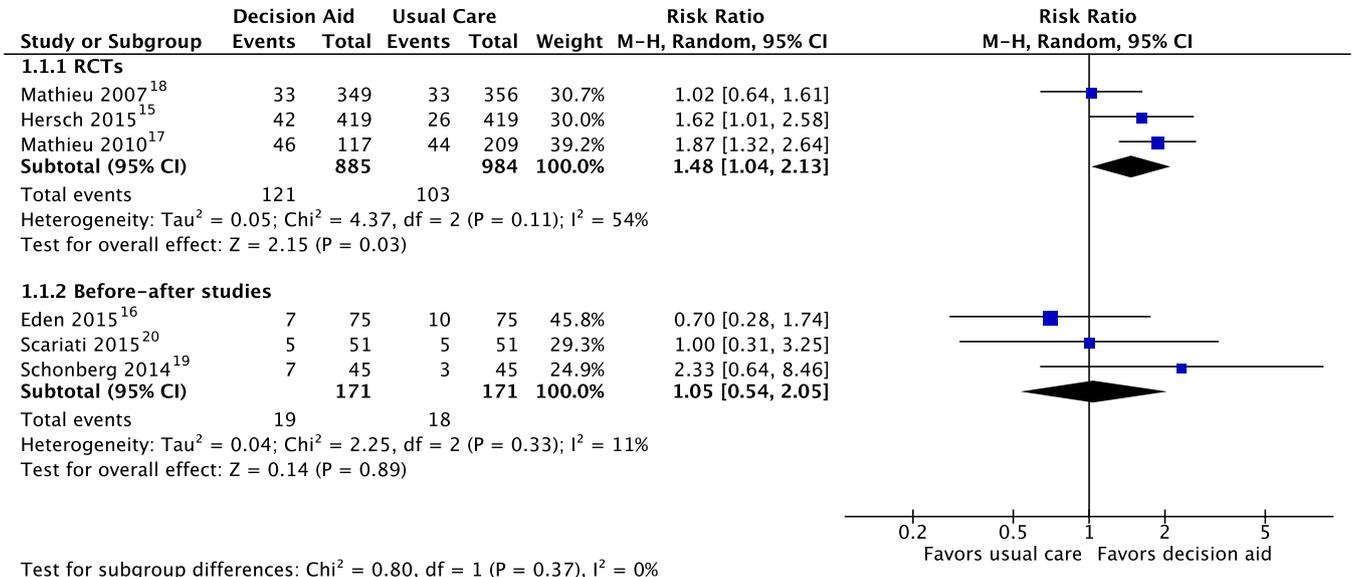
For women aged 69–71 and 75–89, the RCT<sup>18</sup> and observational study<sup>19</sup> comparing women's intentions to continue a screening program displayed a non-significant effect (Fig. 4c) of a BCS-PtDA, with no significant heterogeneity between studies ( $P = 0.24$ ,  $I^2 = 28.9%$ ). Among these women, the BCS-PtDAs appeared to have less effect on their willingness to discontinue screening (Table 2 and Online Appendix 9).

None of our analyses identified a statistically significant difference in the proportion of women who remained undecided, who had decided their screening plans, or who wanted to undergo screening mammography after using a BCS-PtDA (Online Appendix 10).

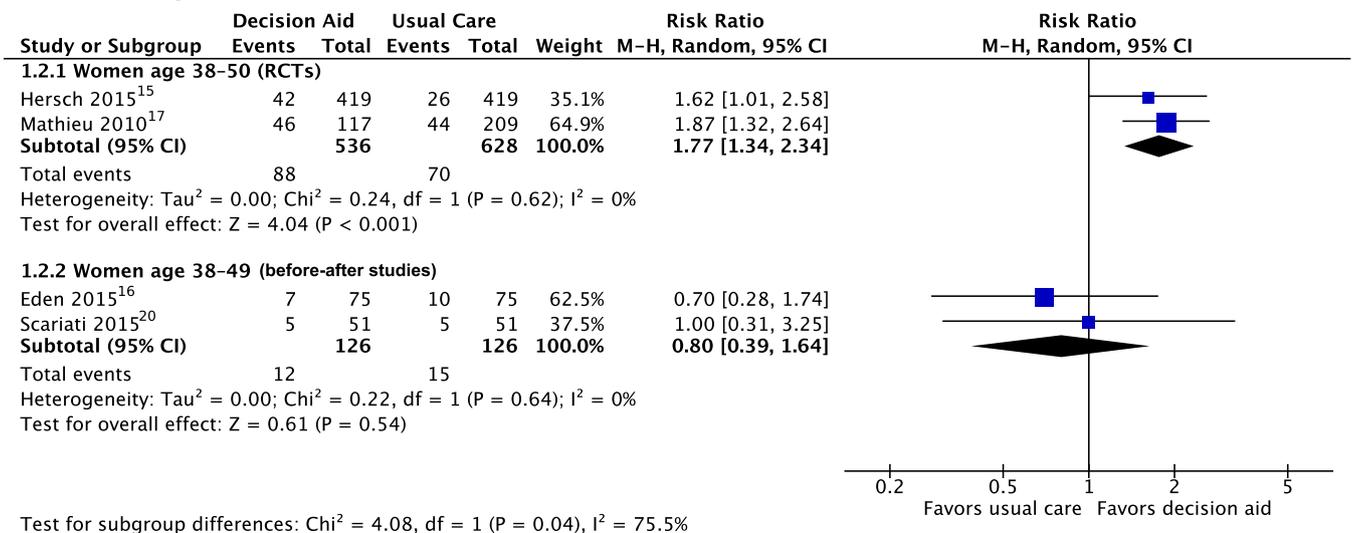
## Exploration for Inconsistency and Results of Additional Analyses

The forest plot shown in Figure 4a visualizes any statistical inconsistency among women who did not plan to undergo screening mammography. Of the six studies, three<sup>15,17,18</sup> used randomization and three<sup>16,19,20</sup> did not. The direction of the effect across the studies is collectively consistent (with the exception of two studies<sup>16,20</sup>) and favors BCS-PtDAs over usual care for reducing intention to undergo screening. A random effects model was used to assess the impact of design differences on the overall result. The overall RR from the three RCTs was 1.48 (95% CI 1.04–2.13;  $P = 0.03$ ; [ $I^2 = 54%$ ;  $P = 0.11$ ]); and the RR from the before–after studies was 1.05 (95% CI 0.54–2.05;  $P = 0.89$ ;  $n = 3$ ; [ $I^2 = 11%$ ;  $P = 0.33$ ]), although no difference among these subgroups was statistically significant ( $I^2 = 0%$ ,  $P = 0.37$ ). The difference between RCTs (women who decided not to undergo screening mammography) cannot be explained in terms of differences in the level of breast cancer risk or by differences in age or decision type (i.e., to begin or continue screening). The disparity in the pooled effect from RCTs and before–after studies (women aged 38–50 years who did not plan to undergo screening mammography) can be explained as the result of different

**A** Women age 38–50 & 69–71 (RCTs: subgroup 1.1.1) and 38–49 & 75–89 (before-after: subgroup 1.1.2)



**B** Women age 38–50



**C** Women age 69–89

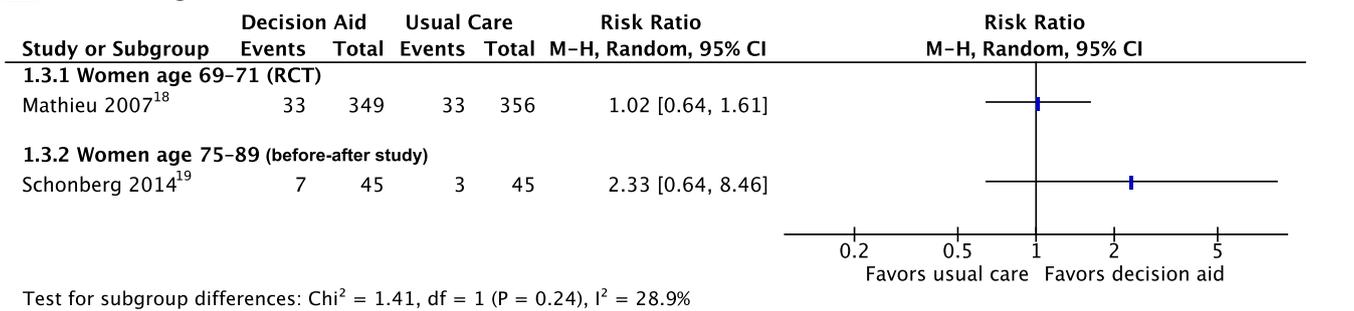


Figure 4 Forest plot of the proportion of women who decided not to a undergo, b begin, or c discontinue screening mammography.

study designs (I<sup>2</sup> = 75.5%; P = 0.04), and may be because the before-after studies<sup>16,20</sup> included only women with an average

risk of breast cancer. In these studies, the women were assessed for average risk before enrollment and again when

Table 2 GRADE Summary of Findings and Quality of Evidence

Use of breast cancer screening patient decision aids compared to usual care in changing women's intention to undergo screening mammography							
Patient or population: asymptomatic women (aged 38–50, 69–89) who were not diagnosed with breast cancer prior to using a screening mammography patient decision aid							
Intervention: breast cancer screening patient decision aid							
Comparator: usual care							
Outcome: change in screening intention							
Setting: primary care, community-based							
Outcomes							
	Anticipated absolute effects†† (95% CI)	Assumed effect in usual care	Corresponding effect after using a BCS-PIDA	Relative effect (95% CI)	No. of participants (studies) Follow-up	Quality of evidence (GRADE)	Comments (for evidence of moderate quality)
KQ1: Reluctance to be screened for breast cancer	Women aged 38–50 and 69–71 105 per 1000	Women aged 38–50 and 69–71 105 per 1000	50 more per 1000 (4–118 more)	RR 1.48 (1.04–2.13)	1869 (3 RCTs) <sup>15,17,18</sup>	⊕⊕⊕○ Moderate*	The use of BCS-PIDAs can increase the proportion of women who do not intend to be screened.
KQ2a: Reluctance to be screened for breast cancer in women 38–50	Women aged 38–49 and 75–89 105 per 1000	Women aged 38–50 and 75–89 111 per 1000	5 more per 1000 (48 fewer to 111 more)	RR 1.05 (0.54–2.05)	171 (3 before–after studies) <sup>16,19,20</sup>	⊕○○○ Very low**§§	
KQ2b: Reluctance to be screened for breast cancer in women 69–71 and 75–89	Women aged 38–49 and 75–89 119 per 1000	Women aged 38–50 and 75–89 119 per 1000	85 more per 1000 (38–149 more)	RR 1.77 (1.34–2.34)	1164 (2 RCTs) <sup>15,17</sup>	⊕⊕⊕○ Moderate*	It suggests that in younger women, the use of BCS-PIDAs increased the proportion of women who did not intend to be screened.
	Women aged 69–71 and 75–89 93 per 1000	Women aged 69–71 and 75–89 93 per 1000	24 fewer per 1000 (73 fewer to 76 more)	RR 0.80 (0.39–1.64)	126 (2 before–after studies) <sup>16,20</sup>	⊕○○○ Very low**§§	
	Women aged 75–89 67 per 1000	Women aged 75–89 67 per 1000	2 more per 1000 (33 fewer to 57 more)	RR 1.02 (0.64–1.61)	705 (1 RCT) <sup>18</sup>	⊕⊕○○ Low*§§	
			89 more per 1000 (24 fewer to 497 more)	RR 2.33 (0.64–8.46)	45 (1 before–after study) <sup>19</sup>	⊕○○○ Very low**§§  #	

†† The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI)<sup>44</sup>  
 GRADE Working Group grades of evidence

**Moderate quality:** We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low quality:** Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimated effect

**Very low quality:** We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimated effect

\* Downgraded because of a low number of events and low optimal information size (imprecision)<sup>†</sup> Outcomes of interest were not measured multiple times before the intervention and multiple times after the intervention (risk of bias)<sup>‡</sup> Participants in both studies are not representative of those who would be eligible for the intervention in the general population (risk of bias)

† Unknown risk of performance bias: blinding of participants and personnel (risk of bias)

‡ The sample size was not sufficiently large to provide confidence in the findings (risk of bias)

# Large effect

using the BCS-PtDA. Initially, only a random effects model was used; the application of the fixed effects model did not alter any of the significant results that were obtained using the random effects model.

## DISCUSSION

### Summary of Evidence

The questions addressed by the present study were (i) whether BCS-PtDAs influence changes in women's intentions to undergo screening mammography and (ii) whether women from different age groups, who face different screening decisions, display similar changes in screening intentions after using a BCS-PtDA. Our results indicate that the use of BCS-PtDAs increased reluctance to undergo screening, particularly in younger women (38–50 years). Additional analyses did not identify any effect of BCS-PtDAs on the proportion of women (aged 38–50 and 69–89 years) who planned to undergo screening mammography (Online Appendix 10). No evidence was found that BCS-PtDAs influenced the proportion of women who were unsure about starting screening or women who were unsure about discontinuing screening. This analysis of intention reveals that the implementation of BCS-PtDAs for women over the age of 68 years may not influence their plans to continue with screening mammography.

### Limitations

We did not use any language restrictions in the search strategy, which was an advantage of the present study. However, the study has several limitations. First, the level of evidence varied across the studies that were included. Only three studies used controlled randomization; the other three were uncontrolled before–after studies with a low level of evidence. Second, all six of the included studies were performed in two countries (Australia and USA). Only three studies (one RCT<sup>15</sup> and two before–after<sup>16,20</sup>) assessed for breast cancer risk and only enrolled women at average risk for breast cancer. Two of the RCTs<sup>17,18</sup> and one before–after study<sup>19</sup> included women who did not have a history of breast cancer but did not formally assess for risk of breast cancer. The use of a BCS-PtDA designed for average-risk women can mislead women who are at above-average risk for breast cancer and may result in inadequate preventive care. It is important to note that changes in women's intentions to undergo breast cancer screening after using a PtDA can differ from actual patient behavior and should be tested in RCTs; however, there is evidence that screening intention correlates positively with actual patient screening behavior.<sup>45</sup>

## CONCLUSIONS

As breast cancer screening guidelines have recently changed, additional investigation was necessary to fully understand the effect of breast cancer screening patient decision aids (BCS-

PtDAs) on changes in women's screening behavior in age groups for which shared decision making is recommended. To the best of our knowledge, this is the first comprehensive systematic review and meta-analysis of changes in women's intentions to undergo mammography screening after using BCS-PtDAs. Our findings showed that BCS-PtDA use resulted in a significantly greater number of women—particularly younger women (38–50 years)—not planning to begin mammography screening than those under usual care. The analysis revealed that the implementation of BCS-PtDAs in clinical practice at the national level, in accordance with the new recommendations, may result in a 77% increase in the number of women aged 38–50 who would not want to begin mammography screening, compared to the corresponding number of women under usual care. The implementation of BCS-PtDAs for women over 68 years of age may not influence their plans to continue mammography screening. The results of this study should be considered by healthcare policymakers and managers when deciding whether to incorporate BCS-PtDAs into regular practice. We support the need for large-scale randomized controlled trials of evidence-based BCS-PtDAs and a subsequent update of our systematic review and meta-analysis, to better understand the behavior affected by BCS-PtDAs and possible change in utilization of screening mammography.

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**Contributors:** *II came up with the research idea. II, EH, MM, and KE designed the protocol. II and EH were responsible for data collection, extraction, and assessment of risk of bias. Statistical supervision was provided by II, and input by KE and MM. II wrote the first draft of the report and collated subsequent inputs. All authors commented and edited the report.*

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### Compliance with Ethical Standards:

**Conflict of Interest:** *The authors declare that they have no conflicts of interest.*

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