

# BMJ Open How information about overdetection changes breast cancer screening decisions: a mediation analysis within a randomised controlled trial

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## ABSTRACT

**Objectives** In a randomised controlled trial, we found that informing women about overdetection changed their breast screening decisions. We now present a mediation analysis exploring the psychological pathways through which study participants who received the intervention processed information about overdetection and how this influenced their decision-making. We examined a series of potential mediators in the causal chain between exposure to overdetection information and women's subsequently reported breast screening intentions.

**Design** Serial multiple mediation analysis within a randomised controlled trial.

**Setting** New South Wales, Australia.

**Participants** 811 women aged 48–50 years with no personal history of breast cancer.

**Interventions** Two versions of a decision aid giving women information about breast cancer deaths averted and false positives from mammography screening, either with (intervention) or without (control) information on overdetection.

**Main outcome** Intentions to undergo breast cancer screening in the next 2–3 years.

**Mediators** Knowledge about overdetection, worry about breast cancer, attitudes towards breast screening and anticipated regret.

**Results** The effect of information about overdetection on women's breast screening intentions was mediated through multiple cognitive and affective processes. In particular, the information led to substantial improvements in women's understanding of overdetection, and it influenced—both directly and indirectly via its effect on knowledge—their attitudes towards having screening. Mediation analysis showed that the mechanisms involving knowledge and attitudes were particularly important in determining women's intentions about screening participation.

**Conclusions** Even in this emotive context, new information influenced women's decision-making by changing their understanding of possible consequences of screening and their attitudes towards undergoing it. These findings emphasise the need to provide good-quality information on screening outcomes and to communicate this information effectively, so that women can make well-informed decisions.

## Strengths and limitations of this study

- Random allocation between two decision aids, differing only in the presence or absence of information about overdetection, enabled a rigorous test of the specific effects of this information when described in the context of other screening outcomes.
- Participants were women entering the target age range for breast screening, who were sampled randomly from the general community and were facing real decisions.
- Our serial mediation model controlled for a comprehensive set of baseline variables and examined plausible, theory-driven cause–effect relationships between exposure to the intervention and subsequently measured variables.
- Nonetheless, given the cross-sectional nature of the outcome and mediator data, we cannot definitively establish the causal sequence of these variables.

**Trial registration number** This study was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613001035718) on 17 September 2013.

## INTRODUCTION

Breast cancer screening is a complex and emotionally charged issue,<sup>1</sup> a topic surrounded by what has been described as a perfect storm of politics and science.<sup>2</sup> While screening can reduce deaths from breast cancer, it can also cause harm through the counterintuitive phenomenon of overdetection or overdiagnosis. The term overdetection is increasingly accepted in the specific context of screening to distinguish it from overdiagnosis that occurs via other mechanisms, such as broadening disease definitions. An overdetection breast cancer is one found by screening, and consequently treated,

that would not have caused any health problems had it been left undetected and untreated.<sup>3</sup> Without screening, such a cancer would never have been diagnosed. Over-detected cancers are ‘real’ cancers in the sense that they meet current pathological criteria for cancer diagnosis, but finding and treating them does not improve health outcomes. Such a diagnosis and the resulting treatment can cause serious lifelong harm, and over-detection is, therefore, considered the major downside to breast screening.

Mounting evidence of the extent of over-detection (estimated as 19% of breast cancers diagnosed in women invited to screen from age 50 to 69 years<sup>4</sup> and 30% for those who attend screening<sup>5</sup>) has led to recognition that the benefits and harms of breast screening are finely balanced for women at population-level risk of breast cancer. The risk of over-detection and its consequences must be weighed against the benefit of reducing breast cancer mortality (relative risk reduction estimated as 20% for women invited to screen from age 50 to 69<sup>4</sup> and 30% for those screened<sup>5</sup>). Experts familiar with the evidence now acknowledge that individual women may perceive the harm-benefit trade-off differently depending on their personal context and preferences—some will opt for screening while others decline, and either choice may be appropriate if it represents an informed decision.<sup>6–8</sup> Throughout the history of breast screening, however, women invited to participate have not been given all the relevant information.<sup>9–11</sup> Consensus is growing that information on screening benefits and harms, including over-detection, must be communicated clearly and transparently to women offered screening so that they can make informed decisions about whether to be screened.<sup>4 12 13</sup> This is all the more important because of evidence that women hold misconceptions about breast screening and its effects.<sup>14 15</sup>

Against the background of this recommended shift in communication, the issue of how information about over-detection affects women and their screening decisions is critical. In a randomised trial, we addressed this question in women approaching the recommended age for starting mammography screening (age 50, when women are invited for screening in many countries including Australia).<sup>16</sup> We sent women one of two versions of a decision aid (evidence-based information booklet) giving information about breast cancer deaths averted and false positives from screening (abnormal mammograms in women without cancer), either with or without information on over-detection.<sup>17</sup> The intervention produced several significant effects on decision-making.<sup>16</sup> The additional over-detection information improved knowledge, increased the number of women making an informed choice about screening (primary outcome of the trial), and also reduced positive attitudes to screening and the number of women intending to be screened.<sup>16</sup>

From our study design—chosen to identify the specific impact of information about over-detection—it appears that communicating this information influenced women’s

assessment of the value of screening to them, leading to lower intentions to be screened within the intervention group. This finding has never been observed before and raises important questions. To facilitate the translation of intervention research findings into other contexts, it is recommended to test hypothesised causal mechanisms.<sup>18</sup> However, causal processes leading from the use of decision aids to the decisions subsequently made are not well understood, as few studies have addressed questions about how these interventions achieve their effects.<sup>19</sup> Only recently have decision aid developers started to critically examine in detail how behavioural, cognitive and social theories of decision-making could inform the design and evaluation of decision support interventions.<sup>20</sup> In this paper, we explore the psychological pathways through which study participants processed over-detection information and integrated it into their decision-making. We provide an explanatory account incorporating cognitive and affective pathways, using psychological theories<sup>21</sup> and mediation analysis.<sup>22</sup>

## METHODS

We did a parallel-group randomised controlled trial with women aged 48–50 years, recruited from the general community in New South Wales, Australia. The trial is described in detail elsewhere.<sup>16 23</sup> Trained interviewers from an independent non-profit company recruited participants via telephone. Women were eligible if they had not undergone mammography in the past 2 years and did not have a personal or strong family history of breast cancer. Participants knew that they would receive one of two versions of a breast screening information booklet but did not know how these differed or which was the intervention.

We collected sociodemographics and baseline data on women’s stage of decision-making (how far along they were with their decision about breast screening), basic conceptual knowledge, attitudes and intentions (table 1).<sup>16 23</sup> We then randomly assigned 879 women to the intervention (n=440) or control group (n=439) and sent their allocated decision aid by post. A programmer who had no contact with participants generated the randomisation sequence, which was inaccessible until after recruitment, ensuring allocation concealment.

The intervention decision aid contained evidence-based explanatory and quantitative information about important outcomes of undergoing screening biennially from age 50 to 69 years (breast cancer mortality reduction, over-detection and false positives) compared with not screening over this period. The control decision aid omitted all over-detection content but was otherwise identical to the intervention. The decision aids were short booklets combining text and visual formats and are published.<sup>16 17</sup>

Our purpose in the analysis reported here was to explore causal pathways between exposure to information about over-detection in a decision aid (intervention)

**Table 1** Baseline sample characteristics (N=811)

Variable	Intervention group (n=406)	Control group (n=405)
<b>Sociodemographics</b>		
	<b>n (%)</b>	<b>n (%)</b>
Family history of breast cancer		
No close blood relative ever diagnosed	389 (96)	386 (95)
One close blood relative diagnosed aged ≥50 years	17 (4)	19 (5)
Country of birth		
Australia or New Zealand	327 (81)	335 (83)
Other	79 (19)	70 (17)
Main language spoken at home		
English	390 (96)	396 (98)
Other	16 (4)	9 (2)
Education		
School only or trade certificate	226 (56)	225 (56)
Diploma or university degree or higher	180 (44)	180 (44)
Marital status		
Married or living with a partner	317 (78)	333 (82)
Not currently living with a partner	89 (22)	72 (18)
Parent status		
Has one or more children	361 (89)	363 (90)
No children	45 (11)	42 (10)
Work status		
Working full time or part time	333 (82)	341 (84)
No paid job currently	73 (18)	64 (16)
Age		
48–49 years	289 (71)	294 (73)
50 years	117 (29)	111 (27)
<b>Preintervention measures</b>		
	<b>Mean (SD)</b>	<b>Mean (SD)</b>
Stage of decision-making about screening	3.4 (1.0)	3.4 (0.9)
Knowledge (basic concepts of screening)	4.4 (0.8)	4.4 (0.8)
Baseline attitudes to breast screening	26.5 (3.6)	26.8 (3.6)
Baseline intentions about screening	4.5 (0.8)	4.6 (0.8)

All baseline variables appearing above were included as covariates in the mediation analysis (sociodemographic factors were dichotomised as shown). Possible ranges: stage of decision-making 1 (not yet thought about the options) to 4 (already made a choice), knowledge 0 (none correct) to 5 (all correct), attitudes 6 (least positive) to 30 (most positive), intentions 1 (definitely not) to 5 (definitely).

and subsequent breast screening intentions (outcome). We examined a series of potential mediators of this relationship: knowledge about overdetection, worry about breast cancer, attitudes towards breast screening and anticipated regret. We collected follow-up data for these variables using standardised questions in a structured postintervention telephone interview, 1–4 weeks after randomisation. The participant's group assignment was unknown to the interviewer until the end of the interview.

Our postintervention knowledge scale assessed conceptual understanding of three key screening outcomes (breast cancer mortality reduction, overdetection and false positives) and awareness of the approximate numbers affected.<sup>16</sup> For the mediation analysis, we used

the overdetection knowledge subscale (scored 0–10, including conceptual and numeric components) because conveying this new information was the main aim of the intervention. We assessed attitudes to breast screening via a widely used 6-item instrument (possible range: 6–30), intentions to undergo screening in the next 2–3 years (1 item, 5-point response scale from definitely to definitely not) and worry about developing breast cancer (1 item, 4-point scale).<sup>16 23 24</sup> Higher scores on these measures reflect better knowledge, more positive attitudes and intentions, and greater worry, respectively. We collected women's anticipated regret both for screening (anticipating that if she undergoes screening (action) she may later wish she had not) and not screening (anticipating

that if she does not undergo screening (inaction) she may later wish she had).<sup>25</sup> We then calculated a differential anticipated regret score<sup>26</sup> by subtracting the action from the inaction score. Higher scores on the resulting measure (possible range: -4 to 4) reflect greater anticipated regret for not screening, adjusted for the woman's anticipated regret for screening. See the (online supplementary appendix 1) for further details about these measures.

We tested whether these variables functioned in a chain with a specified direction of causal flow (serial mediation).<sup>22</sup> Based on health psychology theories (eg, theory of planned behaviour<sup>27 28</sup>) we tested the following causal chain: intervention (group allocation) → over-detection knowledge → worry → attitudes → anticipated regret → intentions. One could hypothesise, for example, that exposure to information (if communicated effectively) should increase knowledge about over-detection. Understanding that some breast cancers would not cause harm even if untreated might reduce worry about breast cancer, which may affect attitudes towards screening. Anticipation of feeling regret if one does not (vs does) undergo screening might depend on attitudes and in turn influence intentions.

Mediation models were tested using model 6 in the PROCESS macro (V.2.16) for SPSS (V.24).<sup>22</sup> This procedure applies an ordinary least squares path analytic framework to estimate both direct and indirect effects (IEs) of the intervention on screening intentions. To derive these effects, PROCESS fits a series of linear regression models with each variable treated as the outcome in turn. The regression coefficients estimate how each variable affects other variables later in the sequence. Baseline variables in [table 1](#) (all measured preintervention, including baseline screening intentions) were statistically controlled by including them as covariates during mediation analyses. Outcome and mediator variables were standardised (expressed in units of SD from the sample mean) for the mediation analysis. We used a bootstrapping procedure in order to conduct inference tests for the IEs. This involved repeatedly drawing samples (with replacement) of size n (where n equals the original sample size) from the existing data, and then estimating the IE in each re-sampled dataset. By repeating this process thousands of times, PROCESS generated an empirical approximation of the underlying sampling distribution of the IE which was then used to construct a CI for the effect. In this study, 50 000 bootstrap samples were used to create 95% bias-corrected CIs (95% CIs) for the IEs, which we considered significant if the CI did not include zero.

## RESULTS

Of 879 participants randomised, 838 completed the follow-up interview. Among these, 27 did not answer all relevant questions and were excluded from the mediation analysis. Sociodemographic characteristics were similar for randomised participants who were and were not included in the mediation analysis. [Table 1](#) shows

**Table 2** Means and SDs for study groups on screening intentions and mediator variables

Variable	Intervention group (n=406)	Control group (n=405)	p Value
	Mean (SD)	Mean (SD)	
Overdetection knowledge	6.2 (2.2)	4.0 (1.6)	<0.001
Breast cancer worry	1.7 (0.7)	1.8 (0.7)	<0.001
Screening attitudes	24.5 (4.4)	26.1 (4.1)	<0.001
Anticipated regret	1.9 (1.7)	2.5 (1.6)	<0.001
Screening intentions	4.1 (1.1)	4.5 (0.9)	<0.001

Possible score ranges were as follows: overdetection knowledge 0–10, breast cancer worry 1–4, attitudes 6–30, anticipated regret -4 to 4, intentions 1–5. See (online supplementary appendix 1) for further details on measures. Groups were compared here using t-tests.

baseline characteristics of the 811 included participants, which were well balanced between the intervention and control groups.

[Table 2](#) presents mean postintervention scores for intervention and control groups on the variables included in the mediation model. Compared with controls, the intervention group showed greater knowledge about over-detection, lower worry about breast cancer, less positive attitudes towards breast screening, lower anticipated regret for not screening (vs for screening) and lower intentions to undergo screening. Correlations between these variables were significant ( $p < 0.001$ ) as shown in the (online supplementary appendix).

Serial mediation analysis found that the total IE of the intervention on intentions was statistically significant, indicating that the intervention influenced intentions indirectly through its effects on the combined set of mediators. Reading the intervention rather than the control decision aid was associated with a decrease in screening intentions as a result of all specific indirect causal sequences in the model ([table 3](#)). As the direct effect was not significant, there was no evidence that the intervention affected intentions independently of its influence on the mediators modelled.

The specific path coefficients are shown in [figure 1](#). The figure illustrates, for example, that participants who received the intervention decision aid demonstrated greater knowledge than controls, participants with greater knowledge expressed less positive attitudes and participants with less positive attitudes also had less positive intentions.

[Table 3](#) presents effect estimates and 95% CIs for the 15 specific IEs representing causal pathways through the various mediator sequences. The main significant IEs of the intervention on intentions were those involving knowledge and attitudes as mediators, both separately (IE1, IE13 in [table 3](#)) and together in sequence (IE3). The first specific IE (IE1) tested whether overdetection

**Table 3** Direct and indirect effects (IEs) of the intervention on intentions via four sequential mediators

Path	Effect	SE	95% CI	
<b>Total effect</b>	<b>-0.2768</b>	<b>0.0540</b>	<b>-0.3828</b>	<b>-0.1708</b>
Direct effect	-0.0192	0.0501	-0.1175	0.0791
<b>Total IE</b>	<b>-0.2576</b>	<b>0.0449</b>	<b>-0.3488</b>	<b>-0.1734</b>
Specific IEs				
<b>1. Knowledge</b>	<b>-0.0731</b>	<b>0.0267</b>	<b>-0.1281</b>	<b>-0.0230</b>
2. Knowledge, worry	-0.0010	0.0017	-0.0073	0.0007
<b>3. Knowledge, attitudes</b>	<b>-0.0700</b>	<b>0.0171</b>	<b>-0.1071</b>	<b>-0.0396</b>
<b>4. Knowledge, anticipated regret</b>	<b>-0.0201</b>	<b>0.0072</b>	<b>-0.0375</b>	<b>-0.0088</b>
5. Knowledge, worry, attitudes	-0.0001	0.0007	-0.0023	0.0011
6. Knowledge, worry, anticipated regret	-0.0004	0.0005	-0.0021	0.0002
<b>7. Knowledge, attitudes, anticipated regret</b>	<b>-0.0121</b>	<b>0.0040</b>	<b>-0.0220</b>	<b>-0.0059</b>
8. Knowledge, worry, attitudes, anticipated regret	-0.0000	0.0001	-0.0004	0.0021
9. Worry	-0.0047	0.0050	-0.0191	0.0021
10. Worry, attitudes	-0.0003	0.0027	-0.0063	0.0046
<b>11. Worry, anticipated regret</b>	<b>-0.0020</b>	<b>0.0014</b>	<b>-0.0063</b>	<b>-0.0003</b>
12. Worry, attitudes, anticipated regret	-0.0001	0.0005	-0.0012	0.0008
<b>13. Attitudes</b>	<b>-0.0618</b>	<b>0.0285</b>	<b>-0.1178</b>	<b>-0.0065</b>
<b>14. Attitudes, anticipated regret</b>	<b>-0.0106</b>	<b>0.0056</b>	<b>-0.0241</b>	<b>-0.0016</b>
15. Anticipated regret	-0.0012	0.0104	-0.0216	0.0200

N=811; 50000 bootstrap samples; bias-corrected CIs. The sequential mediators are: overdetection knowledge, breast cancer worry, attitudes, anticipated regret. Bold effects are significant ( $p < 0.05$ ).

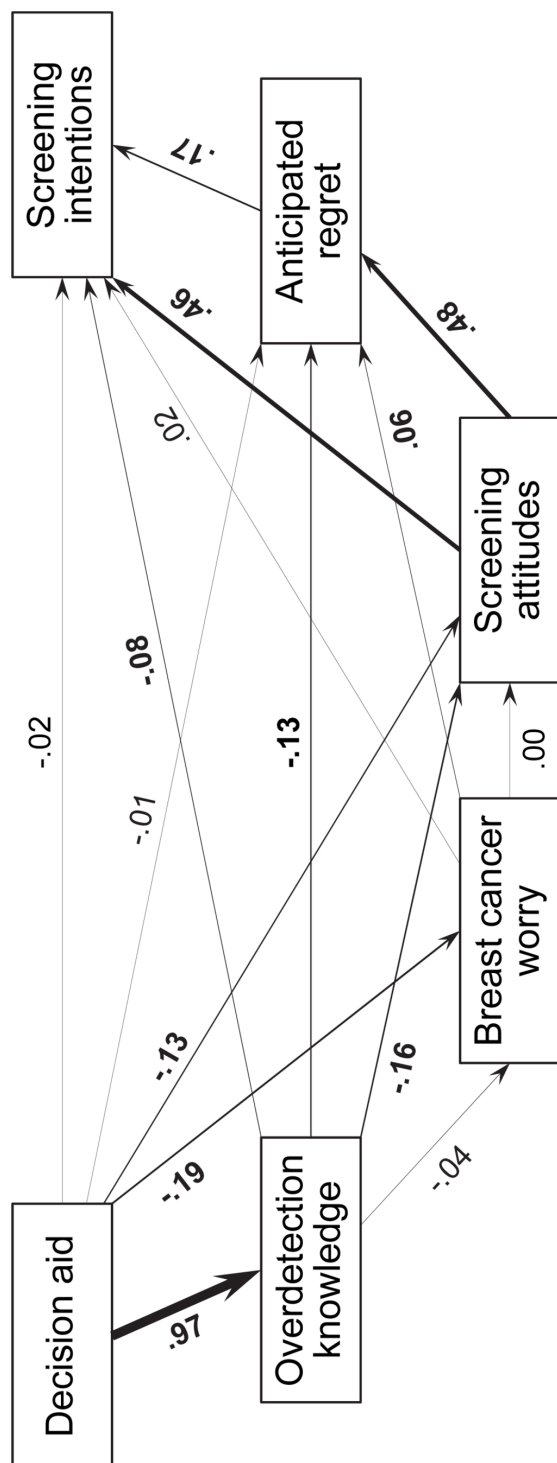
knowledge mediated the relationship between the decision aid received and subsequent breast screening intentions; this effect was significant. Relative to those assigned to the control decision aid, participants receiving the intervention demonstrated better knowledge about overdetection and consequently expressed lower intentions to have screening. Another significant effect, IE13 showed that the intervention resulted in less positive attitudes, which also led to lower screening intentions. IE3 tested the causal chain: intervention  $\rightarrow$  knowledge  $\rightarrow$  attitudes  $\rightarrow$  intentions. This was also significant and demonstrated that participants exposed to the intervention gained better overdetection knowledge, those with better knowledge had less positive attitudes, and these attitudes were in turn associated with reduced intentions to screen. Pairwise contrasts revealed that the three largest specific IEs (IE1, IE3 and IE13) did not significantly differ in size.

The anticipated regret variable was also involved in several significant mediation pathways, influenced by knowledge and attitudes separately (IE4, IE14) and together (IE7). The most complex of the significant IEs was IE7 leading from the intervention  $\rightarrow$  overdetection knowledge  $\rightarrow$  screening attitude  $\rightarrow$  anticipated regret  $\rightarrow$  screening intention. Compared with the control group, women receiving the intervention had greater overdetection knowledge, which led to less positive attitudes (as above); these were in turn associated with lower anticipated regret for not screening (vs screening), which translated into reduced intentions to screen.

The specific IE for the pathway through the complete causal chain involving all four mediators in sequence (IE8)—that is, adding breast cancer worry to the mediators discussed above—was not significant. Worry was part of only one significant IE (IE11). The intervention reduced breast cancer worry; women with lower worry had lower anticipated regret for not screening, which again reduced screening intentions.

## DISCUSSION

This study showed that the relationship between exposure to information on overdetection and women's subsequent breast screening intentions was mediated by multiple cognitive and affective pathways. The intervention decision aid substantially improved understanding of overdetection, and it influenced—both directly and indirectly via its effect on knowledge—women's attitudes towards having screening. The mediation analysis revealed that these mechanisms involving knowledge and attitudes were particularly important in determining intentions about screening participation. Anticipated regret played a role in several additional pathways linking knowledge, attitudes and intentions. As women became more knowledgeable about overdetection and their screening attitudes became less positive, this lessened their expectation that not screening would cause regret and increased the realisation that screening might cause regret, which in turn influenced intentions. The non-significance of the



**Figure 1** Graphic representation of the serial multiple mediation model of decision aid effects on breast screening intentions via four sequential mediators (overdetection knowledge, breast cancer worry, screening attitudes and anticipated regret). The intervention was hypothesised to exert an effect on screening intentions through the four mediators in sequence. Outcome and mediator variables were standardised prior to analysis. Bold coefficients are significant ( $p < 0.05$ ). Analyses controlled for baseline measures including screening intentions and attitudes, basic screening knowledge, stage of decision-making, breast cancer family history, birthplace, main language spoken, education, marital status, parent status, work status and age.

direct effect (ie, relationship between study group and intentions after adjusting for all mediators) confirms that our model captured the key relevant constructs, suggesting little of the observed total effect was due to other differences between the intervention and control decision aids (eg, length, newness of information and time spent reading).

The randomised controlled trial design is a key strength of this study. Random allocation between two decision aids, differing only in the presence or absence of information about overdetection, enabled a rigorous test of the specific effects of this information when described in the context of other screening outcomes. Our serial mediation model controlled for a comprehensive set of baseline variables and examined plausible, theory-driven cause–effect relationships between exposure to the intervention and subsequently measured variables. Nonetheless, a limitation is that given the cross-sectional nature of the outcome and mediator data, we cannot definitively establish the causal sequence of these variables. While some of the group differences shown in [table 2](#) are small, our purpose in this article was not to establish the clinical significance of such differences (see elsewhere for more detailed analysis<sup>16</sup>) but rather to explore possible causal mechanisms involved. Whether the outcome variables in the serial mediation model are normally distributed or not, the inferences are likely to remain valid due to the large sample size of the study.<sup>22–29</sup> Participants had not been screened in the 2 years prior to the study and were close to the age (50 years) at which women are invited into the Australian national breast screening programme. Intervention effects could vary in other populations depending on age and cultural context. For example, providing information about overdetection to women who already have more personal experience with screening (eg, women in their 60s) might produce less of an effect on attitudes and intentions, as suggested by our previous qualitative research.<sup>30</sup>

Although previous literature has reported on screening decisions aided by decision support techniques,<sup>31–32</sup> little work to date has examined mechanisms for how information provided in such resources translates into decisions. Our mediation findings are in line with the explanatory account of health decisions offered by the theory of planned behaviour.<sup>27–28</sup> Under this theory, attitudes towards a behaviour are determined by salient beliefs about its consequences (in this case, the understanding conveyed by the decision aid that overdetection is a possible consequence of screening); these attitudes in turn determine intentions. Our observed mediation effects involving anticipated regret accord with other empirical evidence supporting its usefulness as an extension to the theory of planned behaviour.<sup>33</sup> Worry about the threat of breast cancer, though emphasised by other health psychology theories, did not appear to play a major role in determining screening intentions among our study participants. While the power of emotion has been cited as a challenge for communicating harms of



mammography,<sup>34</sup> our findings reinforce the vital role of good educational materials by demonstrating how evidence-based information influenced women's cognitions about screening and showing that cognitions, rather than emotions, were instrumental in decision-making. Using a theoretical basis in behavioural psychology or decision-making theory is often overlooked but may strengthen the design and evaluation of decision support materials, although operationalising such theories can be challenging.<sup>20</sup> There is a need to develop and employ comprehensive theoretical frameworks that help us better understand the role of comprehension of benefits and harms in shaping informed screening decisions, as well as how external factors—such as conflicting information from different sources—may influence both information processing and decision-making in this sometimes controversial area.<sup>2 35–37</sup>

## CONCLUSIONS

We have previously shown that giving women evidence-based written information about overdiagnosis in breast screening can change women's screening intentions. Importantly, for the first time we now provide evidence, using mediation analysis, of how this cognitive and affective process works: the decision aid intervention achieved substantial knowledge gains, and thereby influenced attitudes and intentions towards screening. Our findings underline the importance of providing good-quality information to women when they are invited to consider screening, using materials with the capacity to successfully impart new and relevant knowledge. Effective communication tools and decision support resources are especially needed against a background of widely documented unrealistic public expectations of screening which may be driven by psychological factors in combination with sometimes misleading messages about benefits and lack of attention to harms.<sup>38 39</sup> Our findings are a reminder that information can be a powerful intervention, and that the development of information resources must be done properly with rigour and care.

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**Data sharing statement** The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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