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A qualitative study on a decision aid for breast cancer screening: Views from women and health professionals

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This qualitative study evaluates a decision aid that includes the benefits and harms of breast cancer screening and analyses women's perception of the information received and healthcare professionals' perceptions of the convenience of providing it. Seven focus groups of women aged 40–69 years (n = 39) and two groups of healthcare professionals (n = 23) were conducted in Catalonia and the Canary Islands. The focus groups consisted of guided discussions regarding decision-making about breast cancer screening, and acceptability and feasibility of the decision aid. A content analysis was performed. Women positively value receiving information regarding the benefits and harms of breast cancer screening. Several women had difficulties understanding some concepts, especially those regarding overdiagnosis. Women preferred to share the decisions on screening with healthcare professionals. The professionals noted the lack of inclusion of some harms and benefits in the decision aid, and proposed improving the clarity of the statistical information. The information on overdiagnosis generates confusion among women and controversy among professionals. Faced with the new information presented by the decision aid, the majority of women prefer shared decision-making; however, its feasibility might be limited by a lack of knowledge and attitudes of rejection from healthcare professionals.

KEYWORDS
breast cancer screening, decision aid, decision-making, patients' information

*See Appendix 1.

1 | INTRODUCTION

The objective of breast cancer screening is early detection before the presentation of symptoms. Evidence shows that treatment in early stages is more effective than in late detection with a 20% reduction in breast cancer mortality (Marmot et al., 2013); however, screening can produce adverse effects such as false positives, false negatives and overdiagnosis of tumours that might not produce symptoms during the woman's life.

In Spain, one out of every five women between 50 and 70 years of age who participate biennially in an early detection programme is estimated to have at least one false-positive result (Román et al., 2012). Approximately, 2% of women over the same period will undergo an invasive procedure (e.g. a biopsy) with a benign outcome (Román et al., 2012). These figures differ significantly between countries (Hofvind et al., 2012) and are higher in the USA than in Europe (Hubbard et al., 2011; Smith-Bindman, Ballard-Barbash, Miglioretti, Patnick, & Kerlikowske, 2005).

Over the last decade, two findings have raised an intense amount of debate about the benefits and harms of population-based screening: (1) the considerable increase in the incidence of breast cancer associated with the intensity of the use of screening and (2) the increase in the incidence of screen-detected "in situ" cancers not compensated by a decrease in the incidence of tumours in more advanced stages (Esserman, Shieh, & Thompson, 2009; Welch, Prorok, O'Malley, & Kramer, 2016).

Ductal carcinoma in situ (DCIS) was a low-incidence pathological alteration before screening programmes were established. In the USA States, DCIS incidence rose from 1.87 per 100,000 in 1973–1975 to 32.5 in 2004, an increase that was in part due to the dissemination of mammography (Virnig, Tuttle, Shamliyan, & Kane, 2010). DCIS is more likely to be overdiagnosed than invasive cancer (Esserman et al., 2009, 2014). Some studies suggest that only some DCIS evolve into invasive cancer during a woman's lifetime (Elmore et al., 2012; Ozanne et al., 2011). The overdiagnosis and resulting treatment of breast cancer can have substantial physical and psychological consequences (Esserman et al., 2009). Overdiagnosis can lead to treatments as invasive as mastectomy, whose consequences are well known (Esserman et al., 2014).

Estimates of breast cancer overdiagnosis vary widely across studies, with values between 0% and 50% (Gøtzsche & Jørgensen, 2013; Martinez-Alonso, Vilaprinyo, Marcos-Gragera, & Rue, 2010; Puliti et al., 2012). This variability might be explained by the designs, methods and measurements used. The most recent systematic reviews estimate values between 20% and 25% (Marmot et al., 2013; Welch & Black, 2010). According to the American Cancer Society, the quality of evidence is insufficient to estimate a lifetime risk with confidence, and the World Health Organization (WHO) considers its quality to range from low to very low (Oeffinger et al., 2015; World Health Organization 2014). More valid estimates of overdiagnosis should come from randomised studies (Elshof et al., 2015; Francis et al., 2015). Despite the variability in the estimates, the specialised literature agrees that the number of overdiagnosed cases is non-negligible (Marmot et al., 2013).

The uncertainty caused by the coexistence of benefits and harms makes it ethically necessary to inform women so that they can actively participate in decision-making and make an informed choice based on their values and preferences (Braddock, 2010). Currently, the information on screening targeting women generally emphasises the benefits and underestimates harms (Fowler, Gerstein, & Barry, 2013; Jørgensen & Gøtzsche, 2006). Decision Aids (DAs) might help to solve this informational gap. DAs are systematically designed interventions that contain information based on the best available scientific evidence regarding the benefits, harms and uncertainties of each option (Eden et al., 2015; Gummersbach et al., 2015; Hersch et al., 2015; Mathieu et al., 2010). They show information in a clear, understandable and balanced way to support decision-making by laypeople (Stacey et al., 2014). The challenge is to develop a DA that responds to women's informational needs and that is acceptable, feasible and well valued for both women and health professionals (Coulter et al., 2013).

1.1 | Objective

We aimed to evaluate a DA that includes the benefits and harms of breast cancer screening and analyses women's perceptions of the information received and healthcare professionals' perceptions regarding the convenience of providing it.

2 | METHODS

We conducted a socio-constructivist qualitative study through focus groups. This theoretical approach lies on the need to understand how people construct and interpret social reality in their daily lives (in this study, screening of breast cancer) (Denzin & Lincoln, 2011). Women aged 40–69 years and healthcare professionals were included and asked to evaluate a DA.

The DA consisted of an informative brochure based on two systematic reviews (Gøtzsche & Jørgensen, 2013; Marmot et al., 2013), one narrative review (Paci & EUROSCREEN Working Group, 2012), and other DAs or related materials summarised in Table 1. The International Patient Decision Aid Standards (IPDAS) were followed (http://ipdas.ohri.ca/) for the DA development. The DA is shown in Figures 1 and 2.

2.1 | Context/Setting

In Spain the National Health System, financed mainly by taxes, provides universal and health coverage, including early detection of breast cancer. All women resident in Spain aged 50–69 years are actively invited to participate in the population-based screening programme by a written letter every 2 years. The invitation letter contains basic information about the programme, mostly about its benefits (Queiro Verdes, Cerdà Mota, & España Fernández, 2007).

2.2 | Participant selection and recruitment

Women were selected according to a theoretical sample whose criteria were age, previous screening experience and education level.

TABLE 1 Websites examined in the decision aid elaboration process

Country	Organisation	URL
Australia	Sydney Health Decision Group. Sydney School of Public Health. The University of Sydney, Australia	http://sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php http://www.mammogram.med.usyd.edu.au/
Canada	Ottawa hospital Research Institute	http://www.ohri.ca/decisionaid/ https://decisionaid.ohri.ca/
	Public Health Agency of Canada	www.publichealth.gc.ca/decisionaids
United Kingdom	Cancer Research UK	http://www.cancerresearchuk.org/about-cancer/type/breast-cancer/about/screening/who-is-screened-for-breast-cancer
	NICE, National Institute for Health and Care Excellence	http://www.evidence.nhs.uk/Search?ps=30&q=informed+choices
	GOV.UK	https://www.gov.uk/government/publications/breast-screening-helping-women-decide
	Winton programme for the public understanding of risk based in the Statistical Laboratory in the University of Cambridge	https://understandinguncertainty.org/visualisation-information-nhs-breast-cancer-screening-leaflet
Spain	Fundació Lliga per a la Investigació i Prevenció del Càncer (FUNCA)	https://funca.cat/prevencio_cancer_mama
	Grup de treball de Comunicació del Programa de Detecció Precoç del Càncer de mama de Barcelona	http://www.parcdesalutmar.cat/media/upload/arxius/epidemiologia_avaluacio/deteccio_cmama.pdf
USA	Breast cancer action. San Francisco, CA	http://www.bcaction.org/
	Darmouth-Hitchcock Center for Shared Decision Making, Darmouth, NH	http://www.dartmouth-hitchcock.org/medical-information/health_encyclopedia/abh0460
International	The International Patient Decision Aid Standards (IPDAS) Collaboration	http://ipdas.ohri.ca/

All the urls could be accessed on December 2, 2016.

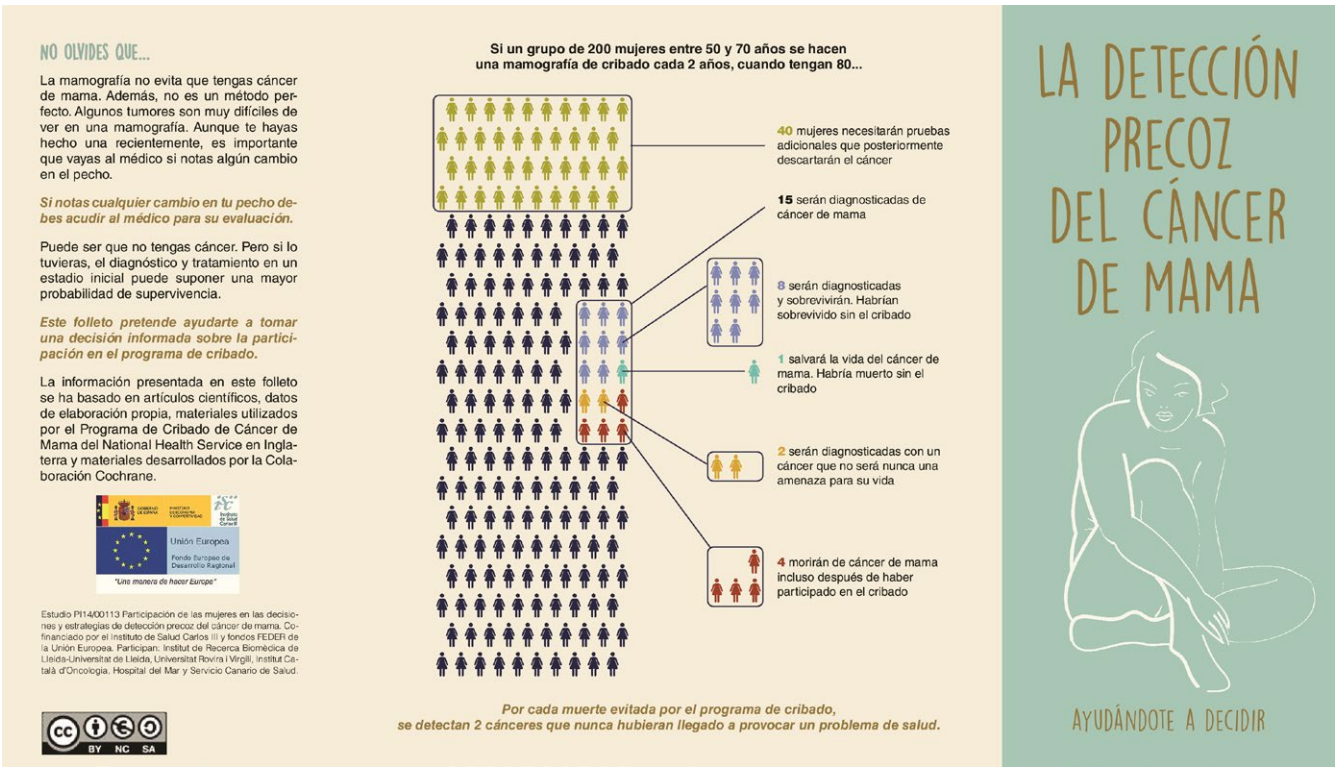

FIGURE 1 Decision aid of breast cancer screening—front

FIGURE 2 Decision aid of breast cancer screening—back

Having a history of breast cancer was an exclusion criterion, nevertheless a few women with breast cancer history were included as they did not notify it when asked. We recruited women aged 50–69 years through the population-based breast cancer screening programmes (BCSP) of three regions in Catalonia (two BCSP in the Barcelona Health Region and one in the Lleida Health Region) and the BCSP of the Canary Islands. Women were asked for consent to be contacted by the study researchers. Workers of the BCSP and primary care centres made this first consent call by phone. Then, women who accepted were contacted by phone by a study researcher who checked the inclusion criteria and invited them to participate in the study. One in five women invited agreed to participate in the study. Women aged 40–49 years, which were not included in the target population, but would face the decision to participate in the future were recruited through primary care centres of the same regions.

The focus groups of women were stratified by education level (primary education, secondary education or University degree) as criterion of homogenisation, except one group that was mixed. Heterogeneity was based on age and experiences on breast cancer screening (including women with negative results, false positives and non-participant in screening).

The selection criterion for the healthcare professionals was that their work (research, public health, diagnosis, treatment, primary care or specialised) was related to breast cancer. This criterion provided group homogeneity, whereas the type of healthcare service and field of expertise ensured the heterogeneity of the sample. We used a snowball sampling technique for their recruitment.

Seven focus groups of women (three in the Canary Islands and four in Catalonia) and two focus groups of professionals (one in each region) were conducted. A total of 39 women and 23 professionals participated in the study. The size of the health professionals groups was large because there are many different professional profiles involved in breast cancer. Table 2 shows the characteristics of the focus groups.

2.3 | Conducting the focus groups

The focus groups of women were semi-structured, with a presentation and guided discussions about decision-making and the benefits and risks of screening (see Table 3). The leading conductors (NC and AT) were qualitative researchers with solid experience in guiding focus groups. The team previously discussed and agreed on how to conduct the groups. There was an observer in each group that took notes and recorded the session. Project researchers introduced the study to the professional groups (AR and MR). The duration of all the sessions was 2 hr.

The focus groups of Catalan women were held either at the medical school of the University of Lleida (two of them) or at IDIAP Jordi Gol, Institute of Research in Primary Health Care in Barcelona (the other two). In the Canary Islands, three groups of women and one of health professionals were held at the Tenerife's Health Service Headquarters. As Table 3 shows, the discussion in the women's groups began with the participants' opinions and experiences on early detection of breast cancer. At the second stage, they were asked to evaluate the DA. Finally, the role that the DA should play in decision-making regarding screening participation was discussed. In the professional groups, the benefits and risks of population-based screening were debated first.

TABLE 2 Characteristics of the focus group participants

Level of educational attainment	*n* = 39
Primary Education	18
Secondary Education	6
University Degree	15
Age (years)	
40–49	9
50–59	13
≥60	17
Screening mammography experience	
Negative results (normal)	11
At least one false-positive result	13
Not participating in the population-based screening programme but attending screening by a private insurance	7
Not in the age target for the population-based screening programme or not undertaking screening	4
Family history of breast cancer, surveillance by private insurance	4
Characteristics of the professionals in the focus groups	(*n* = 23)
Social worker	1
Nurse	2
Primary care physician	6
Psychooncologist	1
Radiologist	2
Epidemiologist	1
Oncologist	2
Population-based screening programme professionals (epidemiologist, physician, nurse, administrative, management)	6
Physician working in a research centre	2

Then, the participants commented on their experiences of shared decision-making (SDM). Finally, the group discussion focused on the evaluation of the DA.

2.4 | Data analysis

All sessions were audio recorded and transcribed, while guaranteeing the anonymity and confidentiality of the data. Independent content analyses were performed; manually (Hsieh & Shannon, 2005) by MF and using Atlas.ti 7.5.15 software (Atlas.ti 2016) by NC. Transcriptions and field notes were also reviewed by the rest of the team. Initial ideas and interpretations (together with the research questions) were discussed, constituting the framework of the initial codification. An analysis triangulation was performed. A consensus on the final results was made with the team researchers that had not participated either in the focus groups or in the analysis, and therefore provided an external perspective. To increase the credibility of the results, the whole research team discussed the interpretation of the findings.

As a final step, women and health professionals feedback on the format and content of the DA was used to revise it. A new version of the DA was obtained that was tested for acceptability in a sample of 60 women and 43 health professionals.

The Research Ethics Committee of the University Hospital Arnau de Vilanova at Lleida approved the study. All of the participants participated voluntarily, signing the informed consent document.

3 | RESULTS

3.1 | Women's perception of decision-making in early detection and evaluation of the DA acceptability and feasibility

All the participant women positively evaluated receiving general information on cancer screening (see Table 4). Once the DA was reviewed, most women understood the benefits of screening, although they were struck by the fact that only one woman out of 200 who participate biennially in screening between the ages of 50 and 70 years will survive breast cancer, thanks to early detection. This estimate generated debate about the efficacy of mammography, and some women defended the inclusion of an additional ultrasound as a screening test. This perception was consistent with their overestimation of both risks of suffering from breast cancer and benefits of screening.

Regarding the risks, some women lacked information about radiation. Others had difficulty understanding the meaning and implications of the concepts of overdiagnosis and overtreatment. After reading the DA, only two women (one of them a healthcare professional) commented that they had heard of overdiagnosis, although they were unable to define it. The term overdiagnosis generated confusion not only because of its novelty but also because the wording of the DA was not clear to them. Similarly, the presentation of the screening outcomes in the form of cumulative frequencies was confusing for the women with a medium-low level of education.

Two attitudes were observed, against and for, regarding receiving information on the benefits and risks of screening. Women against receiving the information considered it unnecessary either because screening was assumed to be positive and therefore participation was seen as a duty or because the decision should be made by a doctor. Other women were in favour of receiving information and consulting with a professional in the form of an informed or shared decision.

Some women commented that they would have preferred not to know the information related to overdiagnosis. It caused them anxiety and increased their uncertainty about screening. In any case, despite the information on screening risks, the vast majority of the women who had already considered participating expressed that they would participate.

3.2 | Evaluating the acceptability and feasibility of the DA and the perception of decision-making regarding screening, among healthcare professionals

Regarding the format and content of the DA, the professionals discussed different ways of expressing the information for it to be understandable and not too technical or imprecise.

TABLE 3 Summarised Focus Group Guides

Women's Focus group presentation topics and key discussion questions
Brief introduction about breast cancer screening, adverse effects, and the purpose of the session. Explanation of the study, its objectives and how results will be used.
Views and experiences in breast cancer screening: Have you participated in screening? What are your experiences? How do you value your participation?
At this point, participants were asked to read the Decision Aid (DA)
Overall assessment of DA: How do you feel about it? What do you think? Did you know this information about benefits and risks?
Assessment of the DA by sections. (re-reading each section out loud and commenting): Is it easy to understand? What do you think about the content? And about the format? Would you need to know anything else? Is there anything that you would exclude? Do you want to decide if you want to participate or not in screening?
Figures: What do you think about the figures? Do they help to understand the risks of screening? Does knowing these risks affect your decision to participate in a screening programme? Why? Why not?
Making decisions to have or not to have a screening mammogram. Does this information affect your decision? Would you like to know anything else before making a decision?
Healthcare professionals focus group presentation topics and key discussion questions
Brief introduction about risks and benefits in breast cancer screening. *Researchers present the study*. Discussion on risks and benefits.
Experiences and opinions about shared decision-making in breast cancer screening: Have you had any experience in shared decision-making in breast cancer screening?
At this point, participants was asked to read the Decision Aid (DA)
DA assessment: What do you think about the content? And the format?
Assessment of the possibility of incorporating shared decision-making within the current health system: what professionals should participate? What barriers would they encounter?

Several participants (epidemiologists and primary care physicians) noted that the graphical representation of overdiagnosis via cumulative frequencies over the lifetime was not clear enough. In addition, they debated how to present the information on benefits and risks, adapting it to the statistical literacy level of the target population, especially as the evidence is based on mathematical models, which are difficult to understand even by some professionals.

The professionals noted that the DA failed to mention certain risks and benefits. The most notable absences were false-negative results and the fact that screening often lessens the aggressiveness of treatments when breast cancer is present, resulting in an improvement in quality of life. Some clinicians also questioned the conceptualisation and magnitude of overdiagnosis, arguing that it might include biopsies that remove all of the cancer tissue, which for them would not imply overdiagnosis but rather elimination of the cancer.

The discussion regarding the convenience of informing people about the risks of screening and providing specific data on overdiagnosis and overtreatment generated an intense debate that we have summarised as two opposing attitudes.

3.2.1 | Against

Some professionals, both clinicians and screening programme workers, positioned themselves against providing information about the screening harms. They argued that there exists enough evidence on the benefits of the programme and therefore, screening is not ethically questionable. This evidence guides the screening programmes' design and does not allow for any decision-making process among women. For these professionals, overtreatment was a consequence of the interventions, which are necessary to diagnose cancer, and their effects on women were considered minimal. Some posited that the risks of overdiagnosis and overtreatment cannot be shared with women because that would decrease participation. In relation to the adaptation of the DA, they called into question terms such as "false positive", suggesting alternative definitions that indicate an error in mammography interpretation.

3.2.2 | For

Other professionals, mostly primary care physicians and public health specialists, and some screening programme workers positioned themselves in favour of providing information about the risks of screening. They considered that enough evidence of overtreatment exists to justify sharing these data with women. On an ethical level, they posited that it is imperative to inform people about the available evidence because these data change the balance between the benefits and harms. They were in favour of informed participation and SDM, although some specified that their support was limited to situations that did not generate fear or confusion.

In short, informed participation or SDM in breast cancer screening generated four different and conflicting attitudes among the healthcare professionals, which we classify into the four categories (see principal citations in Table 5):

1. Those who consider that screening is beneficial for women's health, and therefore it is not necessary that women participate in the decision-making process because it is clear that they should participate in screening.
2. Those who believe that SDM is not possible because the rationale for the screening programmes is the evidence of benefit. The

TABLE 4 Selected quotations from focus groups of women on assessment of the Decision Aid (DA) and perception of decision-making in early detection

Views and experiences in breast cancer screening
For me mammographies give me, let's say … security (G5P1: 59, Primary Education, does not participate in the population-based screening programme, monitored through private insurance).
I have always doubts about… if being irradiated so often it's harmful… (G7P3: 61, Primary Education, normal screening results).
It took some time since I received the letter. They called me to do an ultrasonography. Then they said "there's something there, it's like a lump, you have to go to… you'll be called to get a needle biopsy. It took nearly a month to call me and I felt an unnecessary distress (G3P1: 52, Secondary Education, does not participate in the population-based screening programme, monitored through private insurance).
DA assessment; Acceptability and feasibility
I do not understand this "some will be treated without being necessary". I don't really understand it. *Researcher: This is what I was talking about before, it is what research has found, overtreatment happens as a result of overdiagnosis.* In other words, they believe it's cancer but it's not and chemo is given? (G7P5: 42, University Degree, annual screening exams because of family history).
If only one is diagnosed with cancer, how come that two women will be treated? (G2P6: 54, University Degree, false positive result) And also, forty will have a false alarm but here it says "ten of two hundred". Forty along all the time… is that it? (G2P7: 54, University Degree, participates in the population-based screening programme, false positive).
Researcher: It says "some would have even disappeared spontaneously without treatment." Doctors cannot always know if an early breast cancer may endanger the life of a woman, so they offer treatment to all women diagnosed. This means that some women will be offered treatment they do not need " That is so crazy! (G4P3: 68, University Degree, does not participate in the population-based screening programme).
Well, it causes to me a little more confusion, uncertainty, I do not know what to do about it, (G1P1: 59, elementary studies, does not participate in the population-based screening programme, monitored by private insurance). No, I think it is better (G1P2: 62, Primary Education, false positive result). I think they shouldn't have told me (G1P1).
To inform always is positive, of course, but this kind of alarmism… (G4P4: 69, University Degree, does not participate in the population-based screening programme).
Let's see, I think it's good to know, we always have the right to know (…) this overdiagnosis, if I had any doubt with this information I would consult a professional because they understand. And I would resolved from there. I always think that is better to have information (G2P5: 44, University Degree, does not participate in the population-based screening programme).
Researcher: that's it, those overdiagnosed are all this. (researcher points on a figure of the DA) It is better not to know (…) (G2P4: 52, Secondary Education, does not participate in the population-based screening programme) I did not need that information (G2P3: 46, University Degree, no family history).
Perception about decision-making in screening participation
How can I make a decision if it is beneficial to my health? I mean, I don't quite understand why you're asking me if I need a tool, when I know it's beneficial (G2P1: 51, Secondary Education, does not participate in the population-based screening programme).
Everybody must choose, you can't say "I'm going to get it (referring to screening)," no, everybody must choose and be confident of herself (G3P3: 61, Primary Education, participates in the population-based screening programme, false-positive result).
If the doctor says you have to do it, you do it (G2P2: 56, University Degree participates in the population-based screening programme, false-positive result). We have become accustomed to prevailing medical opinion, right? (G1P1: 50, Primary Education, does not participate in the population-based screening programme).
It is true that with information and support it's much easier or much more justified to make this decision, which is ultimately what we have to do (G2P6: 54, University Degree, participates in the population-based screening programme, false-positive result).
I mean, I think it's a general feeling that perhaps it exists the risk of being overdiagnosed but nevertheless it's worth it… (G2P7: 51, University Degree, does not participate in the population-based screening programme).

decision is "Yes, participate" as it is recommended by the programme because there is no margin for SDM within the current health system.

3. Those who defend that the decision is already informed because women decide whether to participate based on a letter that mentions some harms, such as false positives.
4. Those who think that the decision should be shared between professionals and women. In this case, it is necessary to establish a dialogue between women and health professionals to discuss risks and benefits of screening.

The majority of professionals favoured providing information to women, although no consensus was reached regarding the need to inform them of adverse effects. In general, the professionals indicated the need for complementary support to whoever receives the DA. They suggested that women should participate in an SDM process and

TABLE 5 Selected quotations from focus groups of professionals on assessment of the DA and perception of decision-making in early detection

Attitudes towards shared decision-making in breast cancer screening
Our premise was that screening was effective, so it had to be done, not only because many Spanish regions were already doing it but also it was a political obligation (oncologist).
Yes, but when they go to the doctor, you have to inform them, you have to encourage them to participate (doctor in a cancer research centre).
We are nowhere near reaching the whole population, but we cannot patronise. If you say "you have to do this", people are going to do it because the doctor recommends it, but if there are reasonable doubts because of the evidence on harms, although I am in favour of screening, we should inform the population (primary care doctor).
In primary care there are increasingly shared decisions (…) but in breast cancer (screening) my impression is that in primary care everything is organised, very much guided, and decisions are not shared with the patient (primary care doctor).
Women should participate in an informed manner in screening and not be forced. A woman never goes forced, you invite her and she is free to decide (…) there is greater health education and there is more concern among women to seek out information and we give information on the (screening) programme with booklets, both risks and benefits, and to women with prosthesis (screening programme professional).
Don't do it (SDM in breast cancer screening). That is what I am perceiving (from the discussion in this group): "Let's not do it as we (meaning healthcare professionals) know what is right (…). We do not want a shared decision; let's not give information because if we give it, considering that there are dubious studies, participation will go down. That's the conclusion I drawn (from the discussion), and I don't agree (primary care doctor).
Let's see, I really think that (…) we all have worked on these issues, no matter how much - or how little, but we have worked on them and we are sliding in: It is no necessary shared decision-making in that issue. Don't do it. That is what I am perceiving (from the discussion into this group). As we know breast cancer screening is right women don't have to decide (…). We do not want a shared decision; that is what I understand (…). In addition not giving information because if we give it, considering that there are dubious studies, participation will go down. That's the conclusion I don't agree (primary care doctor).
Information is important, but the decision is made by the person not only based in the information received but also in their beliefs, values, a lot of things (…). Many times talking about the pros and cons and making the decision oneself, this is not an informed decision. They have to put in value these things (primary care doctor).
Controversies associated to overdiagnosis and overtreatment in professionals' discourses after receiving the DA
There is enough evidence about benefits of the programme and, therefore, they can't be debated nor ethically questioned. Its role is to guide screening programmes planning and not women's decisions. Those are things that can't be debated, as there are some standards that have already been established by scientific evidence and are not debatable (screening programme professional).
It is true that all prevention programmes, and that has been demonstrated, have important side effects, and not all of them have the same benefits to compensate these side effects (…). We know that breast cancer screening reduces mortality, although there are some data that question it, and we also know that there is overdiagnosis, that many women are treated unnecessarily, which produces important psychological damage and a number of interventions in healthy women. Therefore we are producing harm. That is what data says after 20 years of studies (primary care doctor).
Overdiagnosis and overtreatment risks can't be shared with women because participation would decrease. Imagine if you inform that it should not be undertaken… then no one would come (doctor in a cancer research unit).
We come from a perception that the intervention was very beneficial, once we have had more data and information, we have seen that the benefit-harm balance is much narrower than it was thought, therefore it is necessary to give more information so women can decide (epidemiologist).
In favour of informed, even shared decision-making, but only if it does not produce fear and confusion, those are the limits for information (social worker).
How to transmit this information to women is difficult. If we have difficulty interpreting it here, imagine women at home (screening programme professional).
Make the benefits a little bit clearer: mortality reduction, quality of life improvement because they wouldn't have such invasive treatments, etc., and in another section, very clear, potential harms, false positives by their name and overdiagnosis, if it is wanted, but explained differently (clinician).
Sometimes a biopsy is done with thick needles in a lesion formed only by grouped microcalcification and incidentally it takes out all the tumour material. Indeed, when the patient arrives to the operating room and they made a resection of the area, then, they think that she does not have cancer at all, but no, it's in the biopsy! If in the biopsy there is cancer from the morphological or immunohistochemical, there is cancer, and that woman, for better or worse, that this controversy appears or is maintained because someone can say "oh, I don't have anything and when they removed that nothing appeared", because a grouped microcalcification was removed and the tumour was all there (oncologist).
"From 200 women having mammograms biennially, in the 50 to 69 years interval, 40 will have a false alarm". This is not a false positive. A false positive is when I say something and then it's not there. The other thing is simply a suspicious sign or symptom, and therefore I want to verify it through another method (oncologist).
DA evaluation: acceptability and feasibility
I found it too long. It's like it is from professionals and I do not think if this will reach women (…) I got lost, I would be more direct and use language much closer to women, this is still too scientific (doctor in a cancer research centre).
We talked at first about early detection and afterwards we always say screening and that confuses women (epidemiologist).
It is not very clear, benefits and harms must be better separated. Benefits are missing and harms are missing, clearly, a lot of them. When we talk about harmless tumours, this sentence: "some women will be offered a treatment that they do not need", that "maybe they do not need" (epidemiologist).

that professionals should receive more training. Others proposed that informed participation should be the primary endpoint to assess the effectiveness of the screening programme rather than the per cent of participation.

3.3 | DA review and further testing

Based on the feedback of women and health professionals, the content of the DA was simplified, some medical terms were changed to improve understanding, and one figure with cross-sectional data on cancer detection and false-positive rates at each screening round was removed. The acceptability of the new DA in a new sample of women and health professionals was high.

4 | DISCUSSION

This qualitative study on Spanish women and health professionals adds evidence to work done in other countries on women's perception of the benefits and harms of breast cancer screening, and healthcare professionals' perceptions of the convenience of providing this information. In addition, our work contributes to encourage Spanish women to participate in their healthcare decisions and reminds professionals about patients' rights to be informed and participate in decisions about their healthcare.

From this study, it can be deduced that women know that breast cancer screening lowers mortality, and issues such as radiation and false-positive results concern them. The DA did not answer all their doubts. The concepts of overdiagnosis and overtreatment as well as their frequencies generated confusion among the participants, a consistent finding with previous studies (Baena-Cañada et al., 2014; Waller, Douglas, Whitaker, & Wardle, 2013). Despite this confusion, and similar to other published results, the information on overdiagnosis does not appear to influence the intention to participate in the short term, most likely because screening programmes have effectively transmitted the advantages of participation (Waller et al., 2013).

In the professional groups, the DA generated discussion regarding absent or questionable concepts, and participants demanded for a more balanced tool. A balanced DA includes evidence and references for all relevant options and informs the recipient in formats and contexts that allow individuals to assimilate the information without bias (Abhyankar et al., 2013). In the case of screening, the international consensus recommends including information on the follow-up actions that can derive from positive results in addition to the identified informational needs (Feldman-Stewart et al., 2013). Although it is true that the study participants showed a preference for brief DAs, it is a communicative and ethical challenge to develop a tool to respond to women's informational needs in an understandable format with the best evidence available. In line with this view, Hersch et al. emphasised that it is an ethical imperative "to provide information about overdiagnosis… balanced with the responsibility to address misconceptions that may lead to problems in clinical practice" (2013:8). The DA developed by Hersch et al. (supplement of Hersch et al., 2015) is an example of communicating the best evidence, objectively, and in an understandable format. Our DA follows the schema of the DA developed by Hersch et al., although some sections were shortened following the recommendations of women's and health professionals. We are currently working on a web-based DA that will expand the information of the current DA and will include additional tools to help women to elicit their preferences.

However, as some authors have expressed (Duffy, 2014; Heath, 2014; Parker, Rychetnik, & Carter, 2015; Sasieni, Smith, & Duffy, 2015, 2016), the evidence of overdiagnosis produces a significant controversy among professionals whose views range from rejecting to defending the importance of informing women of the screening risks. In our study, the debate questioned whether women should be informed and to what extent, given the existing uncertainty regarding overdiagnosis estimates. Until the results of clinical studies such as the LORD, the LORIS (Elshof et al., 2015; Francis et al., 2015) or WISDOM (https://wisdom.secure.force.com/portal/) are available, it will be difficult to reach an agreement between the relevant actors.

Currently, an open debate exists about the best way to communicate the concept of overdiagnosis to a non-specialised public. In their studies, Waller and Hersch concluded that, even leaving out the fact that estimates are controversial, the concept of overdiagnosis itself is difficult to understand (Hersch et al., 2015; Waller et al., 2013). In our case, presenting results that corresponded to a unique screening exam or the complete screening history in the 50–70 age interval in the same brochure complicated the interpretation of the data, both for women and professionals. The difficulties of communicating risk estimates both to lay people (e.g. patients, politicians and journalists) and professionals are widely documented (Gigerenzer, Gaissmaier, Kurz-Milcke, Schwartz, & Woloshin, 2007). For Zikmund-Fisher et al., the most adequate presentation is to use a large denominator (1,000 or 10,000) so that the data can be presented in whole numbers (Zikmund-Fisher et al., 2008). Nevertheless, Waller et al. (Waller, Whitaker, Winstanley, Power, & Wardle, 2014) found small differences in the intention to participate between different versions of numerical information. Information expressed in the proportion 1:3 (one life saved for three overdiagnosed women) was associated with a greater decrease in intention to participate than other information formats, although it did not enable a greater understanding of the term "overdiagnosis". Gigerenzer et al. (2007) recommend using absolute risks instead of relative risks and mortality rates instead of survival rates. The conclusions of our focus groups allowed to improve the DA that currently is being assessed in a randomised controlled trial.

The information about adverse effects in our study did not seem to affect the intention to participate in screening (at least not in our sample over the course of the discussions). This result is similar to those of Waller et al. (2013), Schwartz, Woloshin, Fowler, and Welch (2004), and Domenighetti et al. (2003). Some authors argue that it is not efficient to invest effort in providing this information if it is not going to change participation (Baena-Cañada et al., 2015). However, other studies indicate that it is necessary to provide the information more often and via multiple information sources (e.g. social media,

billboards, healthcare professionals and so on) to influence participation (Cooper, Gelb, & Hawkins, 2014), especially considering that the messages associated with breast cancer screening have been mostly positive over decades (Fowler et al., 2013; Queiro Verdes et al., 2007) and that, as this study shows, neither the women nor some professionals have directly experienced overdiagnosis.

Our study has two principal limitations. First, only two focus groups of professionals were tested, and they had a heterogeneous profile that limited the saturation of specific perspectives on the evaluation of the DA or decision-making about screening. Second, we observed that group discussion was conditioned when participants had a personal or family history of breast cancer.

Both studied groups showed diverse opinions regarding what type of information about the risks and benefits of screening should be provided to women invited to participate. In our study, women showed lack of knowledge of the existence of overdiagnosis, and they were surprised that they had not been informed of this issue. Many women showed a preference for SDM. In the light of the professional focus groups, however, it would be necessary to inform and train healthcare professionals on the risks and benefits of screening as well as how to incorporate women into this SDM in their practice.

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APPENDIX 1

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