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Including women in the decisions of screening mammography: a deliberative approach

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Title

Including women in the decisions of screening mammography: a deliberative approach

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Abstract

Objectives: To analyse a citizen jury-type deliberative democracy study.

Design: Qualitative research study with methodology of citizens jury.

Setting: Breast cancer screening programme in Andalusia (Spain).

Participants: Thirteen women aged 50-69 with secondary school or higher education accepted to participate as a jury. Two epidemiologists were the expert witnesses. The main researcher in this study was the neutral moderator.

Interventions: Jury met on Monday, 15 February 2016. The moderator indicated the jury it had to assess the key benefits of the screening programme and the main harm. On Tuesday 16, the expert witnesses positioned for and against. On Thursday 18, the jury deliberated, reached final conclusions, submitted its vote to the research question of whether the Andalusian Public Health System must continue offering screening mammography services to women aged 50-69 and stated its recommendations to politicians. The deliberation session was transcribed and analyzed with the support of ATLAS.ti.5.2 software.

Primary and secondary outcome measures: To verify whether the study is applicable to the Andalusian population and to know if women, when well informed, are able to answer the research question. The reasons for the pertinent decision and recommendations to the political authorities will be stated.

Results: 11 participants voted yes and 2 voted no. There are three reasons to vote "yes": health, the nature of the test, and individual freedom. Some women invoke the lack of efficacy and the cost to justify their negative vote, at least in universal terms. Upon completion, they made suggestions to be submitted to the pertinent authorities for the improvement of information, psychology services, and research.

Conclusions: The deliberative strategy is applicable and causes a favourable positioning regarding screening mammography, although the information changes the opinion of some

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women, who wish an informed decision-making and to keep or increase medicalisation in their lives.

Key words: Cancer: Breast; Heath services; Public health policy; Qualitative research; Screening.

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Strengths and limitations of this study

- The jury of citizens was carried out in accordance with the previous protocol.
- The deliberative process was planned, with a description of the selection and roles of the research team and experts, and a description of the recruitment strategy and the characteristics and instructions for the jury.
- The technical and procedural information is available and clearly documented.
- The study was designed as a research project, so there was not a directive committee with the participation of women and without taking into account its critical perspective.
- The information submitted arises from a sole process of deliberative democracy, which is why it will be necessary to apply, as programmed, other methodological strategies allowing for the gathering of more information to fulfil the categories and be certain that the information collected covers every possibility.

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Text

There is more and more evidence indicating that screening mammography may constitute a low-value service where benefits do not exceed its harm and cost.[1] Some women will be benefitted, while others would be harmed.[2] However, public sensing is not realistic.[3] For instance, women in Spain accept the invitation to participate in screening mammography and receive little information [4] and, in general, tend to overestimate the benefits [5] and to not get involved in the physical or psychological impact caused by overdiagnosis and false positives [6,7]. Any help in the decision making related to screening mammography could potentially lead to an informed decision,[8,9] but it is not clear yet how to apply such optimally.[9] In this context, there are still arguments in favour of screening mammography [10] and it has not been removed in western countries, except for Switzerland.[11] Spain has a National Health System but every region is autonomous regarding decisions on screening mammography programme coverage. In Andalusia, a population-based screening programme invites, through letter, women every 2 years. In 2013, a report [12] was prepared and served to fix the age between 50 and 69, ceasing to invite women aged 45-49 in districts where they were invited before.

Citizens' juries gather a group of citizens, randomly chosen, to discuss a particular topic. They are exposed to information and opinions on such topic for several days, which information and opinions are derived from witnesses selected because of their expertise or because they represent their interest. Along with a moderator qualified to guarantee a fair process, the jury members have the opportunity to question the witnesses and, after a deliberation process, they reach a decision and make recommendations to the pertinent authorities. The latter are compelled to provide an answer, either by acting pursuant to the citizens' report or by explaining why they do not agree.[13] The implementation of citizens' juries has been proposed as a tool to provoke the population's positioning in public health issues involving

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scientific controversy as well as for political decision-making purposes.[14,15] Democratic deliberation is useful for the participation in health affairs where it is difficult to obtain an individual and informed consent, it being a consent representing community.[16]

We have designed, carried out, and analysed a citizen jury-type deliberative democracy study to verify whether it is applicable to the Andalusian population and to know if women, when well informed, are able to answer the research question of whether the Andalusian Public Health System (SSPA) must continue offering screening mammography to women aged 50-69. The reasons for the pertinent decision and recommendations to the political authorities will be stated.

METHODS

Research protocol (Supplementary File) was approved by the Bahía de Cádiz - La Janda Ethics Committee and all participants gave written informed consent. Their names referred to in the quotations are fictitious to guarantee confidentiality.

Jury selection

A sample of 70 women aged 50-69, with secondary school or higher education, without relationship established between them or with the researchers prior to study commencement, was selected from the list of invitations of the breast cancer screening programme. Telephone contact started 3 months before the process. If, after 3 attempts on different days, it was not possible to contact them, they were excluded. In the first contact, information on features and purposes was provided and, if they accepted, they were contacted a month before and a week before for confirmation. The purpose was to recruit at least 12 women.

Expert witnesses selection

Two expert epidemiologists (women) defended the positions for and against screening mammography. The one positioned in favour works at the Provincial Cancer Registry of Cadiz (EBR) and was selected because she has been a member of the research team for years. The

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one against (SMC) was selected due to her expertise in the development of the Andalusian screening mammography programme and because of her critical position towards it. The main researcher (man) in this study was the neutral moderator (JMBC).

Documentation preparation

Informed consents and an information gathering sheet with respect to the participants' features were prepared. The research team and the expert witnesses prepared four documents to be delivered to the jury (Supplementary File): 1.- General information document and a presentation for the jury members regarding the screening mammography. 2.- Document with arguments for and against mammographies, containing the experts' presentations. For its preparation, the report published by the General Secretariat of Public Health, Social Inclusion, and Life Quality was employed as a guide.[12] 3.- Information document regarding the Andalusian early detection of breast cancer programme available at http://www.juntadeandalucia.es/servicioandaluzdesalud/principal/documentosacc.asp?pagina=gr_sabermas_cancermama. 4.- Finally, presentation with recommendations for deliberation.

Process

The jury members met 3 afternoons for 4 hours at a hotel in the city. On the first day, introductions were performed, the study's features and purposes were explained, doubts were resolved, informed consents were signed, and socio-demographic information questionnaires were fulfilled. They were provided with a dossier containing the described information. The moderator indicated the jury it had to assess the key benefits of the screening programme (breast cancer mortality reduction), the main harm (overdiagnosis, overtreatment, and false positives) and other benefits and harms. To that effect, a presentation was made in order to understand the arguments for and against to be presented the next day. The opportunity to resolve doubts was granted.

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On the second day, the experts made their presentations for and against and the jury asked questions. The moderator motivated the debate and discussion.

On the last day, the jury discussed without the presence of the experts or moderator and reached a conclusion. They issued their vote and wrote suggestions to political decision-makers.

During three days, an observer expert in qualitative research (VLR) took notes of the sessions without participating actively. The entire process was supervised by an expert in Bioethics (JMRB). All the sessions were audio and visual recorded. A gift valued at 20 euros was given to each participant.

Information analysis

Upon transcription of the deliberation session by independent parties (see acknowledgements), it was analysed with the support of ATLAS.ti.5.2 software. A systematic reading of the information was performed, the categories derived from the deliberation were identified, and, in this paper, only the analysis of the category "opinion on whether the SSPA must continue offering mammographies to women aged 50-69" is presented. The deliberation session was deconstructed, assigning and reducing information in this category. Later, the information was reconstructed and summarized to conclude with its interpretation. A theoretical approach based on health psychology from a feminist approach and Liberation Psychology was established.

A process of verification by informants (member checking) was carried out. The participants were returned an abbreviated report on results where they had to score, in a Likert-type scale from 1 to 5, the adjustment and sufficiency of the definition of categories and sub-categories and the relevance of quotations by means of which categories were justified and illustrated. 6 scores were obtained which, in general, agreed with the interpretation of the information and participants stated they recognised their voices in the report.

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Likewise, a researchers/analysts triangulation was performed to reduce the distortion of the information interpretation and to increase the validity of results. To that effect, a person not related to the team, an expert in qualitative information analysis and Health Social Psychology was incorporated. Such individual was provided with a detailed report on results and, by means of a Likert-type scale from 1 to 5, had to assess the relevance of categories, sub-categories, and identified features, their definitions, and the examples provided. Such person also scored the information interpretations. Among their suggestions, we may find: to gather and remove some categories, to deepen in the definition of others and to provide more examples in some categories and sub-categories for being insufficiently based on the information. Their recommendations were followed.

RESULTS

Figure 1 shows a flowchart of jury recruitment and Table 1 shows its main features. Thirteen women attended the three sessions and, after deliberation, 11 of them voted "yes" and 2 voted "no" to the question of whether the SSPA must offer mammographies to women aged 50-69.

Table 1. Jury members' features.

Age (median and category)	55 (51-65)
Level of education:	
Secondary	5
University	8
Working status:	
Active	8
Unemployed	3
Pensioner	2
Marital status:	
Married	10
Separated	2
Widow	1
Do you have a mammography performed regularly?:	
Yes	12
No	1
You have a mammography performed with:	
Public screening programme	11

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Private healthcare	1
Both	1
Previous mammography rounds:	
1	1
2	0
3	2
4	1
5	3
>5	6
Family history of breast cancer:	
Yes	4
No	9
Previous favourable opinion on screening mammography:	
Yes	13
No	0

The reasons why participants think mammographies must continue being offered have been grouped in three: health, test nature, and individual freedom (Table 2). Different opinions are observed regarding coverage among those who believe they must continue being offered; some women deem necessary the universal nature while others consider they should be offered on demand. There are participants who mention the lack of efficacy and the high cost to justify they must not continue being offered. Tables 3 and 4 present some women's indicative quotations.

Table 2. Categories on whether the SSPA must continue offering screening mammography

Category	**Sub-category**	**Features**	**Indicators**
Yes	Reason	Health	Mortality reduction
			Prevents “greater harm”
			Few negative consequences
		Nature of the test	Diagnostic test
			Absence of alternatives
			High efficacy
			Public good
		Individual freedom	Women's freedom
			Capacity and right to take decisions
	Type of offering	On demand	
		Universal	
No	Reason	Lack of efficacy	
		High cost	

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Table 3. Indicative quotations: Reasons to continue and to not continue offering screening mammographies

Jury member	Indicative quotation
	Health as a reason to continue offering screening mammography
Juana	I'm in favour of its continuance, because as from the moment it reduces mortality, I believe it must be offered.
Rosario	…The fact that it reduces mortality, even for two people, is enough to me, because if I'm one of those people, I will tell you whether it is worth it or not.
Rosa	Of course I'm in favour because I think greater harm may be prevented.
María	…in favour of mammographies. More significant harms can be prevented and there is no possibility of surgery or treatment.
Milagros	…it's OK because negative things are very few … Because, the negative, what is it? The radiation? Well, we already know it's a normal X-ray...
	The nature of the screening test as a reason to continue offering screening mammography
Juana	…Mammography itself, in my opinion, is really good because it detects any possible problem, so you say "it may find out a problem".
Manuela	I'm in favour of every preventive measure, at the public health level, for the entire population. I'm in favour of mammographies. I'm in favour of mammographies…, if we are not offered alternatives, we know it has some risks and side effects, but, between not having anything and having this test, well, I'd rather continue having it.
Milagros	We must take into account that overdiagnosis is one out of seventy seven, I mean, it's really small, so death is one out of one thousand but overdiagnosis, which is one of the negative things, is one out of seventy seven, it's very small, the fact that one out of seventy seven is overdiagnosed is really small, I thinks it's lottery. …I wouldn't remove it, because it's a public good … in addition, it's up to you, because it's voluntary.
	Individual freedom as a reason to continue offering screening mammography
Carmen	Yes, yes, I think women are free to take decisions.
	Lack of efficacy as a reason not to continue offering screening mammography
Ana	…But the point is the programme. It doesn't work … one out of seventy seven in the population is a lot.
Mercedes	The point is that with the figures and data we have, I see it so dependent on fate, because it's such a small portion among so many

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	that it gives the impression that...
	High cost as a reason not to continue offering screening mammography
Ana	So, let's see, the cost derived from performing mammographies, treatments because something is detected is a quite high cost. So, we should see if there other more effective ways of prevention and that money we are employing should be used for another thing, maybe research on…medicines.
Juana	In favour of women being provided with enough information so that they can decide freely, considering the pros and cons, whether to have it made or not voluntarily.

Table 4. Indicative quotations: Type of screening mammography offering

Jury member	**Indicative quotation**
	On demand
Mercedes	I say mammographies are always there, you may request one whenever you want, so they won't be denied.
Rosa	No, no, no, no they won't perform it because you request it...
Milagros	You request a test now and, when will it occur? A DEXA, how long does it take? It's an institutionalised programme that once it's been implemented, now yes, and maybe the campaign is to remove it, we don't know what's behind…
	Universal offering
Milagros	The plan [the Screening Programme] exists and it's optional whether to perform it or not. So it's better for it to exist because there are people who will want to perform it … no one obliges you to do it right now. It's a thing that has been established, institutionalised, which is good because we see very few negative things, the fact that you may opt to perform it or not is voluntary.
Juana	… they may decide freely, considering the pros and cons, if they perform it or not voluntarily.

Health as a reason to continue offering screening mammography

Mortality reduction arises as a reason for which some participants believe it must continue being offered between 50 and 69 years old. During deliberation, there were different opinions on whether mortality reduction is significant. Rosario mentions that the reduction degree is

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not an aspect to be considered and that any reduction is acceptable when it comes to human lives (Table 3). When participants indicate that mammography may prevent greater harm they refer to its diagnostic nature (please note Rosa's words in Table 3). They think participation in screening facilitates an early diagnosis and improves treatment possibility (see María's quotation in Table 3), prevents any harm derived from the advanced cancer stage and helps extend a decent life. Furthermore, reference is made to the negative consequences and some participants believe they are few and minimise them, such as radiation. They consider that some of the negative consequences are also present in other tests and this justifies the continuance of mammography (Table 3).

The nature of the screening test as a reason to continue offering mammographies

Some participants believe screening mammography is a diagnostic test. They see it as the only efficient test to detect breast cancer, which they invoke as a reason to support it. Consequently, they think every kind of risk, side effect, or error possibility is reasonable. Milagros, even when she recognises that overdiagnosis may be a risk, appreciates it seldom occurs. That is how she justifies it must continue being offered (Table 3). Moreover, there is the idea that screening is a preventive test, as another argument in favour of the offering thereof. However, it is based on the wrong idea that screening mammography serves to prevent, which denotes a wrong use of the diagnosis and prevention concepts.

Related to its universal nature, there appears the concept of "public good" as a reason to continue offering mammographies. The public "good" is understood as general conditions which are advantageous to every person, regardless of their condition, facilitating equality. In this case, mammography is understood as a valuable resource that must be offered to women with the sole requirement of being aged 50-69 (Table 3).

Individual freedom as a reason to continue offering screening mammography

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Women's freedom to decide what to do once they are offered the opportunity to participate in screening mammography is revealed as another argument for. There is the demand of being treated as active users of SSPA and not as mere passive users or consumers. Such demand involves the participants' desire to be well informed, to be able to undertake responsibility in the form of decision-taking. Somehow, it is a way to reduce the anxiety that may be caused by the mammography, trying to increase control and reduce ambiguity (Table 3).

Lack of efficacy as a reason not to continue offering screening mammography

If efficacy was previously an argument to justify mammographies should continue being offered, it is now an argument to question it. Some participants, like Ana and Mercedes, question its efficacy, and believe that, on some occasions, it depends on fate (Table 3).

High cost as a reason not to continue offering screening mammography

Ana mentions the high cost of the screening programme and, in the face of the inefficacy of the test, considers the investment unjustified. That is why she suggests other measures, such as research, in order to make economic cost profitable and make progress regarding the issue (Table 3).

Availability on demand

From the participants' words there arises the idea that the SSPA must continue offering screening mammography, although there are some nuances. Some participants consider it must be offered on demand, that is, offered to those women requesting it. However, there are opinions against this possibility. Part of this rejection is based on the mistrust towards SSPA and its good operation. Another part is based on the mistrust towards the latest goal of this research. Milagros expresses her fear related to the removal of the breast cancer screening programme's universal nature (Table 3).

Universal availability

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Some participants believe the screening test must continue being offered on a universal basis to women aged 50-69, since this does not make it compulsory. Therefore, the voluntary nature of participation is deemed a key feature (Table 4).

Recommendations to sanitary authorities

After joint consideration, the jury prepared a list of recommendations addressed to the sanitary authorities to improve the screening mammography programme. They focused on the improvement of information, the psychology service demand, and the promotion of research on breast cancer screening:

Recommendation 1: Women must be informed when receiving an invitation to participate in the programme, so that their decision is informed, (e.g., being aware of the possibility of overdiagnosis, false positives, radiation).

Recommendation 2: Information must be given in such a manner that it is widely known (e.g., information campaigns in the media, in particular, addressed to women aged 49-50).

Recommendation 3: During the screening test process, women must have specialised psychological support. Particularly, in the case of evidence of presence of disease.

Recommendation 4: Modify protocols of action after mammographies so that, in case of signs of cancer, the patient may know to what tests they will be subjected.

Recommendation 5: Use less harmful techniques than mammographies and offer alternatives to the latter.

Recommendation 6: Provide more resources to research on breast cancer, its prevention, early diagnosis, and treatment (e.g., be able to select which women may benefit and which may be harmed upon participation in the programme).

Recommendation 7: Studies on which the debate on benefits and cost of screening tests are based must be updated. The most recent ones are from the 80's.

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DISCUSSION

The deliberative democracy process has been applicable to a group of SSPA users and it has caused a favourable positioning, although the study information changed some participants' opinion (2 out of 13, 15%). On the grounds of health, test nature, and individual freedom, women believe screening must continue being offered and they make suggestions to the political authorities for them to improve information, psychology services, and research. In general, most of them fight for keeping or increasing medicalisation of their lives (not "losing" mammographies and psychology services to fight problems derived therefrom), although there are women who invoke its lack of efficacy and cost to justify it must not be offered, at least on a universal basis.

Despite it is largely known that screening mammography is not perfect and despite the recommendation from the citizens' jury to reflect on its implementation,[17] there are few deliberative experiences in relation thereto. The purpose of one of them was to collect recommendations on how to submit the information so that it would be easier for participants to take informed decisions on whether to attend or not a mammography.[18] In another one, the citizens' jury was mostly against screening mammography for women under the age of 50 in New Zealand.[19] Citizens' juries have been efficient when it comes to changing the positioning of population in the face of other screenings, such as the prostate screening.[20] In our study, the change was limited but significant, since 15% of participants do not recommend screening now.

The results of our deliberative democracy study may serve as a justification for political authorities to maintain screening mammography in women aged 50-69. However, we believe it would be interesting that they should consider the studies indicating the harmful effects of the test as well as the opinion of the participants who were against and that they should re-consider the type of offering too (universal vs. on demand), although some experts think that if

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a screening is implemented, it must be for the entire population.[21] On the other hand, it is necessary to consider the power of pre-existing ideas and prevailing social speech that highlights the possible positive effects of screening mammography, barely considering negative arguments.[3,22]

Our study's implications on managers and clinical doctors must involve understanding the participants' claim for their right to choose freely. This involves placing such desire in the context where it takes place, which is characterized by the prevailing social speech in which, despite the lack of consent of the scientific community with respect to the benefits of the screening test,[1,2,5-7] these are overvalued, thus disregarding its harm. Such social speech is motivated, among others, by awareness and sensitization campaigns related to breast cancer which clearly show signs of lack of information [23] and by the few information received by women invited to participate in the screening programme.[4] Finally, screening mammography has been institutionalised [24] in a more and more medicalised [25] state determined by the logics of a consumption society in which women [26] are immersed.

This study presents a series of weaknesses to be taken into account when considering results, which must serve as elements to be strengthened in the future. The study was designed as a research project, so there was not a directive committee with the participation of women and without taking into account its critical perspective.[14,27] Nevertheless, the research team included expert witnesses, a moderator, a psychology expert in qualitative research and an expert in bioethics. The process lasted a bit less than recommended [14] but there was enough time to explore the issues addressed. The information submitted arises from a sole process of deliberative democracy, which is why it will be necessary to apply, as programmed, other methodological strategies allowing for the gathering of more information to fulfil the categories and be certain that the information collected covers every possibility. Apart from

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that, although the political authority accepted to be an observer interested in the project, there was no genuine commitment to incorporate results in their decisions.

At a procedure level, weaknesses closely related to the qualitative methodology have been detected. It has been observed that some participants did not pose every question they had and, therefore, they were not as well informed as it was expected. The expert condition of the research team was highlighted, which could deepen the differences of power between the former and the participants and prevent their participation. Moreover, certain hierarchy was observed among some participants.

Furthermore, certain mistrust is derived from the words towards the latest purposes of the research given that some participants are afraid that SSPA might be considering the removal of mammographies. Said mistrust may have affected their opinions. Lastly, it must be taken into account that this work has been developed with a sample of literate women, with a medium-high level of education, economic resources, natives, and without functional diversity. It would be necessary to perform works in other social realities whose needs must also be satisfied.

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Declarations

Ethics approval and consent to participate

This study was approved by The Bahía de Cádiz - La Janda Ethics Committee. Participants gave informed consent to take part in the study.

Patient consent for publication

Not applicable.

Availability of data and material

Presentations of the moderator and experts, and recordings and texts analysed during the current study are available from the corresponding author on reasonable request.

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Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: financial support from the Ministry of Health, Equality, and Social Policies of Andalusia for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Authors´ contributions:

José M. Baena-Cañada conceptualized the project. **José M. Baena-Cañada, Violeta Luque-Ribelles, Alicia Quílez-Cutillas, Petra Rosado Varela, Encarnación Benítez-Rodríguez, Soledad Márquez-Calderón,** and **Juan M. Rivera-Bautista** contributed to the design and methodology. **Violeta Luque-Ribelles,** and **Alicia Quílez-Cutillas** performed analysis of texts. **José M. Baena-Cañada, Violeta Luque-Ribelles, Alicia Quílez-Cutillas, Petra Rosado**

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Varela, Encarnación Benítez-Rodríguez, Soledad Márquez-Calderón, and **Juan M. Rivera-Bautista** contributed to the development of the process of deliberative democracy (investigation). **José M. Baena-Cañada** contributed key resources. **Violeta Luque-Ribelles, Alicia Quílez-Cutillas,** and **Petra Rosado Varela** contributed to data curation and management. **José M. Baena-Cañada** wrote the original first draft of the article. **José M. Baena-Cañada, Violeta Luque-Ribelles, Alicia Quílez-Cutillas, Petra Rosado Varela, Encarnación Benítez-Rodríguez, Soledad Márquez-Calderón,** and **Juan M. Rivera-Bautista** played key roles in writing with respect to review and editing (all authors contributed to the final article). **José M. Baena-Cañada, Violeta Luque-Ribelles,** and **Petra Rosado Varela** provided oversight and leadership (supervision).

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Table and Figure legends

Table 1. Jury members' features.

Table 2. Categories on whether the SSPA must continue offering screening mammography.

Table 3. Indicative quotations: Reasons to continue and to not continue offering screening mammographies.

Table 4. Indicative quotations: Type of screening mammography offering.

Figure 1. Flowchart of jury recruitment

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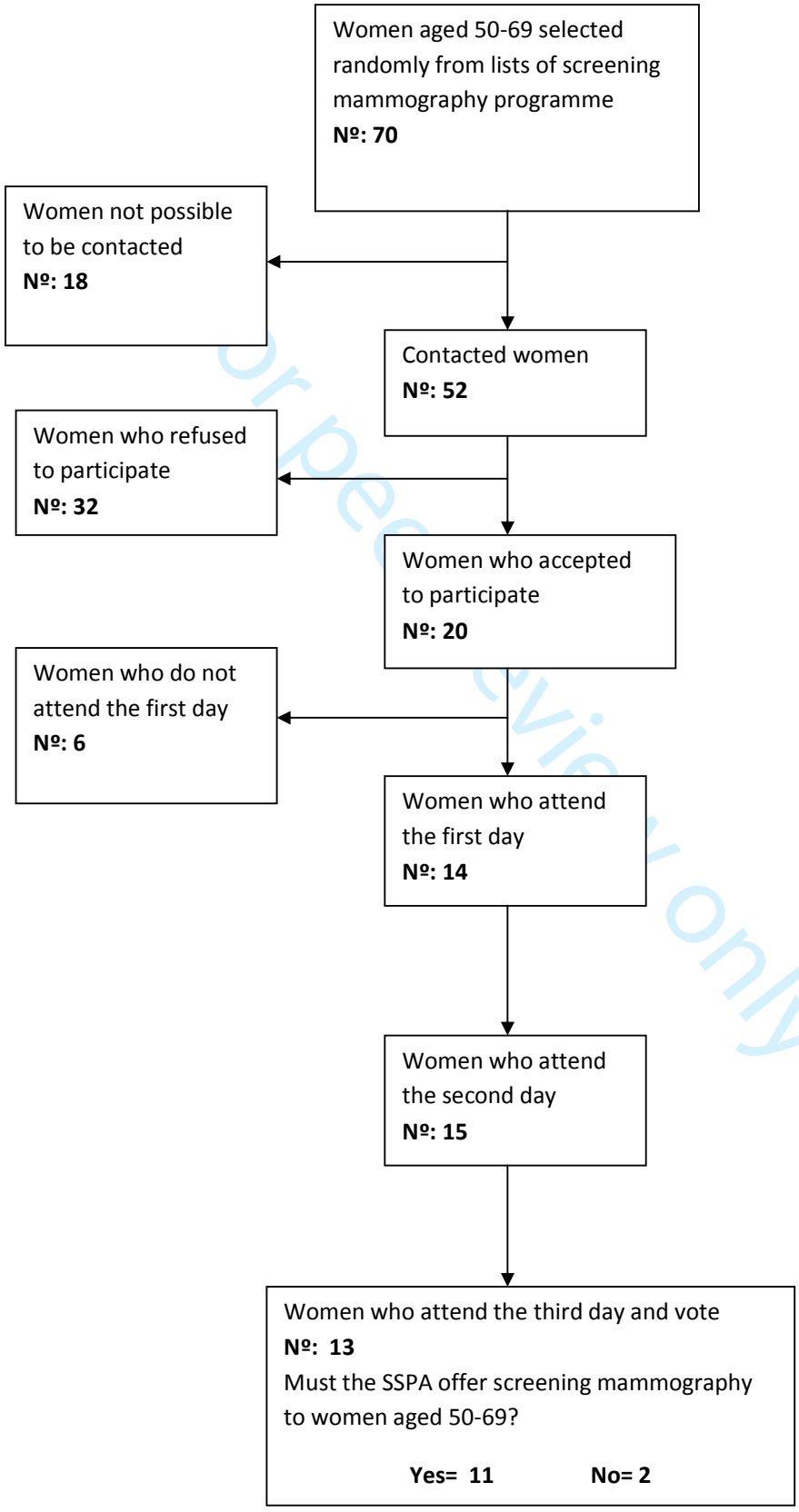
Figure 1. Flowchart of jury recruitment



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OFFICIAL ANNOUNCEMENT OF FINANCIAL AID BY THE ANDALUSIAN PUBLIC FOUNDATION FUNDACIÓN PROGRESO Y SALUD FOR THE FINANCING OF BIOMEDICAL I+i AND HEALTH SCIENCES OF ANDALUSIA FOR YEAR 2014

SCIENTIFIC-TECHNICAL AND FINANCIAL REPORT _ RESEARCH PROJECTS

MAIN RESEARCHER	
LAST NAME BAENA CAÑADA	FIRST NAME JOSÉ MANUEL

PROJECT TITLE

Deliberative democracy study on women participating in the screening mammography programme

KEY WORDS

Screening mammography. Community's opinions. Health policy. People's jury.

ABSTRACT

(250 words maximum)

Purpose: Try a method to determine if population, when well informed, would be able to support or reject the political decision on breast cancer early detection. In particular, whether the government of Andalusia should maintain or not the invitation to undergo screening mammography to women aged 50- 69.

Design: Development of people's jury-like deliberative democracy methodology.

Subjects and area of study: There will be 12 women selected between 50 and 69 years old who undergo screening mammography in the Bahía de Cádiz-La Janda District. Experts defending the position in favour and against the screening programme will be two epidemiologists who are experts in cancer prevention.

Realization: Study by a people's jury with randomly selected participants. Information is provided to participants via documentation, multimedia presentations, and sessions recording. A final report containing the decision based on votes in favour, against, and abstentions, as well as on women's deliberation, will be prepared.

Factors: contacted women, included in the study, final participants, informed consent, participants' sociobiographic features, qualitative analysis of the deliberation process, votes in favour, against, and abstentions, reasons justifying votes in favour and against, participant's recommendations.

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1. SCIENTIFIC-TECHNICAL ASPECTS OF THE PROJECT

1.1 BACKGROUND AND CURRENT STATE OF THE STUDY TOPIC

Knowledge of background and current state of the topic will be assessed. Explain previous works published regarding the project topic, both performed by the research team and by other national or international groups (3 pages maximum)

The controversy related to screening mammography programmes commenced in year 2000 when Peter Gøtzsche (Nordic Cochrane Centre) published in The Lancet his meta-analysis of randomized clinical trials published so far on the efficacy of reduction in breast cancer mortality (1). Pursuant to said author, should methodologically inappropriate trials be excluded, screening mammography does not reduce breast cancer mortality, so it would be unjustified (1). Similar conclusions were reached in the systematic review of the Canadian Task Force on Preventive Health Care (CTFPHC) (2). The Cochrane review (3) concludes that it is unclear that screening mammography causes more benefits than harm and that it seems unreasonable to participate in breast cancer screening.

In 2009, the controversy was intensified again when the U.S. prevention services (USPSTF) decided not to recommend, on a routine basis, screening mammography to women between 40 and 49 years old (4). Such decision, as opposed to the 2002 recommendations (5), was based on a computerised analytical model of 9 randomized and controlled trials carried out in the last century (6-14).

Recently, a new version in the United Kingdom does not shed more light on the controversy (15). The Marmot report concludes on its significant benefits, but it suggests that every woman should make their decisions and, therefore, true information on the benefits and harms (15) must be provided.

The decision taken by every western country to implement and maintain their mammography screening programmes active is based on breast cancer mortality reduction which is estimated, in general, around 20%, with relative risks (RR) near 0.80 (2) (3) (4) (16).

The main risks for a woman who undergoes screening mammography are overdiagnosis, overtreatment, and false positives. There is uncertainty in the quantification of breast cancer detection that would have never been diagnosed and treated if the women would not have undergone mammography. The most certain estimates are derived from calculations performed in proven-quality clinical trials that did not offer mammographies to the control group upon completion of the study. Again, the results vary according to the systematic review, but they vary between 11-19% and 30% in relative terms and in 1 case of overdiagnosis out of 77 to 100 women subjected to screening for 20 years (15) (16) (17) (18) (19). Overtreatment was also assessed in the Cochrane review (3). There were more surgeries (RR 1.31), more mastectomies (RR 1.20) and more radiation therapy (RR 1.24) in women subjected to screening. However, less chemotherapy (RR 0.63) and less hormone therapy (RR 0.81) were employed, without reaching statistical significance. The update of the Canadian trial finds out that after 25 years of follow-up there were 106 overdiganoses out of 484 detected cancer cases (21.9%) (20) (106 out of 44,925 healthy women who underwent screening were diagnosed and treated unnecessarily of breast cancer) (20). Furthermore, the update of this paper does not find any reduction in breast cancer mortality (20), a contrary result conflicting with the mortality reduction of 40% found in the analysis of observational data in 7 out of 12 Canadian provincial screening programmes from 1990 to 2009 (21).

There is more unanimity with respect to other screening programme risks: re-call in 4% of cases to repeat the mammography, and a potential biopsy. Of these women, one out of five will be finally diagnosed with cancer. Of the remaining women, 70% will only need another imaging test and 30% will require biopsy, almost always -90%- with local anaesthetic. All such procedures, as well as the final cancer diagnosis and the pertinent treatment, may have a great psychological impact (22).

Scientific societies continue recommending mammography even as from 40 years old (23) (24) and no western country has dismantled their screening mammography programmes. Only Switzerland has initiated an institutional debate regarding such topic (25) (26). In Andalusia, after an excellent literature review, a report (27) was prepared, which has served as the basis to fix the age for screening mammography between 50 and 69 years old, ceasing to invite women aged 45-49 in districts where they were.

The deliberative democracy methodology is employed to involve citizens in a formal dialogue with the government or other public institutions, in order to provide a solution to complex problems. It includes people's jury, consensus conferences, deliberative surveys, study groups, citizens' meetings, and new online options. Deliberative democracy's primary purpose is to approach opinion and citizens' values to the political decision-making process (28). It is particularly useful for surveys where personal values, ethics, and existing trials on the topic in question are significant. In such issues, citizens need time to understand them fully and to consider all relevant aspects (29). Moreover, an informed consent method representing the community (30) must be considered. There is no consensus on which is the best way for women to be well informed regarding screening mammography and to make informed decisions on this breast cancer secondary prevention method (31), but the point is that women show a very poor level of knowledge and an enthusiastically positive attitude towards mammography (32).

The screening mammography programme is a public issue with great relevance because it affects a great volume of the population. The impact of its implementation is morally significant since there exist conflicts as to benefits, harms, autonomy and justice. The decision of its implementation cannot be resolved through scientific evidence given that, as we have already seen, there is no consensus among experts and such decision depends on the values of the women involved, who will probably have different opinions.

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In 2007, in New Zealand, 80 women aged 40-49 were randomly selected from the electoral register to participate in a deliberative process regarding the question "Must the government of New Zealand offer free mammographies to women in that range of age?" Out of the 46 contacted women, 17 accepted to participate and out of these, the 12 that first did accept were finally selected for the study. Such 12 women magnified in advance the benefits of screening mammography and all of them supported it, without reservations, within their age range. A Wednesday afternoon the group was provided with information. On Friday, the group met again and listened to experts' presentations, made questions, analysed evidence, and discussed with the support of an independent moderator. During the morning of the following day, without the presence of experts or the moderator, the women expressed their conclusions. The answer: 10 women voted against and 1, in favour (32).

1.2 BIBLIOGRAPHY

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1.3 HYPOTHESIS, RESEARCH QUESTION, OR DESCRIPTIVE STUDY

The relevance and novelty of the hypothesis, research question, or descriptive study will be assessed in relation to the state of knowledge in the scientific-technological area. Expected scientific benefits (advance of knowledge and training of human resources) as well as social benefits (health, environment, industrial, etc.) will be taken into account.

The people's jury-type deliberative democracy methodology is applicable, operative, and useful to provide a favourable or unfavourable answer to citizens on whether the Andalusian public health system must offer screening mammography to women between 50 and 69 years old.

Researchers of this study think it is innovative in the work hypothesis. Although the main contribution of the study is based on citizens' participation in health policies, there is a great potential of high capacity of transfer of result and applicability of results. And this is so because the possibility of disinvestment in the screening mammography programme with new scientific data, whose efficacy is doubtful, is also high. The opinion against screening mammography will provide politicians with a justification and support to perform different ways of disinvestment. The favourable opinion will provide grounds and validity to the political decision of maintaining this way of breast cancer prevention. On the other hand, researchers also find the fact of trying an informed consent method representative of community in an area, like breast cancer prevention, where the informed decision-taking is not resolved, applicable.

1.4 PURPOSES

List briefly, clearly, accurately, in a priority order, and according to the expected project duration, the specific purposes pursued. Clarity, scientific-health relevance and novelty of purposes will be assessed. Remember that in this section they must only be listed, it being possible to develop them in the next sections.

1. Evaluate whether the people's jury-type deliberative democracy methodology is applicable to the Andalusian population.
2. Analyse women's deliberative process.
3. Know the result of women's deliberation on whether the Andalusian public health system must offer screening mammography to women aged 50 and 69.
4. Know the reasons for such decision and the participants' recommendations on the application of screening mammography to women between 50 and 69 years old.

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1.5	METHODOLOGY AND WORK PLAN

Detail and justify activities or tasks to be developed, indicating the individual(s) performing each task and a timeline of foreseen scientific milestones (not less than a three-month period or more than a year). Feasibility of the research project will be assessed: adaptation to methodology, design of research, analysis of data and work plan according to purposes (5 pages maximum).

It is a deliberative democracy-type qualitative study to help the pertinent politicians decide on the prescription for screening mammography to women aged 50-69.

Selection of jury members: a sample of 70 women between 50 and 69 years old will be selected from the Screening Programme list. The first telephone contact will occur three months before performance of the study. If after three attempts on different days it is not possible to make contact, the woman will be excluded. In the first telephone contact, they will be provided with information on the features and purposes of the study and, should they accept to participate, contact will be made again one month and one week before it to confirm availability. The goal is to recruit at least 12 women.

Experts selection: they will be chosen to defend the points of view in favour and against the prescription for screening mammography. The experts positioning for and against the screening mammography programme will be Dr. Encarnación Benítez and Dr. Soledad Márquez, both epidemiologists who are experts in cancer prevention. The main researcher of this study (a medical oncologist with expertise in research associated with assistance and with a line of research in screening mammography) will be the neutral moderator and will train experts. Information written with arguments for and against the prescription and presentations on the topic will be prepared jointly with experts and the main researcher. The report recently published by the General Secretariat of Public Health, Social Inclusion, and Life Quality (Márquez S, Lacalle JR. *Beneficios y efectos adversos del cribado de cáncer de mama: revisión de la evidencia científica. Secretaría General de Salud Pública, Inclusión Social y Calidad de Vida. Consejería de Salud y Bienestar Social*. January 2013) will be used as a guideline for the preparation of the written information and presentations, as well as of a deliberation manual.

Process: Participants will meet a Monday afternoon at a hotel in the city centre. In such meeting, the features and purposes of the study will be reminded, clearing up any doubts, an informed consent will be signed, sheets with participants' features will be filled in, and formal introductions of participants and researchers will take place. Participants will receive written information with arguments for and against screening mammography as well as instructions on how to assess the screening programme. They will also be provided with official information supplied by the Andalusian Public Health System in relation thereto. Participants will be instructed to assess the key benefit of screening programmes (breast cancer mortality reduction) and the main harms (overdiagnosis, overtreatment, and false positives), as well as other benefits and harms.

On Tuesday, experts will submit their presentations on the topic and participants will have the opportunity to make questions. The neutral moderator will promote a debate and discussion in the group.

On Thursday, the jury members will discuss without the presence of experts or the moderator and will reach final conclusions. On the same day, an observing researcher will record and take notes of the deliberation process but will not participate actively. Participants will issue their votes in favour, against, or abstentions. They will state, in writing, the main reasons for their decisions and their recommendations to the relevant politicians.

The entire process will be supervised by an expert in Bioethics, who will collaborate with the group, and who will also be part of the research team.

Case definition. Subjects of the study: Women invited to the breast cancer early diagnosis programme of Bahía de Cádiz-La Janda Health District and who undergo mammographies. Our health area offers a mammography every two years to women aged 50-69, who are invited to participate via a personal letter. As from April 2013, women between 45 and 49 years old are excluded from invitation, although the ones who had already undergone their first mammography are still invited. The group of women not exceeding 50 years old will be excluded.

In compliance with the requirements of inclusion and exclusion, the selection of participants will follow diversity criteria so that there is a fair representation according to age, level of education, social status, working condition, breast cancer family history, acquaintances or friends suffering from breast cancer, number of previous participations, and previous false positives. Extreme cases and convenience cases will be avoided.

Inclusion criteria:

1. Women living in the Bahía de Cádiz-La Janda Health District
2. Women aged 50-69
3. Women invited to the screening mammography programme, whether they participate or not
4. Women with a secondary school or university level of education
5. Women able to grant their informed consent to participate in the study

Exclusion criteria:

1. Women not reaching 50 years old or older than 69 years old
2. Women with breast cancer personal history
3. Women without any education or with primary-school studies only

Criteria for removal from the study:

1. Patient's explicit desire to abandon the study

Data collection and analysis: Sessions involving introduction of experts and debate of participants will be recorded.

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Participants will be identified as P-1, P-2... P12. The deliberation session will be recorded and notes will be taken by two observing researchers. A literal transcription of recordings of all participants will be carried out. Analysis will be performed following the participants' speech. After successive readings, the main ideas derived from the group deliberation will be extracted. These ideas will be later compared to the reasons for the decision.
Collection of sociobiographic data of participants will occur in data collection notebooks designed to that effect. The first interview with women will occur on a face-to-face basis at the Health District, where mammographies are performed. Deliberation sessions will be at a place different from the health environment (hotel in the city centre).
Sample size: Calculation is not applicable. In a group of 36 preselected women, the first 12 will be finally invited to participate and the rest of them will be reserved in case any of the former may revoke their consent or may not participate on any other ground.
Statistical analysis: To process the qualitative study results, it will not be necessary to have a particular digital hardware or statistical analysis, since their usefulness is addressed to the analyses including a big number of interviews. Furthermore, the following variables will be collected: age, level of education, social status, working situation, breast cancer family history, acquaintances or friends suffering from breast cancer, number of previous participations, and previous false positives. A descriptive analysis of such data will be performed, through an estimate of absolute and relative frequencies for qualitative variables and the average and standard deviation for quantitative variables.
Study limitations: Representativeness of the selected group is a common problem in qualitative studies. Women having a low level of education were excluded because, in previous studies of our group, they constitute a part of the population where the degree of knowledge if difficult to modify and it is difficult for them to make an informed decision (Baena-Cañada JM, Rosado-Varela P, Expósito-Álvarez I, González-Guerrero M, Nieto-Vera J, Benítez-Rodríguez E. Women's perceptions of breast cancer screening. Spanish screening programme survey. The Breast 2014, 10.1016/j.breast.2014.09.010). It is also difficult to modify the certainty that the population sample will understand, assimilate, and analyse the information provided and draw appropriate conclusions. Finally, results may depend on the choice of experts, but such limitation is lessened by the preparation, by consensus, of presentations to participants and, since the two presenters are women too, the gender-based influence will be controlled. The population sample including women aged 50 and 69 to whom screening mammography has been offered lessens the representativeness bias. The potential reaction of the main researcher in the participants' deliberation scenario will be impartial and controlled by the expert in Bioethics. Such limitations are common to all deliberative democracy studies and well known (Street J, et al. The use of citizens' juries in health policy decision-making: A systematic review. Soc Sci Med. 2014; 109: 1-9.), so researchers will try to mitigate them.
Work plan: It is a qualitative study, whose original idea comes from the main researcher and will be performed with the cooperation of the Department of Medical Oncology of University Hospital Puerta del Mar, Cádiz, and the Bahía de Cádiz-La Janda Health District. Members of the Provincial Cancer Registry of Cadiz, of the Quality Service and Process of the General Department of Quality, Research, Development, and Innovation of the Department of Equality, Health, and Social Policies of Andalusia will also participate, as well as, finally, of the Bahía de Cádiz Ethics Committee, and a professional having a licentiate in Chemical Sciences, who has a master's degree in clinical trials. Therefore, the professionals involved in the project come from a clearly multidisciplinary group, with members pertaining to the areas of Oncology, Public Health, Nursing, and a professional not related to Health Sciences, most of them being women. The date stipulated for the commencement of participants recruitment will be the first quarter of year 2015 and the deliberation process sessions will be carried out during the second quarter of year 2015. The expert will present their position for and against screening mammography. The main office of the Screening Programme commits to collaborating and making things easier. The oncologist being the main researcher will act as a neutral moderator. Researching oncologists will be responsible for the identification of cases to be included in the study and this will be performed actively through their physical presence at the main office of the screening mammography programme during non-working hours. Moreover, they will work along with the experts in the preparation of the material to be supplied to participants. A technician specialised in audiovisual media will perform the recording and an oncologist and the expert in clinical trials will take notes on the deliberation process but will not participate actively in it. The nurse expert in Bioethics will give professional advice and supervise the study. A psychologist expert in qualitative research, from the area of Social Psychology of the Department of Psychology of the School of Educational Sciences, University of Cádiz (DPS), Violeta Luque Ribelles, will cooperate with the project.

1.6	PROMOTION AND DISSEMINATION PLAN

The quality of the promotion plan and dissemination of the research project results will be assessed (publications in scientific magazines indexed in JCR, patents, etc.)

As far as we know, there are no similar studies in our country. The research team has informed the management of the Andalusian Oncology Integral Plan of this research project and such Plan has accepted to be mentioned as a promoter interested in it.
We believe the dissemination of results at quality scientific meetings and in magazines with national and international impact is justified (national and international conferences on screening mammography, Medical Oncology, Assistance Quality, national and international Medical Oncology magazines, Cancer Prevention,

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Assistance Quality).
The report on conclusions will be made available to the citizenship representatives of the Integral Attention Unit of Cancer at University Hospital Puerta del Mar and interested associations (Asociación Española Contra el Cáncer and Asociación Gaditana de Mujeres con Cáncer de Mama).
A mandatory section of the promotion plan is related to its own nature. It is a deliberative democracy-type qualitative study, where participants will judge the prescription for screening mammography. Deliberation will not only include votes for, against, and abstentions, but also the dissemination of those results to the relevant politicians will take place through the management of the Andalusian Integral Oncology Plan.

1.7	ETHICAL ASPECTS OF THE RESEARCH

The detail of the ethical aspects that must be taken into consideration when performing the project will be assessed.
IMPORTANT: There are three models of management of samples in biomedical research: research project, research collection, research biobank. Advantages and legal requirements associated with the use of each model may be found in the "Use Guide of Samples in Biomedical Research" (**http://biobanco.csalud.junta-andalucia.es/salud/biobanco/sites/default/files/Guia_de%20uso_de_muestras_biologicas-Biobanco.pdf**). In any case, for the handling of your project it is essential that you have **a contingency plan for samples** at the time of completion of your project. Should the samples of your project be derived from a research collection, you must provide the registry code of the collection with the ISCIII Catalogue of Collections. Should you use a biobank for the handling of samples required by your project, you must provide the compromise of said Biobank. They will always be biobanks registered with ISCIII.

A woman participating in the screening programme shows an ethical situation completely different from that of a sick person. Individual informed consent is not easily obtained from women who undergo screening mammography and it constitutes a real challenge that women make an informed choice. Although our group has demonstrated that individual informed consent increases the level of knowledge of women invited to screening mammography (Rosado P, Baena JM, Ramírez P, et. al., Using an informed consent in mammography screening: Final result of a randomized trial. Ann Oncol 2014; 25 suppl 4: Iv478 - iv480. doi: 10.1093/annonc/mdu351.3), in the screening context we propose a joint consent derived from a randomised sample of the population to be invited to participate. It is necessary to develop an optimum form to submit information on benefits and risks of the screening mammography programme and to help women make a decision. This study involves an excellent opportunity in that sense, since a sample representing the community involved will be selected and a deliberative process will be performed whose conclusions will not only serve to strengthen or refute the political decision thereon, but which may also be deemed a consent representative of community. Said women will not be subject to any supplementary diagnostic trial or to a treatment different from the usual one. Participation will be voluntary and will involve no cost at all. Every participant will be given a gift with a value not exceeding 30 euros. Should a woman decide to participate and change her opinion later, she is free to do so and is not obliged to provide any explanation. Personal data will be treated as stated in the Spanish legislation in force (Organic Law 15/1999, dated December 13, on Personal Data Protection).

2. MAIN RESEARCHER AND RESEARCH TEAM

2.1	CV OF MAIN RESEARCHER AND OF RESEARCH TEAM

The CVs are attached in the computer Management of Calls

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3. AVAILABLE MEANS AND REQUESTED BUDGET

3.1 AVAILABLE MEANS AND RESOURCES TO CARRY OUT THE PROJECT

A) MATERIAL ABLE TO BE INVENTORIED

The amount of infrastructure resources allow for the performance of this study without any special difficulty through the means available at the Bahía de Cádiz-La Janda Health District and at University Hospital Puerta del Mar, Cádiz.

B) BIBLIOGRAPHIC MATERIAL

The Medical Oncology Department has Internet access to perform bibliographic searches and to obtain the necessary bibliographic material. Puerta del Mar Hospital makes the SAS virtual library available to the researches of its centre.

C) PERSONNEL

At the Bahía de Cádiz-La Janda Health District, a sufficient number of women attend in order to recruit the required number of participants. The human resources personnel allows for the performance of this study without any special difficulty. As support for the researching activity, the Medical Oncology department has a research nurse hired by the Foundation *Fundación para la Gestión de la Investigación Biomedica de Cádiz*. Researchers have methodological and statistical assessment by the Preventive Medicine department and the support of the Bahía de Cádiz-La Janda Health District. Likewise, The Andalusian Integral Oncology Plan sponsors this research project.

3.2 REQUESTED BUDGET AND JUSTIFICATION.

Every item in the requested budget indicating items, units, unit prices, etc., must be broken down, and if information is available, it is recommendable that supplier be indicated. **In case of not matching with the budget stated in the computer application, the one stated therein shall prevail** (See annex).

CONCEPT	REQUESTED BUDGET		
	YEAR 1	YEAR 2	TOTAL
Goods and Services: (detail and justification for need)			
Material able to be inventoried			
Portable PC	00.00		
Image and voice recorder	00.00		
Projector	00.00		
Printer	00.00		
Fungible material			
Documentation, folders, and pens for participants' dossier	00.00		
Dissemination of results: (presentation of results in conferences).			
Attendance to National Conference of 2 speakers	1200.00		
Publication of results (publication in open access magazine)	3000.00		

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Hiring of external services Translation services	500.00		
Other expenses: (Justification and detail) Cafeteria service	00.00		
TOTAL	**4700.00**		

Comments and details of budget: (indicate items, units, conferences, meetings, etc.)

1 portable PC (1000€). Essential for digital hardware in deliberative meetings with participants.
1 image and voice recorder (400€). Essential in qualitative studies, since it will be necessary to analyse, *a posteriori*, the participants' comments.
1 projector (500€). Useful for the experts' presentation to participants.
1 printer (200€). Useful for the preparation of documentation to be submitted to participants.
Documentation, folders, and pens for the dossier to be delivered to participants (300€).
Financing for assisting the two researchers in a national conference where the study results will be presented is also requested (1200€).
Dissemination of results will require translation services for an original document (500€) to be sent to an international English-speaking open access magazine (3000€).
Catering services (300€). The three meetings are expected to last several hours during the afternoon. Cafeteria services are offered to participants as a courtesy.

4. PROJECT APPLICABILITY TO THE ANDALUSIAN PUBLIC HEALTH SYSTEM

4.1 APPLICABILITY

The expectations of transfer of research results to clinical practice, technological innovation, organization, resource management, and health services or health policies will be assessed.

1) Expected research results are applicable and include improvements to the Health System's usual clinical practice.
YES

Justify your answer and indicate application environment:

Researchers find the fact of trying an informed consent method representing community in an environment, like breast cancer prevention, where informed decision-taking is not resolved applicable.

Knowing the deliberation result of a sample representing community and submitting it to the pertinent politicians has an incomparable potential to include improvements in the usual clinical practice related to screening mammography. In case after the study, with the hypothetical negative vote of participants, some type of disinvestment is chosen, the non-performing of screening mammographies to some women would have, among others, the consequence of preventing overdiagnosis, overtreatment, and false positives, which are the main side effects of screening mammography.

2) Expected research results may be transferred to the organization, resources management, health services, or health policies.
YES

Justify your answer.

Citizens' participation in health policies will contribute improvements to the Health System. There is a great potential of capacity of transfer of result and high applicability of results. This is so because the possibility of disinvestment in the screening mammography programme, with the new scientific data of doubtful efficacy, is also high. The opinion against screening mammography will provide politicians with a justification and support to perform different types of disinvestment. The opinion in favour will provide grounds and validity to the political decision to maintain this type of breast cancer prevention.

Recommendations to the pertinent politicians will provide value, regardless of their decision. Conclusions obtained in the study will serve, therefore, to guide the resources management and health policies.

3) Expected research results may lead to the generation of technological innovations, patents, or utility models.
YES

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Justify your answer.

Citizens' juries approach, somehow, the deliberative survey technique, which suggests gathering at the same place, in general for 2 days, a sample representing the reference population, to be faced with experts and to make them discuss in small groups, before collecting their informed opinions. Said technique has been employed a dozen times in Great Britain, Australia and the United States. Despite its limited number of applications, such technique may be analysed, not only as an attempt to renew traditional surveys, but also as a symptom of a new link to public opinion in western democracies. Even when the contrast between the method's ambitions and the modesty of its performance is surprising, the emergence of this new way of public action must be taken seriously as a utility model.

The fact that the Integral Oncology Plan of the Andalusian Health Service is an observer interested in the project must be considered a cooperation with a company (in the present case, a public one) for the development of new services which will result in health improvements for citizens.

4) Expected research results may be published in a document having a great impact and commonly used by health professionals, such as the scientific magazines indexed by the Journal Citation Reports of the ISI Web of Science.
YES

Justify your answer.

The validity, current nature and original methodology, as well as the significance of results, justify the dissemination at quality scientific meetings and impact magazines, both national and international (national and international conferences on screening mammography, Medical Oncology, assistance quality, national and international magazines of Medical Oncology, cancer prevention, assistance quality). We cannot state accurately in advance the specific magazines and conferences in which results will be published or informed, but their bibliometric impact will always be considered.

5) Expected research results may be transferred through consensus documents, clinical practice guides published, etc., and applicable in the Health System
YES

Justify your answer.

Regardless of women's deliberation results in this study, we believe consensus documents and guides on the application of screening mammography should consider them, being applicable to the Health System.

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What is screening mammography?

Diagnostic screening consists in performing diagnostic tests on a presumably healthy population on a periodical basis, regardless of the type of test, in order to detect a particular disease (generally, a type of cancer, although there are screening campaigns for other diseases) before it manifests clinically – shows symptoms– which is generally associated with a more advanced stage of the disease.

A screening mammography is an x-ray of the mammary glands of a woman who is healthy, rather than a woman who has found a lump or any other alteration in her breasts, and does not appear to have any signs of breast disease. Mammography allows for the detection of certain small lesions that are suggestive of cancer because they are stiffer than the surrounding tissue.

It is a diagnostic method of breast cancer in its earliest stages. The purpose of offering mammographies to healthy women is to diagnose breast cancer before it manifests. By detecting breast cancer in its earliest stages, when the tumour is small, it is logical to believe that less aggressive treatments would be needed, and more healings would be possible.

Virtually all Health Systems in western countries have put in place early diagnostic programmes for breast cancer urging the female population aged 50-69 to have a mammography every 2 years (age and frequency differ from country to country or region to region).

Where does the idea that having preventive mammographies is good come from?

Health Systems have put in place mammography-based breast cancer detection programmes on the basis of studies that show that breast cancer mortality is thereby reduced. However, not all tests can be used to suggest that a treatment or preventive method should be definitely adopted. For example, there are medical actions that have been, or are intended to be, adopted only on the basis of expert opinions but without any supporting study. On some other occasions, the tests conducted lack the quality required to support a medical action.

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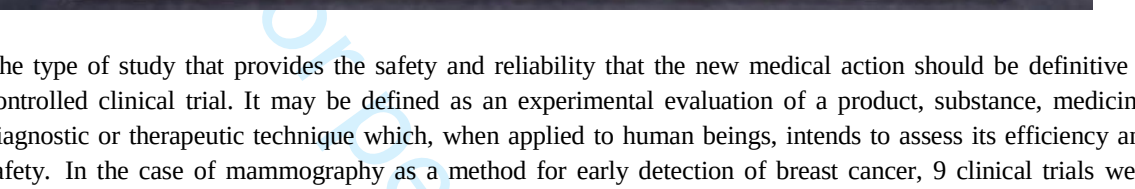
The type of study that provides the safety and reliability that the new medical action should be definitive is controlled clinical trial. It may be defined as an experimental evaluation of a product, substance, medicine, diagnostic or therapeutic technique which, when applied to human beings, intends to assess its efficiency and safety. In the case of mammography as a method for early detection of breast cancer, 9 clinical trials were conducted, mostly in the 70's and 80's of the last century. These trials compared two populations: one in which women had mammographies, and the other in which they did not. It was shown that in the population where women had mammographies, the breast cancer mortality rate decreased relative to the population of women who did not. Women were allocated to the groups (mammography or non-mammography) using a procedure that was similar to rolling a dice, making sure that both groups were similar in all aspects –hence comparable– except for the fact that the women in one group had mammographies while the women in the other did not. Accordingly, any difference found in the groups (for example, mortality) could be attributed to the use of mammographies.



Systematic reviews are scientific research studies where analysis units consist of the primary original studies (in the case of mammographies, the 9 clinical trials mentioned above). They are an essential tool to summarize the scientific information available, increase the validity of findings from individual studies, and identify uncertainty areas that need further research.

When you are presented arguments for and against screening mammographies by experts, you will be presented with the results from clinical trials and systematic reviews.

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Benefits of screening mammography and presentation

The main benefit of a screening mammography is to reduce the risk of death from breast cancer (reduction in breast cancer mortality), reducing treatment aggressiveness (less extensive surgery, less radiation therapy, less chemotherapy). The ideal objective would be to reduce global mortality, that is, all-cause mortality, because mammographies may reduce breast cancer mortality, but increase mortality due to other causes. However, it is accepted that breast cancer mortality reduction is a proper target.

When you debate about whether voting for or against screening mammography, you should bear in mind whether this test performed in the population at large does indeed reduce breast cancer mortality.

Early mammography-based diagnosis allows for an earlier detection of breast cancer relative to women who do not have mammographies, who are diagnosed later. Accordingly, women's survival rate is higher because time starts to run before, in other words, women are considered ill before. The real benefit would be attained by increasing women's survival but delaying death.

How will the benefit in terms of mortality be presented to you? The reduction of the risk of death from breast cancer in women who participate in screening mammography relative to women who do not is typically presented as a relative risk (RR). For example, if the risk of dying of breast cancer is 5 women out of 1,000 if they **do not** have a mammography, the risk will be 0.5% (5 out of 1,000 equals 0.5 out of 100). Likewise, if women **do** have mammographies, this risk reduces to 4 women out of 1,000, or 0.4%. Absolute risk will reduce to 0.5-0.4=0.1. But it is relative risk that will be presented to you more frequently, which is obtained by dividing the risk of death in women who **do** have mammographies by the risk of death in women who **do not** have mammographies. In our example above: 0.4/0.5=0.80, and it provides the same information as the relative risk reduction expressed as a percentage. Let us think that a relative risk of 1 means that both groups of women (those who **do** have and those who **do not** have mammographies) have the same risk of dying, and a relative risk of 0.80 means that women who **do** have mammographies have a 20% lower risk (0.80 is 20% lower than 1). You will receive information such as the following:

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"Screening mammography reduces the risk of death by 20%, with a relative risk of 0.80".

This form of presenting the reduction in breast cancer mortality is, in fact, barely informative. It is much more informative to present the number of women who should have a mammography in order to prevent death from breast cancer. It is the concept of "Number Needed to Treat" or, in our case, "to Screen"". It is known as NNT and indicates whether the benefit offered by mammography pays for the implementation efforts and costs. For example, a 20% reduction in the risk of death may look impressive, but says little about the real benefit. However, if we say that 2,000 women should have mammographies in order to avoid death from breast cancer (NNT: 2,000), we have a more accurate idea of its real benefit. Likewise, if the NNT is 500, it means that 500 women should have a mammography in order to prevent 1 death from breast cancer.

Therefore, you will also receive information about the reduction in breast cancer mortality through the NNT and its graphical representation:

In this example, which is different from the example above, 8 women out of 1,000 who do not have a mammography die.

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Furthermore, in this representation, 6 out of 1,000 women who do have a mammography die. Accordingly, 2 deaths out of 1,000 people are prevented (NNT: 500).

Risks of screening mammography. False positives

As any other diagnostic test, the result of a mammography may be positive or negative. But both possibilities may be true or false. A false-negative result means that the mammography has not detected cancer although cancer is present. However, mammographies have a high degree of sensitivity because they are able to detect almost all types of cancer that are present at the time of the test. The problem lies in the false positives, which presuppose an error, that is, the result determines that cancer is present when actually it is not.

Types of diagnoses		**Cancer**	
		absent	present
Mammography	negative	True negative (negative diagnosis, cancer is absent)	False negative (negative diagnosis, cancer is present)
	positive	**False positive** (positive diagnosis, cancer is absent)	True positive (positive diagnosis, cancer is present)

The detection of a false-positive mammography result presupposes harm for a woman because, despite being healthy, she will be followed-up and have further testing some time later in order to check whether the mammography readings have changed or not, and learn if they are more or less likely to be breast cancer. On other occasions, additional imaging tests are used to find whether they are more or less likely to be breast cancer. These may also be imaging tests such as spot compression mammography, ultrasound or magnetic resonance and, sometimes, needle biopsy to obtain a sample of the mammographic finding for analysis. Sometimes the woman will undergo surgery to have the detected lesion removed. If after all this, the doctor concludes it is not cancer, the woman will feel relieved, but the psychological impact and physical and mental suffering she has gone through, and sometimes will continue going through, are evident.

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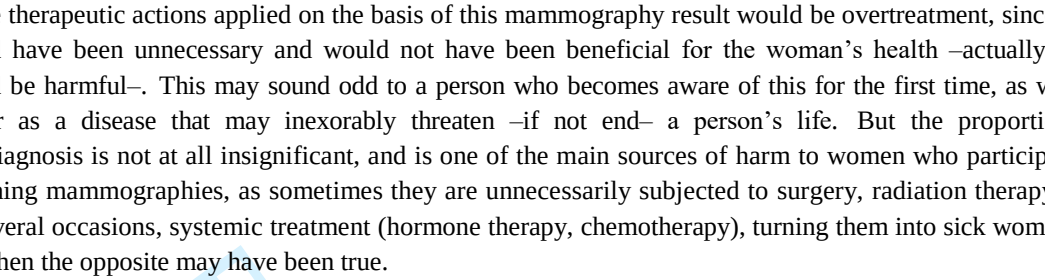
Risks of screening mammography. Overdiagnosis and overtreatment

Can breast cancer detected by screening mammography actually remit without treatment or progress so slowly so as not to compromise the woman's health? The answer is *yes*. This is known as overdiagnosis because cancer would have remitted spontaneously or would have never manifested over the woman's life. As a result, all the therapeutic actions applied on the basis of this mammography result would be overtreatment, since they would have been unnecessary and would not have been beneficial for the woman's health –actually, they would be harmful–. This may sound odd to a person who becomes aware of this for the first time, as we see cancer as a disease that may inexorably threaten –if not end– a person's life. But the proportion of overdiagnosis is not at all insignificant, and is one of the main sources of harm to women who participate in screening mammographies, as sometimes they are unnecessarily subjected to surgery, radiation therapy and, on several occasions, systemic treatment (hormone therapy, chemotherapy), turning them into sick women for life when the opposite may have been true.



Types of tumour growth

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Let us introduce you to Carmen. She is 64 years old and has developed a small breast cancer.

Carmen has a mammography exam. Her cancer is found and she undergoes treatment. Carmen lives until she turns 86, and then dies of a heart condition. Alternatively, Carmen does not have a mammography exam. Her cancer grows, is detected, but treated later. Carmen dies at the age of 70 from breast cancer.

Yet Carmen may not have a mammography exam, but her cancer does not grow or progress and is never detected. Nonetheless, Carmen lives until turning 86 and dies of a heart condition.

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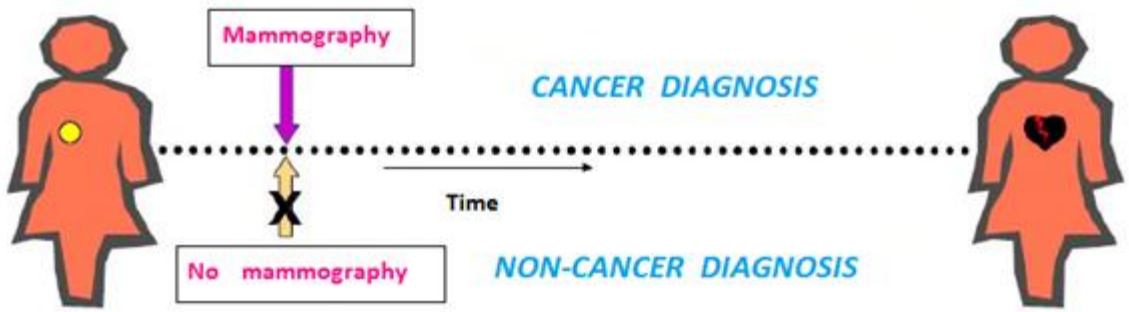

This represents the concept of overdiagnosis and, unfortunately, when cancer is found in a screening mammography, there is no way of knowing whether it is harmful or not. Therefore, all cancers should be equally treated (as if they were harmful). This means that screening mammography causes some women to be treated when such treatment is not necessary (overtreatment).

Risks of screening mammography. Other risks

Slight discomfort or pain during the mammographic screening, a bit of anxiety for some women while waiting for the results, a small possibility of developing cancer induced by the radiation from mammographies are also risks associated with mammography.

Finally, another risk of mammography is a woman's false sensation of security after learning of a negative result for cancer, which leads her to disregard symptoms or signs in the breasts and not to make consultations upon their occurrence ("I've just found a lump in my breast, but I've just had a mammography and was normal, so there's nothing to worry about").

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SCREENING MAMMOGRAPHY. ARGUMENTS FOR

Diagnostic screening consists in performing diagnostic tests on a healthy population in order to detect a particular disease (generally, a type of cancer, although there are screening campaigns for other diseases) before it manifests clinically showing symptoms.

The main benefit of screening of female population is the earlier detection of cancer, reducing treatment aggressiveness and increasing healings. Based on this compelling and attractive hypothesis, all western countries have put in place mammography-based breast cancer early detection programmes. But, has this hypothesis proved to be true? And, if so, are the negative effects outnumbered by the benefits?

Women have mammographies to reduce death from breast cancer and, if diagnosed with breast cancer, to receive less aggressive treatments, even though they are usually unaware of the risks or side effects associated with this type of procedure, such as false positives, overdiagnosis and overtreatment, pain, and exposure to radiation.

Breast cancer is the malignant tumour most frequently diagnosed in female population. In Europe, it represents 30% of all the diagnosed tumours and it is the first cause of death from cancer among women. In Spain, the incidence and mortality rates are similar to the European rates, with 26,000 new cases being diagnosed in 2014.

The most common risk factors which are related to breast cancer cannot be modified and account for less than half of the detected cases. On the other hand, controlling the risk factors that can be modified would not cause a significant reduction in the incidence rate, therefore, there is no clear possibility of preventing them from occurring. Hence, we can conclude that we do not have effective strategies of primary prevention, which makes secondary prevention by screening mammography a key instrument to control the disease nowadays. Currently, the Andalusian Health System includes within its basic services the screening of female population for breast cancer, which, in general terms, consists in performing a mammography every two years among female population aged 50-69.

Evidence that screening mammography reduces breast cancer mortality

As previously explained, the most reliable evidence showing that a mammography reduces breast cancer mortality comes from two types of tests: high-quality clinical trials and systematic reviews. Since the 60's of last century, 9 randomized clinical trials have been conducted on around 600,000 women. These trials compared two populations: one in which women had mammographies, and the other in which they did not. Furthermore, 4 systematic reviews have been conducted: Cochrane, American, Canadian and British. The American and British reviews considered that all the trials had an acceptable standard of quality; however, the Cochrane and Canadian reviews stated that 4 trials did not have any inconsistencies regarding the number of recruited women and guaranteed an adequate random assignment (that is, the group of women who had a mammography and the group of women who did not have the mammography had similar characteristics). Nevertheless, 5 trials could not assert that the two groups of women could be compared or had inconsistencies in the number of women assigned to one or the other group. Therefore, should any differences be found in mortality in both groups, it may not be assured that such results are derived from performing a mammography, but they could have derived from other differences between the groups instead.

In general, most systematic reviews agree that performing a mammography reduces breast cancer mortality by 20%, with a relative risk (RR) of 0.80. Many experts do not agree with differentiating clinical trials according to their methodological quality and also propose, as a key parameter in the assessment, the reduction in breast cancer mortality instead of overall mortality.

Even though the same data has been analysed and a similar reduction in breast cancer mortality has been

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achieved (reduction of 20% and RR of 0.80), NNT estimates (number of women aged 50-69 who should have a mammography over a 10-year period in order to prevent death from breast cancer) show many differences. According to the British review, 1 death from breast cancer was prevented out of 235 women who participated in the procedure, whereas to other institutions such as the Nordic Cochrane Centre, at least 2,000 women need to participate in the procedure to obtain the same benefit. If we apply such data to the overall population, we can understand the importance of this benefit: 10 deaths out of 2,350 women are prevented, 100 deaths out of 23,500 women are prevented, 1,000 deaths out of 235,000 are prevented… Likewise, the Cochrane review shows the following data: 10 deaths out of 20,000 women are prevented, 100 deaths out of 200,000 women are prevented, 1,000 deaths out of 2,000,000 women are prevented…

Evidence that screening mammography allows women to receive less aggressive treatments

The fact that women receive less aggressive treatments has not been sufficiently studied. Only the Cochrane review described that the early detection of breast cancer by a screening mammography was most frequently associated with any type of surgery (RR 1.20) and increased use of radiation therapy (RR 1.24), but on the contrary, the need to administer other complementary and aggressive treatments such as chemotherapy (RR 0.63) and hormone therapy was reduced.

Most of the tumours detected in screening mammography programmes were at an early stage of the disease, reducing the need for chemotherapy as complementary treatment.

Evidence that screening mammography causes overdiagnosis and overtreatment

The best approach to measure overdiagnosis is to analyse the clinical trials with adequate random assignment and which did not offer the screening mammography to the control group at the end of the test. Three clinical trials meet these requirements (Malmö I and the 2 Canadian trials) and two reviews (the British and Cochrane reviews) have assessed the percentage of overdiagnosis based on those trials. The assessed data offers variable results. According to the Cochrane review, the percentage of overdiagnosis is 30% or 10 overdiagnosed cases out of 2,000 screened women over a 10-year period. Nonetheless, the British review estimates that 11% of all cancers would be overdiagnosed, and if a woman is diagnosed as a result of a screening mammography, the likelihood of being overdiagnosed is 19%, with an estimated NNT of 1 overdiagnosed case out of 77 screened women.

However, these are estimated figures and the true measure and impact of overdiagnosis are unknown.

Evidence that mammography causes false positives

Despite the variable estimates of false positive results according to the different reviews, the obtained results show a low likelihood of suffering this side effect based on the volume of women who participate in this type of procedure. In accordance with the British review, the percentage of false positives is 3.36% and according to the Cochrane review, the percentage is 10%. As a consequence, further diagnostic tests will be needed, which will cause psychological impact on the individual. 70% of these cases will require other imaging tests and 30% of the cases will require a biopsy.

The discomfort and psychological impact suffered until the diagnosis are discarded and for some time thereafter are inevitable. In spite of all these consequences as well as the anxiety and psychological discomfort that can be associated with the need to run further tests, several studies show that most women believe that the benefits they expect to obtain from their participation in the screening programme are greater than the possibility of suffering from such negative effects.

Evidence that mammography can cause other side effects

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Although some women suffer pain during a mammography, for most of them the pain is only mild. The sensation of relief and security derived from receiving a non-pathological result in the test is significantly greater than the discomfort it may cause.

A study estimates a rate of 3-6 cancers out of every 10,000 screened women aged 47-73 every 3 years due to exposure to radiation from mammographies. In addition to this low rate, currently, the digital mammography, which is frequently used in screening strategies replacing the classic analogue mammography device, exposes women to a lower degree of radiation and thus the percentage of tumours associated with this risk factor would be reduced.

Controversy on the screening mammography programme

There are discrepancies regarding the methodological aspects used to estimate benefits and risks: different degrees of importance are given to the quality of the original clinical trials (randomization, other biases) and different degrees of importance are given to the role played by studies other than the clinical trials (observational studies).

There are also discrepancies regarding the validity given to the clinical trials conducted in the 60's, 70's and 80's with old radiologic technology. It is likely that the improvement of breast cancer treatments and healthcare services in general has made mammography screening less important.

Even though estimates on Relative Risks frequently match, the different systematic reviews provide different estimates regarding the required number of women to be screened in order to prevent death or to be overdiagnosed.

The assessment of the benefits and risks is different depending on the review and it is subject to different interpretations, therefore, recommendations are also different.

Recommendations for discussion

The key measure of the benefit of the screening mammography programme is the reduction in breast cancer mortality. As it has been described, despite the various results obtained according to the reviews analysed, overall, most of the systematic reviews agree that performing a mammography reduces breast cancer mortality by 20%, with relative risk (RR) of 0.80.

Regarding the assessment on mortality reduction as opposed to overdiagnosis, there is no conclusive evidence that the number of overdiagnosed cases is significant, therefore, such negative effect should not be considered to be greater than the expected benefit of mortality reduction. In this respect, other less serious side effects, despite causing some harm on women, are counterbalanced with the benefit of mortality reduction that women expect to obtain by participating in the screening mammography programme.

Even after receiving such positive data in favour of mammography screening, some women may prefer not to have a mammography. It is essential to improve the type of information women receive so that they can make informed decisions. It is also essential that research be conducted in order to select which women may benefit from having a mammography and which women may suffer from its negative effects.

Should the Andalusian public health system offer a screening mammography to women aged 50-69?

Yes.

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SCREENING MAMMOGRAPHY. ARGUMENTS AGAINST

Diagnostic screening consists in performing diagnostic tests on a healthy population in order to detect a particular disease (generally, a type of cancer, although there are screening campaigns for other diseases) before it manifests clinically showing symptoms.

The main benefit of a mammography-based screening is the earlier detection of breast cancer, reducing treatment aggressiveness and increasing healings. Based on this compelling and attractive hypothesis, all western countries have put in place mammography-based breast cancer early detection programmes. But, might this hypothesis be wrong? Or, even if it were true, could it have a negative impact?

Women have mammographies to reduce death from breast cancer and, if diagnosed with breast cancer, to receive less aggressive treatments. However, they are usually unaware of the risks or side effects associated with screening mammographies. We have provided information about such negative effects: false positives, overdiagnosis and overtreatment, false sensation of security, pain and radiation.

Evidence that screening mammography reduces breast cancer mortality

As previously explained, the most reliable evidence showing that a mammography reduces breast cancer mortality comes from two types of tests: high-quality clinical trials and systematic reviews. Since the 60's of last century, 9 controlled clinical trials have been conducted on around 600,000 women. These trials compared two populations: one in which women had mammographies, and the other in which they did not. Furthermore, 4 systematic reviews have been conducted: Cochrane, American, Canadian and British collaboration. The American and British reviews considered that all the trials had an acceptable standard of quality; however, the Cochrane and Canadian reviews stated as follows:

- 4 trials did not have any inconsistencies regarding the number of recruited women and guaranteed an adequate random assignment (that is, the group of women who had a mammography and the group of women who did not have a mammography had similar characteristics)
- Nevertheless, 5 trials were unable to assert that the two groups of women could be compared or had inconsistencies in the number of women assigned to one or the other group. Therefore, should any difference be found, it could not be assured that such results derived from performing a mammography, but they could have derived from other differences between the groups instead.

In general, systematic reviews agree that performing a mammography reduces breast cancer mortality by 20%, with a relative risk (RR) of 0.80. But when the analysis narrows down to methodologically appropriate trials, in statistical terms, no significant reduction of death from breast cancer is found, with RR around 1 (without any difference between the screened and non-screened women). Furthermore, the Canadian and Cochrane reviews find no reduction in the global mortality between women who have the screening mammography relative to those who do not.

Even though the same data has been analysed and a similar reduction in breast cancer mortality has been achieved (reduction of 20% and RR of 0.80), NNT estimates (number of women aged 50-69 who should have a mammography over a period of 20 years in order to prevent death from breast cancer) show many differences, ranging from 235 according to the British review, and 1,000 according to the Cochrane review.

Evidence that screening mammography allows women to receive less aggressive treatments

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According to the Cochrane review, not only are more aggressive treatments not reduced, but also more women undergo a mastectomy instead of breast-conserving surgery if they participate in screening (RR of undergoing a mastectomy of 1.20) and the use of radiation therapy is higher (RR 1.24).

The number of mastectomies peaked immediately after the implementation of the screening programme in Copenhagen and Funen, while this is not the case in some regions of Denmark, where screening mammography was not implemented.

Evidence that screening mammography causes overdiagnosis and overtreatment

The best approach to measure overdiagnosis is to analyse the clinical trials with adequate random assignment, for they compare similar groups in terms of the risk to develop breast cancer. These trials are also required to have never offered mammographies to the control group and that sufficient follow-up is pursued for 5 years (5-10 years). In this way, we would be able to count how many breast cancers were overdiagnosed in women who have mammographies relative to those who do not. Three clinical trials meet these requirements (Malmö I and the 2 Canadian trials) and two reviews (the British and Cochrane reviews) have assessed the percentage of overdiagnosis based on these 3 contrasted quality trials which did not offer mammographies to the control group at the end of the test: 11% all of cancers would be overdiagnosed and, if a woman is diagnosed as a result of a screening mammography, the likelihood of being overdiagnosed is 19%, with an NNT of 1 overdiagnosed case out of 77 screened women, according to the British review, and 30% or 10 overdiagnosed cases out of 2,000 screened women, according to the Cochrane review.

Evidence that mammography causes false positives

In accordance with the British review, the percentage of false positives is 3.36%, and according to the Cochrane review, the percentage is 10%. As a consequence, further diagnostic tests will be needed, which will cause psychological impact on the individual. 70% of these cases will require other imaging tests and 30% of the cases will require a biopsy.

The discomfort and psychological impact suffered until the diagnosis is discarded and for some time thereafter are inevitable. Many tests have been conducted about the psychological impact of false positives, with diverse results, although it would seem that it may be significant on many occasions. It has also been proved that being well-informed can work as material mitigation of anxiety and psychological discomfort.

Evidence that mammography can cause other side effects

Some women suffer pain during a mammography and, in some cases, this causes them to avoid returning to screening rounds. Obtaining a negative result in the test creates a sensation of relief and false security that may lead them to not see a doctor if they find a symptom or sign in their breasts. The exposure to the radiation from mammographies may cause breast cancer. A study estimates a rate of 3-6 cancers out of every 10,000 screened women aged 47-73 every 3 years. Currently, the digital mammography exposes women to a lower degree of radiation.

Controversies on screening mammography programmes

There are discrepancies regarding the methodological aspects used to estimate benefits and risks: different degrees of importance are given to the quality of the original clinical trials (randomization, other biases) and different degrees of importance are given to the role played by studies other than the clinical trials (observational studies).

There are also discrepancies regarding the validity given to the clinical trials conducted in the 60's, 70's, and

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80's with old radiologic technology. It is likely that the improvement of breast cancer treatments and healthcare services in general has made screening less important.

Even though estimates on Relative Risks frequently match, the different systematic reviews provide different estimates regarding the required number of women to be screened in order to prevent death or to be overdiagnosed.

The assessment of the benefits and risks is different depending on the review and it is subject to different interpretations, therefore, recommendations are also different.

Recommendations for discussion

The key measure of the benefit of the screening mammography is mortality, not only from breast cancer but also total mortality (from any cause). As it has been described, breast cancer mortality is not favourable in methodologically appropriate trials and mortality from any cause is not favourable for mammography either. Regarding the assessment on mortality reduction as opposed to overdiagnosis, evidence suggests that the number of overdiagnosed cases is significant and greater than the benefit of mortality reduction. Other side effects are not as serious, but they also cause harm on women which harm is not counterbalanced with the benefit of mortality reduction.

Even after receiving this negative data against screening mammography, some women may still prefer to have a mammography. It is essential to improve the type of information women receive so that they can make informed decisions. It is also essential that research be conducted in order to select which women may benefit from having a mammography and which women may suffer from its negative effects.

Should the Andalusian public health system offer a screening mammography to women aged 50-69?

No.

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No Item	Guide questions/description	Reported on page No

Domain 1: Research team and reflexivity

Personal Characteristics

1. Interviewer/facilitator. Which author/s conducted the interview or focus group?. Page 6-7

2. Credentials. What were the researcher's credentials? E.g. PhD, MD. Page 1,6,7+protocol

3. Occupation. What was their occupation at the time of the study? Page 1,6,7+protocol

4. Gender Was the researcher male or female? Page 1,6,7+protocol

5. Experience and training. What experience or training did the researcher have? Page 6,7+protocol

Relationship with participants

6. Relationship established. Was a relationship established prior to study commencement? Page 6.

7. Participant knowledge of the interviewer. What did the participants know about the researcher? e.g. personal goals, reasons for doing the research. Page 6.

8. Interviewer characteristics. What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic. Page 6,7.

Domain 2: study design

Theoretical framework

9. Methodological orientation and Theory. What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis. Page 8.

Participant selection

10. Sampling. How were participants selected? e.g. purposive, convenience, consecutive, snowball. Page 6.

11. Method of approach. How were participants approached? e.g. face-to-face, telephone, mail, email. Page 6,7.

12. Sample size. How many participants were in the study?. Page 6,9.

13. Non-participation. How many people refused to participate or dropped out? Reasons?. Page 6,9.

Setting

14. Setting of data collection. Where was the data collected? e.g. home, clinic, workplace. Page 7.

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15. Presence of non-participants. Was anyone else present besides the participants and researchers?. Page 6,7,8.

16. Description of sample. What are the important characteristics of the sample? e.g. demographic data, date Data collection. Page 6,9.

17. Interview guide. Were questions, prompts, guides provided by the authors? Was it pilot tested?. Page 7+protocol.

18. Repeat interviews. Were repeat interviews carried out? If yes, how many? n/a

19. Audio/visual recording. Did the research use audio or visual recording to collect the data?. Page 8.

20. Field notes. Were field notes made during and/or after the interview or focus group?. Page 8.

21. Duration. What was the duration of the interviews or focus group?. Page 7.

22. Data saturation. Was data saturation discussed?. Page 17.

23. Transcripts returned. Were transcripts returned to participants for comment and/or correction?. Page 8.

Domain 3: analysis and findings

Data analysis

24. Number of data coders. How many data coders coded the data?. Page 8,19.

25. Description of the coding tree. Did authors provide a description of the coding tree?. Page 10.

26. Derivation of themes. Were themes identified in advance or derived from the data?. Page 8.

27. Software. What software, if applicable, was used to manage the data?. Page 8.

28. Participant checking. Did participants provide feedback on the findings?. Page 8.

Reporting

29. Quotations presented. Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number. Page 10,11,12.

30. Data and findings consistent. Was there consistency between the data presented and the findings?. Page 16.

31. Clarity of major themes. Were major themes clearly presented in the findings?. page 10-15.

32. Clarity of minor themes. Is there a description of diverse cases or discussion of minor themes?. Page 10-15.

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How deliberative approach includes women in the decisions of screening mammography: a citizens' jury feasibility study in Andalusia

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Title

How deliberative approach includes women in the decisions of screening mammography: a citizens' jury feasibility study in Andalusia

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Abstract

Objectives: To verify whether a citizens' jury type deliberative democracy study is applicable to the Andalusian population and to know if women, when better informed, are able to answer the research question of whether the Andalusian Public Health System must continue offering screening mammography to women aged 50-69. The reasons for the pertinent decision and recommendations to the political authorities will be stated.

Design: Qualitative research study with methodology of citizens' jury.

Setting: Breast cancer screening programme in Andalusia (Spain).

Participants: Thirteen women aged 50-69 with secondary school or higher education accepted to participate as a jury. Two epidemiologists were the expert witnesses. The main researcher was the neutral moderator.

Interventions: Jury met on Monday, 15 February 2016. The moderator indicated the jury it had to assess the screening programme's key benefits and main harm. On Tuesday 16, the expert witnesses positioned for and against. On Thursday 18, the jury deliberated, reached final conclusions, submitted its vote, and stated its recommendations to politicians. The deliberation session was transcribed and analysed with the support of ATLAS.ti.5.2 software.

Primary and secondary outcome measures: Applicability to the Andalusian population, women's vote and opinion, reasons for votes and recommendations to political authorities.

Results: 11 participants voted yes and 2 voted no. There are three reasons to vote "yes": health, the test nature, and individual freedom. Some women invoke the lack of efficacy and the cost to justify their negative vote, at least in universal terms. Upon completion, they made suggestions to be submitted to the pertinent authorities for the improvement of information, psychology services, and research.

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Conclusions: The deliberative strategy is applicable and causes a favourable positioning regarding screening mammography, although the information changes the opinion of some women, who wish an informed decision-making and to keep or increase medicalisation in their lives.

Key words: Cancer: Breast; Heath services; Public health policy; Qualitative research; Screening.

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Strengths and limitations of this study

- Most of the important elements of the Citizens' Jury have been reported.
- The deliberative process was planned, with a description of the selection and roles of the research team and experts, and a description of the recruitment strategy and the characteristics and instructions for the jury.
- The technical and procedural information is available and clearly documented.
- The study was designed as a research project, so since there was no representation of participating women in the research time, their opinion and possible critical perspective with respect to the study's design and performance have not been taken into account.
- The information submitted arises from a sole process of deliberative democracy, which is why it will be necessary to apply, as programmed, other methodological strategies allowing for the gathering of more information to fulfil the categories and be certain that the information collected covers every possibility.

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Text

INTRODUCTION

There is more and more evidence indicating that screening mammography may constitute a low-value service where benefits do not exceed its harm and cost.[1] Some women will be benefitted, while others would be harmed.[2] However, public perception is not realistic.[3] For instance, women in Spain accept the invitation to participate in screening mammography and receive little information [4] and, in general, tend to overestimate the benefits [5] and to not get involved in the physical or psychological impact caused by overdiagnosis and false positives [6,7]. Any help in the decision making related to screening mammography could potentially lead to an informed decision,[8,9, 10] but it is not clear yet how to apply such optimally.[9] In this context, there are still arguments in favour of screening mammography [11] and it has not been removed in western countries, except for Switzerland.[12] Spain has a National Health System but every region is autonomous regarding decisions on screening mammography programme coverage. In Andalusia, a population-based screening programme invites, through letter, women every 2 years. In 2013, a report [13] was prepared and served to fix the age between 50 and 69, ceasing to invite women aged 45-49 in districts where they were invited before.

Citizens' juries gather a group of citizens, randomly chosen, to discuss a particular topic. They are exposed to information and opinions on such topic for several days, which information and opinions are derived from witnesses selected because of their expertise or because they represent their interest. Along with a moderator qualified to guarantee a fair process, the jury members have the opportunity to question the witnesses and, after a deliberation process, they reach a decision and make recommendations to the pertinent authorities. The latter are compelled to provide an answer, either by acting pursuant to the citizens' report or by

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explaining why they do not agree.[14] The implementation of citizens' juries has been proposed as a tool to provoke the population's positioning in public health issues involving scientific controversy as well as for political decision-making purposes.[15,16] Democratic deliberation is useful for the participation in health affairs where it is difficult to obtain an individual and informed consent, it being a consent representing community.[17]

We have designed, carried out, and analysed a citizens' jury-type deliberative democracy study to verify whether it is applicable to the Andalusian population. As secondary objectives we have established the following: to know if women, when better informed, are able to answer the research question of whether the Andalusian Public Health System (SSPA) must continue offering screening mammography to women aged 50-69; to know the reasons for the pertinent decision, and recommendations to the political authorities.

METHODS

Research protocol (Supplementary File 1) was approved by the Bahía de Cádiz - La Janda Ethics Committee and all participants gave written informed consent. Their names referred to in the quotations are fictitious to guarantee confidentiality.

Primary and secondary outcome measures were the applicability thereof in the Andalusian population (if performance and execution of the study were carried out without any problem as planned, if the study was accepted by women and if its objectives were reached), women's votes and opinions, the reasons for such votes, and recommendations to the political authorities.

Jury selection

A sample of 70 women aged 50-69, with secondary school or higher education, without any relationship established between them or with the researchers prior to study commencement, was selected from the list of invitations of the breast cancer screening programme. Telephone contact started 3 months before the process. If, after 3 attempts on different days, it was not

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possible to contact them, they were excluded. In the first contact, information on features and purposes was provided and, if they accepted, they were contacted a month before and a week before for confirmation. The purpose was to recruit at least 12 women.

Expert witnesses selection

Two expert epidemiologists (women) defended the positions for and against screening mammography. The one positioned in favour works at the Provincial Cancer Registry of Cadiz (EBR) and was selected because she has been a member of the research team for years. The one against (SMC) was selected due to her expertise in the development of the Andalusian screening mammography programme and because of her critical position towards it. The main researcher (man) in this study was the neutral moderator (JMBC).

Documentation preparation

Informed consents and an information gathering sheet with respect to the participants' features were prepared. The research team and the expert witnesses prepared four documents to be delivered to the jury (Supplementary File 2): 1.- General information document and a presentation for the jury members regarding the screening mammography. 2.- Document with arguments for and against mammographies, containing the experts' presentations. For its preparation, the report published by the General Secretariat of Public Health, Social Inclusion, and Life Quality was employed as a guide.[13] 3.- Information document regarding the Andalusian early detection of breast cancer programme available at http://www.juntadeandalucia.es/servicioandaluzdesalud/principal/documentosacc.asp?pagina=gr_sabermas_cancermama. 4.- Finally, presentation with recommendations for deliberation.

Process

The jury members met 3 afternoons for 4 hours at a hotel in the city. On the first day, introductions were performed, the study's features and purposes were explained, doubts were resolved, informed consents were signed, and socio-demographic information questionnaires

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were fulfilled. They were provided with a dossier containing the described information. The moderator indicated the jury it had to assess the key benefits of the screening programme (breast cancer mortality reduction), the main harm (overdiagnosis, overtreatment, and false positives), and other benefits and harms. To that effect, a presentation was made in order to understand the arguments for and against to be presented the next day. The opportunity to resolve doubts was granted.

On the second day, the experts made their presentations for and against and the jury asked questions. The moderator motivated the debate and discussion.

On the last day, the jury discussed without the presence of the experts or moderator and reached a conclusion. They issued their vote and wrote suggestions to political decision-makers.

During three days, an observer expert in qualitative research (VLR) took notes of the sessions without participating actively. The entire process was supervised by an expert in Bioethics (JMRB). All the sessions were audio and visual recorded. A gift valued at 20 euros was given to each participant.

Information analysis

Upon transcription of the deliberation session by independent parties (see acknowledgements), it was analysed with the support of ATLAS.ti.5.2 software. A systematic reading of the information was performed, the categories derived from the deliberation were identified, and, in this paper, only the analysis of the category "opinion on whether the SSPA must continue offering mammographies to women aged 50-69" is presented. The deliberation session was deconstructed, assigning and reducing information in this category. Later, the information was reconstructed and summarized to conclude with its interpretation. A theoretical approach based on health psychology from a feminist approach [18] was established.

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A process of verification by informants (member checking) was carried out. The participants were returned an abbreviated report on results where they had to score, in a Likert-type scale from 1 to 5, the adjustment and sufficiency of the definition of categories and sub-categories and the relevance of quotations by means of which categories were justified and illustrated. 6 scores were obtained which, in general, agreed with the interpretation of the information and participants stated they recognised their voices in the report.

Likewise, a researchers/analysts triangulation was performed to reduce the distortion of the information interpretation and to increase the validity of results. To that effect, a person not related to the team, an expert in qualitative information analysis and Health Social Psychology was incorporated. Such individual was provided with a detailed report on results and, by means of a Likert-type scale from 1 to 5, had to assess the relevance of categories, sub-categories, and identified features, their definitions, and the examples provided. Such person also scored the information interpretations. Among their suggestions, we may find: to gather and remove some categories, to deepen in the definition of others and to provide more examples in some categories and sub-categories for being insufficiently based on the information. Their recommendations were followed.

RESULTS

Figure 1 shows a flowchart of jury recruitment and Table 1 shows its main features. Attendance was consistent since 13 women attended 3 days. None of the 13 women who deliberated and voted missed any information provided on the first and second days. Eleven of them voted "yes" and 2 voted "no" to the question of whether the SSPA must offer mammographies to women aged 50-69.

Table 1. Jury members' features.

Age (median and category)	55 (51-65)
Level of education:	

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Secondary	5
University	8
Working status:	
Active	8
Unemployed	3
Pensioner	2
Marital status:	
Married	10
Separated	2
Widow	1
Do you have a mammography performed regularly?:	
Yes	12
No	1
You have a mammography performed with:	
Public screening programme	11
Private healthcare	1
Both	1
Previous mammography rounds:	
1	1
2	0
3	2
4	1
5	3
>5	6
Family history of breast cancer:	
Yes	4
No	9
Previous favourable opinion on screening mammography:	
Yes	13
No	0

The reasons why participants think mammographies must continue being offered have been grouped in three: health, test nature, and individual freedom (Table 2). Different opinions are observed regarding coverage among those who believe they must continue being offered; some women deem necessary the universal nature while others consider they should be offered on demand. There are participants who mention the lack of efficacy and the high cost to justify they must not continue being offered. Tables 3 and 4 present some women's indicative quotations.

Table 2. Categories on whether the SSPA must continue offering screening mammography

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Category	Sub-category	Features	Indicators
Yes	Reason	Health	Mortality reduction
			Prevents "greater harm"
			Few negative consequences
		Nature of the test	Diagnostic test
			Absence of alternatives
			High efficacy
			Public good
		Individual freedom	Women's freedom
			Capacity and right to take decisions
	Type of offering	On demand	
		Universal	
No	Reason	Lack of efficacy	
		High cost	

Table 3. Indicative quotations: Reasons to continue and to not continue offering screening mammographies

Jury member	Indicative quotation
	Health as a reason to continue offering screening mammography
Juana	I'm in favour of its continuance, because as from the moment it reduces mortality, I believe it must be offered.
Rosario	…The fact that it reduces mortality, even for two people, is enough to me, because if I'm one of those people, I will tell you whether it is worth it or not.
Rosa	Of course I'm in favour because I think greater harm may be prevented.
María	…in favour of mammographies. More significant harms can be prevented and there is no possibility of surgery or treatment.
Milagros	…it's OK because negative things are very few … Because, the negative, what is it? The radiation? Well, we already know it's a normal X-ray...
	The nature of the screening test as a reason to continue offering screening mammography
Juana	…Mammography itself, in my opinion, is really good because it detects any possible problem, so you say "it may find out a problem".
Manuela	I'm in favour of every preventive measure, at the public health level, for the entire population. I'm in favour of mammographies. I'm in favour of mammographies…, if we are not offered alternatives, we know it has some risks and side effects, but, between not having anything and having this test, well, I'd rather continue having it.
Milagros	We must take into account that overdiagnosis is one out of seventy seven, I mean, it's really small, so death is one out of one thousand

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	but overdiagnosis, which is one of the negative things, is one out of seventy seven, it's very small, the fact that one out of seventy seven is overdiagnosed is really small, I thinks it's a lottery. …I wouldn't remove it, because it's a public good … in addition, it's up to you, because it's voluntary.
	Individual freedom as a reason to continue offering screening mammography
Carmen	Yes, yes, I think women are free to take decisions.
	Lack of efficacy as a reason not to continue offering screening mammography
Ana	…But the point is the programme. It doesn't work … one out of seventy seven in the population is a lot.
Mercedes	The point is that with the figures and data we have, I see it so dependent on fate, because it's such a small portion among so many that it gives the impression that...
	High cost as a reason not to continue offering screening mammography
Ana	So, let's see, the cost derived from performing mammographies, treatments because something is detected is a quite high cost. So, we should see if there are other, more effective, ways of prevention and that money we are employing should be used for another thing, maybe research on…medicines.
Juana	In favour of women being provided with enough information so that they can decide freely, considering the pros and cons, whether to have it made or not voluntarily.

Table 4. Indicative quotations: Type of screening mammography offering

Jury member	**Indicative quotation**
	On demand
Mercedes	I say mammographies are always there, you may request one whenever you want, so they won't be denied.
Rosa	No, no, no, no they won't perform it because you request it...
Milagros	You request a test now and, when will it occur? A DEXA, how long does it take? It's an institutionalised programme that once it's been implemented, now yes, and maybe the campaign is to remove it, we don't know what's behind…
	Universal offering

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Milagros	The plan [the Screening Programme] exists and it's optional whether to perform it or not. So it's better for it to exist because there are people who will want to perform it … no one obliges you to do it right now. It's a thing that has been established, institutionalised, which is good because we see very few negative things, the fact that you may opt to perform it or not is voluntary.
Juana	… they may decide freely, considering the pros and cons, if they perform it or not voluntarily.

Health as a reason to continue offering screening mammography

Mortality reduction arises as a reason for which some participants believe it must continue being offered between 50 and 69 years old. During deliberation, there were different opinions on whether mortality reduction is significant. Rosario mentions that the reduction degree is not an aspect to be considered and that any reduction is acceptable when it comes to human lives (Table 3). When participants indicate that mammography may prevent greater harm they refer to its diagnostic nature (please note Rosa's words in Table 3). They think participation in screening facilitates an early diagnosis and improves treatment possibility (see María's quotation in Table 3), prevents any harm derived from the advanced cancer stage and helps extend a decent life. Furthermore, reference is made to the negative consequences and some participants believe they are few and minimise them, such as radiation. They consider that some of the negative consequences are also present in other tests and this justifies the continuance of mammography (Table 3).

The nature of the screening test as a reason to continue offering mammographies

Some participants believe screening mammography is a diagnostic test. They see it as the only efficient test to detect breast cancer, which they invoke as a reason to support it. Consequently, they think every kind of risk, side effect, or error possibility is reasonable. Milagros, even when she recognises that overdiagnosis may be a risk, appreciates it seldom occurs. That is how she justifies it must continue being offered (Table 3). Moreover, there is the idea that screening is a preventive test, as another argument in favour of the offering

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thereof. However, it is based on the wrong idea that screening mammography serves to prevent, which denotes a wrong use of the diagnosis and prevention concepts.

Related to its universal nature, there appears the concept of "public good" as a reason to continue offering mammographies. The public "good" is understood as general conditions which are advantageous to every person, regardless of their condition, facilitating equality. In this case, mammography is understood as a valuable resource that must be offered to women with the sole requirement of being aged 50-69 (Table 3).

Individual freedom as a reason to continue offering screening mammography

Women's freedom to decide what to do once they are offered the opportunity to participate in screening mammography is revealed as another argument for. There is the demand of being treated as active users of SSPA and not as mere passive users or consumers. Such demand involves the participants' desire to be well informed, to be able to undertake responsibility in the form of decision-taking. Somehow, it is a way to reduce the anxiety that may be caused by the mammography, trying to increase control and reduce ambiguity (Table 3).

Lack of efficacy as a reason not to continue offering screening mammography

If efficacy was previously an argument to justify mammographies should continue being offered, it is now an argument to question it. Some participants, like Ana and Mercedes, question its efficacy, and believe that, on some occasions, it depends on fate (Table 3).

High cost as a reason not to continue offering screening mammography

Ana mentions the high cost of the screening programme and, in the face of the inefficacy of the test, considers the investment unjustified. That is why she suggests other measures, such as research, in order to make economic cost profitable and make progress regarding the issue (Table 3).

Availability on demand

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From the participants' words there arises the idea that the SSPA must continue offering screening mammography, although there are some nuances. Some participants consider it must be offered on demand, that is, offered to those women requesting it. However, there are opinions against this possibility. Part of this rejection is based on the mistrust towards SSPA and its good operation. Another part is based on the mistrust towards the latest goal of this research. Milagros expresses her fear related to the removal of the breast cancer screening programme's universal nature (Table 3).

Universal availability

Some participants believe the screening test must continue being offered on a universal basis to women aged 50-69, since this does not make it compulsory. Therefore, the voluntary nature of participation is deemed a key feature (Table 4).

Recommendations to health authorities

After joint consideration, the jury prepared a list of recommendations addressed to the health authorities to improve the screening mammography programme. They focused on the improvement of information, the psychology service demand, and the promotion of research on breast cancer screening:

Recommendation 1: Women must be informed when receiving an invitation to participate in the programme, so that their decision is informed (e.g., being aware of the possibility of overdiagnosis, false positives, radiation).

Recommendation 2: Information must be given in such a manner that it is widely known (e.g., information campaigns in the media, in particular, addressed to women aged 49-50).

Recommendation 3: During the screening test process, women must have specialised psychological support. Particularly, in the case of evidence of presence of disease.

Recommendation 4: Modify protocols of action after mammographies so that, in case of signs of cancer, the patient may know to what tests they will be subjected.

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Recommendation 5: Use less harmful techniques than mammographies and offer alternatives to the latter.

Recommendation 6: Provide more resources to research on breast cancer, its prevention, early diagnosis, and treatment (e.g., be able to select which women may benefit and which may be harmed upon participation in the programme).

Recommendation 7: Studies on which the debate on benefits and cost of screening tests are based must be updated. The most recent ones are from the 80's.

DISCUSSION

The deliberative democracy process has been applicable to a group of SSPA users and it has caused a favourable positioning, although the study information changed some participants' opinion (2 out of 13, 15%). On the grounds of health, test nature, and individual freedom, women believe screening must continue being offered and they make suggestions to the political authorities for them to improve information, psychology services, and research. In general, most of them fight for keeping or increasing medicalisation of their lives (not "losing" mammographies and psychology services to fight problems derived therefrom), although there are women who invoke its lack of efficacy and cost to justify it must not be offered, at least on a universal basis.

Despite it is largely known that screening mammography is not perfect [19] and despite the recommendation from the citizens' jury to reflect on its implementation,[20] there are few deliberative experiences in relation thereto. The purpose of one of them was to collect recommendations on how to submit the information so that it would be easier for participants to take informed decisions on whether to attend or not a mammography.[21] In another one, the citizens' jury was mostly against screening mammography for women under the age of 50 in New Zealand.[22] Citizens' juries have been efficient when it comes to changing the

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positioning of population in the face of other screenings, such as the prostate screening.[23] In our study, the change was limited but significant, since 15% of participants do not recommend screening now.

The results of our deliberative democracy study may serve as a justification for political authorities to maintain screening mammography in women aged 50-69. However, we believe it would be interesting that they should consider the studies indicating the harmful effects of the test as well as the opinion of the participants who were against and that they should re-consider the type of offering too (universal vs. on demand), although some experts think that if a screening is implemented, it must be for the entire population.[24] On the other hand, it is necessary to consider the power of pre-existing ideas and prevailing social speech that highlights the possible positive effects of screening mammography, barely considering negative arguments.[3,25]

Our study's implications on managers and clinical doctors must involve understanding the participants' claim for their right to choose freely. This involves placing such desire in the context where it takes place, which is characterized by the prevailing social speech in which, despite the lack of consent of the scientific community with respect to the benefits of the screening test,[1,2,5-7] these are overvalued, thus disregarding its harm. Such social speech is motivated, among others, by awareness and sensitization campaigns related to breast cancer which clearly show signs of lack of information [26] and by the few information received by women invited to participate in the screening programme.[4] Finally, screening mammography has been institutionalised [27] in a more and more medicalised [28] state determined by the logics of a consumption society in which women [29] are immersed.

This study presents a series of weaknesses to be taken into account when considering results, which must serve as elements to be strengthened in the future. The study was designed as a research project, so there was not a directive committee with the participation of women and

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without taking into account its critical perspective.[15,30] Nevertheless, the research team included expert witnesses, a moderator, a psychology expert in qualitative research and an expert in bioethics. The process lasted a bit less than recommended [15] but there was enough time to explore the issues addressed. The information submitted arises from a sole process of deliberative democracy, which is why it will be necessary to apply, as programmed, other methodological strategies allowing for the gathering of more information to fulfil the categories and be certain that the information collected covers every possibility. Apart from that, although the political authority accepted to be an observer interested in the project, there was no genuine commitment to incorporate results in their decisions.

At a procedure level, weaknesses closely related to the qualitative methodology have been detected. It has been observed that some participants did not pose every question they had and, therefore, they were not as well informed as it was expected. The expert condition of the research team was highlighted, which could deepen the differences of power between the former and the participants and prevent their participation. Moreover, certain hierarchy was observed among some participants.

Furthermore, certain mistrust is derived from the words towards the latest purposes of the research given that some participants are afraid that SSPA might be considering the removal of mammographies. Said mistrust may have affected their opinions. Lastly, it must be taken into account that this work has been developed with a sample of literate women, with a medium-high level of education, economic resources, natives, and without functional diversity. It would be necessary to perform works in other social realities whose needs must also be satisfied.

In conclusion, the deliberative strategy is applicable and causes a favourable positioning regarding screening mammography, although the information changes the opinion of some

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women, who wish an informed decision-making and to keep or increase medicalisation in their lives.

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Declarations

Ethics approval and consent to participate

This study was approved by The Bahía de Cádiz - La Janda Ethics Committee. Participants gave informed consent to take part in the study.

Patient consent for publication

Not applicable.

Availability of data and material

Presentations of the moderator and experts, and recordings and texts analysed during the current study are available from the corresponding author on reasonable request.

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Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: financial support from the Ministry of Health, Equality, and Social Policies of Andalusia for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Authors' contributions:

José M. Baena-Cañada conceptualized the project. **José M. Baena-Cañada, Violeta Luque-Ribelles, Alicia Quílez-Cutillas, Petra Rosado Varela, Encarnación Benítez-Rodríguez, Soledad Márquez-Calderón,** and **Juan M. Rivera-Bautista** contributed to the design and methodology. **Violeta Luque-Ribelles** and **Alicia Quílez-Cutillas** performed analysis of texts. **José M. Baena-Cañada, Violeta Luque-Ribelles, Alicia Quílez-Cutillas, Petra Rosado**

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Varela, Encarnación Benítez-Rodríguez, Soledad Márquez-Calderón, and **Juan M. Rivera-Bautista** contributed to the development of the process of deliberative democracy (investigation). **José M. Baena-Cañada** contributed key resources. **Violeta Luque-Ribelles, Alicia Quílez-Cutillas,** and **Petra Rosado Varela** contributed to data curation and management. **José M. Baena-Cañada** wrote the original first draft of the article. **José M. Baena-Cañada, Violeta Luque-Ribelles, Alicia Quílez-Cutillas, Petra Rosado Varela, Encarnación Benítez-Rodríguez, Soledad Márquez-Calderón,** and **Juan M. Rivera-Bautista** played key roles in writing with respect to review and editing (all authors contributed to the final article). **José M. Baena-Cañada, Violeta Luque-Ribelles,** and **Petra Rosado Varela** provided oversight and leadership (supervision).

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Table and Figure legends

Table 1. Jury members' features.

Table 2. Categories on whether the SSPA must continue offering screening mammography.

Table 3. Indicative quotations: Reasons to continue and to not continue offering screening mammographies.

Table 4. Indicative quotations: Type of screening mammography offering.

Figure 1. Flowchart of jury recruitment

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Figure 1. Flowchart of jury recruitment

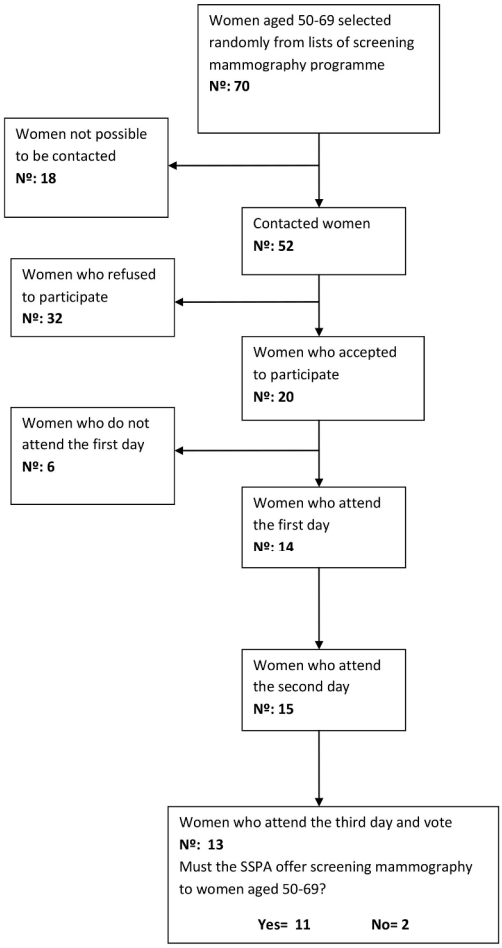

Figure 1. Flowchart of jury recruitment

209x296mm (300 x 300 DPI)

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OFFICIAL ANNOUNCEMENT OF FINANCIAL AID BY THE ANDALUSIAN PUBLIC FOUNDATION FUNDACIÓN PROGRESO Y SALUD FOR THE FINANCING OF BIOMEDICAL I+i AND HEALTH SCIENCES OF ANDALUSIA FOR YEAR 2014

SCIENTIFIC-TECHNICAL AND FINANCIAL REPORT _ RESEARCH PROJECTS

MAIN RESEARCHER	
LAST NAME BAENA CAÑADA	FIRST NAME JOSÉ MANUEL

PROJECT TITLE

Deliberative democracy study on women participating in the screening mammography programme

KEY WORDS

Screening mammography. Community's opinions. Health policy. People's jury.

ABSTRACT

(250 words maximum)

Purpose: Try a method to determine if population, when well informed, would be able to support or reject the political decision on breast cancer early detection. In particular, whether the government of Andalusia should maintain or not the invitation to undergo screening mammography to women aged 50- 69.

Design: Development of people's jury-like deliberative democracy methodology.

Subjects and area of study: There will be 12 women selected between 50 and 69 years old who undergo screening mammography in the Bahía de Cádiz-La Janda District. Experts defending the position in favour and against the screening programme will be two epidemiologists who are experts in cancer prevention.

Realization: Study by a people's jury with randomly selected participants. Information is provided to participants via documentation, multimedia presentations, and sessions recording. A final report containing the decision based on votes in favour, against, and abstentions, as well as on women's deliberation, will be prepared.

Factors: contacted women, included in the study, final participants, informed consent, participants' sociobiographic features, qualitative analysis of the deliberation process, votes in favour, against, and abstentions, reasons justifying votes in favour and against, participant's recommendations.

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1. SCIENTIFIC-TECHNICAL ASPECTS OF THE PROJECT

1.1 BACKGROUND AND CURRENT STATE OF THE STUDY TOPIC

Knowledge of background and current state of the topic will be assessed. Explain previous works published regarding the project topic, both performed by the research team and by other national or international groups (3 pages maximum)

The controversy related to screening mammography programmes commenced in year 2000 when Peter Gøtzsche (Nordic Cochrane Centre) published in The Lancet his meta-analysis of randomized clinical trials published so far on the efficacy of reduction in breast cancer mortality (1). Pursuant to said author, should methodologically inappropriate trials be excluded, screening mammography does not reduce breast cancer mortality, so it would be unjustified (1). Similar conclusions were reached in the systematic review of the Canadian Task Force on Preventive Health Care (CTFPHC) (2). The Cochrane review (3) concludes that it is unclear that screening mammography causes more benefits than harm and that it seems unreasonable to participate in breast cancer screening.

In 2009, the controversy was intensified again when the U.S. prevention services (USPSTF) decided not to recommend, on a routine basis, screening mammography to women between 40 and 49 years old (4). Such decision, as opposed to the 2002 recommendations (5), was based on a computerised analytical model of 9 randomized and controlled trials carried out in the last century (6-14).

Recently, a new version in the United Kingdom does not shed more light on the controversy (15). The Marmot report concludes on its significant benefits, but it suggests that every woman should make their decisions and, therefore, true information on the benefits and harms (15) must be provided.

The decision taken by every western country to implement and maintain their mammography screening programmes active is based on breast cancer mortality reduction which is estimated, in general, around 20%, with relative risks (RR) near 0.80 (2) (3) (4) (16).

The main risks for a woman who undergoes screening mammography are overdiagnosis, overtreatment, and false positives. There is uncertainty in the quantification of breast cancer detection that would have never been diagnosed and treated if the women would not have undergone mammography. The most certain estimates are derived from calculations performed in proven-quality clinical trials that did not offer mammographies to the control group upon completion of the study. Again, the results vary according to the systematic review, but they vary between 11-19% and 30% in relative terms and in 1 case of overdiagnosis out of 77 to 100 women subjected to screening for 20 years (15) (16) (17) (18) (19). Overtreatment was also assessed in the Cochrane review (3). There were more surgeries (RR 1.31), more mastectomies (RR 1.20) and more radiation therapy (RR 1.24) in women subjected to screening. However, less chemotherapy (RR 0.63) and less hormone therapy (RR 0.81) were employed, without reaching statistical significance. The update of the Canadian trial finds out that after 25 years of follow-up there were 106 overdiganoses out of 484 detected cancer cases (21.9%) (20) (106 out of 44,925 healthy women who underwent screening were diagnosed and treated unnecessarily of breast cancer) (20). Furthermore, the update of this paper does not find any reduction in breast cancer mortality (20), a contrary result conflicting with the mortality reduction of 40% found in the analysis of observational data in 7 out of 12 Canadian provincial screening programmes from 1990 to 2009 (21).

There is more unanimity with respect to other screening programme risks: re-call in 4% of cases to repeat the mammography, and a potential biopsy. Of these women, one out of five will be finally diagnosed with cancer. Of the remaining women, 70% will only need another imaging test and 30% will require biopsy, almost always -90%- with local anaesthetic. All such procedures, as well as the final cancer diagnosis and the pertinent treatment, may have a great psychological impact (22).

Scientific societies continue recommending mammography even as from 40 years old (23) (24) and no western country has dismantled their screening mammography programmes. Only Switzerland has initiated an institutional debate regarding such topic (25) (26). In Andalusia, after an excellent literature review, a report (27) was prepared, which has served as the basis to fix the age for screening mammography between 50 and 69 years old, ceasing to invite women aged 45-49 in districts where they were.

The deliberative democracy methodology is employed to involve citizens in a formal dialogue with the government or other public institutions, in order to provide a solution to complex problems. It includes people's jury, consensus conferences, deliberative surveys, study groups, citizens' meetings, and new online options. Deliberative democracy's primary purpose is to approach opinion and citizens' values to the political decision-making process (28). It is particularly useful for surveys where personal values, ethics, and existing trials on the topic in question are significant. In such issues, citizens need time to understand them fully and to consider all relevant aspects (29). Moreover, an informed consent method representing the community (30) must be considered. There is no consensus on which is the best way for women to be well informed regarding screening mammography and to make informed decisions on this breast cancer secondary prevention method (31), but the point is that women show a very poor level of knowledge and an enthusiastically positive attitude towards mammography (32).

The screening mammography programme is a public issue with great relevance because it affects a great volume of the population. The impact of its implementation is morally significant since there exist conflicts as to benefits, harms, autonomy and justice. The decision of its implementation cannot be resolved through scientific evidence given that, as we have already seen, there is no consensus among experts and such decision depends on the values of the women involved, who will probably have different opinions.

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In 2007, in New Zealand, 80 women aged 40-49 were randomly selected from the electoral register to participate in a deliberative process regarding the question "Must the government of New Zealand offer free mammographies to women in that range of age?" Out of the 46 contacted women, 17 accepted to participate and out of these, the 12 that first did accept were finally selected for the study. Such 12 women magnified in advance the benefits of screening mammography and all of them supported it, without reservations, within their age range. A Wednesday afternoon the group was provided with information. On Friday, the group met again and listened to experts' presentations, made questions, analysed evidence, and discussed with the support of an independent moderator. During the morning of the following day, without the presence of experts or the moderator, the women expressed their conclusions. The answer: 10 women voted against and 1, in favour (32).

1.2 BIBLIOGRAPHY

Bibliography related to the suggested topic and which is updated, containing the latest publications on said topic, will be assessed (years 2012-2014). Furthermore, quotations of bibliographic references throughout the project will be assessed. (2 pages maximum)

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1.3 HYPOTHESIS, RESEARCH QUESTION, OR DESCRIPTIVE STUDY

The relevance and novelty of the hypothesis, research question, or descriptive study will be assessed in relation to the state of knowledge in the scientific-technological area. Expected scientific benefits (advance of knowledge and training of human resources) as well as social benefits (health, environment, industrial, etc.) will be taken into account.

The people's jury-type deliberative democracy methodology is applicable, operative, and useful to provide a favourable or unfavourable answer to citizens on whether the Andalusian public health system must offer screening mammography to women between 50 and 69 years old.

Researchers of this study think it is innovative in the work hypothesis. Although the main contribution of the study is based on citizens' participation in health policies, there is a great potential of high capacity of transfer of result and applicability of results. And this is so because the possibility of disinvestment in the screening mammography programme with new scientific data, whose efficacy is doubtful, is also high. The opinion against screening mammography will provide politicians with a justification and support to perform different ways of disinvestment. The favourable opinion will provide grounds and validity to the political decision of maintaining this way of breast cancer prevention. On the other hand, researchers also find the fact of trying an informed consent method representative of community in an area, like breast cancer prevention, where the informed decision-taking is not resolved, applicable.

1.4 PURPOSES

List briefly, clearly, accurately, in a priority order, and according to the expected project duration, the specific purposes pursued. Clarity, scientific-health relevance and novelty of purposes will be assessed. Remember that in this section they must only be listed, it being possible to develop them in the next sections.

1. Evaluate whether the people's jury-type deliberative democracy methodology is applicable to the Andalusian population.
2. Analyse women's deliberative process.
3. Know the result of women's deliberation on whether the Andalusian public health system must offer screening mammography to women aged 50 and 69.
4. Know the reasons for such decision and the participants' recommendations on the application of screening mammography to women between 50 and 69 years old.

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1.5	METHODOLOGY AND WORK PLAN

Detail and justify activities or tasks to be developed, indicating the individual(s) performing each task and a timeline of foreseen scientific milestones (not less than a three-month period or more than a year). Feasibility of the research project will be assessed: adaptation to methodology, design of research, analysis of data and work plan according to purposes (5 pages maximum).

It is a deliberative democracy-type qualitative study to help the pertinent politicians decide on the prescription for screening mammography to women aged 50-69.

Selection of jury members: a sample of 70 women between 50 and 69 years old will be selected from the Screening Programme list. The first telephone contact will occur three months before performance of the study. If after three attempts on different days it is not possible to make contact, the woman will be excluded. In the first telephone contact, they will be provided with information on the features and purposes of the study and, should they accept to participate, contact will be made again one month and one week before it to confirm availability. The goal is to recruit at least 12 women.

Experts selection: they will be chosen to defend the points of view in favour and against the prescription for screening mammography. The experts positioning for and against the screening mammography programme will be Dr. Encarnación Benítez and Dr. Soledad Márquez, both epidemiologists who are experts in cancer prevention. The main researcher of this study (a medical oncologist with expertise in research associated with assistance and with a line of research in screening mammography) will be the neutral moderator and will train experts. Information written with arguments for and against the prescription and presentations on the topic will be prepared jointly with experts and the main researcher. The report recently published by the General Secretariat of Public Health, Social Inclusion, and Life Quality (Márquez S, Lacalle JR. *Beneficios y efectos adversos del cribado de cáncer de mama: revisión de la evidencia científica. Secretaría General de Salud Pública, Inclusión Social y Calidad de Vida. Consejería de Salud y Bienestar Social*. January 2013) will be used as a guideline for the preparation of the written information and presentations, as well as of a deliberation manual.

Process: Participants will meet a Monday afternoon at a hotel in the city centre. In such meeting, the features and purposes of the study will be reminded, clearing up any doubts, an informed consent will be signed, sheets with participants' features will be filled in, and formal introductions of participants and researchers will take place. Participants will receive written information with arguments for and against screening mammography as well as instructions on how to assess the screening programme. They will also be provided with official information supplied by the Andalusian Public Health System in relation thereto. Participants will be instructed to assess the key benefit of screening programmes (breast cancer mortality reduction) and the main harms (overdiagnosis, overtreatment, and false positives), as well as other benefits and harms.

On Tuesday, experts will submit their presentations on the topic and participants will have the opportunity to make questions. The neutral moderator will promote a debate and discussion in the group.

On Thursday, the jury members will discuss without the presence of experts or the moderator and will reach final conclusions. On the same day, an observing researcher will record and take notes of the deliberation process but will not participate actively. Participants will issue their votes in favour, against, or abstentions. They will state, in writing, the main reasons for their decisions and their recommendations to the relevant politicians.

The entire process will be supervised by an expert in Bioethics, who will collaborate with the group, and who will also be part of the research team.

Case definition. Subjects of the study: Women invited to the breast cancer early diagnosis programme of Bahía de Cádiz-La Janda Health District and who undergo mammographies. Our health area offers a mammography every two years to women aged 50-69, who are invited to participate via a personal letter. As from April 2013, women between 45 and 49 years old are excluded from invitation, although the ones who had already undergone their first mammography are still invited. The group of women not exceeding 50 years old will be excluded.

In compliance with the requirements of inclusion and exclusion, the selection of participants will follow diversity criteria so that there is a fair representation according to age, level of education, social status, working condition, breast cancer family history, acquaintances or friends suffering from breast cancer, number of previous participations, and previous false positives. Extreme cases and convenience cases will be avoided.

Inclusion criteria:

1. Women living in the Bahía de Cádiz-La Janda Health District
2. Women aged 50-69
3. Women invited to the screening mammography programme, whether they participate or not
4. Women with a secondary school or university level of education
5. Women able to grant their informed consent to participate in the study

Exclusion criteria:

1. Women not reaching 50 years old or older than 69 years old
2. Women with breast cancer personal history
3. Women without any education or with primary-school studies only

Criteria for removal from the study:

1. Patient's explicit desire to abandon the study

Data collection and analysis: Sessions involving introduction of experts and debate of participants will be recorded.

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Participants will be identified as P-1, P-2... P12. The deliberation session will be recorded and notes will be taken by two observing researchers. A literal transcription of recordings of all participants will be carried out. Analysis will be performed following the participants' speech. After successive readings, the main ideas derived from the group deliberation will be extracted. These ideas will be later compared to the reasons for the decision.
Collection of sociobiographic data of participants will occur in data collection notebooks designed to that effect. The first interview with women will occur on a face-to-face basis at the Health District, where mammographies are performed. Deliberation sessions will be at a place different from the health environment (hotel in the city centre).
Sample size: Calculation is not applicable. In a group of 36 preselected women, the first 12 will be finally invited to participate and the rest of them will be reserved in case any of the former may revoke their consent or may not participate on any other ground.
Statistical analysis: To process the qualitative study results, it will not be necessary to have a particular digital hardware or statistical analysis, since their usefulness is addressed to the analyses including a big number of interviews. Furthermore, the following variables will be collected: age, level of education, social status, working situation, breast cancer family history, acquaintances or friends suffering from breast cancer, number of previous participations, and previous false positives. A descriptive analysis of such data will be performed, through an estimate of absolute and relative frequencies for qualitative variables and the average and standard deviation for quantitative variables.
Study limitations: Representativeness of the selected group is a common problem in qualitative studies. Women having a low level of education were excluded because, in previous studies of our group, they constitute a part of the population where the degree of knowledge if difficult to modify and it is difficult for them to make an informed decision (Baena-Cañada JM, Rosado-Varela P, Expósito-Álvarez I, González-Guerrero M, Nieto-Vera J, Benítez-Rodríguez E. Women's perceptions of breast cancer screening. Spanish screening programme survey. The Breast 2014, 10.1016/j.breast.2014.09.010). It is also difficult to modify the certainty that the population sample will understand, assimilate, and analyse the information provided and draw appropriate conclusions. Finally, results may depend on the choice of experts, but such limitation is lessened by the preparation, by consensus, of presentations to participants and, since the two presenters are women too, the gender-based influence will be controlled. The population sample including women aged 50 and 69 to whom screening mammography has been offered lessens the representativeness bias. The potential reaction of the main researcher in the participants' deliberation scenario will be impartial and controlled by the expert in Bioethics. Such limitations are common to all deliberative democracy studies and well known (Street J, et al. The use of citizens' juries in health policy decision-making: A systematic review. Soc Sci Med. 2014; 109: 1-9.), so researchers will try to mitigate them.
Work plan: It is a qualitative study, whose original idea comes from the main researcher and will be performed with the cooperation of the Department of Medical Oncology of University Hospital Puerta del Mar, Cádiz, and the Bahía de Cádiz-La Janda Health District. Members of the Provincial Cancer Registry of Cadiz, of the Quality Service and Process of the General Department of Quality, Research, Development, and Innovation of the Department of Equality, Health, and Social Policies of Andalusia will also participate, as well as, finally, of the Bahía de Cádiz Ethics Committee, and a professional having a licentiate in Chemical Sciences, who has a master's degree in clinical trials. Therefore, the professionals involved in the project come from a clearly multidisciplinary group, with members pertaining to the areas of Oncology, Public Health, Nursing, and a professional not related to Health Sciences, most of them being women. The date stipulated for the commencement of participants recruitment will be the first quarter of year 2015 and the deliberation process sessions will be carried out during the second quarter of year 2015. The expert will present their position for and against screening mammography. The main office of the Screening Programme commits to collaborating and making things easier. The oncologist being the main researcher will act as a neutral moderator. Researching oncologists will be responsible for the identification of cases to be included in the study and this will be performed actively through their physical presence at the main office of the screening mammography programme during non-working hours. Moreover, they will work along with the experts in the preparation of the material to be supplied to participants. A technician specialised in audiovisual media will perform the recording and an oncologist and the expert in clinical trials will take notes on the deliberation process but will not participate actively in it. The nurse expert in Bioethics will give professional advice and supervise the study. A psychologist expert in qualitative research, from the area of Social Psychology of the Department of Psychology of the School of Educational Sciences, University of Cádiz (DPS), Violeta Luque Ribelles, will cooperate with the project.

1.6	PROMOTION AND DISSEMINATION PLAN

The quality of the promotion plan and dissemination of the research project results will be assessed (publications in scientific magazines indexed in JCR, patents, etc.)

As far as we know, there are no similar studies in our country. The research team has informed the management of the Andalusian Oncology Integral Plan of this research project and such Plan has accepted to be mentioned as a promoter interested in it.
We believe the dissemination of results at quality scientific meetings and in magazines with national and international impact is justified (national and international conferences on screening mammography, Medical Oncology, Assistance Quality, national and international Medical Oncology magazines, Cancer Prevention,

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Assistance Quality).
The report on conclusions will be made available to the citizenship representatives of the Integral Attention Unit of Cancer at University Hospital Puerta del Mar and interested associations (Asociación Española Contra el Cáncer and Asociación Gaditana de Mujeres con Cáncer de Mama).
A mandatory section of the promotion plan is related to its own nature. It is a deliberative democracy-type qualitative study, where participants will judge the prescription for screening mammography. Deliberation will not only include votes for, against, and abstentions, but also the dissemination of those results to the relevant politicians will take place through the management of the Andalusian Integral Oncology Plan.

1.7	ETHICAL ASPECTS OF THE RESEARCH

The detail of the ethical aspects that must be taken into consideration when performing the project will be assessed.
IMPORTANT: There are three models of management of samples in biomedical research: research project, research collection, research biobank. Advantages and legal requirements associated with the use of each model may be found in the "Use Guide of Samples in Biomedical Research" (**http://biobanco.csalud.junta-andalucia.es/salud/biobanco/sites/default/files/Guia_de%20uso_de_muestras_biologicas-Biobanco.pdf**). In any case, for the handling of your project it is essential that you have **a contingency plan for samples** at the time of completion of your project. Should the samples of your project be derived from a research collection, you must provide the registry code of the collection with the ISCIII Catalogue of Collections. Should you use a biobank for the handling of samples required by your project, you must provide the compromise of said Biobank. They will always be biobanks registered with ISCIII.

A woman participating in the screening programme shows an ethical situation completely different from that of a sick person. Individual informed consent is not easily obtained from women who undergo screening mammography and it constitutes a real challenge that women make an informed choice. Although our group has demonstrated that individual informed consent increases the level of knowledge of women invited to screening mammography (Rosado P, Baena JM, Ramírez P, et. al., Using an informed consent in mammography screening: Final result of a randomized trial. Ann Oncol 2014; 25 suppl 4: Iv478 - iv480. doi: 10.1093/annonc/mdu351.3), in the screening context we propose a joint consent derived from a randomised sample of the population to be invited to participate. It is necessary to develop an optimum form to submit information on benefits and risks of the screening mammography programme and to help women make a decision. This study involves an excellent opportunity in that sense, since a sample representing the community involved will be selected and a deliberative process will be performed whose conclusions will not only serve to strengthen or refute the political decision thereon, but which may also be deemed a consent representative of community. Said women will not be subject to any supplementary diagnostic trial or to a treatment different from the usual one. Participation will be voluntary and will involve no cost at all. Every participant will be given a gift with a value not exceeding 30 euros. Should a woman decide to participate and change her opinion later, she is free to do so and is not obliged to provide any explanation. Personal data will be treated as stated in the Spanish legislation in force (Organic Law 15/1999, dated December 13, on Personal Data Protection).

2. MAIN RESEARCHER AND RESEARCH TEAM

2.1	CV OF MAIN RESEARCHER AND OF RESEARCH TEAM

The CVs are attached in the computer Management of Calls

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Fundación Progreso y Salud
CONSEJERÍA DE IGUALDAD, SALUD Y POLÍTICAS SOCIALES

3. AVAILABLE MEANS AND REQUESTED BUDGET

3.1 AVAILABLE MEANS AND RESOURCES TO CARRY OUT THE PROJECT

A) MATERIAL ABLE TO BE INVENTORIED

The amount of infrastructure resources allow for the performance of this study without any special difficulty through the means available at the Bahía de Cádiz-La Janda Health District and at University Hospital Puerta del Mar, Cádiz.

B) BIBLIOGRAPHIC MATERIAL

The Medical Oncology Department has Internet access to perform bibliographic searches and to obtain the necessary bibliographic material. Puerta del Mar Hospital makes the SAS virtual library available to the researches of its centre.

C) PERSONNEL

At the Bahía de Cádiz-La Janda Health District, a sufficient number of women attend in order to recruit the required number of participants. The human resources personnel allows for the performance of this study without any special difficulty. As support for the researching activity, the Medical Oncology department has a research nurse hired by the Foundation *Fundación para la Gestión de la Investigación Biomedica de Cádiz*. Researchers have methodological and statistical assessment by the Preventive Medicine department and the support of the Bahía de Cádiz-La Janda Health District. Likewise, The Andalusian Integral Oncology Plan sponsors this research project.

3.2 REQUESTED BUDGET AND JUSTIFICATION.

Every item in the requested budget indicating items, units, unit prices, etc., must be broken down, and if information is available, it is recommendable that supplier be indicated. **In case of not matching with the budget stated in the computer application, the one stated therein shall prevail** (See annex).

CONCEPT	REQUESTED BUDGET		
	YEAR 1	YEAR 2	TOTAL
Goods and Services: (detail and justification for need)			
Material able to be inventoried			
Portable PC	00.00		
Image and voice recorder	00.00		
Projector	00.00		
Printer	00.00		
Fungible material			
Documentation, folders, and pens for participants' dossier	00.00		
Dissemination of results: (presentation of results in conferences).			
Attendance to National Conference of 2 speakers	1200.00		
Publication of results (publication in open access magazine)	3000.00		

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Hiring of external services Translation services	500.00		
Other expenses: (Justification and detail) Cafeteria service	00.00		
TOTAL	**4700.00**		

Comments and details of budget: (indicate items, units, conferences, meetings, etc.)

1 portable PC (1000€). Essential for digital hardware in deliberative meetings with participants.
1 image and voice recorder (400€). Essential in qualitative studies, since it will be necessary to analyse, *a posteriori*, the participants' comments.
1 projector (500€). Useful for the experts' presentation to participants.
1 printer (200€). Useful for the preparation of documentation to be submitted to participants.
Documentation, folders, and pens for the dossier to be delivered to participants (300€).
Financing for assisting the two researchers in a national conference where the study results will be presented is also requested (1200€).
Dissemination of results will require translation services for an original document (500€) to be sent to an international English-speaking open access magazine (3000€).
Catering services (300€). The three meetings are expected to last several hours during the afternoon. Cafeteria services are offered to participants as a courtesy.

4. PROJECT APPLICABILITY TO THE ANDALUSIAN PUBLIC HEALTH SYSTEM

4.1 APPLICABILITY

The expectations of transfer of research results to clinical practice, technological innovation, organization, resource management, and health services or health policies will be assessed.

1) Expected research results are applicable and include improvements to the Health System's usual clinical practice.
YES

Justify your answer and indicate application environment:

Researchers find the fact of trying an informed consent method representing community in an environment, like breast cancer prevention, where informed decision-taking is not resolved applicable.

Knowing the deliberation result of a sample representing community and submitting it to the pertinent politicians has an incomparable potential to include improvements in the usual clinical practice related to screening mammography. In case after the study, with the hypothetical negative vote of participants, some type of disinvestment is chosen, the non-performing of screening mammographies to some women would have, among others, the consequence of preventing overdiagnosis, overtreatment, and false positives, which are the main side effects of screening mammography.

2) Expected research results may be transferred to the organization, resources management, health services, or health policies.
YES

Justify your answer.

Citizens' participation in health policies will contribute improvements to the Health System. There is a great potential of capacity of transfer of result and high applicability of results. This is so because the possibility of disinvestment in the screening mammography programme, with the new scientific data of doubtful efficacy, is also high. The opinion against screening mammography will provide politicians with a justification and support to perform different types of disinvestment. The opinion in favour will provide grounds and validity to the political decision to maintain this type of breast cancer prevention.

Recommendations to the pertinent politicians will provide value, regardless of their decision. Conclusions obtained in the study will serve, therefore, to guide the resources management and health policies.

3) Expected research results may lead to the generation of technological innovations, patents, or utility models.
YES

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Justify your answer.

Citizens' juries approach, somehow, the deliberative survey technique, which suggests gathering at the same place, in general for 2 days, a sample representing the reference population, to be faced with experts and to make them discuss in small groups, before collecting their informed opinions. Said technique has been employed a dozen times in Great Britain, Australia and the United States. Despite its limited number of applications, such technique may be analysed, not only as an attempt to renew traditional surveys, but also as a symptom of a new link to public opinion in western democracies. Even when the contrast between the method's ambitions and the modesty of its performance is surprising, the emergence of this new way of public action must be taken seriously as a utility model.

The fact that the Integral Oncology Plan of the Andalusian Health Service is an observer interested in the project must be considered a cooperation with a company (in the present case, a public one) for the development of new services which will result in health improvements for citizens.

4) Expected research results may be published in a document having a great impact and commonly used by health professionals, such as the scientific magazines indexed by the Journal Citation Reports of the ISI Web of Science.
YES

Justify your answer.

The validity, current nature and original methodology, as well as the significance of results, justify the dissemination at quality scientific meetings and impact magazines, both national and international (national and international conferences on screening mammography, Medical Oncology, assistance quality, national and international magazines of Medical Oncology, cancer prevention, assistance quality). We cannot state accurately in advance the specific magazines and conferences in which results will be published or informed, but their bibliometric impact will always be considered.

5) Expected research results may be transferred through consensus documents, clinical practice guides published, etc., and applicable in the Health System
YES

Justify your answer.

Regardless of women's deliberation results in this study, we believe consensus documents and guides on the application of screening mammography should consider them, being applicable to the Health System.

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GENERAL INFORMATION FOR WOMEN

What is screening mammography?

Diagnostic screening consists in performing diagnostic tests on a presumably healthy population on a periodical basis, regardless of the type of test, in order to detect a particular disease (generally, a type of cancer, although there are screening campaigns for other diseases) before it manifests clinically –shows symptoms– which is generally associated with a more advanced stage of the disease.

A screening mammography is an x-ray of the mammary glands of a woman who is healthy, rather than a woman who has found a lump or any other alteration in her breasts, and does not appear to have any signs of breast disease. Mammography allows for the detection of certain small lesions that are suggestive of cancer because they are stiffer than the surrounding tissue.

It is a diagnostic method of breast cancer in its earliest stages. The purpose of offering mammographies to healthy women is to diagnose breast cancer before it manifests. By detecting breast cancer in its earliest stages, when the tumour is small, it is logical to believe that less aggressive treatments would be needed, and more healings would be possible.

Virtually all Health Systems in western countries have put in place early diagnostic programmes for breast cancer urging the female population aged 50-69 to have a mammography every 2 years (age and frequency differ from country to country or region to region).

Where does the idea that having preventive mammographies is good come from?

Health Systems have put in place mammography-based breast cancer detection programmes on the basis of studies that show that breast cancer mortality is thereby reduced. However, not all tests can be used to suggest that a treatment or preventive method should be definitely adopted. For example, there are medical actions that have been, or are intended to be, adopted only on the basis of expert opinions but without any supporting study. On some other occasions, the tests conducted lack the quality required to support a medical action.

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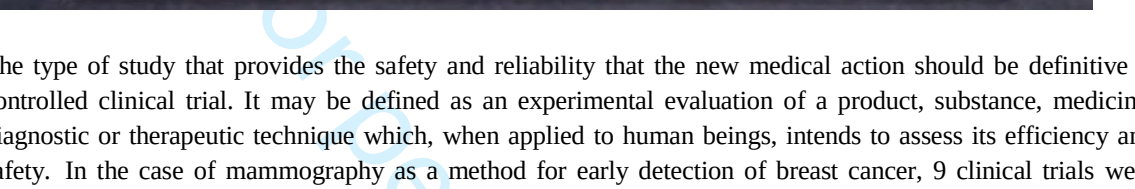
The type of study that provides the safety and reliability that the new medical action should be definitive is controlled clinical trial. It may be defined as an experimental evaluation of a product, substance, medicine, diagnostic or therapeutic technique which, when applied to human beings, intends to assess its efficiency and safety. In the case of mammography as a method for early detection of breast cancer, 9 clinical trials were conducted, mostly in the 70's and 80's of the last century. These trials compared two populations: one in which women had mammographies, and the other in which they did not. It was shown that in the population where women had mammographies, the breast cancer mortality rate decreased relative to the population of women who did not. Women were allocated to the groups (mammography or non-mammography) using a procedure that was similar to rolling a dice, making sure that both groups were similar in all aspects –hence comparable– except for the fact that the women in one group had mammographies while the women in the other did not. Accordingly, any difference found in the groups (for example, mortality) could be attributed to the use of mammographies.



Systematic reviews are scientific research studies where analysis units consist of the primary original studies (in the case of mammographies, the 9 clinical trials mentioned above). They are an essential tool to summarize the scientific information available, increase the validity of findings from individual studies, and identify uncertainty areas that need further research.

When you are presented arguments for and against screening mammographies by experts, you will be presented with the results from clinical trials and systematic reviews.

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Benefits of screening mammography and presentation

The main benefit of a screening mammography is to reduce the risk of death from breast cancer (reduction in breast cancer mortality), reducing treatment aggressiveness (less extensive surgery, less radiation therapy, less chemotherapy). The ideal objective would be to reduce global mortality, that is, all-cause mortality, because mammographies may reduce breast cancer mortality, but increase mortality due to other causes. However, it is accepted that breast cancer mortality reduction is a proper target.

When you debate about whether voting for or against screening mammography, you should bear in mind whether this test performed in the population at large does indeed reduce breast cancer mortality.

Early mammography-based diagnosis allows for an earlier detection of breast cancer relative to women who do not have mammographies, who are diagnosed later. Accordingly, women's survival rate is higher because time starts to run before, in other words, women are considered ill before. The real benefit would be attained by increasing women's survival but delaying death.

How will the benefit in terms of mortality be presented to you? The reduction of the risk of death from breast cancer in women who participate in screening mammography relative to women who do not is typically presented as a relative risk (RR). For example, if the risk of dying of breast cancer is 5 women out of 1,000 if they **do not** have a mammography, the risk will be 0.5% (5 out of 1,000 equals 0.5 out of 100). Likewise, if women **do** have mammographies, this risk reduces to 4 women out of 1,000, or 0.4%. Absolute risk will reduce to 0.5-0.4=0.1. But it is relative risk that will be presented to you more frequently, which is obtained by dividing the risk of death in women who **do** have mammographies by the risk of death in women who **do not** have mammographies. In our example above: 0.4/0.5=0.80, and it provides the same information as the relative risk reduction expressed as a percentage. Let us think that a relative risk of 1 means that both groups of women (those who **do** have and those who **do not** have mammographies) have the same risk of dying, and a relative risk of 0.80 means that women who **do** have mammographies have a 20% lower risk (0.80 is 20% lower than 1). You will receive information such as the following:

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"Screening mammography reduces the risk of death by 20%, with a relative risk of 0.80".

This form of presenting the reduction in breast cancer mortality is, in fact, barely informative. It is much more informative to present the number of women who should have a mammography in order to prevent death from breast cancer. It is the concept of “Number Needed to Treat” or, in our case, “to Screen”. It is known as NNT and indicates whether the benefit offered by mammography pays for the implementation efforts and costs. For example, a 20% reduction in the risk of death may look impressive, but says little about the real benefit. However, if we say that 2,000 women should have mammographies in order to avoid death from breast cancer (NNT: 2,000), we have a more accurate idea of its real benefit. Likewise, if the NNT is 500, it means that 500 women should have a mammography in order to prevent 1 death from breast cancer.

Therefore, you will also receive information about the reduction in breast cancer mortality through the NNT and its graphical representation:

In this example, which is different from the example above, 8 women out of 1,000 who do not have a mammography die.

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Furthermore, in this representation, 6 out of 1,000 women who do have a mammography die. Accordingly, 2 deaths out of 1,000 people are prevented (NNT: 500).

Risks of screening mammography. False positives

As any other diagnostic test, the result of a mammography may be positive or negative. But both possibilities may be true or false. A false-negative result means that the mammography has not detected cancer although cancer is present. However, mammographies have a high degree of sensitivity because they are able to detect almost all types of cancer that are present at the time of the test. The problem lies in the false positives, which presuppose an error, that is, the result determines that cancer is present when actually it is not.

Types of diagnoses		**Cancer**	
		absent	present
Mammography	negative	True negative (negative diagnosis, cancer is absent)	False negative (negative diagnosis, cancer is present)
	positive	**False positive** (positive diagnosis, cancer is absent)	True positive (positive diagnosis, cancer is present)

The detection of a false-positive mammography result presupposes harm for a woman because, despite being healthy, she will be followed-up and have further testing some time later in order to check whether the mammography readings have changed or not, and learn if they are more or less likely to be breast cancer. On other occasions, additional imaging tests are used to find whether they are more or less likely to be breast cancer. These may also be imaging tests such as spot compression mammography, ultrasound or magnetic resonance and, sometimes, needle biopsy to obtain a sample of the mammographic finding for analysis. Sometimes the woman will undergo surgery to have the detected lesion removed. If after all this, the doctor concludes it is not cancer, the woman will feel relieved, but the psychological impact and physical and mental suffering she has gone through, and sometimes will continue going through, are evident.

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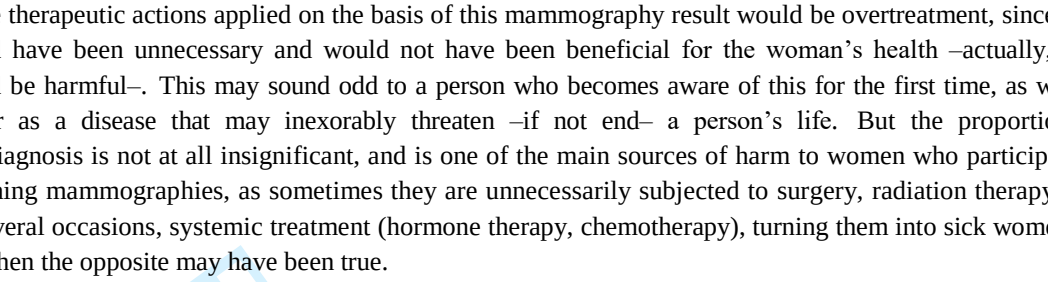
Risks of screening mammography. Overdiagnosis and overtreatment

Can breast cancer detected by screening mammography actually remit without treatment or progress so slowly so as not to compromise the woman's health? The answer is *yes*. This is known as overdiagnosis because cancer would have remitted spontaneously or would have never manifested over the woman's life. As a result, all the therapeutic actions applied on the basis of this mammography result would be overtreatment, since they would have been unnecessary and would not have been beneficial for the woman's health –actually, they would be harmful–. This may sound odd to a person who becomes aware of this for the first time, as we see cancer as a disease that may inexorably threaten –if not end– a person's life. But the proportion of overdiagnosis is not at all insignificant, and is one of the main sources of harm to women who participate in screening mammographies, as sometimes they are unnecessarily subjected to surgery, radiation therapy and, on several occasions, systemic treatment (hormone therapy, chemotherapy), turning them into sick women for life when the opposite may have been true.



Types of tumour growth. Source: Gilbert Welch. Should I Be Tested for Cancer?: Maybe Not and Here's Why. University of California Press. 2006. ISBN 0520248369, 9780520248366

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Let us introduce you to Carmen. She is 64 years old and has developed a small breast cancer (Source: Jolyn Hersch. Use of a decision aid including information on overdetection to support informed choice about breast cancer screening: a randomised controlled trial. The Lancet 2015; 385 (9978): 1642-52).

Carmen has a mammography exam. Her cancer is found and she undergoes treatment. Carmen lives until she turns 86, and then dies of a heart condition. Alternatively, Carmen does not have a mammography exam. Her cancer grows, is detected, but treated later. Carmen dies at the age of 70 from breast cancer.

Yet Carmen may not have a mammography exam, but her cancer does not grow or progress and is never detected. Nonetheless, Carmen lives until turning 86 and dies of a heart condition.

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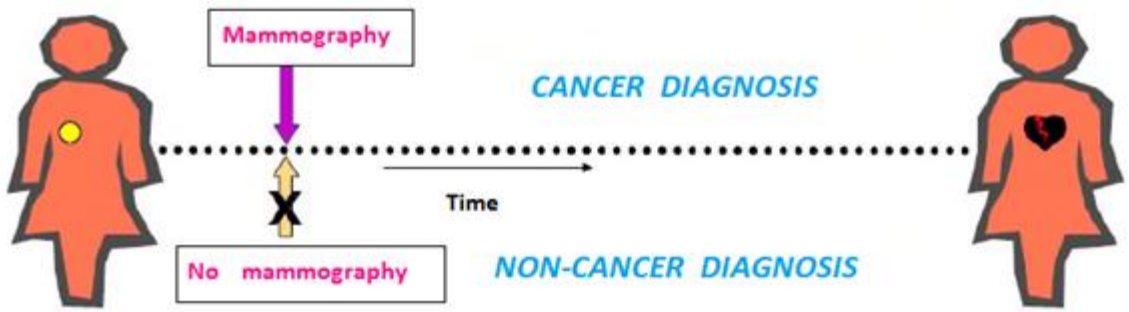

This represents the concept of overdiagnosis and, unfortunately, when cancer is found in a screening mammography, there is no way of knowing whether it is harmful or not. Therefore, all cancers should be equally treated (as if they were harmful). This means that screening mammography causes some women to be treated when such treatment is not necessary (overtreatment).

Risks of screening mammography. Other risks

Slight discomfort or pain during the mammographic screening, a bit of anxiety for some women while waiting for the results, a small possibility of developing cancer induced by the radiation from mammographies are also risks associated with mammography.

Finally, another risk of mammography is a woman's false sensation of security after learning of a negative result for cancer, which leads her to disregard symptoms or signs in the breasts and not to make consultations upon their occurrence ("I've just found a lump in my breast, but I've just had a mammography and was normal, so there's nothing to worry about").

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SCREENING MAMMOGRAPHY. ARGUMENTS FOR

Diagnostic screening consists in performing diagnostic tests on a healthy population in order to detect a particular disease (generally, a type of cancer, although there are screening campaigns for other diseases) before it manifests clinically showing symptoms.

The main benefit of screening of female population is the earlier detection of cancer, reducing treatment aggressiveness and increasing healings. Based on this compelling and attractive hypothesis, all western countries have put in place mammography-based breast cancer early detection programmes. But, has this hypothesis proved to be true? And, if so, are the negative effects outnumbered by the benefits?

Women have mammographies to reduce death from breast cancer and, if diagnosed with breast cancer, to receive less aggressive treatments, even though they are usually unaware of the risks or side effects associated with this type of procedure, such as false positives, overdiagnosis and overtreatment, pain, and exposure to radiation.

Breast cancer is the malignant tumour most frequently diagnosed in female population. In Europe, it represents 30% of all the diagnosed tumours and it is the first cause of death from cancer among women. In Spain, the incidence and mortality rates are similar to the European rates, with 26,000 new cases being diagnosed in 2014.

The most common risk factors which are related to breast cancer cannot be modified and account for less than half of the detected cases. On the other hand, controlling the risk factors that can be modified would not cause a significant reduction in the incidence rate, therefore, there is no clear possibility of preventing them from occurring. Hence, we can conclude that we do not have effective strategies of primary prevention, which makes secondary prevention by screening mammography a key instrument to control the disease nowadays. Currently, the Andalusian Health System includes within its basic services the screening of female population for breast cancer, which, in general terms, consists in performing a mammography every two years among female population aged 50-69.

Evidence that screening mammography reduces breast cancer mortality

As previously explained, the most reliable evidence showing that a mammography reduces breast cancer mortality comes from two types of tests: high-quality clinical trials and systematic reviews. Since the 60's of last century, 9 randomized clinical trials have been conducted on around 600,000 women. These trials compared two populations: one in which women had mammographies, and the other in which they did not. Furthermore, 4 systematic reviews have been conducted: Cochrane, American, Canadian, and British. The American and British reviews considered that all the trials had an acceptable standard of quality; however, the Cochrane and Canadian reviews stated that 4 trials did not have any inconsistencies regarding the number of recruited women and guaranteed an adequate random assignment (that is, the group of women who had a mammography and the group of women who did not have the mammography had similar characteristics). Nevertheless, 5 trials could not assert that the two groups of women could be compared or had inconsistencies in the number of women assigned to one or the other group. Therefore, should any differences be found in mortality in both groups, it may not be assured that such results are derived from performing a mammography, but they could have derived from other differences between the groups instead.

In general, most systematic reviews agree that performing a mammography reduces breast cancer mortality by 20%, with a relative risk (RR) of 0.80. Many experts do not agree with differentiating clinical trials according to their methodological quality and also propose, as a key parameter in the assessment, the reduction in breast cancer mortality instead of overall mortality.

Even though the same data has been analysed and a similar reduction in breast cancer mortality has been

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achieved (reduction of 20% and RR of 0.80), NNT estimates (number of women aged 50-69 who should have a mammography over a 10-year period in order to prevent death from breast cancer) show many differences. According to the British review, 1 death from breast cancer was prevented out of 235 women who participated in the procedure, whereas to other institutions such as the Nordic Cochrane Centre, at least 2,000 women need to participate in the procedure to obtain the same benefit. If we apply such data to the overall population, we can understand the importance of this benefit: 10 deaths out of 2,350 women are prevented, 100 deaths out of 23,500 women are prevented, 1,000 deaths out of 235,000 are prevented… Likewise, the Cochrane review shows the following data: 10 deaths out of 20,000 women are prevented, 100 deaths out of 200,000 women are prevented, 1,000 deaths out of 2,000,000 women are prevented…

Evidence that screening mammography allows women to receive less aggressive treatments

The fact that women receive less aggressive treatments has not been sufficiently studied. Only the Cochrane review described that the early detection of breast cancer by a screening mammography was most frequently associated with any type of surgery (RR 1.20) and increased use of radiation therapy (RR 1.24), but on the contrary, the need to administer other complementary and aggressive treatments such as chemotherapy (RR 0.63) and hormone therapy was reduced.

Most of the tumours detected in screening mammography programmes were at an early stage of the disease, reducing the need for chemotherapy as complementary treatment.

Evidence that screening mammography causes overdiagnosis and overtreatment

The best approach to measure overdiagnosis is to analyse the clinical trials with adequate random assignment and which did not offer the screening mammography to the control group at the end of the test. Three clinical trials meet these requirements (Malmö I and the 2 Canadian trials) and two reviews (the British and Cochrane reviews) have assessed the percentage of overdiagnosis based on those trials. The assessed data offers variable results. According to the Cochrane review, the percentage of overdiagnosis is 30% or 10 overdiagnosed cases out of 2,000 screened women over a 10-year period. Nonetheless, the British review estimates that 11% of all cancers would be overdiagnosed, and if a woman is diagnosed as a result of a screening mammography, the likelihood of being overdiagnosed is 19%, with an estimated NNT of 1 overdiagnosed case out of 77 screened women.

However, these are estimated figures and the true measure and impact of overdiagnosis are unknown.

Evidence that mammography causes false positives

Despite the variable estimates of false positive results according to the different reviews, the obtained results show a low likelihood of suffering this side effect based on the volume of women who participate in this type of procedure. In accordance with the British review, the percentage of false positives is 3.36% and according to the Cochrane review, the percentage is 10%. As a consequence, further diagnostic tests will be needed, which will cause psychological impact on the individual. 70% of these cases will require other imaging tests and 30% of the cases will require a biopsy.

The discomfort and psychological impact suffered until the diagnosis are discarded and for some time thereafter are inevitable. In spite of all these consequences as well as the anxiety and psychological discomfort that can be associated with the need to run further tests, several studies show that most women believe that the benefits they expect to obtain from their participation in the screening programme are greater than the possibility of suffering from such negative effects.

Evidence that mammography can cause other side effects

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Although some women suffer pain during a mammography, for most of them the pain is only mild. The sensation of relief and security derived from receiving a non-pathological result in the test is significantly greater than the discomfort it may cause.

A study estimates a rate of 3-6 cancers out of every 10,000 screened women aged 47-73 every 3 years due to exposure to radiation from mammographies. In addition to this low rate, currently, the digital mammography, which is frequently used in screening strategies replacing the classic analogue mammography device, exposes women to a lower degree of radiation and thus the percentage of tumours associated with this risk factor would be reduced.

Controversy on the screening mammography programme

There are discrepancies regarding the methodological aspects used to estimate benefits and risks: different degrees of importance are given to the quality of the original clinical trials (randomization, other biases) and different degrees of importance are given to the role played by studies other than the clinical trials (observational studies).

There are also discrepancies regarding the validity given to the clinical trials conducted in the 60's, 70's and 80's with old radiologic technology. It is likely that the improvement of breast cancer treatments and healthcare services in general has made mammography screening less important.

Even though estimates on Relative Risks frequently match, the different systematic reviews provide different estimates regarding the required number of women to be screened in order to prevent death or to be overdiagnosed.

The assessment of the benefits and risks is different depending on the review and it is subject to different interpretations, therefore, recommendations are also different.

Recommendations for discussion

The key measure of the benefit of the screening mammography programme is the reduction in breast cancer mortality. As it has been described, despite the various results obtained according to the reviews analysed, overall, most of the systematic reviews agree that performing a mammography reduces breast cancer mortality by 20%, with relative risk (RR) of 0.80.

Regarding the assessment on mortality reduction as opposed to overdiagnosis, there is no conclusive evidence that the number of overdiagnosed cases is significant, therefore, such negative effect should not be considered to be greater than the expected benefit of mortality reduction. In this respect, other less serious side effects, despite causing some harm on women, are counterbalanced with the benefit of mortality reduction that women expect to obtain by participating in the screening mammography programme.

Even after receiving such positive data in favour of mammography screening, some women may prefer not to have a mammography. It is essential to improve the type of information women receive so that they can make informed decisions. It is also essential that research be conducted in order to select which women may benefit from having a mammography and which women may suffer from its negative effects.

Should the Andalusian public health system offer a screening mammography to women aged 50-69?

Yes.

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SCREENING MAMMOGRAPHY. ARGUMENTS AGAINST

Diagnostic screening consists in performing diagnostic tests on a healthy population in order to detect a particular disease (generally, a type of cancer, although there are screening campaigns for other diseases) before it manifests clinically showing symptoms.

The main benefit of a mammography-based screening is the earlier detection of breast cancer, reducing treatment aggressiveness and increasing healings. Based on this compelling and attractive hypothesis, all western countries have put in place mammography-based breast cancer early detection programmes. But, might this hypothesis be wrong? Or, even if it were true, could it have a negative impact?

Women have mammographies to reduce death from breast cancer and, if diagnosed with breast cancer, to receive less aggressive treatments. However, they are usually unaware of the risks or side effects associated with screening mammographies. We have provided information about such negative effects: false positives, overdiagnosis and overtreatment, false sensation of security, pain and radiation.

Evidence that screening mammography reduces breast cancer mortality

As previously explained, the most reliable evidence showing that a mammography reduces breast cancer mortality comes from two types of tests: high-quality clinical trials and systematic reviews. Since the 60's of last century, 9 controlled clinical trials have been conducted on around 600,000 women. These trials compared two populations: one in which women had mammographies, and the other in which they did not. Furthermore, 4 systematic reviews have been conducted: Cochrane, American, Canadian, and British collaboration. The American and British reviews considered that all the trials had an acceptable standard of quality; however, the Cochrane and Canadian reviews stated as follows:

- 4 trials did not have any inconsistencies regarding the number of recruited women and guaranteed an adequate random assignment (that is, the group of women who had a mammography and the group of women who did not have a mammography had similar characteristics).
- Nevertheless, 5 trials were unable to assert that the two groups of women could be compared or had inconsistencies in the number of women assigned to one or the other group. Therefore, should any difference be found, it could not be assured that such results derived from performing a mammography, but they could have derived from other differences between the groups instead.

In general, systematic reviews agree that performing a mammography reduces breast cancer mortality by 20%, with a relative risk (RR) of 0.80. But when the analysis narrows down to methodologically appropriate trials, in statistical terms, no significant reduction of death from breast cancer is found, with RR around 1 (without any difference between the screened and non-screened women). Furthermore, the Canadian and Cochrane reviews find no reduction in global mortality between women who have the screening mammography relative to those who do not.

Even though the same data has been analysed and a similar reduction in breast cancer mortality has been achieved (reduction of 20% and RR of 0.80), NNT estimates (number of women aged 50-69 who should have a mammography over a period of 20 years in order to prevent death from breast cancer) show many differences, ranging from 235 according to the British review, and 1,000 according to the Cochrane review.

Evidence that screening mammography allows women to receive less aggressive treatments

According to the Cochrane review, not only are more aggressive treatments not reduced, but also more

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women undergo a mastectomy instead of breast-conserving surgery if they participate in screening (RR of undergoing a mastectomy of 1.20) and the use of radiation therapy is higher (RR 1.24).

The number of mastectomies peaked immediately after the implementation of the screening programme in Copenhagen and Funen, while this is not the case in some regions of Denmark, where screening mammography was not implemented.

Evidence that screening mammography causes overdiagnosis and overtreatment

The best approach to measure overdiagnosis is to analyse the clinical trials with adequate random assignment, for they compare similar groups in terms of the risk to develop breast cancer. These trials are also required to have never offered mammographies to the control group and that sufficient follow-up is pursued for 5 years (5-10 years). In this way, we would be able to count how many breast cancers were overdiagnosed in women who have mammographies relative to those who do not. Three clinical trials meet these requirements (Malmö I and the 2 Canadian trials) and two reviews (the British and Cochrane reviews) have assessed the percentage of overdiagnosis based on these 3 contrasted quality trials which did not offer mammographies to the control group at the end of the test: 11% of all cancers would be overdiagnosed and, if a woman is diagnosed as a result of a screening mammography, the likelihood of being overdiagnosed is 19%, with an NNT of 1 overdiagnosed case out of 77 screened women, according to the British review, and 30% or 10 overdiagnosed cases out of 2,000 screened women, according to the Cochrane review.

Evidence that mammography causes false positives

In accordance with the British review, the percentage of false positives is 3.36%, and according to the Cochrane review, the percentage is 10%. As a consequence, further diagnostic tests will be needed, which will cause psychological impact on the individual. 70% of these cases will require other imaging tests and 30% of the cases will require a biopsy.

The discomfort and psychological impact suffered until the diagnosis are discarded and for some time thereafter are inevitable. Many tests have been conducted on the psychological impact of false positives, with diverse results, although it would seem that it may be significant on many occasions. It has also been proved that being well-informed can work as material mitigation of anxiety and psychological discomfort.

Evidence that mammography can cause other side effects

Some women suffer pain during a mammography and, in some cases, this causes them to avoid returning to screening rounds. Obtaining a negative result in the test creates a sensation of relief and false security that may lead them to not see a doctor if they find a symptom or sign in their breasts. The exposure to the radiation from mammographies may cause breast cancer. A study estimates a rate of 3-6 cancers out of every 10,000 screened women aged 47-73 every 3 years. Currently, the digital mammography exposes women to a lower degree of radiation.

Controversies on screening mammography programmes

There are discrepancies regarding the methodological aspects used to estimate benefits and risks: different degrees of importance are given to the quality of the original clinical trials (randomization, other biases) and different degrees of importance are given to the role played by studies other than the clinical trials (observational studies).

There are also discrepancies regarding the validity given to the clinical trials conducted in the 60's, 70's, and 80's with old radiologic technology. It is likely that the improvement of breast cancer treatments and healthcare services in general has made screening less important.

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Even though estimates on Relative Risks frequently match, the different systematic reviews provide different estimates regarding the required number of women to be screened in order to prevent death or to be overdiagnosed.

The assessment of the benefits and risks is different depending on the review and it is subject to different interpretations, therefore, recommendations are also different.

Recommendations for discussion

The key measure of the benefit of screening mammography is mortality reduction, not only derived from breast cancer but also total mortality (from any cause). As it has been described, breast cancer mortality is not favourable in methodologically appropriate trials and mortality from any cause is not favourable for mammography either. Regarding the assessment on mortality reduction as opposed to overdiagnosis, evidence suggests that the number of overdiagnosed cases is significant and greater than the benefit of mortality reduction. Other side effects are not as serious, but they also cause harm on women which harm is not counterbalanced with the benefit of mortality reduction.

Even after receiving this negative data against screening mammography, some women may still prefer to have a mammography. It is essential to improve the type of information women receive so that they can make informed decisions. It is also essential that research be conducted in order to select which women may benefit from having a mammography and which women may suffer from its negative effects.

Should the Andalusian public health system offer a screening mammography to women aged 50-69?

No.

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CITIZENS' JURY
Schedule of proceedings
Day 1:

- **4.00-4.30 p.m.**
  - Arrival of research team (JMBC, VLR, AQC, PRV, JRB) and of image and sound technician
  - Preparation of conference room
  - Preparation of computing equipment and projector
  - Preparation of recording equipment
- **4.30-5.00 p.m.**
  - Arrival and reception of jury members
- **5.00-5.30 p.m.**
  - Presentation of research team (JMBC)
  - Presentation of jury members
  - Explanation by the moderator of features and objectives of the citizens' jury study (JMBC)
  - Compliance by the jury members with the participants' features sheet and with the informed consent document
- **5.30-7.30 p.m. (6.30-6.45 p.m., coffee break).**
  - Oral presentation supported by PowerPoint presentations by the moderator on screening mammography (JMBC):
    - What is screening mammography?
    - Benefits and risks of screening mammography
- **7.30-8.30 p.m.**
  - Questions and debate
- **8.30-9.00 p.m.**
  - Closure

Day 2:

- **4.00-4.30 p.m.**
  - Arrival of research team (JMBC, VLR, AQC, PRV, JRB), expert witnesses (EBR, SMC), and image and sound technician
  - Preparation of conference room
  - Preparation of computing equipment and projector
  - Preparation of recording equipment
- **4.30-5.00 p.m.**
  - Arrival and reception of jury members
- **5.00-5.15 p.m.**

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- Presentation of expert witnesses

- **5.15-6.15 p.m.**
  - Oral presentation supported by PowerPoint presentations by the expert positioning for screening mammography (EBR)
- **6.15-6.30 p.m.**
  - Coffee break
- **6.30-7.30 p.m.**
  - Oral presentation supported by PowerPoint presentations by the expert positioning against screening mammography (SMC)
- **7.30-8.30 p.m.**
  - Questions and debate
- **8.30-9.00 p.m.**
  - Closure

Day 3:

- **4.00-4.30 p.m.**
  - Arrival of research team (JMBC, VLR, AQC, PRV, JRB) and of image and sound technician
  - Preparation of conference room and placing of ballot box
  - Preparation of computing equipment and projector
  - Preparation of recording equipment
- **4.30-5.00 p.m.**
  - Arrival and reception of jury members
- **5.00-5.30 p.m.**
  - Recommendations for deliberation by the moderator (JMBC)
- **5.30-7.00 p.m.**
  - Deliberation by jury members
  - Recommendations to political authorities
- **7.00 p.m.**
  - Voting
- **7.10-7.30 p.m.**
  - Coffee break
- **7.30-7.45 p.m.**
  - Ballot box opening
- **7.45-8.00 p.m.**
  - Thanks and closure.

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No Item	Guide questions/description	Reported on page No

Domain 1: Research team and reflexivity

Personal Characteristics

1. Interviewer/facilitator. Which author/s conducted the interview or focus group?. Page 6-7

2. Credentials. What were the researcher's credentials? E.g. PhD, MD. Page 1,6,7+protocol

3. Occupation. What was their occupation at the time of the study? Page 1,6,7+protocol

4. Gender Was the researcher male or female? Page 1,6,7+protocol

5. Experience and training. What experience or training did the researcher have? Page 6,7+protocol

Relationship with participants

6. Relationship established. Was a relationship established prior to study commencement? Page 6.

7. Participant knowledge of the interviewer. What did the participants know about the researcher? e.g. personal goals, reasons for doing the research. Page 6.

8. Interviewer characteristics. What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic. Page 6,7.

Domain 2: study design

Theoretical framework

9. Methodological orientation and Theory. What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis. Page 8.

Participant selection

10. Sampling. How were participants selected? e.g. purposive, convenience, consecutive, snowball. Page 6.

11. Method of approach. How were participants approached? e.g. face-to-face, telephone, mail, email. Page 6,7.

12. Sample size. How many participants were in the study?. Page 6,9.

13. Non-participation. How many people refused to participate or dropped out? Reasons?. Page 6,9.

Setting

14. Setting of data collection. Where was the data collected? e.g. home, clinic, workplace. Page 7.

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15. Presence of non-participants. Was anyone else present besides the participants and researchers?. Page 6,7,8.

16. Description of sample. What are the important characteristics of the sample? e.g. demographic data, date Data collection. Page 6,9.

17. Interview guide. Were questions, prompts, guides provided by the authors? Was it pilot tested?. Page 7+protocol.

18. Repeat interviews. Were repeat interviews carried out? If yes, how many? n/a

19. Audio/visual recording. Did the research use audio or visual recording to collect the data?. Page 8.

20. Field notes. Were field notes made during and/or after the interview or focus group?. Page 8.

21. Duration. What was the duration of the interviews or focus group?. Page 7.

22. Data saturation. Was data saturation discussed?. Page 17.

23. Transcripts returned. Were transcripts returned to participants for comment and/or correction?. Page 8.

Domain 3: analysis and findings

Data analysis

24. Number of data coders. How many data coders coded the data?. Page 8,19.

25. Description of the coding tree. Did authors provide a description of the coding tree?. Page 10.

26. Derivation of themes. Were themes identified in advance or derived from the data?. Page 8.

27. Software. What software, if applicable, was used to manage the data?. Page 8.

28. Participant checking. Did participants provide feedback on the findings?. Page 8.

Reporting

29. Quotations presented. Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number. Page 10,11,12.

30. Data and findings consistent. Was there consistency between the data presented and the findings?. Page 16.

31. Clarity of major themes. Were major themes clearly presented in the findings?. page 10-15.

32. Clarity of minor themes. Is there a description of diverse cases or discussion of minor themes?. Page 10-15.

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How a deliberative approach includes women in the decisions of screening mammography: a citizens' jury feasibility study in Andalusia, Spain

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Title

How a deliberative approach includes women in the decisions of screening mammography: a citizens' jury feasibility study in Andalusia, Spain

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Word count: 3.534

Abstract

Objectives: To verify whether a citizens' jury study is feasible to the Andalusian population and to know if women, when better informed, are able to answer the research question of whether the Andalusian Public Health System must continue offering screening mammography to women aged 50-69. The reasons for the pertinent decision and recommendations to the political authorities will be stated.

Design: Qualitative research study with the methodology of citizens' jury.

Setting: Breast cancer screening programme in Andalusia (Spain).

Participants: Thirteen women aged 50-69 with secondary school or higher education accepted to participate as a jury. Two epidemiologists were the expert witnesses. The main researcher was the neutral moderator.

Interventions: Jury met on Monday, 15 February 2016. The moderator indicated to the jury that it had to assess the screening programme's key benefits and main harm. On Tuesday 16, the expert witnesses positioned for and against the programme. On Thursday 18, the jury deliberated, reached final conclusions, submitted its vote, and stated its recommendations to politicians. The deliberation session was transcribed and analysed with the support of ATLAS.ti.5.2 software.

Primary and secondary outcome measures: Feasibility in the Andalusian population, women's vote and opinion, reasons for votes and recommendations to political authorities.

Results: Eleven participants voted yes and 2 voted no. There are three reasons to vote "yes": health, the test nature, and individual freedom. Some women invoke the lack of efficacy and the cost to justify their negative vote, at least in universal terms. Upon completion, they made suggestions to be submitted to the pertinent authorities for the improvement of information, psychology services, and research.

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Conclusions: The deliberative strategy is feasible and causes a favourable positioning regarding screening mammography, although information changes the opinion of some women, who desire informed decision making and to keep or increase medicalisation in their lives.

Key words: Cancer: Breast; Heath services; Public health policy; Qualitative research; Screening.

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Strengths and limitations of this study

- Consolidated criteria for reporting qualitative studies (COREQ) were followed, and the most important elements of the Citizens' Jury have been addressed.
- The deliberative process was planned, with a description of the selection and roles of the research team and experts, and a description of the recruitment strategy and the characteristics and instructions for the jury.
- The technical and procedural information is available and clearly documented.
- The study was designed as a research project, and since there was no representation of participating women on the research team, their opinion and possible critical perspective with respect to the study's design and performance have not been considered.
- The information submitted arises from a sole process of deliberative democracy, which is why it will be necessary to apply, as programmed, other methodological strategies allowing for the gathering of more information to fulfil the categories and be certain that the collected information covers every possibility.

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Text

INTRODUCTION

There is increasing evidence indicating that screening mammography may constitute a low-value service where benefits do not exceed harm and cost.[1] Some women will benefit, while others would be harmed.[2] However, public perception is not realistic.[3] For instance, women in Spain accept the invitation to participate in screening mammography and receive little information [4] and, in general, tend to overestimate the benefits [5] and are not involved in the physical or psychological impact caused by overdiagnosis and false positives [6,7]. Any help in decision making related to screening mammography potentially could lead to an informed decision,[8,9, 10] but it is not yet clear how to apply such information in an optimal fashion.[9] In this context, there are still arguments in favour of screening mammography [11] and it has not been removed in western countries, except for Switzerland.[12] Spain has a National Health System, but every region is autonomous regarding decisions on screening mammography programme coverage. In Andalusia, a population-based screening programme invites women every 2 years, through a letter. In 2013, a report [13] was prepared and served to fix the age between 50 and 69, ceasing to invite women aged 45-49 in districts where they were invited before.

Citizens' juries gather a group of citizens, randomly chosen, to discuss a particular topic. They are exposed to information and opinions on such topics for several days, in which information and opinions are derived from witnesses selected because of their expertise or because they represent their interests. Along with a moderator qualified to guarantee a fair process, jury members have the opportunity to question the witnesses and, after a deliberation process, they reach a decision and make recommendations to the pertinent authorities. The latter are compelled to provide an answer, either by acting pursuant to the citizens' report or by

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explaining why they do not agree.[14] The implementation of citizens' juries has been proposed as a tool to provoke the population's position on public health issues involving scientific controversy, as well as for political decision-making purposes.[15,16] Democratic deliberation is useful for participation in health affairs where it is difficult to obtain an individual and informed consent, where consent represents the community.[17]

We have designed, carried out, and analysed a citizens' jury-type deliberative democracy study to verify whether it is feasible in the Andalusian population. We have established the following as secondary objectives: to know if women, when better informed via the information provided during the citizen jury process, are able to answer the research question of whether the Andalusian Public Health System (SSPA) must continue offering screening mammography to women aged 50-69, to know the reasons for the pertinent decision and recommendations to the political authorities.

METHODS

Research protocol (Supplementary File 1) was approved by the Bahía de Cádiz - La Janda Ethics Committee and all participants gave written informed consent. Their names as referred to in the quotations are fictitious to guarantee confidentiality.

Primary and secondary outcome measures were feasibility in the Andalusian population (if performance and execution of the study were carried out without any problem as planned, if the study was accepted by women, and if its objectives were reached), women's votes and opinions, the reasons for such votes, and recommendations to the political authorities.

Jury selection

A sample of 70 women aged 50-69, with secondary school or higher education, and without any relationship established between them or with the researchers prior to study commencement, was selected from the list of invitations of the breast cancer screening programme. Telephone contact started 3 months before the process. They were excluded if,

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after 3 attempts on different days, it was not possible to contact them. In the first contact, information on features and purposes was provided and, if they accepted, they were contacted a month before and a week before for confirmation. The purpose was to recruit at least 12 women.

Expert witness selection

Two expert epidemiologists (female) defended the positions for and against screening mammography. The one positioned in favour works at the Provincial Cancer Registry of Cadiz (EBR) and was selected because she has been a member of the research team for many years. The one against (SMC) was selected due to her expertise in the development of the Andalusian screening mammography programme and because of her critical position toward it. The main researcher (male) in this study was the neutral moderator (JMBC).

Documentation preparation

Informed consents and an information gathering sheet with respect to the participants' features were prepared. The research team and the expert witnesses prepared four documents to be delivered to the jury (Supplementary File 2). 1. General information document and a presentation for the jury members regarding the screening mammography. 2. Document with arguments for and against mammographies, containing the experts' presentations. For its preparation, the report published by the General Secretariat of Public Health, Social Inclusion, and Life Quality was employed as a guide.[13] 3. An information document regarding the Andalusian early detection of breast cancer programme available at http://www.juntadeandalucia.es/servicioandaluzdesalud/principal/documentosacc.asp?pagina=gr_sabermas_cancermama. 4. Presentation with recommendations for deliberation.

Process

The jury members met 3 afternoons for 4 hours at a hotel in the city. On the first day, introductions were performed, the study's features and purposes were explained, doubts were

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resolved, informed consents were signed, and sociodemographic information questionnaires were fulfilled. They were provided with a dossier containing the described information. The moderator indicated to the jury that it had to assess the key benefits of the screening programme (breast cancer mortality reduction), the main harm (overdiagnosis, overtreatment, and false positives), and other benefits and harms. To that effect, a presentation was made to understand the arguments for and against that would be presented the next day. The opportunity to resolve doubts was granted.

On the second day, the experts made their presentations using a PowerPoint presentation (Supplementary File 3) for and against the programme, and the jury asked questions. The moderator led the debate and discussion.

On the last day, the jury discussed the presentations and programme without the presence of the experts or moderator and reached a conclusion. They issued their vote and wrote suggestions to political decision makers.

During the three days, an observer expert in qualitative research (VLR) took notes on the sessions without participating actively. The entire process was supervised by an expert in Bioethics (JMRB). All the sessions were audio and visual recorded. A gift valued at 20 Euros was given to each participant.

Information analysis

Upon transcription of the deliberation session by independent parties (see acknowledgements), the session was analysed with the support of ATLAS.ti.5.2 software. A systematic reading of the information was performed, the categories derived from the deliberation were identified, and, in this paper, only the analysis of the category "opinion on whether the SSPA must continue offering mammographies to women aged 50-69" is presented. The deliberation session was deconstructed, assigning and reducing the information in this category. The information later was reconstructed and summarised to

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conclude with its interpretation. A theoretical approach based on health psychology from a feminist approach [18] was established.

A process of verification by informants (member checking) was carried out. The participants were given an abbreviated report on the results where they had to score, in a Likert-type scale from 1 to 5, the adjustment and sufficiency of the definition of categories and subcategories and the relevance of quotations by means of which categories were justified and illustrated. Six scores were obtained that, in general, agreed with the interpretation of the information and participants stated they recognised their voices in the report.

Likewise, a researchers/analyst's triangulation was performed to reduce the distortion of the information interpretation and to increase the validity of results. To that effect, a person not related to the team, an expert in qualitative information analysis and health social psychology was incorporated. Such individual was provided with a detailed report on the results and, by means of a Likert-type scale from 1 to 5, had to assess the relevance of categories, subcategories, and identified features, their definitions, and the examples provided. This person also scored the information interpretations. Among their suggestions, we found the following: to gather and remove some categories, to deepen the definition of others and to provide more examples in some categories and subcategories for being insufficiently based on the information. Their recommendations were followed.

Patient and Public Involvement

The study was designed as a research project, and since there was no representation of participating women on the research team, their opinion and possible critical perspective with respect to the study´s design and performance have not been considered.

A process of verification by informants (member checking) was carried out. The participants were given an abbreviated report on the results where they had to score, in a Likert-type scale

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from 1 to 5, the adjustment and sufficiency of the definition of categories and subcategories and the relevance of quotations by means of which categories were justified and illustrated. Six scores were obtained that, in general, agreed with the interpretation of the information and participants stated they recognised their voices in the report.

RESULTS

Figure 1 shows a flowchart of jury recruitment and Table 1 shows its main features. Attendance was consistent since 13 women attended 3 days. None of the 13 women who deliberated and voted missed any information provided on the first and second days. Eleven of them voted "yes" and 2 voted "no" to the question of whether the SSPA must offer mammographies to women aged 50-69.

Table 1. Jury members' features.

Age (median and category)	55 (51-65)
Level of education:	
Secondary	5
University	8
Working status:	
Active	8
Unemployed	3
Pensioner	2
Marital status:	
Married	10
Separated	2
Widow	1
Do you have a mammography performed regularly?:	
Yes	12
No	1
You have a mammography performed with:	
Public screening programme	11
Private healthcare	1
Both	1
Previous mammography rounds:	
1	1
2	0
3	2
4	1

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5	3
>5	6
Family history of breast cancer:	
Yes	4
No	9
Previous favourable opinion on screening mammography:	
Yes	13
No	0

The reasons why participants think mammographies must continue being offered form three groups: health, test nature, and individual freedom (Table 2). Different opinions are observed regarding coverage among those who believe they must continue being offered; some women deem the universal nature necessary while others believe that mammographies should be offered on demand. There are participants who mention lack of efficacy and high cost to justify why they must not continue being offered. Tables 3 and 4 present some women's indicative quotations.

Table 2. Categories on whether the SSPA must continue offering screening mammography

Category	**Subcategory**	**Features**	**Indicators**
Yes	Reason	Health	Mortality reduction
			Prevents “greater harm”
			Few negative consequences
		Nature of the test	Diagnostic test
			Absence of alternatives
			High efficacy
			Public good
		Individual freedom	Women's freedom
			Capacity and right to make decisions
	Type of offering	On demand	
		Universal	
No	Reason	Lack of efficacy	
		High cost	

Table 3. Indicative quotations: Reasons to continue and to not continue offering screening mammographies

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Jury member	Indicative quotation
	Health as a reason to continue offering screening mammography
Juana	I'm in favour of its continuance, because as from the moment it reduces mortality, I believe it must be offered.
Rosario	…The fact that it reduces mortality, even for two people, is enough to me, because if I'm one of those people, I will tell you whether it is worth it or not.
Rosa	Of course I'm in favour because I think greater harm may be prevented.
María	…in favour of mammographies. More significant harms can be prevented and there is no possibility of surgery or treatment.
Milagros	…it's OK because negative things are very few … Because, the negative, what is it? The radiation? Well, we already know it's a normal X-ray...
	The nature of the screening test as a reason to continue offering screening mammography
Juana	…Mammography itself, in my opinion, is really good because it detects any possible problem, so you say "it may find out a problem".
Manuela	I'm in favour of every preventive measure, at the public health level, for the entire population. I'm in favour of mammographies. I'm in favour of mammographies…, if we are not offered alternatives, we know it has some risks and side effects, but, between not having anything and having this test, well, I'd rather continue having it.
Milagros	We must take into account that overdiagnosis is one out of seventy-seven, I mean, it's really small, so death is one out of one thousand but overdiagnosis, which is one of the negative things, is one out of seventy-seven, it's very small, the fact that one out of seventy-seven is overdiagnosed is really small, I think it's a lottery. …I wouldn't remove it, because it's a public good … in addition, it's up to you, because it's voluntary.
	Individual freedom as a reason to continue offering screening mammography
Carmen	Yes, yes, I think women are free to make decisions.
	Lack of efficacy as a reason not to continue offering screening mammography
Ana	…But the point is the programme. It doesn't work … one out of seventy-seven in the population is a lot.
Mercedes	The point is that with the figures and data we have, I see it so dependent on fate, because it's such a small portion among so many that it gives the impression that...
	High cost as a reason not to continue offering screening mammography
Ana	So, let's see, the cost derived from performing mammographies, treatments because something is detected is a quite high cost. So, we

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	should see if there are other, more effective, ways of prevention and that money we are employing should be used for another thing, maybe research on…medicines.
Juana	In favour of women being provided with enough information so that they can decide freely, considering the pros and cons, whether to have it made or not voluntarily.

Table 4. Indicative quotations: Type of screening mammography offering

Jury member	**Indicative quotation**
	On demand
Mercedes	I say mammographies are always there, you may request one whenever you want, so they won't be denied.
Rosa	No, no, no, no they won't perform it because you request it...
Milagros	You request a test now and, when will it occur? A DEXA, how long does it take? It's an institutionalised programme that once it's been implemented, now yes, and maybe the campaign is to remove it, we don't know what's behind…
	Universal offering
Milagros	The plan [the Screening Programme] exists and it's optional whether to perform it or not. So it's better for it to exist because there are people who will want to perform it … no one obliges you to do it right now. It's a thing that has been established, institutionalised, which is good because we see very few negative things, the fact that you may opt to perform it or not is voluntary.
Juana	… they may decide freely, considering the pros and cons, if they perform it or not voluntarily.

Health as a reason to continue offering screening mammography

Mortality reduction arises as a reason for which some participants believe it must continue being offered between 50 and 69 years old. During deliberation, there were different opinions on whether mortality reduction is significant. Rosario mentions that the reduction degree is not an aspect to be considered and that any reduction is acceptable in regard to human lives (Table 3). Participants refer to mammography's diagnostic nature when they indicate that mammography may prevent greater harm (note Rosa's words in Table 3). They think

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participation in screening facilitates an early diagnosis and improves treatment possibility (see María's quotation in Table 3), prevents any harm derived from the advanced cancer stage and helps extend a decent life. Furthermore, reference is made to the negative consequences; some participants believe they are few and minimise them, such as radiation. They consider that some of the negative consequences are also present in other tests and this justifies the continuance of mammography (Table 3).

The nature of the screening test as a reason to continue offering mammographies

Some participants believe screening mammography is a diagnostic test. They see it as the only efficient test to detect breast cancer, which they invoke as a reason to support it. Consequently, they think every kind of risk, side effect, or error possibility is reasonable. Milagros, even when she recognises that overdiagnosis may be a risk, appreciates that it seldom occurs. That is how she justifies that it must continue being offered (Table 3). Moreover, there is the idea that screening is a preventive test, as another argument in favour of the offering thereof. However, it is based on the wrong idea that screening mammography serves to prevent, which denotes a wrong use of the diagnosis and prevention concepts.

Related to its universal nature, the concept of "public good" appears as a reason to continue offering mammographies. The public "good" is understood as general conditions that are advantageous to every person, regardless of their condition, facilitating equality. In this case, mammography is understood as a valuable resource that must be offered to women with the sole requirement of being aged 50-69 (Table 3).

Individual freedom as a reason to continue offering screening mammography

Women's freedom to decide what to do once they are offered the opportunity to participate in screening mammography is revealed as another argument in favour of continuing the programme. There is the demand of being treated as active users of SSPA and not as mere passive users or consumers. Such demand involves the participants' desire to be well informed

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and to be able to undertake responsibility in the form of decision making. Somehow, it is a way to reduce the anxiety that may be caused by the mammography, trying to increase control, and reduce ambiguity (Table 3).

Lack of efficacy as a reason not to continue offering screening mammography

If efficacy was previously an argument to justify mammographies' continued offering, it is now an argument to question it. Some participants, such as Ana and Mercedes, question its efficacy and believe that, on some occasions, it depends on fate (Table 3).

High cost as a reason not to continue offering screening mammography

Ana mentions the high cost of the screening programme and, in the face of the inefficacy of the test, considers the investment unjustified. That is why she suggests other measures, such as research, to make economic cost profitable and make progress regarding the issue (Table 3).

Availability on demand

From the participants' words there arises the idea that the SSPA must continue offering screening mammography, although there are some nuances. Some participants state that it must be offered on demand, that is, offered to those women requesting it. However, there are opinions against this possibility. Part of this rejection is based on the mistrust toward the SSPA and its good operation. Another part is based on the mistrust toward the latest goal of this research. Milagros expresses her fear related to the removal of the breast cancer screening programme's universal nature (Table 3).

Universal availability

Some participants believe the screening test must continue being offered on a universal basis to women aged 50-69 since this does not make it compulsory. Therefore, the voluntary nature of participation is deemed a key feature (Table 4).

Recommendations to health authorities

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After joint consideration, the jury prepared a list of recommendations addressed to the health authorities to improve the screening mammography programme. They focused on the improvement of information, the psychology service demand, and the promotion of research on breast cancer screening:

Recommendation 1: Women must be informed when receiving an invitation to participate in the programme so that their decision is informed (e.g., being aware of the possibility of overdiagnosis, false positives, radiation).

Recommendation 2: Information must be given in such a manner that it is widely known (e.g., information campaigns in the media, in particular, addressed to women aged 49-50).

Recommendation 3: During the screening test process, women must have specialised psychological support, particularly, in the case of evidence of the presence of disease.

Recommendation 4: Modify protocols of action after mammographies so that, in case there are signs of cancer, the patient may know to what tests they will be subjected.

Recommendation 5: Use less harmful techniques than mammographies and offer alternatives.

Recommendation 6: Provide more resources to research on breast cancer, its prevention, early diagnosis, and treatment (e.g., be able to select which women may benefit and which may be harmed upon participation in the programme).

Recommendation 7: Studies on which the debate on benefits and cost of screening tests are based must be updated. The most recent ones are from the 1980s.

DISCUSSION

The deliberative democracy process has been feasible in a group of SSPA users and it has caused a favourable position, although the study information changed some participants' opinion (2 out of 13, 15%). This change should be considered more as a qualitative than as a quantitative assessment and be taken with caution due to the small sample size. From the

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analysis of the texts, it is clear that the participants improved their knowledge about the screening programme. Although there is no direct comparison with the degree of knowledge before the citizen jury, it is obvious that their knowledge was better than before; they were able to position themselves for or against, to comment on the universal offering or the demand for mammography and to express their opinion on its efficacy in terms of reducing mortality, its cost and different aspects of overdiagnosis.

On the grounds of health, test nature, and individual freedom, women believe screening must continue being offered, and they make suggestions to the political authorities for them to improve information, psychology services, and research. In general, most of them fight for maintaining or increasing medicalisation of their lives (not "losing" mammographies and psychology services to fight problems derived therefrom), although there are women who invoke its lack of efficacy and cost to justify why it must not be offered, at least on a universal basis.

Although it is largely known that screening mammography is not perfect [19] and despite the recommendation from the citizens' jury to reflect on its implementation,[20] there are few deliberative experiences in relation thereto. The purpose of one of them was to collect recommendations on how to submit the information so that it would be easier for participants to make informed decisions on whether to attend a mammography or not.[21] In another study, the citizens' jury mostly was against screening mammography for women under the age of 50 in New Zealand.[22] Citizens' juries have been efficient in regard to changing the position of the population in the face of other screenings, such as prostate screenings.[23] In our study, the change was limited but significant since 15% of participants now do not recommend screening.

The results of our deliberative democracy study may serve as a justification for political authorities to maintain screening mammography in women aged 50-69. However, we believe

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it would be interesting that they should consider studies indicating the harmful effects of the test, as well as the opinion of the participants who were against it, and that they also should reconsider the type of offering (universal vs. on demand), although some experts think that if a screening is implemented, it must be for the entire population.[24] This study has provided information on women at standard risk of breast cancer since mixing information about different risks or different screening tests exceeded the scope of the study.However, it is necessary to consider the power of pre-existing ideas and prevailing social speech that highlights the possible positive effects of screening mammography, barely considering negative arguments.[3,25]

Our study's implications for managers and clinical doctors must involve understanding the participants' claim of their right to choose freely. This involves placing such desire in the context where it occurs, which is characterised by the prevailing social speech in which, despite the lack of consent of the scientific community with respect to the benefits of the screening test,[1,2,5-7] these are overvalued, thus disregarding its harm. Such social speech is motivated, among others, by awareness and sensitization campaigns related to breast cancer that clearly show signs of lack of information [26] and by the little information received by women who are invited to participate in the screening programme.[4] Finally, screening mammography has been institutionalised [27] in an increasingly medicalised [28] state determined by the logics of a consumption society in which women [29] are immersed.

This study presents a series of weaknesses to be taken into account when considering the results, which must serve as elements to be strengthened in the future. The study was designed as a research project, so there was not a directive committee with the participation of women and without considering its critical perspective.[15,30] Nevertheless, the research team included expert witnesses, a moderator, a psychology expert in qualitative research, and an expert in bioethics. The process lasted slightly less than recommended [15], but there was

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enough time to explore the issues addressed. The information submitted arises from a sole process of deliberative democracy, which is why it will be necessary to apply, as programmed, other methodological strategies allowing for the gathering of more information to fulfil the categories and be certain that the collected information covers every possibility. Apart from that, although the political authority accepted to be an observer interested in the project, there was no genuine commitment to incorporate results in their decisions.

Weaknesses closely related to the qualitative methodology have been detected at a procedural level. It has been observed that some participants did not pose every question they had and, therefore, they were not as well informed as was expected. The expert condition of the research team was highlighted, which could deepen the differences of power between the former and the participants and prevent their participation. Moreover, a certain hierarchy was observed among some participants.

Furthermore, certain mistrust is derived from the words toward the latest purposes of the research given that some participants are afraid that the SSPA might be considering the removal of mammographies. Said mistrust may have affected their opinions. Last, it must be considered that this work has been developed with a sample of literate women, with a medium-high level of education, economic resources, natives, and without functional diversity. It would be necessary to perform works in other social realities whose needs must also be satisfied.

In conclusion, the deliberative strategy is feasible and causes a favourable position regarding screening mammography, although the information changes the opinion of some women, who desire informed decision making and to maintain or increase medicalisation in their lives (maintaining screening mammography and requesting psychological care to overcome the impact on them means maintaining or increasing the medicalization of their lives).

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Declarations

Ethics approval and consent to participate

This study was approved by The Bahía de Cádiz - La Janda Ethics Committee. Participants gave informed consent to take part in the study.

Patient consent for publication

Not applicable.

Availability of data and material

Presentations of the moderator and experts, and recordings and texts analysed during the current study are available from the corresponding author on reasonable request.

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Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: financial support from the Ministry of Health, Equality, and Social Policies of Andalusia for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Authors' contributions:

José M. Baena-Cañada conceptualised the project. **José M. Baena-Cañada, Violeta Luque-Ribelles, Alicia Quílez-Cutillas, Petra Rosado Varela, Encarnación Benítez-Rodríguez, Soledad Márquez-Calderón,** and **Juan M. Rivera-Bautista** contributed to the design and methodology. **Violeta Luque-Ribelles** and **Alicia Quílez-Cutillas** performed analysis of the texts. **José M. Baena-Cañada, Violeta Luque-Ribelles, Alicia Quílez-Cutillas, Petra Rosado**

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Varela, Encarnación Benítez-Rodríguez, Soledad Márquez-Calderón, and **Juan M. Rivera-Bautista** contributed to the development of the process of deliberative democracy (investigation). **José M. Baena-Cañada** contributed key resources. **Violeta Luque-Ribelles, Alicia Quílez-Cutillas,** and **Petra Rosado Varela** contributed to data curation and management. **José M. Baena-Cañada** wrote the original first draft of the article. **José M. Baena-Cañada, Violeta Luque-Ribelles, Alicia Quílez-Cutillas, Petra Rosado Varela, Encarnación Benítez-Rodríguez, Soledad Márquez-Calderón,** and **Juan M. Rivera-Bautista** played key roles in writing with respect to review and editing (all authors contributed to the final article). **José M. Baena-Cañada, Violeta Luque-Ribelles,** and **Petra Rosado Varela** provided oversight and leadership (supervision).

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Table and Figure legends

Table 1. Jury members' features.

Table 2. Categories on whether the SSPA must continue offering screening mammography.

Table 3. Indicative quotations: Reasons to continue and to not continue offering screening mammographies.

Table 4. Indicative quotations: Type of screening mammography offered.

Figure 1. Flowchart of jury recruitment

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Figure 1. Flowchart of jury recruitment

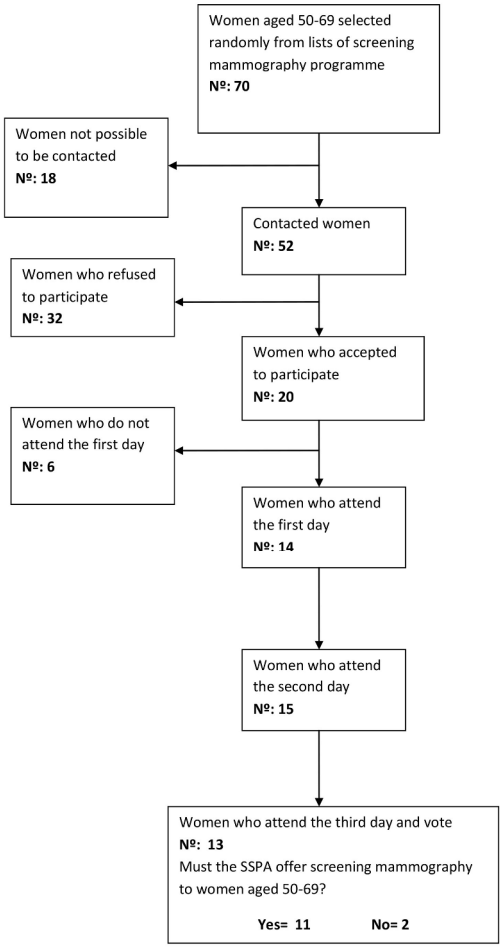

Figure 1. Flowchart of jury recruitment

209x296mm (300 x 300 DPI)

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OFFICIAL ANNOUNCEMENT OF FINANCIAL AID BY THE ANDALUSIAN PUBLIC FOUNDATION FUNDACIÓN PROGRESO Y SALUD FOR THE FINANCING OF BIOMEDICAL I+i AND HEALTH SCIENCES OF ANDALUSIA FOR YEAR 2014

SCIENTIFIC-TECHNICAL AND FINANCIAL REPORT _ RESEARCH PROJECTS

MAIN RESEARCHER	
LAST NAME BAENA CAÑADA	FIRST NAME JOSÉ MANUEL

PROJECT TITLE

Deliberative democracy study on women participating in the screening mammography programme

KEY WORDS

Screening mammography. Community's opinions. Health policy. People's jury.

ABSTRACT

(250 words maximum)

Purpose: Try a method to determine if population, when well informed, would be able to support or reject the political decision on breast cancer early detection. In particular, whether the government of Andalusia should maintain or not the invitation to undergo screening mammography to women aged 50- 69.

Design: Development of people's jury-like deliberative democracy methodology.

Subjects and area of study: There will be 12 women selected between 50 and 69 years old who undergo screening mammography in the Bahía de Cádiz-La Janda District. Experts defending the position in favour and against the screening programme will be two epidemiologists who are experts in cancer prevention.

Realization: Study by a people's jury with randomly selected participants. Information is provided to participants via documentation, multimedia presentations, and sessions recording. A final report containing the decision based on votes in favour, against, and abstentions, as well as on women's deliberation, will be prepared.

Factors: contacted women, included in the study, final participants, informed consent, participants' sociobiographic features, qualitative analysis of the deliberation process, votes in favour, against, and abstentions, reasons justifying votes in favour and against, participant's recommendations.

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1. SCIENTIFIC-TECHNICAL ASPECTS OF THE PROJECT

1.1 BACKGROUND AND CURRENT STATE OF THE STUDY TOPIC

Knowledge of background and current state of the topic will be assessed. Explain previous works published regarding the project topic, both performed by the research team and by other national or international groups (3 pages maximum)

The controversy related to screening mammography programmes commenced in year 2000 when Peter Gøtzsche (Nordic Cochrane Centre) published in The Lancet his meta-analysis of randomized clinical trials published so far on the efficacy of reduction in breast cancer mortality (1). Pursuant to said author, should methodologically inappropriate trials be excluded, screening mammography does not reduce breast cancer mortality, so it would be unjustified (1). Similar conclusions were reached in the systematic review of the Canadian Task Force on Preventive Health Care (CTFPHC) (2). The Cochrane review (3) concludes that it is unclear that screening mammography causes more benefits than harm and that it seems unreasonable to participate in breast cancer screening.

In 2009, the controversy was intensified again when the U.S. prevention services (USPSTF) decided not to recommend, on a routine basis, screening mammography to women between 40 and 49 years old (4). Such decision, as opposed to the 2002 recommendations (5), was based on a computerised analytical model of 9 randomized and controlled trials carried out in the last century (6-14).

Recently, a new version in the United Kingdom does not shed more light on the controversy (15). The Marmot report concludes on its significant benefits, but it suggests that every woman should make their decisions and, therefore, true information on the benefits and harms (15) must be provided.

The decision taken by every western country to implement and maintain their mammography screening programmes active is based on breast cancer mortality reduction which is estimated, in general, around 20%, with relative risks (RR) near 0.80 (2) (3) (4) (16).

The main risks for a woman who undergoes screening mammography are overdiagnosis, overtreatment, and false positives. There is uncertainty in the quantification of breast cancer detection that would have never been diagnosed and treated if the women would not have undergone mammography. The most certain estimates are derived from calculations performed in proven-quality clinical trials that did not offer mammographies to the control group upon completion of the study. Again, the results vary according to the systematic review, but they vary between 11-19% and 30% in relative terms and in 1 case of overdiagnosis out of 77 to 100 women subjected to screening for 20 years (15) (16) (17) (18) (19). Overtreatment was also assessed in the Cochrane review (3). There were more surgeries (RR 1.31), more mastectomies (RR 1.20) and more radiation therapy (RR 1.24) in women subjected to screening. However, less chemotherapy (RR 0.63) and less hormone therapy (RR 0.81) were employed, without reaching statistical significance. The update of the Canadian trial finds out that after 25 years of follow-up there were 106 overdiganoses out of 484 detected cancer cases (21.9%) (20) (106 out of 44,925 healthy women who underwent screening were diagnosed and treated unnecessarily of breast cancer) (20). Furthermore, the update of this paper does not find any reduction in breast cancer mortality (20), a contrary result conflicting with the mortality reduction of 40% found in the analysis of observational data in 7 out of 12 Canadian provincial screening programmes from 1990 to 2009 (21).

There is more unanimity with respect to other screening programme risks: re-call in 4% of cases to repeat the mammography, and a potential biopsy. Of these women, one out of five will be finally diagnosed with cancer. Of the remaining women, 70% will only need another imaging test and 30% will require biopsy, almost always -90%- with local anaesthetic. All such procedures, as well as the final cancer diagnosis and the pertinent treatment, may have a great psychological impact (22).

Scientific societies continue recommending mammography even as from 40 years old (23) (24) and no western country has dismantled their screening mammography programmes. Only Switzerland has initiated an institutional debate regarding such topic (25) (26). In Andalusia, after an excellent literature review, a report (27) was prepared, which has served as the basis to fix the age for screening mammography between 50 and 69 years old, ceasing to invite women aged 45-49 in districts where they were.

The deliberative democracy methodology is employed to involve citizens in a formal dialogue with the government or other public institutions, in order to provide a solution to complex problems. It includes people's jury, consensus conferences, deliberative surveys, study groups, citizens' meetings, and new online options. Deliberative democracy's primary purpose is to approach opinion and citizens' values to the political decision-making process (28). It is particularly useful for surveys where personal values, ethics, and existing trials on the topic in question are significant. In such issues, citizens need time to understand them fully and to consider all relevant aspects (29). Moreover, an informed consent method representing the community (30) must be considered. There is no consensus on which is the best way for women to be well informed regarding screening mammography and to make informed decisions on this breast cancer secondary prevention method (31), but the point is that women show a very poor level of knowledge and an enthusiastically positive attitude towards mammography (32).

The screening mammography programme is a public issue with great relevance because it affects a great volume of the population. The impact of its implementation is morally significant since there exist conflicts as to benefits, harms, autonomy and justice. The decision of its implementation cannot be resolved through scientific evidence given that, as we have already seen, there is no consensus among experts and such decision depends on the values of the women involved, who will probably have different opinions.

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In 2007, in New Zealand, 80 women aged 40-49 were randomly selected from the electoral register to participate in a deliberative process regarding the question "Must the government of New Zealand offer free mammographies to women in that range of age?" Out of the 46 contacted women, 17 accepted to participate and out of these, the 12 that first did accept were finally selected for the study. Such 12 women magnified in advance the benefits of screening mammography and all of them supported it, without reservations, within their age range. A Wednesday afternoon the group was provided with information. On Friday, the group met again and listened to experts' presentations, made questions, analysed evidence, and discussed with the support of an independent moderator. During the morning of the following day, without the presence of experts or the moderator, the women expressed their conclusions. The answer: 10 women voted against and 1, in favour (32).

1.2 BIBLIOGRAPHY

Bibliography related to the suggested topic and which is updated, containing the latest publications on said topic, will be assessed (years 2012-2014). Furthermore, quotations of bibliographic references throughout the project will be assessed. (2 pages maximum)

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1.3 HYPOTHESIS, RESEARCH QUESTION, OR DESCRIPTIVE STUDY

The relevance and novelty of the hypothesis, research question, or descriptive study will be assessed in relation to the state of knowledge in the scientific-technological area. Expected scientific benefits (advance of knowledge and training of human resources) as well as social benefits (health, environment, industrial, etc.) will be taken into account.

The people's jury-type deliberative democracy methodology is applicable, operative, and useful to provide a favourable or unfavourable answer to citizens on whether the Andalusian public health system must offer screening mammography to women between 50 and 69 years old.

Researchers of this study think it is innovative in the work hypothesis. Although the main contribution of the study is based on citizens' participation in health policies, there is a great potential of high capacity of transfer of result and applicability of results. And this is so because the possibility of disinvestment in the screening mammography programme with new scientific data, whose efficacy is doubtful, is also high. The opinion against screening mammography will provide politicians with a justification and support to perform different ways of disinvestment. The favourable opinion will provide grounds and validity to the political decision of maintaining this way of breast cancer prevention. On the other hand, researchers also find the fact of trying an informed consent method representative of community in an area, like breast cancer prevention, where the informed decision-taking is not resolved, applicable.

1.4 PURPOSES

List briefly, clearly, accurately, in a priority order, and according to the expected project duration, the specific purposes pursued. Clarity, scientific-health relevance and novelty of purposes will be assessed. Remember that in this section they must only be listed, it being possible to develop them in the next sections.

1. Evaluate whether the people's jury-type deliberative democracy methodology is applicable to the Andalusian population.
2. Analyse women's deliberative process.
3. Know the result of women's deliberation on whether the Andalusian public health system must offer screening mammography to women aged 50 and 69.
4. Know the reasons for such decision and the participants' recommendations on the application of screening mammography to women between 50 and 69 years old.

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1.5	METHODOLOGY AND WORK PLAN

Detail and justify activities or tasks to be developed, indicating the individual(s) performing each task and a timeline of foreseen scientific milestones (not less than a three-month period or more than a year). Feasibility of the research project will be assessed: adaptation to methodology, design of research, analysis of data and work plan according to purposes (5 pages maximum).

It is a deliberative democracy-type qualitative study to help the pertinent politicians decide on the prescription for screening mammography to women aged 50-69.

Selection of jury members: a sample of 70 women between 50 and 69 years old will be selected from the Screening Programme list. The first telephone contact will occur three months before performance of the study. If after three attempts on different days it is not possible to make contact, the woman will be excluded. In the first telephone contact, they will be provided with information on the features and purposes of the study and, should they accept to participate, contact will be made again one month and one week before it to confirm availability. The goal is to recruit at least 12 women.

Experts selection: they will be chosen to defend the points of view in favour and against the prescription for screening mammography. The experts positioning for and against the screening mammography programme will be Dr. Encarnación Benítez and Dr. Soledad Márquez, both epidemiologists who are experts in cancer prevention. The main researcher of this study (a medical oncologist with expertise in research associated with assistance and with a line of research in screening mammography) will be the neutral moderator and will train experts. Information written with arguments for and against the prescription and presentations on the topic will be prepared jointly with experts and the main researcher. The report recently published by the General Secretariat of Public Health, Social Inclusion, and Life Quality (Márquez S, Lacalle JR. *Beneficios y efectos adversos del cribado de cáncer de mama: revisión de la evidencia científica. Secretaría General de Salud Pública, Inclusión Social y Calidad de Vida. Consejería de Salud y Bienestar Social*. January 2013) will be used as a guideline for the preparation of the written information and presentations, as well as of a deliberation manual.

Process: Participants will meet a Monday afternoon at a hotel in the city centre. In such meeting, the features and purposes of the study will be reminded, clearing up any doubts, an informed consent will be signed, sheets with participants' features will be filled in, and formal introductions of participants and researchers will take place. Participants will receive written information with arguments for and against screening mammography as well as instructions on how to assess the screening programme. They will also be provided with official information supplied by the Andalusian Public Health System in relation thereto. Participants will be instructed to assess the key benefit of screening programmes (breast cancer mortality reduction) and the main harms (overdiagnosis, overtreatment, and false positives), as well as other benefits and harms.

On Tuesday, experts will submit their presentations on the topic and participants will have the opportunity to make questions. The neutral moderator will promote a debate and discussion in the group.

On Thursday, the jury members will discuss without the presence of experts or the moderator and will reach final conclusions. On the same day, an observing researcher will record and take notes of the deliberation process but will not participate actively. Participants will issue their votes in favour, against, or abstentions. They will state, in writing, the main reasons for their decisions and their recommendations to the relevant politicians.

The entire process will be supervised by an expert in Bioethics, who will collaborate with the group, and who will also be part of the research team.

Case definition. Subjects of the study: Women invited to the breast cancer early diagnosis programme of Bahía de Cádiz-La Janda Health District and who undergo mammographies. Our health area offers a mammography every two years to women aged 50-69, who are invited to participate via a personal letter. As from April 2013, women between 45 and 49 years old are excluded from invitation, although the ones who had already undergone their first mammography are still invited. The group of women not exceeding 50 years old will be excluded.

In compliance with the requirements of inclusion and exclusion, the selection of participants will follow diversity criteria so that there is a fair representation according to age, level of education, social status, working condition, breast cancer family history, acquaintances or friends suffering from breast cancer, number of previous participations, and previous false positives. Extreme cases and convenience cases will be avoided.

Inclusion criteria:

1. Women living in the Bahía de Cádiz-La Janda Health District
2. Women aged 50-69
3. Women invited to the screening mammography programme, whether they participate or not
4. Women with a secondary school or university level of education
5. Women able to grant their informed consent to participate in the study

Exclusion criteria:

1. Women not reaching 50 years old or older than 69 years old
2. Women with breast cancer personal history
3. Women without any education or with primary-school studies only

Criteria for removal from the study:

1. Patient's explicit desire to abandon the study

Data collection and analysis: Sessions involving introduction of experts and debate of participants will be recorded.

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Participants will be identified as P-1, P-2... P12. The deliberation session will be recorded and notes will be taken by two observing researchers. A literal transcription of recordings of all participants will be carried out. Analysis will be performed following the participants' speech. After successive readings, the main ideas derived from the group deliberation will be extracted. These ideas will be later compared to the reasons for the decision.
Collection of sociobiographic data of participants will occur in data collection notebooks designed to that effect. The first interview with women will occur on a face-to-face basis at the Health District, where mammographies are performed. Deliberation sessions will be at a place different from the health environment (hotel in the city centre).
Sample size: Calculation is not applicable. In a group of 36 preselected women, the first 12 will be finally invited to participate and the rest of them will be reserved in case any of the former may revoke their consent or may not participate on any other ground.
Statistical analysis: To process the qualitative study results, it will not be necessary to have a particular digital hardware or statistical analysis, since their usefulness is addressed to the analyses including a big number of interviews. Furthermore, the following variables will be collected: age, level of education, social status, working situation, breast cancer family history, acquaintances or friends suffering from breast cancer, number of previous participations, and previous false positives. A descriptive analysis of such data will be performed, through an estimate of absolute and relative frequencies for qualitative variables and the average and standard deviation for quantitative variables.
Study limitations: Representativeness of the selected group is a common problem in qualitative studies. Women having a low level of education were excluded because, in previous studies of our group, they constitute a part of the population where the degree of knowledge if difficult to modify and it is difficult for them to make an informed decision (Baena-Cañada JM, Rosado-Varela P, Expósito-Álvarez I, González-Guerrero M, Nieto-Vera J, Benítez-Rodríguez E. Women's perceptions of breast cancer screening. Spanish screening programme survey. The Breast 2014, 10.1016/j.breast.2014.09.010). It is also difficult to modify the certainty that the population sample will understand, assimilate, and analyse the information provided and draw appropriate conclusions. Finally, results may depend on the choice of experts, but such limitation is lessened by the preparation, by consensus, of presentations to participants and, since the two presenters are women too, the gender-based influence will be controlled. The population sample including women aged 50 and 69 to whom screening mammography has been offered lessens the representativeness bias. The potential reaction of the main researcher in the participants' deliberation scenario will be impartial and controlled by the expert in Bioethics. Such limitations are common to all deliberative democracy studies and well known (Street J, et al. The use of citizens' juries in health policy decision-making: A systematic review. Soc Sci Med. 2014; 109: 1-9.), so researchers will try to mitigate them.
Work plan: It is a qualitative study, whose original idea comes from the main researcher and will be performed with the cooperation of the Department of Medical Oncology of University Hospital Puerta del Mar, Cádiz, and the Bahía de Cádiz-La Janda Health District. Members of the Provincial Cancer Registry of Cadiz, of the Quality Service and Process of the General Department of Quality, Research, Development, and Innovation of the Department of Equality, Health, and Social Policies of Andalusia will also participate, as well as, finally, of the Bahía de Cádiz Ethics Committee, and a professional having a licentiate in Chemical Sciences, who has a master's degree in clinical trials. Therefore, the professionals involved in the project come from a clearly multidisciplinary group, with members pertaining to the areas of Oncology, Public Health, Nursing, and a professional not related to Health Sciences, most of them being women. The date stipulated for the commencement of participants recruitment will be the first quarter of year 2015 and the deliberation process sessions will be carried out during the second quarter of year 2015. The expert will present their position for and against screening mammography. The main office of the Screening Programme commits to collaborating and making things easier. The oncologist being the main researcher will act as a neutral moderator. Researching oncologists will be responsible for the identification of cases to be included in the study and this will be performed actively through their physical presence at the main office of the screening mammography programme during non-working hours. Moreover, they will work along with the experts in the preparation of the material to be supplied to participants. A technician specialised in audiovisual media will perform the recording and an oncologist and the expert in clinical trials will take notes on the deliberation process but will not participate actively in it. The nurse expert in Bioethics will give professional advice and supervise the study. A psychologist expert in qualitative research, from the area of Social Psychology of the Department of Psychology of the School of Educational Sciences, University of Cádiz (DPS), Violeta Luque Ribelles, will cooperate with the project.

1.6	PROMOTION AND DISSEMINATION PLAN

The quality of the promotion plan and dissemination of the research project results will be assessed (publications in scientific magazines indexed in JCR, patents, etc.)

As far as we know, there are no similar studies in our country. The research team has informed the management of the Andalusian Oncology Integral Plan of this research project and such Plan has accepted to be mentioned as a promoter interested in it.
We believe the dissemination of results at quality scientific meetings and in magazines with national and international impact is justified (national and international conferences on screening mammography, Medical Oncology, Assistance Quality, national and international Medical Oncology magazines, Cancer Prevention,

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Assistance Quality).
The report on conclusions will be made available to the citizenship representatives of the Integral Attention Unit of Cancer at University Hospital Puerta del Mar and interested associations (Asociación Española Contra el Cáncer and Asociación Gaditana de Mujeres con Cáncer de Mama).
A mandatory section of the promotion plan is related to its own nature. It is a deliberative democracy-type qualitative study, where participants will judge the prescription for screening mammography. Deliberation will not only include votes for, against, and abstentions, but also the dissemination of those results to the relevant politicians will take place through the management of the Andalusian Integral Oncology Plan.

1.7	ETHICAL ASPECTS OF THE RESEARCH

The detail of the ethical aspects that must be taken into consideration when performing the project will be assessed.
IMPORTANT: There are three models of management of samples in biomedical research: research project, research collection, research biobank. Advantages and legal requirements associated with the use of each model may be found in the "Use Guide of Samples in Biomedical Research" (**http://biobanco.csalud.junta-andalucia.es/salud/biobanco/sites/default/files/Guia_de%20uso_de_muestras_biologicas-Biobanco.pdf**). In any case, for the handling of your project it is essential that you have **a contingency plan for samples** at the time of completion of your project. Should the samples of your project be derived from a research collection, you must provide the registry code of the collection with the ISCIII Catalogue of Collections. Should you use a biobank for the handling of samples required by your project, you must provide the compromise of said Biobank. They will always be biobanks registered with ISCIII.

A woman participating in the screening programme shows an ethical situation completely different from that of a sick person. Individual informed consent is not easily obtained from women who undergo screening mammography and it constitutes a real challenge that women make an informed choice. Although our group has demonstrated that individual informed consent increases the level of knowledge of women invited to screening mammography (Rosado P, Baena JM, Ramírez P, et. al., Using an informed consent in mammography screening: Final result of a randomized trial. Ann Oncol 2014; 25 suppl 4: Iv478 - iv480. doi: 10.1093/annonc/mdu351.3), in the screening context we propose a joint consent derived from a randomised sample of the population to be invited to participate. It is necessary to develop an optimum form to submit information on benefits and risks of the screening mammography programme and to help women make a decision. This study involves an excellent opportunity in that sense, since a sample representing the community involved will be selected and a deliberative process will be performed whose conclusions will not only serve to strengthen or refute the political decision thereon, but which may also be deemed a consent representative of community. Said women will not be subject to any supplementary diagnostic trial or to a treatment different from the usual one. Participation will be voluntary and will involve no cost at all. Every participant will be given a gift with a value not exceeding 30 euros. Should a woman decide to participate and change her opinion later, she is free to do so and is not obliged to provide any explanation. Personal data will be treated as stated in the Spanish legislation in force (Organic Law 15/1999, dated December 13, on Personal Data Protection).

2. MAIN RESEARCHER AND RESEARCH TEAM

2.1	CV OF MAIN RESEARCHER AND OF RESEARCH TEAM

The CVs are attached in the computer Management of Calls

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Fundación Progreso y Salud
CONSEJERÍA DE IGUALDAD, SALUD Y POLÍTICAS SOCIALES

3. AVAILABLE MEANS AND REQUESTED BUDGET

3.1 AVAILABLE MEANS AND RESOURCES TO CARRY OUT THE PROJECT

A) MATERIAL ABLE TO BE INVENTORIED

The amount of infrastructure resources allow for the performance of this study without any special difficulty through the means available at the Bahía de Cádiz-La Janda Health District and at University Hospital Puerta del Mar, Cádiz.

B) BIBLIOGRAPHIC MATERIAL

The Medical Oncology Department has Internet access to perform bibliographic searches and to obtain the necessary bibliographic material. Puerta del Mar Hospital makes the SAS virtual library available to the researches of its centre.

C) PERSONNEL

At the Bahía de Cádiz-La Janda Health District, a sufficient number of women attend in order to recruit the required number of participants. The human resources personnel allows for the performance of this study without any special difficulty. As support for the researching activity, the Medical Oncology department has a research nurse hired by the Foundation *Fundación para la Gestión de la Investigación Biomedica de Cádiz*. Researchers have methodological and statistical assessment by the Preventive Medicine department and the support of the Bahía de Cádiz-La Janda Health District. Likewise, The Andalusian Integral Oncology Plan sponsors this research project.

3.2 REQUESTED BUDGET AND JUSTIFICATION.

Every item in the requested budget indicating items, units, unit prices, etc., must be broken down, and if information is available, it is recommendable that supplier be indicated. **In case of not matching with the budget stated in the computer application, the one stated therein shall prevail** (See annex).

CONCEPT	REQUESTED BUDGET		
	YEAR 1	YEAR 2	TOTAL
Goods and Services: (detail and justification for need)			
Material able to be inventoried			
Portable PC	00.00		
Image and voice recorder	00.00		
Projector	00.00		
Printer	00.00		
Fungible material			
Documentation, folders, and pens for participants' dossier	00.00		
Dissemination of results: (presentation of results in conferences).			
Attendance to National Conference of 2 speakers	1200.00		
Publication of results (publication in open access magazine)	3000.00		

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Hiring of external services Translation services	500.00		
Other expenses: (Justification and detail) Cafeteria service	00.00		
TOTAL	**4700.00**		

Comments and details of budget: (indicate items, units, conferences, meetings, etc.)

1 portable PC (1000€). Essential for digital hardware in deliberative meetings with participants.
1 image and voice recorder (400€). Essential in qualitative studies, since it will be necessary to analyse, *a posteriori*, the participants' comments.
1 projector (500€). Useful for the experts' presentation to participants.
1 printer (200€). Useful for the preparation of documentation to be submitted to participants.
Documentation, folders, and pens for the dossier to be delivered to participants (300€).
Financing for assisting the two researchers in a national conference where the study results will be presented is also requested (1200€).
Dissemination of results will require translation services for an original document (500€) to be sent to an international English-speaking open access magazine (3000€).
Catering services (300€). The three meetings are expected to last several hours during the afternoon. Cafeteria services are offered to participants as a courtesy.

4. PROJECT APPLICABILITY TO THE ANDALUSIAN PUBLIC HEALTH SYSTEM

4.1 APPLICABILITY

The expectations of transfer of research results to clinical practice, technological innovation, organization, resource management, and health services or health policies will be assessed.

1) Expected research results are applicable and include improvements to the Health System's usual clinical practice.
YES

Justify your answer and indicate application environment:

Researchers find the fact of trying an informed consent method representing community in an environment, like breast cancer prevention, where informed decision-taking is not resolved applicable.

Knowing the deliberation result of a sample representing community and submitting it to the pertinent politicians has an incomparable potential to include improvements in the usual clinical practice related to screening mammography. In case after the study, with the hypothetical negative vote of participants, some type of disinvestment is chosen, the non-performing of screening mammographies to some women would have, among others, the consequence of preventing overdiagnosis, overtreatment, and false positives, which are the main side effects of screening mammography.

2) Expected research results may be transferred to the organization, resources management, health services, or health policies.
YES

Justify your answer.

Citizens' participation in health policies will contribute improvements to the Health System. There is a great potential of capacity of transfer of result and high applicability of results. This is so because the possibility of disinvestment in the screening mammography programme, with the new scientific data of doubtful efficacy, is also high. The opinion against screening mammography will provide politicians with a justification and support to perform different types of disinvestment. The opinion in favour will provide grounds and validity to the political decision to maintain this type of breast cancer prevention.

Recommendations to the pertinent politicians will provide value, regardless of their decision. Conclusions obtained in the study will serve, therefore, to guide the resources management and health policies.

3) Expected research results may lead to the generation of technological innovations, patents, or utility models.
YES

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Justify your answer.

Citizens' juries approach, somehow, the deliberative survey technique, which suggests gathering at the same place, in general for 2 days, a sample representing the reference population, to be faced with experts and to make them discuss in small groups, before collecting their informed opinions. Said technique has been employed a dozen times in Great Britain, Australia and the United States. Despite its limited number of applications, such technique may be analysed, not only as an attempt to renew traditional surveys, but also as a symptom of a new link to public opinion in western democracies. Even when the contrast between the method's ambitions and the modesty of its performance is surprising, the emergence of this new way of public action must be taken seriously as a utility model.

The fact that the Integral Oncology Plan of the Andalusian Health Service is an observer interested in the project must be considered a cooperation with a company (in the present case, a public one) for the development of new services which will result in health improvements for citizens.

4) Expected research results may be published in a document having a great impact and commonly used by health professionals, such as the scientific magazines indexed by the Journal Citation Reports of the ISI Web of Science.
YES

Justify your answer.

The validity, current nature and original methodology, as well as the significance of results, justify the dissemination at quality scientific meetings and impact magazines, both national and international (national and international conferences on screening mammography, Medical Oncology, assistance quality, national and international magazines of Medical Oncology, cancer prevention, assistance quality). We cannot state accurately in advance the specific magazines and conferences in which results will be published or informed, but their bibliometric impact will always be considered.

5) Expected research results may be transferred through consensus documents, clinical practice guides published, etc., and applicable in the Health System
YES

Justify your answer.

Regardless of women's deliberation results in this study, we believe consensus documents and guides on the application of screening mammography should consider them, being applicable to the Health System.

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GENERAL INFORMATION FOR WOMEN

What is screening mammography?

Diagnostic screening consists in performing diagnostic tests on a presumably healthy population on a periodical basis, regardless of the type of test, in order to detect a particular disease (generally, a type of cancer, although there are screening campaigns for other diseases) before it manifests clinically –shows symptoms– which is generally associated with a more advanced stage of the disease.

A screening mammography is an x-ray of the mammary glands of a woman who is healthy, rather than a woman who has found a lump or any other alteration in her breasts, and does not appear to have any signs of breast disease. Mammography allows for the detection of certain small lesions that are suggestive of cancer because they are stiffer than the surrounding tissue.

It is a diagnostic method of breast cancer in its earliest stages. The purpose of offering mammographies to healthy women is to diagnose breast cancer before it manifests. By detecting breast cancer in its earliest stages, when the tumour is small, it is logical to believe that less aggressive treatments would be needed, and more healings would be possible.

Virtually all Health Systems in western countries have put in place early diagnostic programmes for breast cancer urging the female population aged 50-69 to have a mammography every 2 years (age and frequency differ from country to country or region to region).

Where does the idea that having preventive mammographies is good come from?

Health Systems have put in place mammography-based breast cancer detection programmes on the basis of studies that show that breast cancer mortality is thereby reduced. However, not all tests can be used to suggest that a treatment or preventive method should be definitely adopted. For example, there are medical actions that have been, or are intended to be, adopted only on the basis of expert opinions but without any supporting study. On some other occasions, the tests conducted lack the quality required to support a medical action.

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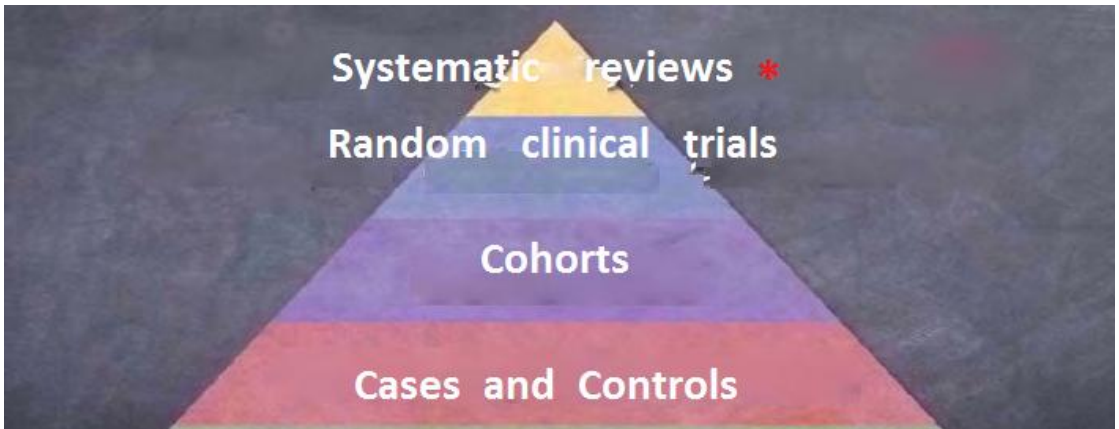
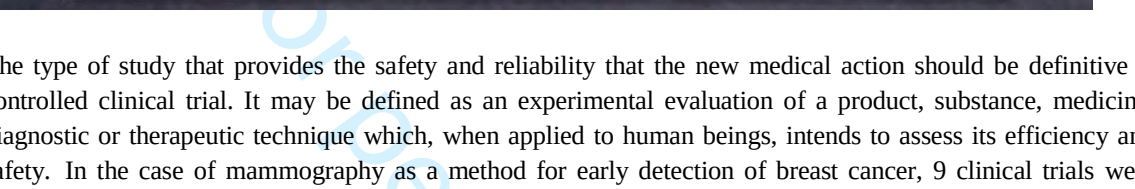


The type of study that provides the safety and reliability that the new medical action should be definitive is controlled clinical trial. It may be defined as an experimental evaluation of a product, substance, medicine, diagnostic or therapeutic technique which, when applied to human beings, intends to assess its efficiency and safety. In the case of mammography as a method for early detection of breast cancer, 9 clinical trials were conducted, mostly in the 70's and 80's of the last century. These trials compared two populations: one in which women had mammographies, and the other in which they did not. It was shown that in the population where women had mammographies, the breast cancer mortality rate decreased relative to the population of women who did not. Women were allocated to the groups (mammography or non-mammography) using a procedure that was similar to rolling a dice, making sure that both groups were similar in all aspects –hence comparable– except for the fact that the women in one group had mammographies while the women in the other did not. Accordingly, any difference found in the groups (for example, mortality) could be attributed to the use of mammographies.



Systematic reviews are scientific research studies where analysis units consist of the primary original studies (in the case of mammographies, the 9 clinical trials mentioned above). They are an essential tool to summarize the scientific information available, increase the validity of findings from individual studies, and identify uncertainty areas that need further research.

When you are presented arguments for and against screening mammographies by experts, you will be presented with the results from clinical trials and systematic reviews.

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Benefits of screening mammography and presentation

The main benefit of a screening mammography is to reduce the risk of death from breast cancer (reduction in breast cancer mortality), reducing treatment aggressiveness (less extensive surgery, less radiation therapy, less chemotherapy). The ideal objective would be to reduce global mortality, that is, all-cause mortality, because mammographies may reduce breast cancer mortality, but increase mortality due to other causes. However, it is accepted that breast cancer mortality reduction is a proper target.

When you debate about whether voting for or against screening mammography, you should bear in mind whether this test performed in the population at large does indeed reduce breast cancer mortality.

Early mammography-based diagnosis allows for an earlier detection of breast cancer relative to women who do not have mammographies, who are diagnosed later. Accordingly, women's survival rate is higher because time starts to run before, in other words, women are considered ill before. The real benefit would be attained by increasing women's survival but delaying death.

How will the benefit in terms of mortality be presented to you? The reduction of the risk of death from breast cancer in women who participate in screening mammography relative to women who do not is typically presented as a relative risk (RR). For example, if the risk of dying of breast cancer is 5 women out of 1,000 if they **do not** have a mammography, the risk will be 0.5% (5 out of 1,000 equals 0.5 out of 100). Likewise, if women **do** have mammographies, this risk reduces to 4 women out of 1,000, or 0.4%. Absolute risk will reduce to 0.5-0.4=0.1. But it is relative risk that will be presented to you more frequently, which is obtained by dividing the risk of death in women who **do** have mammographies by the risk of death in women who **do not** have mammographies. In our example above: 0.4/0.5=0.80, and it provides the same information as the relative risk reduction expressed as a percentage. Let us think that a relative risk of 1 means that both groups of women (those who **do** have and those who **do not** have mammographies) have the same risk of dying, and a relative risk of 0.80 means that women who **do** have mammographies have a 20% lower risk (0.80 is 20% lower than 1). You will receive information such as the following:

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"Screening mammography reduces the risk of death by 20%, with a relative risk of 0.80".

This form of presenting the reduction in breast cancer mortality is, in fact, barely informative. It is much more informative to present the number of women who should have a mammography in order to prevent death from breast cancer. It is the concept of “Number Needed to Treat” or, in our case, “to Screen”. It is known as NNT and indicates whether the benefit offered by mammography pays for the implementation efforts and costs. For example, a 20% reduction in the risk of death may look impressive, but says little about the real benefit. However, if we say that 2,000 women should have mammographies in order to avoid death from breast cancer (NNT: 2,000), we have a more accurate idea of its real benefit. Likewise, if the NNT is 500, it means that 500 women should have a mammography in order to prevent 1 death from breast cancer.

Therefore, you will also receive information about the reduction in breast cancer mortality through the NNT and its graphical representation:

In this example, which is different from the example above, 8 women out of 1,000 who do not have a mammography die.

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Furthermore, in this representation, 6 out of 1,000 women who do have a mammography die. Accordingly, 2 deaths out of 1,000 people are prevented (NNT: 500).

Risks of screening mammography. False positives

As any other diagnostic test, the result of a mammography may be positive or negative. But both possibilities may be true or false. A false-negative result means that the mammography has not detected cancer although cancer is present. However, mammographies have a high degree of sensitivity because they are able to detect almost all types of cancer that are present at the time of the test. The problem lies in the false positives, which presuppose an error, that is, the result determines that cancer is present when actually it is not.

Types of diagnoses		**Cancer**	
		absent	present
Mammography	negative	True negative (negative diagnosis, cancer is absent)	False negative (negative diagnosis, cancer is present)
	positive	**False positive** (positive diagnosis, cancer is absent)	True positive (positive diagnosis, cancer is present)

The detection of a false-positive mammography result presupposes harm for a woman because, despite being healthy, she will be followed-up and have further testing some time later in order to check whether the mammography readings have changed or not, and learn if they are more or less likely to be breast cancer. On other occasions, additional imaging tests are used to find whether they are more or less likely to be breast cancer. These may also be imaging tests such as spot compression mammography, ultrasound or magnetic resonance and, sometimes, needle biopsy to obtain a sample of the mammographic finding for analysis. Sometimes the woman will undergo surgery to have the detected lesion removed. If after all this, the doctor concludes it is not cancer, the woman will feel relieved, but the psychological impact and physical and mental suffering she has gone through, and sometimes will continue going through, are evident.

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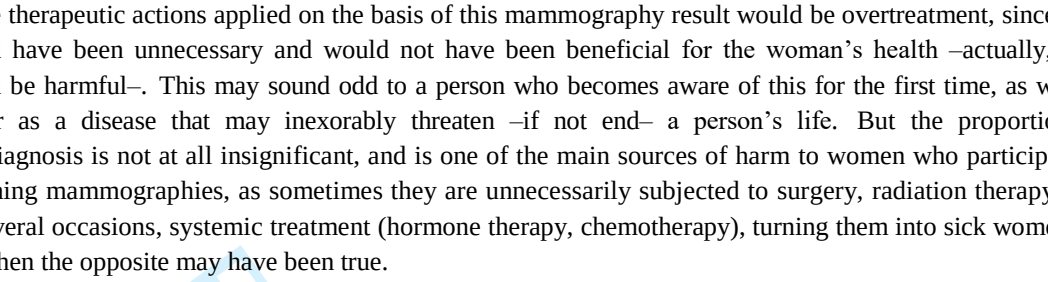
Risks of screening mammography. Overdiagnosis and overtreatment

Can breast cancer detected by screening mammography actually remit without treatment or progress so slowly so as not to compromise the woman's health? The answer is *yes*. This is known as overdiagnosis because cancer would have remitted spontaneously or would have never manifested over the woman's life. As a result, all the therapeutic actions applied on the basis of this mammography result would be overtreatment, since they would have been unnecessary and would not have been beneficial for the woman's health –actually, they would be harmful–. This may sound odd to a person who becomes aware of this for the first time, as we see cancer as a disease that may inexorably threaten –if not end– a person's life. But the proportion of overdiagnosis is not at all insignificant, and is one of the main sources of harm to women who participate in screening mammographies, as sometimes they are unnecessarily subjected to surgery, radiation therapy and, on several occasions, systemic treatment (hormone therapy, chemotherapy), turning them into sick women for life when the opposite may have been true.



Types of tumour growth. Source: Gilbert Welch. Should I Be Tested for Cancer?: Maybe Not and Here's Why. University of California Press. 2006. ISBN 0520248369, 9780520248366

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Let us introduce you to Carmen. She is 64 years old and has developed a small breast cancer (Source: Jolyn Hersch. Use of a decision aid including information on overdetection to support informed choice about breast cancer screening: a randomised controlled trial. The Lancet 2015; 385 (9978): 1642-52).

Carmen has a mammography exam. Her cancer is found and she undergoes treatment. Carmen lives until she turns 86, and then dies of a heart condition. Alternatively, Carmen does not have a mammography exam. Her cancer grows, is detected, but treated later. Carmen dies at the age of 70 from breast cancer.

Yet Carmen may not have a mammography exam, but her cancer does not grow or progress and is never detected. Nonetheless, Carmen lives until turning 86 and dies of a heart condition.

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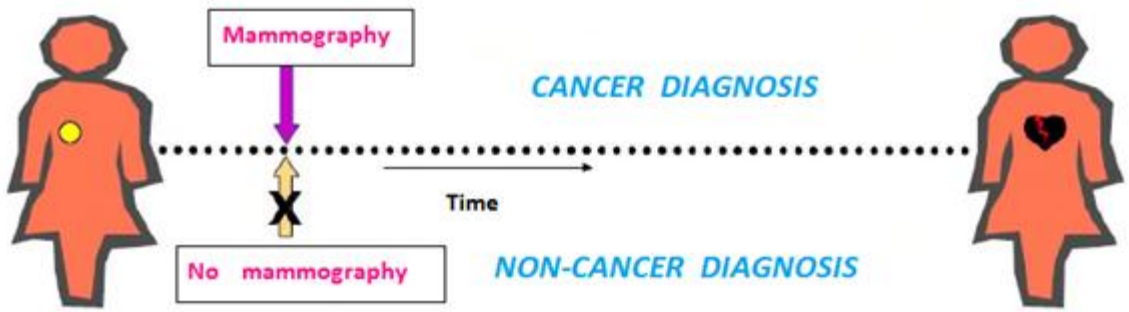

This represents the concept of overdiagnosis and, unfortunately, when cancer is found in a screening mammography, there is no way of knowing whether it is harmful or not. Therefore, all cancers should be equally treated (as if they were harmful). This means that screening mammography causes some women to be treated when such treatment is not necessary (overtreatment).

Risks of screening mammography. Other risks

Slight discomfort or pain during the mammographic screening, a bit of anxiety for some women while waiting for the results, a small possibility of developing cancer induced by the radiation from mammographies are also risks associated with mammography.

Finally, another risk of mammography is a woman's false sensation of security after learning of a negative result for cancer, which leads her to disregard symptoms or signs in the breasts and not to make consultations upon their occurrence ("I've just found a lump in my breast, but I've just had a mammography and was normal, so there's nothing to worry about").

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SCREENING MAMMOGRAPHY. ARGUMENTS FOR

Diagnostic screening consists in performing diagnostic tests on a healthy population in order to detect a particular disease (generally, a type of cancer, although there are screening campaigns for other diseases) before it manifests clinically showing symptoms.

The main benefit of screening of female population is the earlier detection of cancer, reducing treatment aggressiveness and increasing healings. Based on this compelling and attractive hypothesis, all western countries have put in place mammography-based breast cancer early detection programmes. But, has this hypothesis proved to be true? And, if so, are the negative effects outnumbered by the benefits?

Women have mammographies to reduce death from breast cancer and, if diagnosed with breast cancer, to receive less aggressive treatments, even though they are usually unaware of the risks or side effects associated with this type of procedure, such as false positives, overdiagnosis and overtreatment, pain, and exposure to radiation.

Breast cancer is the malignant tumour most frequently diagnosed in female population. In Europe, it represents 30% of all the diagnosed tumours and it is the first cause of death from cancer among women. In Spain, the incidence and mortality rates are similar to the European rates, with 26,000 new cases being diagnosed in 2014.

The most common risk factors which are related to breast cancer cannot be modified and account for less than half of the detected cases. On the other hand, controlling the risk factors that can be modified would not cause a significant reduction in the incidence rate, therefore, there is no clear possibility of preventing them from occurring. Hence, we can conclude that we do not have effective strategies of primary prevention, which makes secondary prevention by screening mammography a key instrument to control the disease nowadays. Currently, the Andalusian Health System includes within its basic services the screening of female population for breast cancer, which, in general terms, consists in performing a mammography every two years among female population aged 50-69.

Evidence that screening mammography reduces breast cancer mortality

As previously explained, the most reliable evidence showing that a mammography reduces breast cancer mortality comes from two types of tests: high-quality clinical trials and systematic reviews. Since the 60's of last century, 9 randomized clinical trials have been conducted on around 600,000 women. These trials compared two populations: one in which women had mammographies, and the other in which they did not. Furthermore, 4 systematic reviews have been conducted: Cochrane, American, Canadian, and British. The American and British reviews considered that all the trials had an acceptable standard of quality; however, the Cochrane and Canadian reviews stated that 4 trials did not have any inconsistencies regarding the number of recruited women and guaranteed an adequate random assignment (that is, the group of women who had a mammography and the group of women who did not have the mammography had similar characteristics). Nevertheless, 5 trials could not assert that the two groups of women could be compared or had inconsistencies in the number of women assigned to one or the other group. Therefore, should any differences be found in mortality in both groups, it may not be assured that such results are derived from performing a mammography, but they could have derived from other differences between the groups instead.

In general, most systematic reviews agree that performing a mammography reduces breast cancer mortality by 20%, with a relative risk (RR) of 0.80. Many experts do not agree with differentiating clinical trials according to their methodological quality and also propose, as a key parameter in the assessment, the reduction in breast cancer mortality instead of overall mortality.

Even though the same data has been analysed and a similar reduction in breast cancer mortality has been

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achieved (reduction of 20% and RR of 0.80), NNT estimates (number of women aged 50-69 who should have a mammography over a 10-year period in order to prevent death from breast cancer) show many differences. According to the British review, 1 death from breast cancer was prevented out of 235 women who participated in the procedure, whereas to other institutions such as the Nordic Cochrane Centre, at least 2,000 women need to participate in the procedure to obtain the same benefit. If we apply such data to the overall population, we can understand the importance of this benefit: 10 deaths out of 2,350 women are prevented, 100 deaths out of 23,500 women are prevented, 1,000 deaths out of 235,000 are prevented… Likewise, the Cochrane review shows the following data: 10 deaths out of 20,000 women are prevented, 100 deaths out of 200,000 women are prevented, 1,000 deaths out of 2,000,000 women are prevented…

Evidence that screening mammography allows women to receive less aggressive treatments

The fact that women receive less aggressive treatments has not been sufficiently studied. Only the Cochrane review described that the early detection of breast cancer by a screening mammography was most frequently associated with any type of surgery (RR 1.20) and increased use of radiation therapy (RR 1.24), but on the contrary, the need to administer other complementary and aggressive treatments such as chemotherapy (RR 0.63) and hormone therapy was reduced.

Most of the tumours detected in screening mammography programmes were at an early stage of the disease, reducing the need for chemotherapy as complementary treatment.

Evidence that screening mammography causes overdiagnosis and overtreatment

The best approach to measure overdiagnosis is to analyse the clinical trials with adequate random assignment and which did not offer the screening mammography to the control group at the end of the test. Three clinical trials meet these requirements (Malmö I and the 2 Canadian trials) and two reviews (the British and Cochrane reviews) have assessed the percentage of overdiagnosis based on those trials. The assessed data offers variable results. According to the Cochrane review, the percentage of overdiagnosis is 30% or 10 overdiagnosed cases out of 2,000 screened women over a 10-year period. Nonetheless, the British review estimates that 11% of all cancers would be overdiagnosed, and if a woman is diagnosed as a result of a screening mammography, the likelihood of being overdiagnosed is 19%, with an estimated NNT of 1 overdiagnosed case out of 77 screened women.

However, these are estimated figures and the true measure and impact of overdiagnosis are unknown.

Evidence that mammography causes false positives

Despite the variable estimates of false positive results according to the different reviews, the obtained results show a low likelihood of suffering this side effect based on the volume of women who participate in this type of procedure. In accordance with the British review, the percentage of false positives is 3.36% and according to the Cochrane review, the percentage is 10%. As a consequence, further diagnostic tests will be needed, which will cause psychological impact on the individual. 70% of these cases will require other imaging tests and 30% of the cases will require a biopsy.

The discomfort and psychological impact suffered until the diagnosis are discarded and for some time thereafter are inevitable. In spite of all these consequences as well as the anxiety and psychological discomfort that can be associated with the need to run further tests, several studies show that most women believe that the benefits they expect to obtain from their participation in the screening programme are greater than the possibility of suffering from such negative effects.

Evidence that mammography can cause other side effects

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Although some women suffer pain during a mammography, for most of them the pain is only mild. The sensation of relief and security derived from receiving a non-pathological result in the test is significantly greater than the discomfort it may cause.

A study estimates a rate of 3-6 cancers out of every 10,000 screened women aged 47-73 every 3 years due to exposure to radiation from mammographies. In addition to this low rate, currently, the digital mammography, which is frequently used in screening strategies replacing the classic analogue mammography device, exposes women to a lower degree of radiation and thus the percentage of tumours associated with this risk factor would be reduced.

Controversy on the screening mammography programme

There are discrepancies regarding the methodological aspects used to estimate benefits and risks: different degrees of importance are given to the quality of the original clinical trials (randomization, other biases) and different degrees of importance are given to the role played by studies other than the clinical trials (observational studies).

There are also discrepancies regarding the validity given to the clinical trials conducted in the 60's, 70's and 80's with old radiologic technology. It is likely that the improvement of breast cancer treatments and healthcare services in general has made mammography screening less important.

Even though estimates on Relative Risks frequently match, the different systematic reviews provide different estimates regarding the required number of women to be screened in order to prevent death or to be overdiagnosed.

The assessment of the benefits and risks is different depending on the review and it is subject to different interpretations, therefore, recommendations are also different.

Recommendations for discussion

The key measure of the benefit of the screening mammography programme is the reduction in breast cancer mortality. As it has been described, despite the various results obtained according to the reviews analysed, overall, most of the systematic reviews agree that performing a mammography reduces breast cancer mortality by 20%, with relative risk (RR) of 0.80.

Regarding the assessment on mortality reduction as opposed to overdiagnosis, there is no conclusive evidence that the number of overdiagnosed cases is significant, therefore, such negative effect should not be considered to be greater than the expected benefit of mortality reduction. In this respect, other less serious side effects, despite causing some harm on women, are counterbalanced with the benefit of mortality reduction that women expect to obtain by participating in the screening mammography programme.

Even after receiving such positive data in favour of mammography screening, some women may prefer not to have a mammography. It is essential to improve the type of information women receive so that they can make informed decisions. It is also essential that research be conducted in order to select which women may benefit from having a mammography and which women may suffer from its negative effects.

Should the Andalusian public health system offer a screening mammography to women aged 50-69?

Yes.

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SCREENING MAMMOGRAPHY. ARGUMENTS AGAINST

Diagnostic screening consists in performing diagnostic tests on a healthy population in order to detect a particular disease (generally, a type of cancer, although there are screening campaigns for other diseases) before it manifests clinically showing symptoms.

The main benefit of a mammography-based screening is the earlier detection of breast cancer, reducing treatment aggressiveness and increasing healings. Based on this compelling and attractive hypothesis, all western countries have put in place mammography-based breast cancer early detection programmes. But, might this hypothesis be wrong? Or, even if it were true, could it have a negative impact?

Women have mammographies to reduce death from breast cancer and, if diagnosed with breast cancer, to receive less aggressive treatments. However, they are usually unaware of the risks or side effects associated with screening mammographies. We have provided information about such negative effects: false positives, overdiagnosis and overtreatment, false sensation of security, pain and radiation.

Evidence that screening mammography reduces breast cancer mortality

As previously explained, the most reliable evidence showing that a mammography reduces breast cancer mortality comes from two types of tests: high-quality clinical trials and systematic reviews. Since the 60's of last century, 9 controlled clinical trials have been conducted on around 600,000 women. These trials compared two populations: one in which women had mammographies, and the other in which they did not. Furthermore, 4 systematic reviews have been conducted: Cochrane, American, Canadian, and British collaboration. The American and British reviews considered that all the trials had an acceptable standard of quality; however, the Cochrane and Canadian reviews stated as follows:

- 4 trials did not have any inconsistencies regarding the number of recruited women and guaranteed an adequate random assignment (that is, the group of women who had a mammography and the group of women who did not have a mammography had similar characteristics).
- Nevertheless, 5 trials were unable to assert that the two groups of women could be compared or had inconsistencies in the number of women assigned to one or the other group. Therefore, should any difference be found, it could not be assured that such results derived from performing a mammography, but they could have derived from other differences between the groups instead.

In general, systematic reviews agree that performing a mammography reduces breast cancer mortality by 20%, with a relative risk (RR) of 0.80. But when the analysis narrows down to methodologically appropriate trials, in statistical terms, no significant reduction of death from breast cancer is found, with RR around 1 (without any difference between the screened and non-screened women). Furthermore, the Canadian and Cochrane reviews find no reduction in global mortality between women who have the screening mammography relative to those who do not.

Even though the same data has been analysed and a similar reduction in breast cancer mortality has been achieved (reduction of 20% and RR of 0.80), NNT estimates (number of women aged 50-69 who should have a mammography over a period of 20 years in order to prevent death from breast cancer) show many differences, ranging from 235 according to the British review, and 1,000 according to the Cochrane review.

Evidence that screening mammography allows women to receive less aggressive treatments

According to the Cochrane review, not only are more aggressive treatments not reduced, but also more

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women undergo a mastectomy instead of breast-conserving surgery if they participate in screening (RR of undergoing a mastectomy of 1.20) and the use of radiation therapy is higher (RR 1.24).

The number of mastectomies peaked immediately after the implementation of the screening programme in Copenhagen and Funen, while this is not the case in some regions of Denmark, where screening mammography was not implemented.

Evidence that screening mammography causes overdiagnosis and overtreatment

The best approach to measure overdiagnosis is to analyse the clinical trials with adequate random assignment, for they compare similar groups in terms of the risk to develop breast cancer. These trials are also required to have never offered mammographies to the control group and that sufficient follow-up is pursued for 5 years (5-10 years). In this way, we would be able to count how many breast cancers were overdiagnosed in women who have mammographies relative to those who do not. Three clinical trials meet these requirements (Malmö I and the 2 Canadian trials) and two reviews (the British and Cochrane reviews) have assessed the percentage of overdiagnosis based on these 3 contrasted quality trials which did not offer mammographies to the control group at the end of the test: 11% of all cancers would be overdiagnosed and, if a woman is diagnosed as a result of a screening mammography, the likelihood of being overdiagnosed is 19%, with an NNT of 1 overdiagnosed case out of 77 screened women, according to the British review, and 30% or 10 overdiagnosed cases out of 2,000 screened women, according to the Cochrane review.

Evidence that mammography causes false positives

In accordance with the British review, the percentage of false positives is 3.36%, and according to the Cochrane review, the percentage is 10%. As a consequence, further diagnostic tests will be needed, which will cause psychological impact on the individual. 70% of these cases will require other imaging tests and 30% of the cases will require a biopsy.

The discomfort and psychological impact suffered until the diagnosis are discarded and for some time thereafter are inevitable. Many tests have been conducted on the psychological impact of false positives, with diverse results, although it would seem that it may be significant on many occasions. It has also been proved that being well-informed can work as material mitigation of anxiety and psychological discomfort.

Evidence that mammography can cause other side effects

Some women suffer pain during a mammography and, in some cases, this causes them to avoid returning to screening rounds. Obtaining a negative result in the test creates a sensation of relief and false security that may lead them to not see a doctor if they find a symptom or sign in their breasts. The exposure to the radiation from mammographies may cause breast cancer. A study estimates a rate of 3-6 cancers out of every 10,000 screened women aged 47-73 every 3 years. Currently, the digital mammography exposes women to a lower degree of radiation.

Controversies on screening mammography programmes

There are discrepancies regarding the methodological aspects used to estimate benefits and risks: different degrees of importance are given to the quality of the original clinical trials (randomization, other biases) and different degrees of importance are given to the role played by studies other than the clinical trials (observational studies).

There are also discrepancies regarding the validity given to the clinical trials conducted in the 60's, 70's, and 80's with old radiologic technology. It is likely that the improvement of breast cancer treatments and healthcare services in general has made screening less important.

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Even though estimates on Relative Risks frequently match, the different systematic reviews provide different estimates regarding the required number of women to be screened in order to prevent death or to be overdiagnosed.

The assessment of the benefits and risks is different depending on the review and it is subject to different interpretations, therefore, recommendations are also different.

Recommendations for discussion

The key measure of the benefit of screening mammography is mortality reduction, not only derived from breast cancer but also total mortality (from any cause). As it has been described, breast cancer mortality is not favourable in methodologically appropriate trials and mortality from any cause is not favourable for mammography either. Regarding the assessment on mortality reduction as opposed to overdiagnosis, evidence suggests that the number of overdiagnosed cases is significant and greater than the benefit of mortality reduction. Other side effects are not as serious, but they also cause harm on women which harm is not counterbalanced with the benefit of mortality reduction.

Even after receiving this negative data against screening mammography, some women may still prefer to have a mammography. It is essential to improve the type of information women receive so that they can make informed decisions. It is also essential that research be conducted in order to select which women may benefit from having a mammography and which women may suffer from its negative effects.

Should the Andalusian public health system offer a screening mammography to women aged 50-69?

No.

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CITIZENS' JURY
Schedule of proceedings
Day 1:

- **4.00-4.30 p.m.**
  - Arrival of research team (JMBC, VLR, AQC, PRV, JRB) and of image and sound technician
  - Preparation of conference room
  - Preparation of computing equipment and projector
  - Preparation of recording equipment
- **4.30-5.00 p.m.**
  - Arrival and reception of jury members
- **5.00-5.30 p.m.**
  - Presentation of research team (JMBC)
  - Presentation of jury members
  - Explanation by the moderator of features and objectives of the citizens' jury study (JMBC)
  - Compliance by the jury members with the participants' features sheet and with the informed consent document
- **5.30-7.30 p.m. (6.30-6.45 p.m., coffee break).**
  - Oral presentation supported by PowerPoint presentations by the moderator on screening mammography (JMBC):
    - What is screening mammography?
    - Benefits and risks of screening mammography
- **7.30-8.30 p.m.**
  - Questions and debate
- **8.30-9.00 p.m.**
  - Closure

Day 2:

- **4.00-4.30 p.m.**
  - Arrival of research team (JMBC, VLR, AQC, PRV, JRB), expert witnesses (EBR, SMC), and image and sound technician
  - Preparation of conference room
  - Preparation of computing equipment and projector
  - Preparation of recording equipment
- **4.30-5.00 p.m.**
  - Arrival and reception of jury members
- **5.00-5.15 p.m.**

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- Presentation of expert witnesses

- **5.15-6.15 p.m.**
  - Oral presentation supported by PowerPoint presentations by the expert positioning for screening mammography (EBR)
- **6.15-6.30 p.m.**
  - Coffee break
- **6.30-7.30 p.m.**
  - Oral presentation supported by PowerPoint presentations by the expert positioning against screening mammography (SMC)
- **7.30-8.30 p.m.**
  - Questions and debate
- **8.30-9.00 p.m.**
  - Closure

Day 3:

- **4.00-4.30 p.m.**
  - Arrival of research team (JMBC, VLR, AQC, PRV, JRB) and of image and sound technician
  - Preparation of conference room and placing of ballot box
  - Preparation of computing equipment and projector
  - Preparation of recording equipment
- **4.30-5.00 p.m.**
  - Arrival and reception of jury members
- **5.00-5.30 p.m.**
  - Recommendations for deliberation by the moderator (JMBC)
- **5.30-7.00 p.m.**
  - Deliberation by jury members
  - Recommendations to political authorities
- **7.00 p.m.**
  - Voting
- **7.10-7.30 p.m.**
  - Coffee break
- **7.30-7.45 p.m.**
  - Ballot box opening
- **7.45-8.00 p.m.**
  - Thanks and closure.

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MAMMOGRAPHIC SCREENING: IN FAVOUR

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HYPOTHESIS PRIOR TO THE IMPLEMENTATION OF SCREENING MAMMOGRAPHY

- The beneficial effect of screening on the health of the population is because cancer is detected earlier, which favours less aggressive treatments and can achieve a higher cure rate.
- This hypothesis sounds compelling and is attractive.
- However, has this hypothesis been confirmed as true and if so, are the negative consequences outweighed by the benefits?

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BENEFITS AND RISKS OF SCREENING MAMMOGRAPHY

- **Reduced risk of dying from breast cancer**
- Less aggressive treatments

- Overdiagnosis and overtreatment
- False positives (false alarms)
- Pain
- False tranquillity
- Radiation

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WHY HAVE A BREAST CANCER SCREENING?

- **Screening programs** are preventive strategies applied to a selected population to detect a disease early, before signs or symptoms related to it appear.
- Breast cancer is the most frequently diagnosed malignant tumour in females. In Europe, it represents 30% of all tumours diagnosed and is the leading cause of death from cancer in women.
- The incidence and mortality rates in Spain are similar to those in Europe.
- More than 26,000 cases were diagnosed in 2014.

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WHY HAVE BREAST CANCER SCREENING?

- The classic recognised risk factors are not modifiable, and they explain fewer than half of all detected cases.
- However, controlling the modifiable risk factors would not produce a significant decrease in incidence, so there is no clear possibility of deterring their appearance.
- Thus, we can conclude that we do not have effective primary prevention strategies; in contrast, secondary prevention through mammographic screening currently constitutes our fundamental instrument for controlling the disease.
- Currently, the Andalusian Health Service includes population screening for breast cancer as a basic benefit that, in general, is carried out through a biennial mammogram in women between 50 and 69 years old.

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CAN THE RISK OF DYING FROM BREAST CANCER REALLY BE REDUCED?

- There have been 9 randomised clinical trials comparing a group of women who had not undergone mammography with a group that had. Some 600,000 women were included.
- Four systematic reviews were carried out:
  - Cochrane Collaboration
  - American
  - Canadian
  - British
- The American and British reviews regarded all trials as being acceptable in quality. The Cochrane and Canadian reviews considered 4 trials as having ensured adequate randomisation (i.e., achieved reliable results) and 5 as having not (i.e., achieved less reliable results).

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CAN THE RISK OF DYING FROM BREAST CANCER REALLY BE REDUCED?

- Overall, the systematic reviews agreed that undergoing mammography reduces breast cancer mortality by **20%** with a risk ratio (RR) of approximately **0.80**.
- Many experts do not agree with differentiating clinical trials according to their methodological quality.
- The fundamental parameter to be measured is the reduction of mortality from breast cancer instead of overall mortality, and this has been accomplished.

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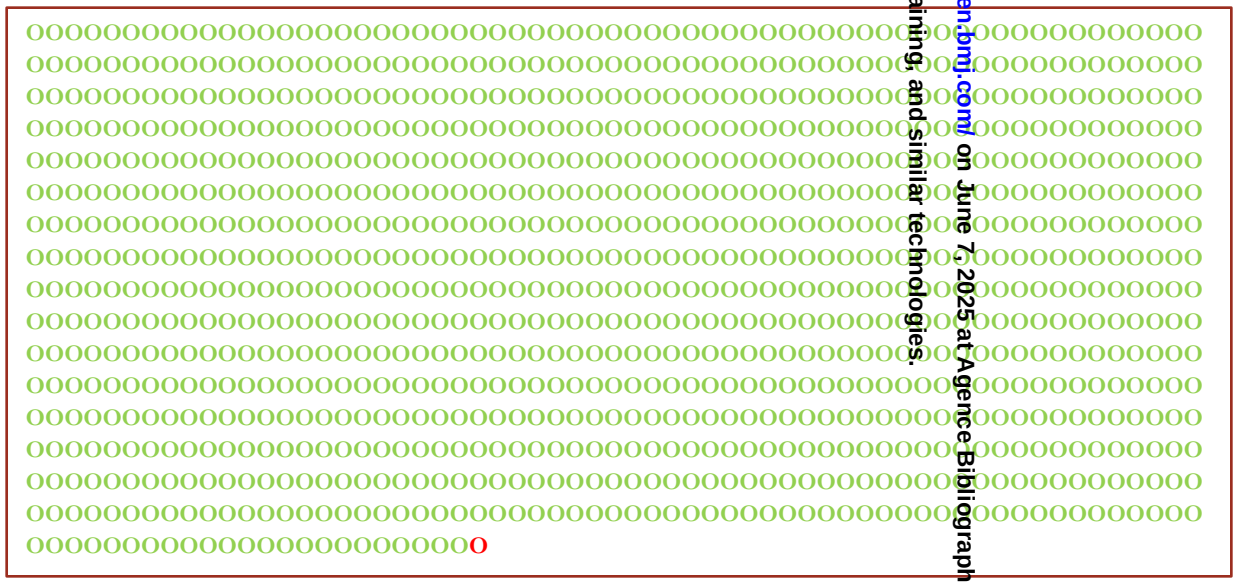
CAN THE RISK OF DYING FROM BREAST CANCER REALLY BE REDUCED?

- Despite analysing the same clinical trials, the estimates of the NNT (number needed to treat: number of women aged 50–69 years who would need to have a biennial mammogram to avoid one death from breast cancer) ranged from **235** in the British review (over 20 years) to **1000** in the Cochrane review (over 20 years).

NNT: 1 / 235



NNT: 1 / 1000

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DO WOMEN WHO PARTICIPATE IN SCREENINGS REALLY RECEIVE LESS AGGRESSIVE TREATMENTS?

- Reduced risk of dying from breast cancer
- **Less aggressive treatments**

- Overdiagnosis and overtreatment
- False positives (false alarms)
- Pain
- False tranquillity
- Radiation

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DO WOMEN WHO PARTICIPATE IN SCREENINGS REALLY RECEIVE LESS AGGRESSIVE TREATMENTS?

- According to the Cochrane review, although there was a greater use of surgery (RR 1.31) and radiotherapy (RR 1.24), the need for treatment with **chemotherapy (RR 0.63)** and **hormone therapy (RR 0.81)** was reduced.

After 5 complete rounds of screening	Group with mammography	Group without mammography
Non-invasive cancer (stage 0)	93 (16%)	53 (11%)
Stage I	296 (51%)	162 (47%)
Stage II	142 (25%)	172 (49%)
Stage III	26 (4%)	27 (6%)
Stage IV	22 (4%)	32 (7%)
Received chemotherapy	26 (5%)	41 (9%)

Characteristics of cancers diagnosed in the Malmö trial

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ARE WOMEN WHO PARTICIPATE IN SCREENINGS REALLY DIAGNOSED AND TREATED UNNECESSARILY FOR BREAST CANCER?

- Reduced risk of dying from breast cancer
- Less aggressive treatments

- **Overdiagnosis and overtreatment**
- False positives (false alarms)
- Pain
- False tranquillity
- Radiation

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ARE WOMEN WHO PARTICIPATE IN SCREENINGS REALLY DIAGNOSED AND TREATED UNNECESSARILY FOR BREAST CANCER?

- Two reviews (British and Cochrane) evaluated the degree of overdiagnosis based on 3 trials of contrasting quality that did not offer mammography to the control group at the end of the study.
  - According to the British review: if a woman was diagnosed with cancer in the screening, the probability that it was an overdiagnosis was **19%**. There was **1** case of overdiagnosis for every **77** women screened.
  - According to the Cochrane review: there was overdiagnosis in **30%** of the cancers diagnosed in the screening. There was **1** case of overdiagnosis for every **200** women screened.

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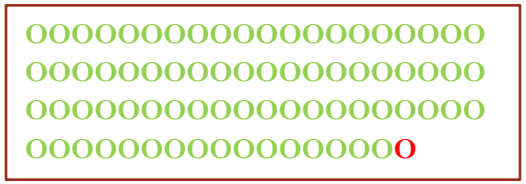
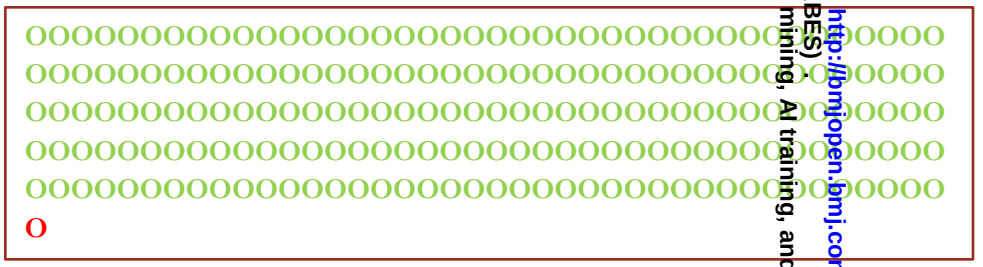
ARE SCREENED WOMEN REALLY DIAGNOSED AND TREATED UNNECESSARILY FOR BREAST CANCER?



NND: 77



NNT: 200

NND: NUMBER OF WOMEN NEEDING TO SUBMIT TO A PROGRAM OF SCREENING WITH MAMMOGRAPHY FOR DAMAGE TO OCCUR (I.E., 1 CASE OF OVERDIAGNOSIS).

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CAN MAMMOGRAPHY REALLY SAY THAT THERE IS CANCER WHEN, IN REALITY, THERE IS NONE?

- Reduced risk of dying from breast cancer
- Less aggressive treatments

- Overdiagnosis and overtreatment
- **False positives (false alarms)**
- Pain
- False tranquillity
- Radiation

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CAN MAMMOGRAPHY REALLY SAY THAT THERE IS CANCER WHEN, IN REALITY, THERE IS NONE?

- False positives: **3.36%** (British review)
- False positives: **10%** (Cochrane review)
- Consequences:
  - Carrying out other diagnostic tests:
    - **70%** were administered other imaging tests
    - **30%** required a biopsy
  - The expected benefit in reducing mortality outweighs the damages that may result from participation in the screening program.

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CAN MAMMOGRAPHY REALLY CAUSE OTHER SECONDARY EFFECTS?

- Reduced risk of dying from breast cancer
- Less aggressive treatments

- Overdiagnosis and overtreatment
- False positives (false alarms)
- **Pain**
- **False tranquillity**
- **Radiation**

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CAN MAMMOGRAPHY REALLY CAUSE OTHER SECONDARY EFFECTS?

- Some women suffer **pain** due to mammography, but in the vast majority of cases, this pain is mild.
- **Exposure to radiation** from mammograms may cause breast cancer. One study estimates a rate of 3–6 cancers per 10,000 women screened every 3 years between 47 and 73 years of age. The current digital mammography exposes women to lower doses of radiation.

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THE CONTROVERSY OVER THE SCREENING PROGRAM

- There are discrepancies in the methodological aspects when estimating the benefits and risks:
  - Differential importance is given to the quality of the original clinical trials (randomisation, other biases).
  - Differential importance is given to the role played by studies that are not clinical trials (observational studies).
- There are discrepancies in the validity assigned to clinical trials conducted in the 1960s, 1970s, and 1980s that used outdated radiological technology. The current digital techniques are associated with less exposure to radiation.
- Although the RR estimates often coincide, different estimates of the NNT are given to avoid one death or to yield one overdiagnosis, although the estimates do not reach an unacceptable magnitude.
- Assessing the balance between benefits and damages differs according to the review; therefore, the recommendations also differ.

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RECOMMENDATIONS FOR DELIBERATION

- The key measurement of benefit:
  - Mortality from breast cancer: reduction of 20%, according the studies carried out.
  - Reduction in the need to administer aggressive treatments, such as chemotherapy.
- Balance between mortality reduction and overdiagnosis:
  - There is no definitive evidence that the amount of overdiagnosis is significant, and we can argue that it does not exceed the mortality benefit.
- Even with these positive data for mammography, there may be women who do not want to undergo it because they prioritise its adverse aspects.
- It is advisable to improve the information that women receive so they can make informed decisions.

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SHOULD THE PUBLIC HEALTH SYSTEM OF ANDALUCÍA OFFER MAMMOGRAPHY TO WOMEN FROM 50 TO 69 YEARS OF AGE?

YES

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No Item	Guide questions/description	Reported on page No

Domain 1: Research team and reflexivity

Personal Characteristics

1. Interviewer/facilitator. Which author/s conducted the interview or focus group?. Page 6-7

2. Credentials. What were the researcher's credentials? E.g. PhD, MD. Page 1,6,7+protocol

3. Occupation. What was their occupation at the time of the study? Page 1,6,7+protocol

4. Gender Was the researcher male or female? Page 1,6,7+protocol

5. Experience and training. What experience or training did the researcher have? Page 6,7+protocol

Relationship with participants

6. Relationship established. Was a relationship established prior to study commencement? Page 6.

7. Participant knowledge of the interviewer. What did the participants know about the researcher? e.g. personal goals, reasons for doing the research. Page 6.

8. Interviewer characteristics. What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic. Page 6,7.

Domain 2: study design

Theoretical framework

9. Methodological orientation and Theory. What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis. Page 8.

Participant selection

10. Sampling. How were participants selected? e.g. purposive, convenience, consecutive, snowball. Page 6.

11. Method of approach. How were participants approached? e.g. face-to-face, telephone, mail, email. Page 6,7.

12. Sample size. How many participants were in the study?. Page 6,9.

13. Non-participation. How many people refused to participate or dropped out? Reasons?. Page 6,9.

Setting

14. Setting of data collection. Where was the data collected? e.g. home, clinic, workplace. Page 7.

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15. Presence of non-participants. Was anyone else present besides the participants and researchers?. Page 6,7,8.

16. Description of sample. What are the important characteristics of the sample? e.g. demographic data, date Data collection. Page 6,9.

17. Interview guide. Were questions, prompts, guides provided by the authors? Was it pilot tested?. Page 7+protocol.

18. Repeat interviews. Were repeat interviews carried out? If yes, how many? n/a

19. Audio/visual recording. Did the research use audio or visual recording to collect the data?. Page 8.

20. Field notes. Were field notes made during and/or after the interview or focus group?. Page 8.

21. Duration. What was the duration of the interviews or focus group?. Page 7.

22. Data saturation. Was data saturation discussed?. Page 17.

23. Transcripts returned. Were transcripts returned to participants for comment and/or correction?. Page 8.

Domain 3: analysis and findings

Data analysis

24. Number of data coders. How many data coders coded the data?. Page 8,19.

25. Description of the coding tree. Did authors provide a description of the coding tree?. Page 10.

26. Derivation of themes. Were themes identified in advance or derived from the data?. Page 8.

27. Software. What software, if applicable, was used to manage the data?. Page 8.

28. Participant checking. Did participants provide feedback on the findings?. Page 8.

Reporting

29. Quotations presented. Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number. Page 10,11,12.

30. Data and findings consistent. Was there consistency between the data presented and the findings?. Page 16.

31. Clarity of major themes. Were major themes clearly presented in the findings?. page 10-15.

32. Clarity of minor themes. Is there a description of diverse cases or discussion of minor themes?. Page 10-15.

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