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The effects of awareness of breast cancer overdiagnosis among women with screen-detected breast cancer: A qualitative interview study

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ABSTRACT

Objectives: To explore experiences of women who identified themselves as having a possible breast cancer overdiagnosis.

Design: Qualitative interview study using key components of a grounded theory analysis.

Setting: International interviews with women diagnosed with breast cancer and aware of the concept of overdiagnosis.

Participants: Twelve women aged 48-77 years from the UK (6), US (4), Canada (1) and Australia (1) who had breast cancer (Ductal Carcinoma in Situ (DCIS) n=9, invasive cancer n=3) diagnosed between 1 and 17 years ago, and who were aware of the possibility of overdiagnosis. Participants were recruited via online blogs and professional clinical networks.

Results: Most women (10/12) became aware of overdiagnosis after their own diagnosis. All were concerned about the possibility of overdiagnosis or overtreatment or both. Finding out about overdiagnosis/overtreatment had negative psychosocial impacts on women's sense of self, quality of interactions with medical professionals, and for some, had triggered deep remorse about past decisions and actions. Many were uncomfortable with being treated as a cancer patient when they did not feel 'diseased'. For most, the recommended treatments seemed excessive compared to the diagnosis given. Most found that their initial clinical teams were not forthcoming about the possibility of overdiagnosis and overtreatment, and many found it difficult to deal with their set management protocols.

Conclusion: The experiences of this small and unusual group of women provide rare insight into the profound negative impact of finding out about overdiagnosis *after* breast cancer diagnosis. Previous studies have found that women valued information about

overdiagnosis before screening and this knowledge did not reduce subsequent screening uptake. Policy makers and clinicians should recognise the diversity of women's perspectives and ensure that women are adequately informed of the possibility of overdiagnosis before screening.

Strengths and limitations of this study

- Qualitative interviews allowed for in-depth exploration of this unique experience of cancer at an individual patient level.
- The study recruited across 4 countries with established breast cancer screening programmes and involved a 3-member consumer advisory panel with lived experience of breast cancer.
- Women's understanding of overdiagnosis and overtreatment was verified as part of the study eligibility process by asking them what they understood by the terms.
- The number of participants is small and the study comprised of a highly selected and unusual sample. They were health literate and highly educated.
- Diagnoses and treatments reported were not verified, and they reflect the participants' perceptions.

What is already known on this topic

- Overdiagnosis that occurs with screening mammography is well recognised, although its extent continues to be debated.
- Previous studies have shown that educating women about overdiagnosis prior to screening improved understanding, reduced worry about breast cancer, and did not increase anxiety or reduce willingness to participate in breast screening.

What this study adds

- Discovering overdiagnosis after detection of breast cancer can have a profound negative impact on women's lives, including on their sense of self, quality of interactions with medical professionals, and for some, deep remorse about past decisions and actions.
- These illustrative data provide further support for a policy that women should be informed about overdiagnosis and overtreatment prior to screening.

INTRODUCTION

Overdiagnosis is the diagnosis or detection of a cancer that never would have led to clinical symptoms or death during a person's lifetime[1]. Estimates of overdiagnosis from observational and modelling studies vary from 10-30%, depending on the study methods[2-4] but the Independent UK Panel concluded that for every 10,000 women invited to screening from age 50 for 20 years, about 681 cancers will be found of which 129 will represent overdiagnosis, and 43 deaths from breast cancer will be prevented. They estimated that in the UK, about 3000 women are overdiagnosed with breast cancer every year, and about 1000 deaths from breast cancer are prevented. The panel recommended that this information should be clearly communicated to women[2].

Overdiagnosis is a difficult concept to communicate and to understand, particularly because women with overdiagnosed cancers cannot be individually identified. In the United Kingdom, information about overdiagnosis has been included in a leaflet sent out with women's invitations to be screened since 2013 but concerns remain that the risk of overdiagnosis is not adequately reflected in the information provided to the public by the National Health Service (NHS)[5]. In the United States, Canada and Australia, women are generally invited to screening without receiving clear information on overdiagnosis[6-8]. Evidence suggests that most women are still not aware of the possibility of overdiagnosis, with the benefits of screening largely dominating public opinion[9 10]. This may change with time as community knowledge grows, and as more women participate in treatment de-escalation trials for low-risk breast cancers.

Being aware of overdiagnosis, however, may increase distress and uncertainty for those women diagnosed with asymptomatic breast cancer, compared to women who are not aware of this possibility. This is because "neither the woman nor her doctor can know whether this particular cancer would have become apparent without screening and could possibly lead to death or is one that would have remained undetected for the rest of the woman's life"[2]. As such women who know about overdiagnosis may wonder whether the cancer found by screening truly requires treatment or if they are enduring treatment and its related side effects for no benefit[11]. Two recent studies – one in thyroid cancer patients and one in men with prostate cancer - found that patients diagnosed with cancer who chose not to undergo recommended treatment because they believed they were overdiagnosed felt overwhelmingly isolated and anxious, with some participants withdrawing themselves from the health care system altogether[12 13]. We are not aware of any comparable studies exploring this issue in breast cancer patients. Therefore, in the current study we aimed to understand women's perceptions and experiences of living with (what they perceived to be) a possibly overdiagnosed screen-detected breast cancer. This study used in-depth interviews to explore how women experience living with a perceived possible overdiagnosis or overtreatment of breast cancer. Throughout this paper, the term 'breast cancer' includes both DCIS and invasive breast cancer.

METHODS

Design.

This study used qualitative interviews to explore the experiences of women diagnosed with screen-detected breast cancer, who knew of the concept of overdiagnosis and overtreatment and had applied this knowledge to their own situation. They were aware

that it is virtually impossible for any individual to know for sure whether their particular cancer was overdiagnosed.

Ethical approval

All study procedures were approved by The University of Sydney Human Research Ethics Committee (Project No. 2017/874). Participants gave written consent prior to participation. We worked with a 3-person consumer advisory committee from the inception of the project.

Identification of participants and recruitment.

Women were recruited to the study through advertisements on blogs where overdiagnosis is discussed ('DCIS411': http://DCIS411.com and 'Even Stars Explode': https://evenstarsexplode.wordpress.com/) (n=6), patients who had contacted AB via her publications on the topic of overdiagnosis of breast cancer (n=4), and through professional networks of the investigators (n=2). This approach was required to enable participation of women who may have been eligible without risking distress to women who were unaware of breast cancer overdiagnosis. Women were eligible if they had been diagnosed with screen-detected (or incidentally detected) breast cancer at least 6 months previously, were already aware of the idea of overdiagnosis or overdetection in relation to screen-detected breast cancer, were 40 years of age or older at the time of diagnosis and were fluent in English. Women who had been diagnosed with breast cancer following symptomatic presentation, or who had advanced cancer at diagnosis, or were at high risk of cancer, for example because of a strong family history of breast cancer were not eligible. Participant's understanding of overdiagnosis was checked before entry to the

study to confirm prior knowledge. All participants provided informed consent to be interviewed.

Participants were recruited from four English speaking countries: Australia, Canada, United States, and the United Kingdom. Such sampling from different countries enabled the researchers to understand how variations in breast screening policy and practice may affect women's experiences and responses to their knowledge about overdiagnosis. For example, information about overdiagnosis is included with breast screening invitations in the UK but not in other countries, and government-funded population-based universal mammographic screening programs exist in the UK but not in the USA.

Interview procedures and content.

The women received an information sheet about the study and completed a short online survey prior to the interview. They reported demographic data, details about their diagnosis and treatment (Table 1) and completed an eligibility check including defining overdiagnosis and overtreatment in their own words (Supplementary 1).

Semi-structured in-depth interviews were conducted by one researcher (KP) trained in qualitative research methods, from 13 December 2019 to 8 December 2020. The interviews occurred remotely by Zoom. This enabled us to easily include women from different countries, despite the ongoing COVID-19 global pandemic.

An interview topic guide was developed by the research team which included a practising breast cancer clinician and our consumer advisory panel (see Supplementary 2). It was piloted with 7 people for whom making decisions about participating in mammography

screening was relevant (4 researchers, 1 breast physician and 2 consumers), and refined prior to commencement of the interviews. Participants were asked to share their experiences related to their diagnosis and decision-making process around management options. They were also asked to give suggestions for other women considering breast screening in the future. (Supplementary 3).

We planned to interview as many women as possible who met the inclusion criteria during the study period as we envisaged that it may be challenging to find women who were aware of overdiagnosis and overtreatment and willing to discuss their experience. One participant requested and received her transcript for review to ensure that she was not recognisable. All clinical data were self-reported.

The interviewer.

The interviewer (KP) has a doctoral degree in public health and was working as a postdoctoral research fellow at the time of the interviews. KP has undertaken formal training in qualitative research methods. She had no immediate personal or professional experience with breast cancer or breast screening and no strong beliefs about the topic of the interviews.

Data analysis.

Audio recordings were transcribed verbatim by a professional transcribing service. Each in-depth interview was analysed using key components of a grounded theory analysis, namely, an iterative thematic approach and constant comparative method[14]. The data were collected and analysed concurrently. KP used the 'comments' function in Microsoft

Word to make detailed notes throughout each transcript and identified points of interest to explore in future interviews.

Two researchers (KP & AB) read the first 4 transcripts to familiarise themselves with the data. This enabled KP, who does not have medical qualifications, to discuss the transcripts with AB who is a registered medical practitioner and epidemiologist, to ensure understanding of the women's diagnoses and treatment descriptions and concepts of overdiagnosis and overtreatment for thematic analysis. Following a second reading, initial codes were developed by KP based on transcripts and notes (e.g. 'conflicting identities', 'incomplete understanding') and discussed with a third researcher, JH, who read two transcripts and generated independent codes which were cross-checked with KP's initial codes. These were then grouped into higher order organising themes. JH read an additional two transcripts and reviewed the preliminary themes to ensure accuracy of interpretation and added further interpretation and insights. The analysis constantly moved from specific codes and themes to the more general, with the aim of generating a comprehensive explanation of our findings across participants and the settings in which we conducted the study.

JSV, a surgeon and oncologist specialising in breast cancer, also read all transcripts to confirm that the analysis adequately conveyed correct and appropriate interpretation of clinical data. Discussion with the broader research team occurred regularly throughout the data analysis, interpretation, and manuscript drafting process. Quotes that best illustrated the developing themes were extracted into tables alongside the themes; a selection of these quotes are included in the Results section. Four case studies are presented in the Supplementary file (Supplementary 4) which were selected to represent a range of diagnoses, decision making, and experiences among the sample. Written consent was obtained from the relevant parties for the publication of the case studies.

Patient and public involvement.

The study was initiated by AB in response to a patient's personal experience of screen-detected breast cancer in 2012 and expressed concern about the possibility of overdiagnosis. This patient (from the UK) and two other women (1 from the UK and 1 from the US) with lived experience of screen-detected breast cancer were invited to join our study as consumer advisors from the inception of the study. All accepted and two also met the study eligibility criteria and were interviewed as research participants. Our consumer advisors reviewed all study materials, assisted recruitment by hosting a study advertisement on their blogs, and reviewed the draft manuscript. It is notable that all participants were given the opportunity to read and comment on the manuscript and their case study (if relevant) prior to publication, resulting in two minor amendments.

RESULTS

Participant characteristics.

22 women expressed interest in participating in an interview; of these, 10 did not complete an interview: 6 were deemed ineligible because they had a strong family history of breast cancer (n=1) or their cancer was not screen-detected (n=5). We were not able to make follow up contact with 3 women who expressed interest, and one potential participant was unavailable to interview during study recruitment phase.

12 women were interviewed. The interviews ranged in duration from 50 to 123 minutes (mean 73 minutes).

Table 1 reports demographic and some clinical characteristics of the participants. Participants were located in four countries where breast screening is well established:

United Kingdom (6), United States (4), Canada (1) and Australia (1). Most had a university degree, and they ranged in age from 48 to 77 years. Age at diagnosis was between 44 and 74 years, and their diagnoses occurred between 2004 and 2019. 11 out of 12 women were diagnosed by a screening mammogram and one participant was diagnosed with DCIS as an incidental histopathology finding following breast reduction surgery. The primary diagnosis was Ductal Carcinoma in Situ (DCIS) in 10 of the 12 women and invasive breast cancer in 2 women. They had undergone a range of treatments (Table 1); 2 women did not have any form of surgery. Almost all of the women interviewed had found out about breast cancer overdiagnosis as a result of personal research following their diagnosis and 2 women found out about it after they had received treatment.

Table 1. Characteristics of the study participants (n=12)

Participant	Education	Year of diagnosis	Age at diagnosis	Diagnosis	Sought a second opinion (or more)	Management received*	When (and how) did you become aware of the concept of overdiagnosis?
P1	University degree	2015	62	DCIS	Yes	Lumpectomy Endocrine (hormone) therapy Currently on tamoxifen	Unsure about timing in relation to diagnosis (personal research, media, the internet)
P2	University degree	2016	58	DCIS	No	Lumpectomy Physiotherapy for lymphatic cording Gene profile test	After receiving treatment (personal research, the internet)
P3	University degree	2019	47	DCIS	Yes	Only diet and lifestyle changes	After diagnosis (personal research)
P4	University degree	2018/19	59	DCIS	Yes	Lumpectomy	After diagnosis (medical professional, personal research, the internet)
P5	University degree	2013	54	Breast cancer	Yes	Mastectomy Endocrine (hormone) therapy	After diagnosis (personal research, the internet)
P6	University degree	2010	44	DCIS	Yes	Lumpectomy Gene profile test	After diagnosis (personal research, the internet)
P7	University degree	2019	60	DCIS	Yes	Active monitoring (personal choice)	After diagnosis (personal research, media, family/friend /colleague, the internet)
P8	University degree	2016	53	Breast cancer	Yes	Lumpectomy Radiotherapy (TARGIT-IORT)+ Endocrine (hormone) therapy Gene profile test Chemotherapy Currently on tamoxifen	After diagnosis (medical professional, personal research, conference lecture)
P9	Certificate / Diploma	2012	69	Breast cancer	Yes	Lumpectomy Radiotherapy (TARGIT-IORT)+	Before screening (personal research, media, family/friend /colleague)
P10	University degree	2019	74	DCIS	Yes	Lumpectomy	After diagnosis (breast, ovarian cancer education centre)

P11	University degree	2004	50	Initially DCIS; invasive cancer found after initial lumpectomy	Yes	Lumpectomy Mastectomy	After receiving treatment (personal research)
P12	University degree	2013	67	DCIS; Invasive cancer after 3 years of no treatment	Yes	Active monitoring for 3 years. Then mastectomy. Then radiation and chemotherapy (to treat metastatic disease)[#]	After diagnosis (personal research, family/friends, internet, medical journals)

*Self-reported. Gene profile test (e.g. MammaPrint, Oncotype DX)

[+] TARGIT-IORT – targeted intraoperative radiotherapy during lumpectomy (no further post-operative radiotherapy)

[#]Participant deceased

Overview of findings.

The women described diverse personal experiences relating to their diagnosis and decision-making processes, but there were also many commonalities in their stories particularly around identity, interactions with medical professionals, uncertainty about decisions made, and responses from others regarding their preferred pathway. Five main themes were identified across the interviews: (1) Discovering overdiagnosis; (2) Am I a cancer patient or not?; (3) Resisting overtreatment; (4) Living with the unknown; and (5) Downstream effects on quality of life. All participants explained how they felt the 'standard' approach to treatment offered by their initial teams was inflexible and the pressure that they encountered to act in the recommended and expected way.

When the women were asked to reflect on their experience of learning about overdiagnosis and overtreatment and applying that knowledge to their personal situation, most of the participants recognised that something about their personal circumstances enabled them to question their diagnosis and recommended management, and in some cases, to be able to avoid overtreatment. For example, a number of the women were employed in a profession that required them to ask questions, had relevant personal or professional networks and connections, private health insurance, or described themselves as being of a particular personality type (i.e. not a shy person, *'stroppy', 'more likely to challenge the opinion of a doctor than the vast majority of patients'* (Participant 8)) which enabled them to ask questions, find answers, and ultimately change the way that they would have been treated.

Discovering overdiagnosis

10 of the 12 women became aware of overdiagnosis after their diagnosis, including 2 who found out after they had received treatment. One was aware of it before screening mammogram, and one was unsure when she found out. Several participants elaborated, saying that while they had heard about the possibility that mammograms can detect non-lethal cancers, they developed a '*much better understanding*' (Participant 1) when undertaking personal research following their diagnosis. Most of the women's accounts indicated that they began their own research because they felt that they received different and often conflicting medical opinions and confusing information regarding their diagnosis. Many felt that the information that they obtained from their initial clinical teams was not sufficient for their personal needs and so this prompted them to proceed with further exploration and research independently. One participant described how,

> '*from the beginning… it just didn't feel right, something felt off…it's not right how they're communicating about it…if I ask any questions it didn't feel right…There was something that led me to continue…asking questions, researching'* (Participant 6).

Some were simply curious or uncertain about their diagnosis from the outset (many had not even heard of DCIS) and were motivated to further their knowledge before agreeing to the recommended treatment. One woman said,

> *'For a lot of women who get a diagnosis of breast cancer, to them it's a no-brainer. Treat it, you know? Let's get rid of it and then, then we're ok. But… my…mental world wasn't… composed in that way'* (Participant 5).

Several women named specific books, articles, and clinicians that they encountered in their search for more information, that had led them to research overdiagnosis in-depth and said that these had been valuable sources of information on overdiagnosis. Finding

out that there are different types of cancer was described as an '*eye opener'* (Participant 12) and motivation to not have the recommended surgery immediately. For some, this process of getting informed became a full-time job, on which they and often their partners put in *'a lot of work'* (Participant 1). Participant 3 initially undertook *'typical googling'* and found the same things the doctor had told her, but

> *'It just didn't feel right. Then, it just kind of snowballed…the more I read the more controversy I found…like finding the idea of overdiagnosis'* (Participant 3).

The women's responses to finding out about overdiagnosis and overtreatment varied, on a spectrum from feeling *'overjoyed'* to *'tortured'.* Finding out, for some – this was where they instantly identified, they felt seen, and it was a relief,

> *'It totally defined what I felt. It totally was validation and recognition…it was instant identification… I was overjoyed that this was being discussed in any way, because that's what I identified with'* (Participant 6).

One participant felt 'relieved' because it confirmed that her preference to not have a mastectomy was not necessarily an overreaction. Women at this end of the spectrum reported that finding out eased some of the uncertainty they were experiencing, validated why they were feeling as they were, asking the questions they were, and verified that they were not the crazy angry irrational women that some had indicated that they were. Participant 7 felt that she had been 'thrown a life raft' when she discovered a blog where people were discussing overdiagnosis.

Yet a number of the women just felt shocked and sad upon learning about overdiagnosis after their diagnosis and/or treatment, realising that they may have endured what they had perhaps unnecessarily:

'I thought, shock. Shock. What? You know? So you mean that I've been told I've got breast cancer and yet I might not have it?.... from that point onwards (finding out about overdiagnosis) then really, I was actually tortured, I'd say, by the idea that I had been caught, unnecessarily by the screening program' (Participant 5).

Several of the women in the cohort we studied expressed deep anger upon finding out that they had not been informed about the possibility of overdiagnosis and overtreatment prior to breast screening. One participant only completely grasped the concept of overdiagnosis and what it possibly meant for her personal circumstances three years after her diagnosis and described finding out, and identifying with it, as one of the most painful experiences of her life.

'I had still thought that in my case because invasive cancer had been found that my life had been saved. It took a long time to come to understand that a lot of the papers written about overdiagnosis some were only talking about invasive cancer they didn't even include DCIS in their estimates of overdiagnosis. Then I realised that even some invasive cancer is known not to progress' (Participant 11).

Two of the 6 UK participants had been invited to screening prior to information about overdiagnosis being included in screening leaflets that go with invitations to UK women for the NHS breast screen program; for them the realisation of overdiagnosis was particularly painful, as they were months short of receiving updated patient information which cited overdiagnosis as a possible harm of mammography.

'That was particularly painful...I just felt I'd been caught on the edge really of a change in policy and that actually the screening service...sent me a leaflet that they knew was not fit for purpose...so that made me extra angry' (Participant 5)

Am I a cancer patient or not?

Most of the women's reports suggested that they soon became aware - once they began asking questions and learning more about their diagnosis, overdiagnosis, and overtreatment - that their circumstances and experience of breast cancer were unusual. Several interconnected issues of identity were apparent in the women's accounts of their experience. Firstly, several women described the challenges their diagnosis posed to their sense of self because they felt well and were without symptoms prior to attending screening. Some were surprised at how quickly they were treated as a cancer patient following their diagnosis.

> *'…And then she told me all the appointments I would need to make. And you just go right into this fast forward…you're a cancer patient now. And you're treated just like a cancer patient'* (Participant 6).

Secondly, some of the women expressed feeling unsure regarding how to classify themselves following their diagnosis,

> '*I had to come to grips with was I a cancer patient or wasn't I a cancer patient?'* *(*Participant 2*)*

which in some cases was only exacerbated by disagreement amongst treating teams on whether their case was considered cancer or not (when the diagnosis was DCIS).

> *'I was getting more and more confused…I had one professional telling me it wasn't cancer…and another telling me, yes, it is cancer'* (Participant 4).

Many said that they had difficulty adjusting to being a 'good compliant patient' (Participant 2) and were dismayed at the expectation to fulfil this identity, especially

those women who at the time were questioning whether the recommended treatment constituted overtreatment.

Lastly, several women who found out about overdiagnosis after diagnosis or treatment, identified entirely with the possibility that they may have been overdiagnosed, and not with being a cancer patient or survivor. These participants reported feeling conflicted over whether they were a cancer patient or not, and struggled against the cancer patient identity, yet were unable to escape or deny having been significantly impacted by a cancer diagnosis. This remained the case even over time, with two of the participants instead identifying themselves as victims of the medical system.

> *'Let's not call this disease. I'm not, I don't feel diseased… I don't identify with disease or illness or cancer… survivor, any of those terms. They're just like… it's almost insulting, especially when you feel like you're a victim of overdiagnosis. Then you're, that's a double whammy. Because now you're a victim in a sense from the medical system…this problem is a medically made problem'* (Participant 6).

Another talked about not being able to relate to the generic image of cancer,

> *'It didn't match my experience…the kind of metaphor was this thing invading your whole life and taking you over…I'm sure that's how it is for many people who have cancer…I never really felt the cancer was the enemy…I felt the whole medical merry-go-round was, was my enemy'* (Participant 5).

They felt that they could not engage with breast cancer support groups because they did not identify as a cancer patient,

> *'You just hear about everyone's mastectomies and the radiation treatments and … I just felt I could never go back because I didn't identify with that'* (Participant 6)

'I didn't want to do any of that because I didn't want to identify as a cancer patient ... their sympathetic nice caring responses to me would not have aligned to what I needed...I didn't want to go to those kind of meetings and then...not say how I felt' (Participant 5).

Resisting perceived overtreatment

All of the women described their disbelief upon learning about the recommended treatment pathway after being told they had a screen-detected (or incidentally-detected, in one case) breast cancer. They perceived the scale of the surgery recommended as disproportionate to their understanding of the diagnosis they had been given which 'might never progress' (Participant 11), especially when they were not experiencing any symptoms.

'*In my head, I'm going, what is stage zero? Why would I need treatment for that?*' (Participant 2)

One participant, diagnosed with DCIS, commented that she did not at the time consider herself to have 'real cancer' so it was 'absolutely ridiculous' that a mastectomy was being recommended (Participant 6). Another said she had found it '*completely ridiculous to have a mastectomy for something you don't have yet. And you may never have. I mean...that will not kill you (DCIS) (*Participant 1).

'They were telling me I needed surgery for something that might never progress...I was put into that dilemma...The surgery proposed at that time was a quadrantectomy, which seemed to me like a big deal, mutilating surgery for something that might never progress so I said no' (Participant 11).

Most participants had encountered criticism in response to their curiosity and requests for more information to enable an informed decision about their management plan. They described the 'uncomfortable' exchanges (Participant 5) that they felt took place when they asked their clinicians questions about their diagnosis or overdiagnosis or challenged the advised treatment pathways. They also described a rising sense that they were taking their life in their own hands (Participant 6), with doctors acting *'totally uncomfortable with the fact that I was now choosing to do, in her words, nothing'* (Participant 3). One participant - who had studied biochemistry - said she was asking informed and intelligent questions of her doctors and radiologist but felt she was not getting any answers, as *'they didn't like me asking'* (Participant 12).

> *'I said to my husband, I don't think I'm having that surgery. And my husband's initial thing was like, I don't know what you're getting into your head. You can't just read stuff on the internet and think that you're better than the doctor. The doctors know best'* (Participant 3)

The women talked about the pressure that they encountered to act in the specified, recommended way, including from partners, friends, and family members. Some women reported requests for a more conservative treatment approach were not readily accepted by medical practitioners: one woman described being told *'you're making a very bad decision'* when she opted not to have a mastectomy (Participant 8), another felt she was treated like she was doing something dangerous (Participant 3) or suicidal (Participant 10). As a consequence, some women sought a second opinion, and in some cases reported being pleased to find an alternative approach, with a doctor who they felt was more open to discussing different options and willing to consider evidence on overdiagnosis or more conservative care.

Our participants described situations where they felt they were laughed at, treated like *'a mad woman'* (Participant 12), *'negligent…foolhardy and arrogant'* (Participant 1). One participant reported being told she had '*anger management issues'* by people on breast cancer internet forums, who felt that it was best '*to just trust my surgeon, not Google'* (Participant 5).

> *'At first everyone treated me like a difficult woman because I said I don't want a mastectomy, I want monitoring please and let's keep an eye on it and see if it develops or not because I was aware of overdiagnosis and didn't want a mastectomy if it wasn't absolutely necessary'* (Participant 12)
>
> *'The clinician…was absolutely incensed that I had decided not to have a mastectomy…she says…what kind of nonsense have you been reading? What are you doing?' (*Participant 1)

Several participants encountered similar responses when they turned to online forums and breast cancer support groups after finding themselves unable to get the conversations that they wanted with medical professionals. However rather than finding support, they reported feeling misunderstood and isolated when they voiced their concerns about overdiagnosis and overtreatment.

> *'It seemed like they were all doing the very aggressive treatments and…they were also kind of bullying me. And making me feel bad and saying, I wouldn't leave it. That's, you know, crazy. Like, I wouldn't wait till… I want to live for my kids and …all that kind of mentality. And I just thought, I'm looking for a support group and I'm not finding any support*' (Participant 6).

It was clear that most of the women had at some point felt lonely and isolated as a result of questioning their diagnosis and treatment, and in their efforts to inform other women about the possibility of overdiagnosis and overtreatment,

> *'It's something you can't really talk about because so many women don't understand. You're saying something terrible and they get quite upset. It's also quite isolating in that I can't mention it to women of my age because they all think it [screening]'s a good thing to do. Far be it for me to rock the boat. I've received too many brickbats and insults. I was only trying to help'* (Participant 11).

Living with the unknown.

It was apparent across the interviews that a number of the women were managing feelings of self-blame and regret many years after receiving their diagnosis and/or treatment because of their knowledge of overdiagnosis and overtreatment. Some of the participants expressed regret for not being more aware or paying more attention at that time,

> *'And yet I'd been started on this journey without my… knowledge, without my consent, without my understanding…I signed some kind of consent to have the screening performed…I kick myself for not taking enough notice of that. So I gave my consent but it wasn't informed consent. I was cross with myself for not being better informed…I just feel a bit like I was hoodwinked and…a bit of it was my own fault, for not paying better attention'* (Participant 5).

They expressed regret for decisions previously made such as going for a mammogram in the first place.

> *'I've got no regrets about my reaction I just wish that I hadn't been to the screening in the first place. If I hadn't gone for that wretched screening… … I might have got*

three more really good years of life not worrying about anything. In fact, once I had been to the biopsy I lived with the fear of cancer coming' (Participant 12).

A few participants did however consider mammography beneficial; for instance, Participant 8 commented that she considered her life to have been saved through a routine mammogram, but at the same time felt very strongly that she had managed to avoid overtreatment and make informed management choices.

All women mentioned some step of their diagnostic and treatment pathway where they felt that they did not provide informed consent; some said that they realised in hindsight that they may have been frightened into making some decisions that they were not ready to make. Some women believed that they had been denied crucial information to enable informed consent.

'One of the things that so hurts is that…(they) gave me half the information. But they knew, they knew all about the controversy and the lack of information and they still wanted more than anything to process me, not to help me' (Participant 11).

Throughout the interviews, the women's reflections on their experiences highlighted the exhausting and lonely nature of the work involved to justify why they had chosen the choices and actions taken. Some said despite having had the recommended surgery, nothing had convinced them that they actually needed it in the first place. Several others reported that they felt confident they had made the right management decisions in choosing not to have a mastectomy, for example,

'I think I made…absolutely the right decision…it was frightening, 'cause when people…who did talk to me about DCIS talked about it, they talked about it as

inevitable advancing to aggressive cancer…but I think we (my partner and I) made the best decision we could make. I think if I had gone along with the mastectomy and the reconstruction..I think I'd be very, very angry now…because I'm fine' (Participant 1).

However, many said they will forever be wondering if they made the right decision – *'am I the needle in the haystack?'* (Participant 11), *'have I done the right thing…would it have been better to…have a mastectomy and move on with life and not keep thinking about it?'* (Participant 4) – even after years spent 'digesting' (Participant 11) the possibility of overdiagnosis. Some described the trauma and anger that they had experienced over the years,

'I was beside myself with rage for several years and eventually that burns down and you just become sick of the whole thing, which now I am' (Participant 11).

With the current state of knowledge, these women can never know if their decision was the right or best one, which is the nature of overdiagnosis.

'And I'm sure that she thinks that I'm alive and well today because they caught it early. Whereas, I still don't know that. I think I might be alive and well today with no further, repercussions at the moment at least, because I wasn't really ill in the first place… I'm contributing to a misleading statistic and that I've reached the 5-year survival point, so everybody can cheer and that knocks that up to a success. But it's not really a success if I was fine anyway and I was still going to be well at this point, and the NHS spent several thousand pounds curing me of something that could have been left well alone' (Participant 5).

Downstream effects on quality of life

A number of the women were living with physical reminders of their experience, such as *'really painful'* (Participant 4) pain in their breasts, disfigurement, scarring, exacerbated anxiety, lymphatic cording, or the side effects of medications and early '*super charged menopause'* (Participant 8) and the prolonged impacts of that on their quality of life. Some mentioned the stress and financial burden of bills and medical appointments, without knowing if the cancer needed to be found in the first place.

> *'(mastectomy) affects things, affects my choices about what I wear and mastectomy bras are uncomfortable, and the whole experience has affected my travel insurance costs…it does have an impact, even after all this time…I had a bad time emotionally'* (Participant 5).

Suggestions for other women

All participants were asked, when reflecting on their personal experience, for advice on how to improve the experience for other women considering breast screening. Their suggestions are summarised in Supplementary file 3.

DISCUSSION

Principal findings

This unique international study is the first to document the experience of a highly selected group of women diagnosed with DCIS or invasive breast cancer. These women have all considered the possibility that they may have experienced breast cancer overdiagnosis. Some felt that they had experienced overtreatment and others had taken steps to avoid overtreatment. Our study shows how learning about overdiagnosis after a breast cancer diagnosis profoundly impacted these women's sense of self, interactions with medical professionals, and for some, deep remorse about past decisions and actions. Many were uncomfortable with being treated as a cancer patient when they did not feel 'diseased' and being recommended treatments that seemed excessive in comparison to the diagnosis given. Some felt anger that critical information was not easily forthcoming and feeling they had not been given a complete picture of overdiagnosis before having screening mammography; and some were frustrated about how difficult it was to connect with medical professionals and others in their social network about overdiagnosis and overtreatment being a possibility. The findings highlight the loneliness of this experience, with little support or reassurance available to the women interviewed in this study. By describing the experience of women who independently self-identify as having a potentially overdiagnosed cancer, this study – which exemplifies the psychosocial harms of learning about overdiagnosis after a breast cancer diagnosis - makes an important contribution to the literature and to clinical practice. The sample also included several women who were more concerned by their recommended treatment which they perceived as overtreatment, rather than whether their cancer was 'overdiagnosed.'

Strengths and limitations

A strength of this study was the use of qualitative interviews that allowed for (a) in-depth exploration of this unique experience of cancer at an individual patient level and (b) unanticipated findings to arise, with opportunity to explore such experiences in detail. The study recruited across 4 countries with established breast cancer screening programmes and involved a 3-member consumer advisory panel with lived experience of breast cancer. This study is novel – other studies including our own have sought to explore how to inform women about overdiagnosis[15 16], whereas our aim was to hear and document the experience of individuals who wondered themselves whether they may have been overdiagnosed and/or overtreated, and possibly realised they are unlikely to ever know for sure as it is practically impossible to identify individuals who have been 'overdiagnosed'. The diversity of our sample allowed us to illustrate a range of possibilities in terms of the impact of discovering overdiagnosis: (1) distress upon finding out and questioning whether a diagnosis and treatment was potentially unnecessary; (2) being protected by this knowledge by taking steps to avoid overtreatment; and (3) potentially damaging, if it encourages patients to decline treatment for potentially curable cancer. Another strength is that we verified women's understanding of overdiagnosis and overtreatment as part of the study eligibility process by asking them what they understood by the terms. Their responses are reported in the Supplementary material (Supplementary 1).

The number of participants is small and the study comprised of a highly selected and unusual sample. They were health literate and highly educated. This was inevitable, given our aim was to explore a specific experience, that of being aware of overdiagnosis and

considering it in relation to one's own experience of cancer diagnosis and treatment. Few women in the community are aware of and understand overdiagnosis[17] and even those who do understand it are unlikely to have experienced it given that most screening mammograms are normal, reflecting that screening is an intervention for asymptomatic women. The experiences of the women documented in this study are therefore likely not shared by the majority of women in a similar position but are valid for those who identify with this experience. As this was a small sample, we cannot state that thematic saturation was achieved. Our study was conceived and led by researchers interested in improving understanding about overdiagnosis and to explore ways to deal with it. To minimise bias, the initial analysis was led and undertaken by a researcher with no previous involvement in breast cancer research. All the data reported were based on the women's survey responses and/or their words during the interviews. It should be noted that diagnoses and treatments reported have not been verified, and they reflect the participants' perceptions. While some treatments may have been perceived by them as overtreatment, our findings should not be taken to suggest that the treatment offered was incorrect or poor quality, as treatment recommendations may be made for many reasons not all of which may be apparent.

Strengths and limitations in relation to other studies

We know from a substantial body of epidemiological evidence that large numbers of women could be harmed by overdiagnosis at a population level, but this is the first study to our knowledge to document how women are personally impacted by the possibility that their screen-detected diagnosis may represent overdiagnosis and/or overtreatment. The women's accounts show the significant negative psychosocial impact of awareness of overdiagnosis in the context of screen-detected breast cancer, particularly when not

forewarned of the risk. The findings are relevant to all women who are considering or are participating in breast screening programs, their clinicians, and policymakers.

A previous study suggested that some women do not consider overdiagnosis information to be an issue for screening participation[15]. However, this study shows the substantial negative impact of finding out about overdiagnosis after a diagnosis of breast cancer at least in some women. Randomised controlled trial data has shown that women can be safely informed about overdiagnosis before screening: educating women about overdiagnosis prior to screening improved understanding, reduced worry about breast cancer, and did not increase anxiety or reduce willingness to participate in breast screening[18]. This is consistent with other evidence showing that women value breast cancer screening and intend to participate in screening even when aware of the risk of overdiagnosis[19]. In the present study most (10/12) women found out about overdiagnosis after diagnosis (rather than before screening).

Unanswered questions and future research

One theme identified was the difficulty of living with uncertainty about the possibility of overdiagnosis or overtreatment. It is not possible to identify whether any individual has been overdiagnosed or not, and as such it remains unknown whether the women in this study made the best decisions for their health or not. With time, it is likely that these issues will become salient to more women as the community becomes more familiar with the potential for overdiagnosis in breast cancer screening. Future biological research may be able to determine more accurately the prognosis of screen-detected breast cancer[20 21]. Until then we recommend consideration be given to how to better inform women about the possibility of overdiagnosis before they undergo screening mammography to avoid

the distress caused to women who are diagnosed and discover it later. Clinical and community support, for example provided by clinical nurse specialists, should also be available to the minority of women who identify with the possibility of having been overdiagnosed and possibly overtreated to cope with the uncertainty about their treatment choices and their prognosis as described by the women in this study.

The findings of this study could be tested in a larger representative sample; a randomised controlled trial could ascertain if there are women who suffer harm from undertreatment when informed about overdiagnosis. Future research could also repeat and improve this research in other jurisdictions and cultures with larger samples of women where breast cancer screening is offered. It is important to consider how best to inform people about the risk of overdiagnosis when establishing screening programs. Such opportunities may exist in relation to lung cancer screening, which will likely be implemented in many countries following recent trials and recommendations[22-25]. Additional implications for clinicians and policymakers are summarised in Box 1.

Box 1
Summary of implications for clinicians and policymakers

- In the spirit of transparency, women should be given opportunity to be informed about the possibility of overdiagnosis and overtreatment prior to screening (and therefore diagnosis). Such an opportunity might avoid the negative psychosocial impact experienced by some of our study participants. An evidence-based information resource presented alongside breast screening invitations has been recommended by three European independent inquiries into breast cancer screening[2 26 27], yet has only been implemented at scale in the United Kingdom.
- Consistent terminology and minimum standards to describe overdiagnosis and overtreatment as a potential downside of cancer screening[28] should be prioritised in information resources. Information about overdiagnosis and overtreatment must be prominent during consent.
- Better support, training, and resources for clinicians to communicate about overdiagnosis and overtreatment during their consultations is warranted. Clinicians must be aware of their own preferences and how that influences the care and advice that they provide[29]. Specialists who consult women who have a screen-detected breast cancer should inform them of the risks and benefits of all management

options available and be prepared to engage in evidence-based conversations about overdiagnosis and overtreatment. However, our study has shown that there were psychosocial harms, including anxiety, of the diagnosis itself, in addition to the harms of perceived overtreatment.

- Strategies for reducing the harms of screen-detected DCIS have been suggested[20 21] and may also have application in the context of mitigating the harms of overdiagnosis of screen-detected breast cancer, whether DCIS or invasive.
- Where appropriate, clinicians should consider participation in trials of active surveillance, de-escalated treatment of low-risk DCIS, newer less harmful treatments such as TARGIT-IORT[30-32], and using lumpectomy for invasive breast cancer.

CONCLUSION

These findings provide rare insight into the experience of a select group of women who found out about overdiagnosis after being given a diagnosis of breast cancer. While this cohort may represent a small proportion of all patients diagnosed with breast cancer, it is important that policy makers and clinicians improve current practice by considering these findings and suggestions made by our study participants. There is a need to adequately inform women considering breast screening of the risks of overdiagnosis and overtreatment.

Competing interest statement

All authors have completed the ICMJE uniform disclosure form at http://www.icmje.org/disclosure-of-interest/ and declare: AB, KM, JH, BN, KP had financial support from the National Health & Medical Research Council, Australia for the submitted work. JSV reports a grant from the Health Technology Assessment Programme of National Institute of Health Research, UK during the conduct of the study. JSV received payment from Carl Zeiss for travel to meetings and honoraria outside the submitted work. AB is a member and Co-Chair of the Scientific Committee for the Preventing Overdiagnosis International Conferences. KP, BN, and JH are members of the early career researcher committee for the Preventing Overdiagnosis International Conferences.

Transparency declaration

The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned (and, if relevant, registered) have been explained.

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Contributorship

AB conceived the study. AB, JH, BN, KM, KP were involved in designing the study and developing the methods. AB and KM obtained funding. AB and KP coordinated the running of the study; KP conducted the interviews. JSV reviewed the study materials and assisted with recruitment. KP and JH developed the analytical framework and performed the analysis. AB, KP, JH, and JSV read transcripts and contributed to the interpretation. KP drafted the manuscript. All authors had significant intellectual contribution to the manuscript and critically revised the manuscript. KP, JH, and AB are guarantors.

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Data sharing

No additional data available

Licence statement

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Supplementary 1. Participant descriptions of overdiagnosis and overtreatment

Participant	Description of overdiagnosis	Description of overtreatment
P1	The diagnosis of a condition that would not cause the person problems if left undetected	Treating a condition more aggressively than is required to manage the condition taking account of the side effects of the treatment(s) on health and quality of life
P2	Diagnosing as disease needing treatment a situation in which no action is the preferred treatment since health and mortality are not affected and in which treatment itself causes harm to the patient	When LESS or NO treatment achieves the same or a more desirable outcome and especially when treatment does not decrease mortality
P3	Identifying or treating things that will likely never become a problem in one's lifetime	Providing intervention for something that likely will never cause problems in a lifetime
P4	As technology has improved, mammograms are now picking up calcium deposit in the breast that may not have previously been detected, with current guidelines and pathology results from biopsies, even at low grade cancer, in the UK the recommendation will be lumpectomy, breast conserving surgery or in my case as I have multifocal DCIS, a mastectomy. Some clinicians consider that such procedures may well represent overdiagnosis/overtreatment	Not only is overtreatment the actual surgery, but also the follow on radiotherapy. It is currently unclear what the outcomes are if surgery is not elected and how this compares to those who elect treatment, as more comparative studies are required to help establish if this is overtreatment or not, for cancers of low grade which are "contained"
P5	The diagnosis of a condition that might not lead to harm within one's natural lifespan	Being treated for a condition - possibly unnecessarily - because it's not possible to know if the condition would progress or not if left untreated
P6	Cancerous cells found on screening that will not cause symptoms or death. This leads to and harms including physical, emotional and financial	Treatment that brings harms but offers no survival benefit or improvement in quality of life
P7	There are studies that show that more detection has not resulted in a decrease in malignant breast cancers, therefore early detection is likely causing	Overtreatment is treating cancers that may never (or so slowly) have developed into anything that affected mortality. For example studies show that mortality is not

	overtreatment to a number of women whose cancer would never have become malignant	any better for those DCIS patients receiving standard of care treatment versus those not receiving this treatment
P8	Routine mammograms often pick up small cysts or tumours which left alone our immune systems would probably get rid of. Overdetection means a lot of women are undergoing unnecessary surgical interventions and treatments	Putting women through unnecessary surgical interventions, external beam radiotherapy, adjacent chemotherapy for very small tumours that the body could probably deal with on its own. I think it's a case of doctors being overcautious, playing safe and not weighing up the side effects of these treatments which can be life changing for a lot of women
P9	Overdiagnosis is giving the patient treatment beyond immediate needs: i.e. assuming the worst case scenario when in fact a discovered tumour may not progress or require anything other than monitoring	Overtreatment, in my case, would have been to allow the locum breast surgeon who first saw me to do what he said I so should have ie: a double mastectomy asap.
P10	Overdetection is, for example, when a mammogram picks up something that frequently is not a problem, but because it is identified and treated as cancer becomes a problem for the woman. She may have been better off not knowing about it. Sometimes, because of various factors, the solution is worse than the perceived problem.	When the treatment does more damage than the problem itself would have caused
P11	The detection of cancerous changes which would not develop into illness before death from other causes if left alone	Treatment of findings that would not have presented with symptoms or caused illness if not treated, or which does not lengthen life or improve quality over leaving treatment till symptoms develop
P12	Overdiagnosis means the detection, usually leading to overtreatment, of a condition, which if left undetected, would not have caused a problem in the person's lifetime	Unnecessary treatment of a condition, sometimes identified through overdiagnosis. The treatment may do harm (iatrogenic) and is wasteful of resources

Supplementary 2. Interview topic guide

Screening and diagnosis

So if we could start from the beginning for you, can you take me through how you came to be diagnosed with DCIS/breast cancer?

- How was the diagnosis described to you by your clinician(s)?
- If you can recall, could you describe your immediate thoughts and feelings in response to the diagnosis at the time?
- How do you feel about the diagnosis now?

Possibility of overdiagnosis

What is your understanding of 'overdiagnosis'? (*re-cap from survey*)

- How did you come to be aware of overdiagnosis?
- How did you feel when you first found out about overdiagnosis?
- What impact has that awareness of overdiagnosis had on you?
- Why have you thought about overdiagnosis in relation to your cancer?
- How does/did this make you feel? What have been the main effects of that possibility for you?

Treatment

- Did you resist or refuse any particular treatments?
    - Could you explain why you resisted/refused any treatment?
- What have been the main physical, psychological and social effects of treatment for you?
- Do you feel your cancer diagnosis was beneficial in any way?
- Do you think different treatment options could have been possible for you (eg, less aggressive?)

Reflections

- Given your experience, what would you say to other women who are about to undergo breast screening or who are considering whether to do so?

- How do you think information about overdiagnosis should be handled for women in the future?
- Should information on overdiagnosis be made available? – given if/when diagnosed or before?
- Is there anything that could be done better / have made it a better experience for you?

- What are your views about campaigns and advertisements that promote mammogram screening to women?

- Do you have any other comments on detection or diagnosis that you would like to tell us about? Is there anything important that we've missed?

Supplementary 3. Participants' suggestions for supporting women making breast screening decisions in the future

What's needed?	**Advice/recommendation – How to implement it**	**Illustrative quotes**
Individual level		
Prioritise patient preferences	Medical preferences quiz elicited by nurses or clinicians and incorporated into decision making about screening, diagnosis, and treatment	*It would be good if there was some way one could try to ascertain which women would welcome more information and which would not… and one thing I remember saying was that, if someone had looked at my medical history and the choices I had taken earlier in my life, they would have figured out that I was a person who wanted to know and was a little bit skeptical…if there was some way of, doing a quiz with women, or something, about what choices they would make in a parallel situation to kind of gauge, I think that would be really good.* (Participant 5)
Communicate screening harms; don't downplay overdiagnosis	Clinician communication training In surgical consultations, provide information about overdiagnosis and the harms of overdiagnosis including what that looks and feels like (Participant 6) – (e.g. having video testimonies of women, because 'people's risk perceptions are off')	*It's (overdiagnosis) a really difficult concept to get hold of actually…It's not intuitive…it is a difficult concept to explain…one part of me understands why the medical establishment doesn't want to complicate things…but at the same time…I think people should know* (Participant 5) *They downplay overdiagnosis. They don't think it even exists. They say you can't measure it. Like it does, like my story and all the women that feel this way, like---doesn't matter…you feel like you're…somewhat of a victim of our medical system, yet nobody's acknowledging that, except for a handful of people* (Participant 6) *Quite a lot of that could be done through training doctors better, how they communicate* (Participant 8) *I think that it's about managing expectations* (Participant 4)
Flexible care pathways, patient-preference-driven		*The other thing I think is absolutely crucial is that once you get the diagnosis there should not be an unambiguous set of steps that are always followed independent of the patient, what they want, and what matters to them at that time in their lives.* (Participant 1)
Medical profession / health system level		

Acknowledge limitations and uncertainty in current knowledge		*I think it's appropriate for people (medical professionals) to acknowledge what they know and acknowledge what they don't know* (Participant 10) *How do you talk to women that already – the problem for you is how do you say it in a way that doesn't offend all the women that went through all this crap including chemo and then you tell them it's for nothing. They're going to fight you* (Participant 7) *What's needed is a much clearer account of what the mammography screen, well any kind of screening, can and can't do. And also what the chances are that you'll get a really ambiguous outcome… like…a false positive…or DCIS* (Participant 1)
Opportunity for proper discussion before screening		*And I think… maybe it should be flagged up to women… that they can go and discuss screening with their GP before they go for it. That should be made more prominent.* (Participant 5)
Lower the anxiety dial	Build in more time between appointments, possibly with nurses	*If people just knew, something this size, this is probably taken 7 years to develop in you. Why can't we give you 30 days…Just to…make a decision? Why do we think that between finding it and doing something is going to like go poof, which it took 7 years to get to this tiny little spot. I hate that whole idea that we kind of assume, well now that you know, you have to do something. 'Cause otherwise you're being stupid…give them stuff to read …this is not a medical emergency* (Participant 3) *Take more time and not panic…everyone just pause…when you make decisions out of fear it can be life changing and you can't go back… I mean I'd just feel awful if someone didn't find out… that there is a controversy and there is a potential overdiagnosis* (Participant 6) *In other words to say look even if they find a small lump actually to say your body can get rid of these things naturally, you have an element of choice. I think to sort of lower the level of anxiety basically about the disease. ..I think if you lower the dial, it allows women to make more informed choices about their treatment and not go for the just give me everything I want to get rid of this* (Participant 8)

Address external factors that pressure women into screening	Remove/address screening incentives, targets, automatic invitations	*The whole system is set up to disempower you* (Participant 10) *I tried to argue that one should make the invitation more neutral it shouldn't be you've been given an appointment or mammogram at this time, because that means if you don't want to go you have to do something* (Participant 12) *And I think that what they should not do is send you a screening invitation for breast cancer screening with a date and a time and a place on it, because that kind of almost preempts your decision. I think it's wrong because I think it steers women towards having screening without them thinking too much about it.* (Participant 5) *It's very hard when you're trying to go around whatever the system is set up to do* (Participant 6)
Culture / Society level		
A shift in thinking about and labelling cancer		*Our culture is teaching us to get rid of this, get help. You've got this whole cultural thing to deal with …People want that from their Doctors, they want a take away and I think this is one of the reasons why people are perhaps over treated…I've got this, you told me I've got this and now I need something to deal with it. We've got to change a whole way of thinking which is not easy* (Participant 9) *You can see that people hate the idea of having a cancer. Oh my god, get rid of it. I can see that but that's because of the way we think of cancers… If the words around it, the language around it was gentler I think people wouldn't feel oh my god I've got to get rid of it. I think there is a lot of that…The whole cultural history of doing big things when it comes to breast cancer…I think that's something that perhaps lingers in people's minds…it's only really recently that we've been talking about quality of life* (Participant 9)

		I still don't think this is a true cancer as we know cancer…it's a mindset that for me shifted pretty quickly …The nature of DCIS, it's not a tumour, it's not like an invasive cancer. And this isn't really explained to women (Participant 6).

Supplementary 4. Case study 1.

Pam was in her early 50s when she had her second routine screening mammogram. She thought it was the sensible and right thing to do. She was called back for further testing and just thought it was a false alarm so didn't take her husband along with her to the appointment, where she had another mammogram and biopsies. Ten days later she was told that she had invasive ductal carcinoma, cancer that had spread beyond the milk ducts. She asked at the time of the diagnosis, *'do these things ever go away on their own?'* and recalled that her husband, the doctor, and the nurse looked at her *'as if I was nuts'.*

Three days later Pam started Googling to find out more about her diagnosis and *'it felt like an avalanche of information came back about the possibility of overdiagnosis'.* Her husband read some of the research papers with her and confirmed that they were good scientific studies. Pam explained that it was at that point that it became clear to her that she might have been caught unnecessarily by the screening program, and described feeling 'shocked' upon finding out about overdiagnosis.

She continued to research for another month and then went to see a breast cancer surgeon to discuss treatment options; this was an 'uncomfortable' exchange because she challenged the treatment options offered (a lumpectomy and possibly radiotherapy). She asked for a second opinion and saw another surgeon three weeks later, who listened to her concerns but didn't have anything different to offer. *'I did ask her about something like active monitoring, because I knew that was what was offered to men with prostate cancer',* where overdiagnosis is also an issue. She was told that (at the time) 'we just don't do that'. Pam 'reluctantly' agreed to a lumpectomy. In preparation, she had an ultrasound where more cancer was detected in the same breast (of the same low grade, both <1cm) after more biopsies and a mammogram. She was told then that a lumpectomy was no longer an option and a mastectomy was recommended.

By this point Pam was exhausted from weighing up all her options (it had been 2 months since her diagnosis). She agreed to have a mastectomy (but refused breast reconstruction) and had the surgery and a sentinel node biopsy soon afterwards. She made a good physical recovery. The result of the biopsy was clear, so no radiotherapy was needed, but this provided little in the way of reassurance, as it *'did nothing to convince me that I actually needed the surgery in the first place...I was left with that uncertainty...(and even years down the track), I still don't know if I actually ever needed that treatment'.* In the years that followed, Pam blamed herself for not paying better attention to information about overdiagnosis that may have been in the media and questioned her decisions. The treatment was not without consequence or burden; it brought on menopause and osteoporosis which limited her activities, still affects her choices about what she wears, and impacted on her travel insurance costs, in addition to the months of emotional turmoil that she endured from the decision making, surgery, drugs, and ongoing questioning about whether it was all in fact necessary. Pam acknowledged the difficulties for the medical profession to communicate overdiagnosis but, '*at the same time...I think people should know'.*

Supplementary 4. Case study 2.

When Jenny received her first invitation for a screening mammogram she wasn't interested in screening because she had *'heard with cancers that it's not always clear and I don't want to be in that situation'*. She was annoyed that an appointment had been made for her without asking her first, so didn't go. The breast screening service called her to ask why she hadn't gone and to rebook her in. She was cooking dinner at the time and wanted the call to end so agreed to go in, assuming that everything would be fine. She was called back and diagnosed with DCIS and advised that she would need surgery (a quadrantectomy). '*They were telling me I needed surgery for something that might never progress…I was put into that dilemma that I had decided I wanted to avoid'.*

Jenny declined the recommended surgery: *'you're telling me this might never progress you don't know whether it will or not and I'm not having surgery for that'*. She sought a second consultation because she thought that the care team hadn't answered all of her questions. At the next consultation she was told that if she didn't have the surgery she might die, because they were unsure whether she might have some invasive cancer (this was the first time that invasive cancer was mentioned); *'I didn't know what to think or how to digest that information. But it was enough to make me think oh god I might be on the brink of death, I've got two children, I have to do this, have the surgery'.* Jenny had a mastectomy, five 'tiny little cancers' were found, the largest 0.25cm (2.5mm). At the time, she believed that *'they had saved my life as we say'.*

It wasn't until a follow-up appointment 3 years later when she said to her surgeon, '*I know I was reluctant, but I would probably be dead by now'* and her surgeon said, *'probably not'* that she worked out *'that really we're talking on a much longer time scale here for the development of the cancer'.* She was filled with 'rage' that she'd not been told before screening and treatment that some invasive cancers are known not to progress, *'even three years later I had still thought although I'd found out a lot about overdiagnosis by then, I had still thought that in my case because invasive cancer had been found that my life had been saved'.* It *'was a process, a slow process of coming to understand what had happened after the event'.*

On reflection she felt that she had been *'utterly railroaded'* and frightened into having surgery when she wasn't ready and was very upset about not feeling fully informed prior to screening and treatment. *'If I had known then what I know now I would have walked away…They put the wind up me, they frightened me. I didn't have a good understanding of the statistics that were quoted'.* She believed that the screening program leaflet (which did not include information about overdiagnosis) had only told her half of the information that she needed to know, that's what hurt so much. She describes the experience as amongst the most painful experiences of her life and commented that she is 'marked by it forever'. '*They've given me as much (information) as they're giving, and I haven't got a right to anymore. That's what hurts a lot. The fact that they knew. It's like being the last woman in town to find out your husband is having an affair'. 'This was a very traumatic experience for me'.*

Supplementary 4. Case study 3.

Sally was aware that mammograms are not absolutely accurate in terms of what they show and thinks that she knew that mammograms can overdiagnose. Eventually she decided to go and have one, reasoning *'It's only information. You don't actually have to do anything about it'.* Sally was diagnosed with ductal carcinoma in situ. She had not heard of DCIS before but was told *'it's not cancer but you'll probably have a mastectomy'*; which she perceived as a 'ridiculous' recommendation, given that she had been told that she didn't have cancer, and may never have. The breast surgeon told her that DCIS will definitely develop into invasive cancer and could kill her if she didn't have the recommended mastectomy. Sally was '*looking for a conversation'* with her surgeon but left feeling *'utterly patronised…no autonomy…No right to have any decision about anything at all'.*

The surgeon that she went to for a second opinion also only offered mastectomy, but she contacted a breast surgeon that she had come across in the DCIS literature by email and said, *'I really wish I hadn't had that mammogram…do you know anyone…who would be prepared to even have a conversation about treatment that (isn't) so radical?'* Surgeon no.3. also said that he had to advise mastectomy but was willing to compromise with a lumpectomy - which she had (plus another to attend to margins) – and regular monitoring. Sally described the surgeon as *'worried the whole time, that he wasn't giving me the treatment…that he understood to be the gold standard'.* She independently read a lot of research to understand her diagnosis and options. Reflecting on her experience, Sally described it as *'frightening…when the people who did talk to me about DCIS talked about it, they talked about it as inevitably advancing to aggressive cancer. Inevitably'.* And described how *'incredibly difficult'* it was to push back against clinicians, one who asked what 'nonsense' she had been reading because she had decided not to have a mastectomy. The conversations she has with her current surgeon are open and supportive.

Sally felt that if she had gone through with the mastectomy and reconstruction she would be *very, very angry* now, because she's fine. She would have missed out on important career opportunities that have presented in that time, she suspects that she would have stopped working or at least reduced her workload, due to the physical consequences of surgery but also because '*you're turned into someone who can't make any decisions…and it's very hard to imagine how you could simultaneously have that identity and also have an identity of someone who's making decisions all the time in their workplace'. …'I have done the things that I really wanted to do in my professional and my personal life in a way that I would not have been able to do if, in my view, I'd had a mastectomy and reconstruction'.* Sally hoped that in future all women could be given a clearer account of what a screening mammogram can and cannot do, including the likelihood of getting an ambiguous outcome like DCIS, and for treating teams to consider patient preferences. She supposed that there are hundreds or thousands of women in positions like her who have had a mastectomy and moved on with their lives, '*they don't go through the…I created the angst for myself in a way, by finding out about it',* but she was aware of other women in her workplace who had undergone mastectomies and now think that they shouldn't have.

Supplementary 4. Case study 4.

Maureen went for a routine screening mammography, *'I just went and did it as you do and thought it would be fine'.* She was called back for a full assessment which she described as *'the worst morning of my life'.* She felt that none of the treating team showed any care for *'what was going on from my point of view…they just treated me like an object. I didn't feel like a person at all'.* Imaging showed a tumour in the whole lower quadrant of her breast. Maureen was interested to learn more about her diagnosis and its significance so asked some questions but was told *'oh you don't need to know that…so I didn't know what was going on, nobody was going to explain it and I got very patronising answers'.*

At the time of recall, Maureen did not know about overdiagnosis, and believes that she was *'one of the last in the UK to get the old-style invitation…It only gave the pluses of the screening not the negative',* rather than the current information that is included with screening invitations, which is 'more balanced about the harms of screening'. When she didn't receive answers to her questions, she asked, *'what would happen if I just walked away now? and he put his head back and just laughed…and then said, well you would be a fool because you won't know what's wrong with you…No one had used the phrase carcinoma, I didn't know there were different kinds of cancer at this stage, I was naïve'.*

Maureen ended up having 14 needle biopsies taken and a vacuum-assisted biopsy, from which she 'bled and bled and bled'. She was diagnosed with high-grade intraductal carcinoma in 8cm of breast tissue and advised that she would have a mastectomy: '*I think he should've been…not taking the forgone conclusion that I would be having a mastectomy.'* She undertook some research online and discovered the concept of overdiagnosis which was an 'eye opener', *'I gradually learned more and more about it and realised that for every life saved there are four overdiagnosis and that it was really serious'.* She learned, *'if you go for screening and have cancer diagnosed you then might have a life expectancy of 15 years whereas if you don't go for screening and then you develop symptoms you might only survive 10 years with cancer but you've already had five good years where you were pre cancer so you're no worse off really.'* On the basis of her own analysis of risk and the advice of some others, '*I ran the risk and kept my breast for another two years'.*

She described being treated as a 'difficult woman' when she asked for monitoring only but eventually the surgeon accepted her decision and she had a clinical breast examination every six months, but refused any further mammograms. Her friends thought she was 'mad', *'they were thinking I was going to drop dead. But I said it's not going to kill me anytime soon'.* Maureen did eventually get a mastectomy three years after her diagnosis, when she developed a symptom of invasive cancer (blood from nipple).

Maureen acknowledged that she '*probably would've got breast cancer eventually. I think if I hadn't gone for screening, I might have lived another three years quite cheerfully not knowing that I had it…not worrying about anything…once I had been to the biopsy, I lived with the fear of cancer coming'.* She explained that her management strategy was to acknowledge that the cancer was there, *'but at the same time to just enjoy life and not get fixated on it'.*

At the time of the interview, it had been 8 years since Maureen's diagnosis, and she was now *'going downhill quite fast'.* She said that she had had 8 good years, and *'I've got no*

regrets about my reaction I just wish that I hadn't been to the screening in the first place'. She believed that the cancer would have developed more slowly if her breast had not been damaged by the biopsy, *'I think I could've delayed the whole process really had I not been at the mammography screening'*. Maureen developed stage 4 (metastatic) cancer and died in 2021.

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The effects of awareness of breast cancer overdiagnosis among women with screen-detected or incidentally found breast cancer: A qualitative interview study

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ABSTRACT

Objectives: To explore experiences of women who identified themselves as having a possible breast cancer overdiagnosis.

Design: Qualitative interview study using key components of a grounded theory analysis.

Setting: International interviews with women diagnosed with breast cancer and aware of the concept of overdiagnosis.

Participants: Twelve women aged 48-77 years from the UK (6), US (4), Canada (1) and Australia (1) who had breast cancer (Ductal Carcinoma in Situ (DCIS) n=9, invasive cancer n=3) diagnosed between 1 and 17 years ago, and who were aware of the possibility of overdiagnosis. Participants were recruited via online blogs and professional clinical networks.

Results: Most women (10/12) became aware of overdiagnosis after their own diagnosis. All were concerned about the possibility of overdiagnosis or overtreatment or both. Finding out about overdiagnosis/overtreatment had negative psychosocial impacts on women's sense of self, quality of interactions with medical professionals, and for some, had triggered deep remorse about past decisions and actions. Many were uncomfortable with being treated as a cancer patient when they did not feel 'diseased'. For most, the recommended treatments seemed excessive compared to the diagnosis given. Most found that their initial clinical teams were not forthcoming about the possibility of overdiagnosis and overtreatment, and many found it difficult to deal with their set management protocols.

Conclusion: The experiences of this small and unusual group of women provide rare insight into the profound negative impact of finding out about overdiagnosis *after* breast cancer diagnosis. Previous studies have found that women valued information about

overdiagnosis before screening and this knowledge did not reduce subsequent screening uptake. Policy makers and clinicians should recognise the diversity of women's perspectives and ensure that women are adequately informed of the possibility of overdiagnosis before screening.

Strengths and limitations of this study

- Qualitative interviews allowed for in-depth exploration of this unique experience of cancer at an individual patient level.
- The study recruited across 4 countries with established breast cancer screening programmes and involved a 3-member consumer advisory panel with lived experience of breast cancer.
- Women's understanding of overdiagnosis and overtreatment was verified as part of the study eligibility process by asking them what they understood by the terms.
- The number of participants is small and the study comprised of a highly selected, health literate, and educated sample.
- Diagnoses and treatments reported were not verified, and they reflect the participants' perceptions.

Overdiagnosis is the diagnosis or detection of a cancer that, without screening, never would have led to clinical symptoms or death during a person's lifetime[1]. Estimates of overdiagnosis from observational and modelling studies vary from 10-30%, depending on the study methods[2-4] but the Independent UK Panel concluded that for every 10,000 women invited to screening from age 50 for 20 years, about 681 cancers will be found of which 129 will represent overdiagnosis, and 43 deaths from breast cancer will be prevented. They estimated that in the UK, about 3000 women are overdiagnosed with breast cancer every year, and about 1000 deaths from breast cancer are prevented. The panel recommended that this information should be clearly communicated to women[2].

Overdiagnosis is a difficult concept to communicate and to understand, particularly because women with overdiagnosed cancers cannot be individually identified. In the United Kingdom, information about overdiagnosis has been included in a leaflet sent out with women's invitations to be screened since 2013 but concerns remain that the risk of overdiagnosis is not adequately reflected in the information provided to the public by the National Health Service (NHS)[5]. In the United States, Canada and Australia, women are generally invited to screening without receiving clear information on overdiagnosis[6-8]. Evidence suggests that most women are still not aware of the possibility of overdiagnosis, with the benefits of screening largely dominating public opinion[9 10]. This may change with time as community knowledge grows, and as more women participate in treatment de-escalation trials for low-risk breast cancers.

Being aware of overdiagnosis, however, may increase distress and uncertainty for those women diagnosed with asymptomatic breast cancer, compared to women who are not aware of this possibility. This is because "neither the woman nor her doctor can know

whether this particular cancer would have become apparent without screening and could possibly lead to death or is one that would have remained undetected for the rest of the woman's life"[2]. As such women who know about overdiagnosis may wonder whether the cancer found by screening truly requires treatment or if they are enduring treatment and its related side effects for no benefit[11]. Two recent studies – one in thyroid cancer patients and one in men with prostate cancer - found that patients diagnosed with cancer who chose not to undergo recommended treatment because they believed they were overdiagnosed felt overwhelmingly isolated and anxious, with some participants withdrawing themselves from the health care system altogether[12 13]. We are not aware of any comparable studies exploring this issue in breast cancer patients. Therefore, in the current study we aimed to understand women's perceptions and experiences of living with (what they perceived to be) a possibly overdiagnosed screen-detected breast cancer. This study used in-depth interviews to explore how women experience living with a perceived possible overdiagnosis or overtreatment of breast cancer. Throughout this paper, the term 'breast cancer' includes both DCIS and invasive breast cancer.

METHODS

Design.

This study used qualitative interviews to explore the experiences of women diagnosed with screen-detected breast cancer, who knew of the concept of overdiagnosis and overtreatment and had applied this knowledge to their own situation. They were aware that it is virtually impossible for any individual to know for sure whether their particular cancer was overdiagnosed.

Ethical approval

All study procedures were approved by The University of Sydney Human Research Ethics Committee (Project No. 2017/874). Participants gave written consent prior to participation. We worked with a 3-person consumer advisory committee from the inception of the project.

Identification of participants and recruitment.

Women were recruited to the study through advertisements on blogs where overdiagnosis is discussed ('DCIS411': http://DCIS411.com and 'Even Stars Explode': https://evenstarsexplode.wordpress.com/) (n=6), patients who had contacted AB via her publications on the topic of overdiagnosis of breast cancer (n=4), and through professional networks of the investigators (n=2). This approach was required to enable participation of women who may have been eligible without risking distress to women who were unaware of breast cancer overdiagnosis. Women were eligible if they had been diagnosed with screen-detected breast cancer (defined as a cancer detected in an asymptomatic woman) at least 6 months previously, were already aware of the idea of overdiagnosis or overdetection in relation to screen-detected breast cancer, were 40 years of age or older at the time of diagnosis and were fluent in English. Women who had been diagnosed with breast cancer following symptomatic presentation, or who had advanced cancer at diagnosis, or were at high risk of cancer, for example because of a strong family history of breast cancer were not eligible. Participant's understanding of overdiagnosis was checked before entry to the study to confirm prior knowledge. All participants provided informed consent to be interviewed.

Participants were recruited from four English speaking countries: Australia, Canada, United States, and the United Kingdom. Such sampling from different countries enabled the researchers to understand how variations in breast screening policy and practice may affect women's experiences and responses to their knowledge about overdiagnosis. For example, information about overdiagnosis is included with breast screening invitations in the UK but not in other countries, and government-funded population-based universal mammographic screening programs exist in the UK but not in the USA.

Interview procedures and content.

The women received an information sheet about the study and completed a short online survey prior to the interview. They reported demographic data, details about their diagnosis and treatment (Table 1) and completed an eligibility check including defining overdiagnosis and overtreatment in their own words (Supplementary 1).

Semi-structured in-depth interviews were conducted by one researcher (KP) trained in qualitative research methods, from 13 December 2019 to 8 December 2020. The interviews occurred remotely by Zoom. This enabled us to easily include women from different countries, despite the ongoing COVID-19 global pandemic.

An interview topic guide was developed by the research team which included a practising breast cancer clinician and our consumer advisory panel (see Supplementary 2). It was piloted with 7 people for whom making decisions about participating in mammography screening was relevant (4 researchers, 1 breast physician and 2 consumers), and refined prior to commencement of the interviews. Participants were asked to share their experiences related to their diagnosis and decision-making process around management

options. They were also asked to give suggestions for other women considering breast screening in the future. (Supplementary 3).

We planned to interview as many women as possible who met the inclusion criteria during the study period as we envisaged that it may be challenging to find women who were aware of overdiagnosis and overtreatment and willing to discuss their experience. One participant requested and received her transcript for review to ensure that she was not recognisable. All clinical data were self-reported.

The interviewer.

The interviewer (KP) has a doctoral degree in public health and was working as a postdoctoral research fellow at the time of the interviews. KP has undertaken formal training in qualitative research methods. She had no immediate personal or professional experience with breast cancer or breast screening and no strong beliefs about the topic of the interviews.

Data analysis.

Audio recordings were transcribed verbatim by a professional transcribing service. Each in-depth interview was analysed using key components of a grounded theory analysis, namely, an iterative thematic approach and constant comparative method[14]. The data were collected and analysed concurrently. KP used the 'comments' function in Microsoft Word to make detailed notes throughout each transcript and identified points of interest to explore in future interviews.

Two researchers (KP & AB) read the first 4 transcripts to familiarise themselves with the data. This enabled KP, who does not have medical qualifications, to discuss the transcripts

with AB who is a registered medical practitioner and epidemiologist, to ensure understanding of the women's diagnoses and treatment descriptions and concepts of overdiagnosis and overtreatment for thematic analysis. Following a second reading, initial codes were developed by KP based on transcripts and notes (e.g. 'conflicting identities', 'incomplete understanding') and discussed with a third researcher, JH, who read two transcripts and generated independent codes which were cross-checked with KP's initial codes. These were then grouped into higher order organising themes. JH read an additional two transcripts and reviewed the preliminary themes to ensure accuracy of interpretation and added further interpretation and insights. The analysis constantly moved from specific codes and themes to the more general, with the aim of generating a comprehensive explanation of our findings across participants and the settings in which we conducted the study.

JSV, a surgeon and oncologist specialising in breast cancer, also read all transcripts to confirm that the analysis adequately conveyed correct and appropriate interpretation of clinical data. Discussion with the broader research team occurred regularly throughout the data analysis, interpretation, and manuscript drafting process. Quotes that best illustrated the developing themes were extracted into tables alongside the themes; a selection of these quotes are included in the Results section. Four case studies are presented in the Supplementary file (Supplementary 4) which were selected to represent a range of diagnoses, decision making, and experiences among the sample. Written consent was obtained from the relevant parties for the publication of the case studies.

Patient and public involvement.

The study was initiated by AB in response to a patient's personal experience of screen-detected breast cancer in 2012 and expressed concern about the possibility of

overdiagnosis. This patient (from the UK) and two other women (1 from the UK and 1 from the US) with lived experience of screen-detected breast cancer were invited to join our study as consumer advisors from the inception of the study. All accepted and two also met the study eligibility criteria and were interviewed as research participants. Our consumer advisors reviewed all study materials, assisted recruitment by hosting a study advertisement on their blogs, and reviewed the draft manuscript. It is notable that all participants were given the opportunity to read and comment on the manuscript and their case study (if relevant) prior to publication, resulting in two minor amendments.

RESULTS

Participant characteristics.

22 women expressed interest in participating in an interview; of these, 10 did not complete an interview: 6 were deemed ineligible because they had a strong family history of breast cancer (n=1) or their cancer was not screen-detected (n=5). We were not able to make follow up contact with 3 women who expressed interest, and one potential participant was unavailable to interview during study recruitment phase.

12 women were interviewed. The interviews ranged in duration from 50 to 123 minutes (mean 73 minutes).

Table 1 reports demographic and some clinical characteristics of the participants. Participants were located in four countries where breast screening is well established: United Kingdom (6), United States (4), Canada (1) and Australia (1). Most had a university degree (11/12), and they ranged in age from 48 to 77 years. Age at diagnosis was between 44 and 74 years (mean age 58 years), and their diagnoses occurred between

2004 and 2019. 11 out of 12 women were diagnosed as a result of participating in mammography screening, and one participant was diagnosed with DCIS as an incidental finding on routine histopathological examination of breast tissue following breast reduction surgery. The primary diagnosis was Ductal Carcinoma in Situ (DCIS) in 10 of the 12 women and invasive breast cancer in 2 women. They had undergone a range of treatments (Table 1); 2 women did not have any form of surgery. Almost all of the women interviewed had found out about breast cancer overdiagnosis as a result of personal research following their diagnosis and 2 women found out about it after they had received treatment.

Table 1. Characteristics of the study participants (n=12)

Participant ID and Year of diagnosis	Diagnosis	Sought a second opinion (or more)	Management received*	When (and how) did you become aware of the concept of overdiagnosis?
P1 2015	DCIS	Yes	Lumpectomy Endocrine (hormone) therapy Currently on tamoxifen	Unsure about timing in relation to diagnosis (personal research, media, the internet)
P2 2016	DCIS	No	Lumpectomy Physiotherapy for lymphatic cording Gene profile test	After receiving treatment (personal research, the internet)
P3 2019	DCIS	Yes	Only diet and lifestyle changes	After diagnosis (personal research)
P4 2018/19	DCIS	Yes	Lumpectomy	After diagnosis (medical professional, personal research, the internet)
P5 2013	Breast cancer	Yes	Mastectomy Endocrine (hormone) therapy	After diagnosis (personal research, the internet)
P6 2010	DCIS	Yes	Lumpectomy Gene profile test	After diagnosis (personal research, the internet)
P7 2019	DCIS	Yes	Active monitoring (personal choice)	After diagnosis (personal research, media, family/friend /colleague, the internet)
P8 2016	Breast cancer	Yes	Lumpectomy Radiotherapy (TARGIT-IORT)[+] Endocrine (hormone) therapy Gene profile test Chemotherapy Currently on tamoxifen	After diagnosis (medical professional, personal research, conference lecture)
P9 2012	Breast cancer	Yes	Lumpectomy Radiotherapy (TARGIT-IORT)[+]	Before screening (personal research, media, family/friend /colleague)
P10 2019	DCIS	Yes	Lumpectomy	After diagnosis (breast, ovarian cancer education centre)
P11 2004	Initially DCIS; invasive cancer found after initial lumpectomy	Yes	Lumpectomy Mastectomy	After receiving treatment (personal research)
P12 2013	DCIS; Invasive cancer after 3 years of no treatment	Yes	Active monitoring for 3 years. Then mastectomy. Then radiation and chemotherapy (to treat metastatic disease)[#]	After diagnosis (personal research, family/friends, internet, medical journals)

*Self-reported. Gene profile test (e.g. MammaPrint, Oncotype DX)

[+] TARGIT-IORT – targeted intraoperative radiotherapy during lumpectomy (no further post-operative radiotherapy)
[#]Participant deceased

Overview of findings.

The women described diverse personal experiences relating to their diagnosis and decision-making processes, but there were also many commonalities in their stories particularly around identity, interactions with medical professionals, uncertainty about decisions made, and responses from others regarding their preferred pathway. Five main themes were identified across the interviews: (1) Discovering overdiagnosis; (2) Am I a cancer patient or not?; (3) Resisting overtreatment; (4) Living with the unknown; and (5) Downstream effects on quality of life. All participants explained how they felt the 'standard' approach to treatment offered by their initial teams was inflexible and the pressure that they encountered to act in the recommended and expected way.

When the women were asked to reflect on their experience of learning about overdiagnosis and overtreatment and applying that knowledge to their personal situation, most of the participants recognised that something about their personal circumstances enabled them to question their diagnosis and recommended management, and in some cases, to be able to avoid overtreatment. For example, a number of the women were employed in a profession that required them to ask questions, had relevant personal or professional networks and connections, private health insurance, or described themselves as being of a particular personality type (i.e. not a shy person, *'stroppy', 'more likely to challenge the opinion of a doctor than the vast majority of patients'* (Participant 8)) which enabled them to ask questions, find answers, and ultimately change the way that they would have been treated.

Discovering overdiagnosis

10 of the 12 women became aware of overdiagnosis after their diagnosis, including 2 who found out after they had received treatment. One was aware of it before screening mammogram, and one was unsure when she found out. Several participants elaborated, saying that while they had heard about the possibility that mammograms can detect non-lethal cancers, they developed a '*much better understanding*' (Participant 1) when undertaking personal research following their diagnosis. Most of the women's accounts indicated that they began their own research because they felt that they received different and often conflicting medical opinions and confusing information regarding their diagnosis. Many felt that the information that they obtained from their initial clinical teams was not sufficient for their personal needs and so this prompted them to proceed with further exploration and research independently. One participant described how,

> '*from the beginning… it just didn't feel right, something felt off…it's not right how they're communicating about it…if I ask any questions it didn't feel right…There was something that led me to continue…asking questions, researching'* (Participant 6).

Some were simply curious or uncertain about their diagnosis from the outset (many had not even heard of DCIS) and were motivated to further their knowledge before agreeing to the recommended treatment. One woman said,

> *'For a lot of women who get a diagnosis of breast cancer, to them it's a no-brainer. Treat it, you know? Let's get rid of it and then, then we're ok. But… my…mental world wasn't… composed in that way'* (Participant 5).

Several women named specific books, articles, and clinicians that they encountered in their search for more information, that had led them to research overdiagnosis in-depth and said that these had been valuable sources of information on overdiagnosis. Finding

out that there are different types of cancer was described as an '*eye opener'* (Participant 12) and motivation to not have the recommended surgery immediately. For some, this process of getting informed became a full-time job, on which they and often their partners put in *'a lot of work'* (Participant 1). Participant 3 initially undertook *'typical googling'* and found the same things the doctor had told her, but

> *'It just didn't feel right. Then, it just kind of snowballed…the more I read the more controversy I found…like finding the idea of overdiagnosis'* (Participant 3).

The women's responses to finding out about overdiagnosis and overtreatment varied, on a spectrum from feeling *'overjoyed'* to *'tortured'.* Finding out, for some – this was where they instantly identified, they felt seen, and it was a relief,

> *'It totally defined what I felt. It totally was validation and recognition…it was instant identification… I was overjoyed that this was being discussed in any way, because that's what I identified with'* (Participant 6).

One participant felt 'relieved' because it confirmed that her preference to not have a mastectomy was not necessarily an overreaction. Women at this end of the spectrum reported that finding out eased some of the uncertainty they were experiencing, validated why they were feeling as they were, asking the questions they were, and verified that they were not the crazy angry irrational women that some had indicated that they were. Participant 7 felt that she had been 'thrown a life raft' when she discovered a blog where people were discussing overdiagnosis.

Yet a number of the women just felt shocked and sad upon learning about overdiagnosis after their diagnosis and/or treatment, realising that they may have endured what they had perhaps unnecessarily:

'I thought, shock. Shock. What? You know? So you mean that I've been told I've got breast cancer and yet I might not have it?.... from that point onwards (finding out about overdiagnosis) then really, I was actually tortured, I'd say, by the idea that I had been caught, unnecessarily by the screening program' (Participant 5).

Several of the women in the cohort we studied expressed deep anger upon finding out that they had not been informed about the possibility of overdiagnosis and overtreatment prior to breast screening. One participant only completely grasped the concept of overdiagnosis and what it possibly meant for her personal circumstances three years after her diagnosis and described finding out, and identifying with it, as one of the most painful experiences of her life.

'I had still thought that in my case because invasive cancer had been found that my life had been saved. It took a long time to come to understand that a lot of the papers written about overdiagnosis some were only talking about invasive cancer they didn't even include DCIS in their estimates of overdiagnosis. Then I realised that even some invasive cancer is known not to progress' (Participant 11).

Two of the 6 UK participants had been invited to screening prior to information about overdiagnosis being included in screening leaflets that go with invitations to UK women for the NHS breast screen program; for them the realisation of overdiagnosis was particularly painful, as they were months short of receiving updated patient information which cited overdiagnosis as a possible harm of mammography.

'That was particularly painful...I just felt I'd been caught on the edge really of a change in policy and that actually the screening service...sent me a leaflet that they knew was not fit for purpose...so that made me extra angry' (Participant 5)

Am I a cancer patient or not?

Most of the women's reports suggested that they soon became aware - once they began asking questions and learning more about their diagnosis, overdiagnosis, and overtreatment - that their circumstances and experience of breast cancer were unusual. Several interconnected issues of identity were apparent in the women's accounts of their experience. Firstly, several women described the challenges their diagnosis posed to their sense of self because they felt well and were without symptoms prior to attending screening. Some were surprised at how quickly they were treated as a cancer patient following their diagnosis.

> *'...And then she told me all the appointments I would need to make. And you just go right into this fast forward...you're a cancer patient now. And you're treated just like a cancer patient'* (Participant 6).

Secondly, some of the women expressed feeling unsure regarding how to classify themselves following their diagnosis,

> '*I had to come to grips with was I a cancer patient or wasn't I a cancer patient?'* *(*Participant 2*)*

which in some cases was only exacerbated by disagreement amongst treating teams on whether their case was considered cancer or not (when the diagnosis was DCIS).

> *'I was getting more and more confused...I had one professional telling me it wasn't cancer...and another telling me, yes, it is cancer'* (Participant 4).

Many said that they had difficulty adjusting to being a 'good compliant patient' (Participant 2) and were dismayed at the expectation to fulfil this identity, especially

those women who at the time were questioning whether the recommended treatment constituted overtreatment.

Lastly, several women who found out about overdiagnosis after diagnosis or treatment, identified entirely with the possibility that they may have been overdiagnosed, and not with being a cancer patient or survivor. These participants reported feeling conflicted over whether they were a cancer patient or not, and struggled against the cancer patient identity, yet were unable to escape or deny having been significantly impacted by a cancer diagnosis. This remained the case even over time, with two of the participants instead identifying themselves as victims of the medical system.

> *'Let's not call this disease. I'm not, I don't feel diseased… I don't identify with disease or illness or cancer… survivor, any of those terms. They're just like… it's almost insulting, especially when you feel like you're a victim of overdiagnosis. Then you're, that's a double whammy. Because now you're a victim in a sense from the medical system…this problem is a medically made problem'* (Participant 6).

Another talked about not being able to relate to the generic image of cancer,

> *'It didn't match my experience…the kind of metaphor was this thing invading your whole life and taking you over…I'm sure that's how it is for many people who have cancer…I never really felt the cancer was the enemy…I felt the whole medical merry-go-round was, was my enemy'* (Participant 5).

They felt that they could not engage with breast cancer support groups because they did not identify as a cancer patient,

> *'You just hear about everyone's mastectomies and the radiation treatments and … I just felt I could never go back because I didn't identify with that'* (Participant 6)

'I didn't want to do any of that because I didn't want to identify as a cancer patient ... their sympathetic nice caring responses to me would not have aligned to what I needed...I didn't want to go to those kind of meetings and then...not say how I felt' (Participant 5).

Resisting perceived overtreatment

All of the women described their disbelief upon learning about the recommended treatment pathway after being told they had a screen-detected (or incidentally-detected, in one case) breast cancer. They perceived the scale of the surgery recommended as disproportionate to their understanding of the diagnosis they had been given which 'might never progress' (Participant 11), especially when they were not experiencing any symptoms.

'*In my head, I'm going, what is stage zero? Why would I need treatment for that?*' (Participant 2)

One participant, diagnosed with DCIS, commented that she did not at the time consider herself to have 'real cancer' so it was 'absolutely ridiculous' that a mastectomy was being recommended (Participant 6). Another said she had found it '*completely ridiculous to have a mastectomy for something you don't have yet. And you may never have. I mean...that will not kill you (DCIS) (*Participant 1).

'They were telling me I needed surgery for something that might never progress...I was put into that dilemma...The surgery proposed at that time was a quadrantectomy, which seemed to me like a big deal, mutilating surgery for something that might never progress so I said no' (Participant 11).

Two of the women (P2 and P12) believed that having biopsies or surgery can stimulate the spread of cancer.

Most participants had encountered criticism in response to their curiosity and requests for more information to enable an informed decision about their management plan. They described the 'uncomfortable' exchanges (Participant 5) that they felt took place when they asked their clinicians questions about their diagnosis or overdiagnosis or challenged the advised treatment pathways. They also described a rising sense that they were taking their life in their own hands (Participant 6), with doctors acting *'totally uncomfortable with the fact that I was now choosing to do, in her words, nothing'* (Participant 3). One participant - who had studied biochemistry - said she was asking informed and intelligent questions of her doctors and radiologist but felt she was not getting any answers, as *'they didn't like me asking'* (Participant 12).

> *'I said to my husband, I don't think I'm having that surgery. And my husband's initial thing was like, I don't know what you're getting into your head. You can't just read stuff on the internet and think that you're better than the doctor. The doctors know best'* (Participant 3)

The women talked about the pressure that they encountered to act in the specified, recommended way, including from partners, friends, and family members. Some women reported requests for a more conservative treatment approach were not readily accepted by medical practitioners: one woman described being told *'you're making a very bad decision'* when she opted not to have a mastectomy (Participant 8), another felt she was treated like she was doing something dangerous (Participant 3) or suicidal (Participant 10). As a consequence, some women sought a second opinion, and in some cases reported being pleased to find an alternative approach, with a doctor who they felt was more open

to discussing different options and willing to consider evidence on overdiagnosis or more conservative care.

Our participants described situations where they felt they were laughed at, treated like *'a mad woman'* (Participant 12), *'negligent…foolhardy and arrogant'* (Participant 1). One participant reported being told she had '*anger management issues'* by people on breast cancer internet forums, who felt that it was best '*to just trust my surgeon, not Google'* (Participant 5).

> *'At first everyone treated me like a difficult woman because I said I don't want a mastectomy, I want monitoring please and let's keep an eye on it and see if it develops or not because I was aware of overdiagnosis and didn't want a mastectomy if it wasn't absolutely necessary'* (Participant 12)
>
> *'The clinician…was absolutely incensed that I had decided not to have a mastectomy…she says…what kind of nonsense have you been reading? What are you doing?' (*Participant 1)

Several participants encountered similar responses when they turned to online forums and breast cancer support groups after finding themselves unable to get the conversations that they wanted with medical professionals. However rather than finding support, they reported feeling misunderstood and isolated when they voiced their concerns about overdiagnosis and overtreatment.

> *'It seemed like they were all doing the very aggressive treatments and…they were also kind of bullying me. And making me feel bad and saying, I wouldn't leave it. That's, you know, crazy. Like, I wouldn't wait till… I want to live for my kids and …all*

that kind of mentality. And I just thought, I'm looking for a support group and I'm not finding any support' (Participant 6).

It was clear that most of the women had at some point felt lonely and isolated as a result of questioning their diagnosis and treatment, and in their efforts to inform other women about the possibility of overdiagnosis and overtreatment,

'It's something you can't really talk about because so many women don't understand. You're saying something terrible and they get quite upset. It's also quite isolating in that I can't mention it to women of my age because they all think it [screening]'s a good thing to do. Far be it for me to rock the boat. I've received too many brickbats and insults. I was only trying to help' (Participant 11).

Living with the unknown.

It was apparent across the interviews that a number of the women were managing feelings of self-blame and regret many years after receiving their diagnosis and/or treatment because of their knowledge of overdiagnosis and overtreatment. Some of the participants expressed regret for not being more aware or paying more attention at that time,

'And yet I'd been started on this journey without my... knowledge, without my consent, without my understanding...I signed some kind of consent to have the screening performed...I kick myself for not taking enough notice of that. So I gave my consent but it wasn't informed consent. I was cross with myself for not being better informed...I just feel a bit like I was hoodwinked and...a bit of it was my own fault, for not paying better attention' (Participant 5).

They expressed regret for decisions previously made such as going for a mammogram in the first place.

> *'I've got no regrets about my reaction I just wish that I hadn't been to the screening in the first place. If I hadn't gone for that wretched screening… … I might have got three more really good years of life not worrying about anything. In fact, once I had been to the biopsy I lived with the fear of cancer coming'* (Participant 12).

A few participants did however consider mammography beneficial; for instance, Participant 8 commented that she considered her life to have been saved through a routine mammogram, but at the same time felt very strongly that she had managed to avoid overtreatment and make informed management choices.

All women mentioned some step of their diagnostic and treatment pathway where they felt that they did not provide informed consent; some said that they realised in hindsight that they may have been frightened into making some decisions that they were not ready to make. Some women believed that they had been denied crucial information to enable informed consent.

> *'One of the things that so hurts is that…(they) gave me half the information. But they knew, they knew all about the controversy and the lack of information and they still wanted more than anything to process me, not to help me'* (Participant 11).

Throughout the interviews, the women's reflections on their experiences highlighted the exhausting and lonely nature of the work involved to justify why they had chosen the choices and actions taken. Some said despite having had the recommended surgery, nothing had convinced them that they actually needed it in the first place. Several others

reported that they felt confident they had made the right management decisions in choosing not to have a mastectomy, for example,

> *'I think I made…absolutely the right decision…it was frightening, 'cause when people…who did talk to me about DCIS talked about it, they talked about it as inevitable advancing to aggressive cancer…but I think we (my partner and I) made the best decision we could make. I think if I had gone along with the mastectomy and the reconstruction..I think I'd be very, very angry now…because I'm fine'* (Participant 1).

However, many said they will forever be wondering if they made the right decision – *'am I the needle in the haystack?'* (Participant 11), *'have I done the right thing…would it have been better to…have a mastectomy and move on with life and not keep thinking about it?'* (Participant 4) – even after years spent 'digesting' (Participant 11) the possibility of overdiagnosis. Some described the trauma and anger that they had experienced over the years,

> *'I was beside myself with rage for several years and eventually that burns down and you just become sick of the whole thing, which now I am'* (Participant 11).

With the current state of knowledge, these women can never know if their decision was the right or best one, which is the nature of overdiagnosis.

> *'And I'm sure that she thinks that I'm alive and well today because they caught it early. Whereas, I still don't know that. I think I might be alive and well today with no further, repercussions at the moment at least, because I wasn't really ill in the first place… I'm contributing to a misleading statistic and that I've reached the 5-year survival point, so everybody can cheer and that knocks that up to a success. But it's*

not really a success if I was fine anyway and I was still going to be well at this point, and the NHS spent several thousand pounds curing me of something that could have been left well alone' (Participant 5).

Downstream effects on quality of life

A number of the women were living with physical reminders of their experience, such as *'really painful'* (Participant 4) pain in their breasts, disfigurement, scarring, exacerbated anxiety, lymphatic cording, or the side effects of medications and early '*super charged menopause'* (Participant 8) and the prolonged impacts of that on their quality of life. Some mentioned the stress and financial burden of bills and medical appointments, without knowing if the cancer needed to be found in the first place.

'(mastectomy) affects things, affects my choices about what I wear and mastectomy bras are uncomfortable, and the whole experience has affected my travel insurance costs…it does have an impact, even after all this time…I had a bad time emotionally' (Participant 5).

Suggestions for other women

All participants were asked, when reflecting on their personal experience, for advice on how to improve the experience for other women considering breast screening. Their suggestions are summarised in Supplementary file 3. Responses focused on individual level factors such as clinician responsibility to elicit and prioritise patient preferences, health system factors including creating opportunity for proper discussion about the benefits and harms of screening prior to attending a screening appointment, and society level factors like influencing a societal shift in thinking about and labelling cancer.

DISCUSSION

Principal findings

This unique international study documents the experience of a highly selected group of women diagnosed with DCIS or invasive breast cancer. These women have all considered the possibility that they may have experienced breast cancer overdiagnosis. Some felt that they had experienced overtreatment and others had taken steps to avoid overtreatment. Our study shows how learning about overdiagnosis after a breast cancer diagnosis profoundly impacted these women's sense of self, interactions with medical professionals, and for some, deep remorse about past decisions and actions. Many were uncomfortable with being treated as a cancer patient when they did not feel 'diseased' and being recommended treatments that seemed excessive in comparison to the diagnosis given. Some felt anger that critical information was not easily forthcoming and feeling they had not been given a complete picture of overdiagnosis before having screening mammography; and some were frustrated about how difficult it was to connect with medical professionals and others in their social network about overdiagnosis and overtreatment being a possibility. The findings highlight the loneliness of this experience, with little support or reassurance available to the women interviewed in this study. By describing the experience of women who independently self-identify as having a potentially overdiagnosed cancer, this study – which exemplifies the psychosocial harms of learning about overdiagnosis after a breast cancer diagnosis - makes an important contribution to the literature and to clinical practice. The sample also included several women who were more concerned by their recommended treatment which they perceived as overtreatment, rather than whether their cancer was 'overdiagnosed.'

Strengths and limitations

A strength of this study was the use of qualitative interviews that allowed for (a) in-depth exploration of this unique experience of cancer at an individual patient level and (b) unanticipated findings to arise, with opportunity to explore such experiences in detail. The study recruited across 4 countries with established breast cancer screening programmes and involved a 3-member consumer advisory panel with lived experience of breast cancer. This study is novel – other studies including our own have sought to explore how to inform women about overdiagnosis[15 16], whereas our aim was to hear and document the experience of individuals who wondered themselves whether they may have been overdiagnosed and/or overtreated, and possibly realised they are unlikely to ever know for sure as it is practically impossible to identify individuals who have been 'overdiagnosed'. The diversity of our sample allowed us to illustrate a range of possibilities in terms of the impact of discovering overdiagnosis: (1) distress upon finding out and questioning whether a diagnosis and treatment was potentially unnecessary; (2) being protected by this knowledge by taking steps to avoid overtreatment; and (3) potentially damaging, if it encourages patients to decline treatment for potentially curable cancer. Another strength is that we verified women's understanding of overdiagnosis and overtreatment as part of the study eligibility process by asking them what they understood by the terms. Their responses are reported in the Supplementary material (Supplementary 1).

The number of participants is small and the study comprised of a highly selected and unusual sample. They were health literate and highly educated. This was inevitable, given our aim was to explore a specific experience, that of being aware of overdiagnosis and

considering it in relation to one's own experience of cancer diagnosis and treatment. Few women in the community are aware of and understand overdiagnosis[17] and even those who do understand it are unlikely to have experienced it given that most screening mammograms are normal, reflecting that screening is an intervention for asymptomatic women. The experiences of the women documented in this study are therefore likely not shared by the majority of women in a similar position but are valid for those who identify with this experience. As this was a small sample, we cannot state that thematic saturation was achieved. Our study was conceived and led by researchers interested in improving understanding about overdiagnosis and to explore ways to deal with it. To minimise bias, the initial analysis was led and undertaken by a researcher with no previous involvement in breast cancer research. All the data reported were based on the women's survey responses and/or their words during the interviews. It should be noted that diagnoses and treatments reported have not been verified, and they reflect the participants' perceptions. While some treatments may have been perceived by them as overtreatment, our findings should not be taken to suggest that the treatment offered was incorrect or poor quality, as treatment recommendations may be made for many reasons not all of which may be apparent.

Strengths and limitations in relation to other studies

We know from a substantial body of epidemiological evidence that large numbers of women could be harmed by overdiagnosis at a population level, but this is the first study to our knowledge to document how women are personally impacted by the possibility that their screen-detected diagnosis may represent overdiagnosis and/or overtreatment. The women's accounts show the significant negative psychosocial impact of awareness of overdiagnosis in the context of screen-detected breast cancer, particularly when not

forewarned of the risk. The findings are relevant to all women who are considering or are participating in breast screening programs, their clinicians, and policymakers.

A previous study suggested that some women do not consider overdiagnosis information to be an issue for screening participation[15]. However, this study shows the substantial negative impact of finding out about overdiagnosis after a diagnosis of breast cancer at least in some women. Randomised controlled trial data has shown that women can be safely informed about overdiagnosis before screening: educating women about overdiagnosis prior to screening improved understanding, reduced worry about breast cancer, and did not increase anxiety or reduce willingness to participate in breast screening[18]. This is consistent with other evidence showing that women value breast cancer screening and intend to participate in screening even when aware of the risk of overdiagnosis[19]. A systematic review on women's values and preferences around breast cancer screening showed that women are willing to tolerate the potential harms of screening for an early diagnosis, but highlighted concern that women may not understand the concept of overdiagnosis[20]. Even in our highly educated, health literate sample of women, most (10/12) women found out about overdiagnosis after diagnosis (rather than before screening).

Research in the context of screening for cancer and in other settings [11 21 22]has shown it is challenging to communicate about overdiagnosis. Overcoming this challenge will be essential however, as screening policy evolves in the light of emerging evidence and new risk assessment tools. A good understanding of the potential benefits and harms of screening will be key to successful implementation of these developments, including risk targeted screening with deintensification of screening for those at low risk [23 24].

Unanswered questions and future research

One theme identified was the difficulty of living with uncertainty about the possibility of overdiagnosis or overtreatment. It is not possible to identify whether any individual has been overdiagnosed or not, and as such it remains unknown whether the women in this study made the best decisions for their health or not. With time, it is likely that these issues will become salient to more women as the community becomes more familiar with the potential for overdiagnosis in breast cancer screening. Future biological research may be able to determine more accurately the prognosis of screen-detected breast cancer[25 26]. Until then we recommend consideration be given to how to better inform women about the possibility of overdiagnosis before they undergo screening mammography to avoid the distress caused to women who are diagnosed and discover it later. Clinical and community support, for example provided by clinical nurse specialists, should also be available to the minority of women who identify with the possibility of having been overdiagnosed and possibly overtreated to cope with the uncertainty about their treatment choices and their prognosis as described by the women in this study.

The findings of this study could be tested in a larger representative sample; a randomised controlled trial could ascertain if there are women who suffer harm from undertreatment when informed about overdiagnosis. Future research could also repeat and improve this research in other jurisdictions and cultures with larger samples of women where breast cancer screening is offered. Investigating clinician-related barriers to effective communication may also be worthy of further investigation to inform communication training programs. It is important to consider how best to inform people about the risk of overdiagnosis when establishing screening programs. Such opportunities may exist in relation to lung cancer screening, which will likely be implemented in many countries

following recent trials and recommendations[27-30]. Additional implications for clinicians and policymakers are summarised in Box 1.

Box 1
Summary of implications for clinicians and policymakers
(Derived from this study in addition to suggestions from previous research where indicated)

- In the spirit of transparency, women should be given opportunity to be informed about the possibility of overdiagnosis and overtreatment prior to screening (and therefore diagnosis). Such an opportunity might avoid the negative psychosocial impact experienced by some of our study participants. An evidence-based information resource presented alongside breast screening invitations has been recommended by three European independent inquiries into breast cancer screening[2 31 32], yet has only been implemented at scale in the United Kingdom.
- Consistent terminology and minimum standards to describe overdiagnosis and overtreatment as a potential downside of cancer screening[33] should be prioritised in information resources. Information about overdiagnosis and overtreatment must be prominent during consent.
- Better support, training, and resources for clinicians to communicate about overdiagnosis and overtreatment during their consultations is warranted. Clinicians must be aware of their own preferences and how that influences the care and advice that they provide[34]. Specialists who consult women who have a screen-detected breast cancer should inform them of the risks and benefits of all management options available and be prepared to engage in evidence-based conversations about overdiagnosis and overtreatment. However, our study has shown that there were psychosocial harms, including anxiety, of the diagnosis itself, in addition to the harms of perceived overtreatment.
- Strategies for reducing the harms of screen-detected DCIS have been suggested[25 26] and may also have application in the context of mitigating the harms of overdiagnosis of screen-detected breast cancer, whether DCIS or invasive.
- Where appropriate, clinicians should consider participation in trials of active surveillance, de-escalated treatment of low-risk DCIS [35], newer less harmful treatments such as TARGIT-IORT[36-38], and using lumpectomy for invasive breast cancer.

CONCLUSION

These findings provide rare insight into the experience of a select group of women who found out about overdiagnosis after being given a diagnosis of breast cancer. While this

cohort may represent a small proportion of all patients diagnosed with breast cancer, it is important that policy makers and clinicians improve current practice by considering these findings and suggestions made by our study participants. There is a need to adequately inform women considering breast screening of the risks of overdiagnosis and overtreatment.

Competing interest statement

All authors have completed the ICMJE uniform disclosure form at http://www.icmje.org/disclosure-of-interest/ and declare: AB, KM, JH, BN, KP had financial support from the National Health & Medical Research Council, Australia for the submitted work. JSV reports a grant from the Health Technology Assessment Programme of National Institute of Health Research, UK during the conduct of the study. JSV received payment from Carl Zeiss for travel to meetings and honoraria outside the submitted work. AB is a member and Co-Chair of the Scientific Committee for the Preventing Overdiagnosis International Conferences. KP, BN, and JH are members of the early career researcher committee for the Preventing Overdiagnosis International Conferences.

Transparency declaration

The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned (and, if relevant, registered) have been explained.

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Contributorship

AB conceived the study. AB, JH, BN, KM, KP were involved in designing the study and developing the methods. AB and KM obtained funding. AB and KP coordinated the running of the study; KP conducted the interviews. JSV reviewed the study materials and assisted with recruitment. KP and JH developed the analytical framework and performed the analysis. AB, KP, JH, and JSV read transcripts and contributed to the interpretation. KP drafted the manuscript. All authors had significant intellectual contribution to the manuscript and critically revised the manuscript. KP, JH, and AB are guarantors.

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Data sharing

No additional data available

Licence statement

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Supplementary 1. Participant descriptions of overdiagnosis and overtreatment

Participant	Description of overdiagnosis	Description of overtreatment
P1	The diagnosis of a condition that would not cause the person problems if left undetected	Treating a condition more aggressively than is required to manage the condition taking account of the side effects of the treatment(s) on health and quality of life
P2	Diagnosing as disease needing treatment a situation in which no action is the preferred treatment since health and mortality are not affected and in which treatment itself causes harm to the patient	When LESS or NO treatment achieves the same or a more desirable outcome and especially when treatment does not decrease mortality
P3	Identifying or treating things that will likely never become a problem in one's lifetime	Providing intervention for something that likely will never cause problems in a lifetime
P4	As technology has improved, mammograms are now picking up calcium deposit in the breast that may not have previously been detected, with current guidelines and pathology results from biopsies, even at low grade cancer, in the UK the recommendation will be lumpectomy, breast conserving surgery or in my case as I have multifocal DCIS, a mastectomy. Some clinicians consider that such procedures may well represent overdiagnosis/overtreatment	Not only is overtreatment the actual surgery, but also the follow on radiotherapy. It is currently unclear what the outcomes are if surgery is not elected and how this compares to those who elect treatment, as more comparative studies are required to help establish if this is overtreatment or not, for cancers of low grade which are "contained"
P5	The diagnosis of a condition that might not lead to harm within one's natural lifespan	Being treated for a condition - possibly unnecessarily - because it's not possible to know if the condition would progress or not if left untreated
P6	Cancerous cells found on screening that will not cause symptoms or death. This leads to and harms including physical, emotional and financial	Treatment that brings harms but offers no survival benefit or improvement in quality of life
P7	There are studies that show that more detection has not resulted in a decrease in malignant breast cancers, therefore early detection is likely causing	Overtreatment is treating cancers that may never (or so slowly) have developed into anything that affected mortality. For example studies show that mortality is not

	overtreatment to a number of women whose cancer would never have become malignant	any better for those DCIS patients receiving standard of care treatment versus those not receiving this treatment
P8	Routine mammograms often pick up small cysts or tumours which left alone our immune systems would probably get rid of. Overdetection means a lot of women are undergoing unnecessary surgical interventions and treatments	Putting women through unnecessary surgical interventions, external beam radiotherapy, adjacent chemotherapy for very small tumours that the body could probably deal with on its own. I think it's a case of doctors being overcautious, playing safe and not weighing up the side effects of these treatments which can be life changing for a lot of women
P9	Overdiagnosis is giving the patient treatment beyond immediate needs: i.e. assuming the worst case scenario when in fact a discovered tumour may not progress or require anything other than monitoring	Overtreatment, in my case, would have been to allow the locum breast surgeon who first saw me to do what he said I so should have ie: a double mastectomy asap.
P10	Overdetection is, for example, when a mammogram picks up something that frequently is not a problem, but because it is identified and treated as cancer becomes a problem for the woman. She may have been better off not knowing about it. Sometimes, because of various factors, the solution is worse than the perceived problem.	When the treatment does more damage than the problem itself would have caused
P11	The detection of cancerous changes which would not develop into illness before death from other causes if left alone	Treatment of findings that would not have presented with symptoms or caused illness if not treated, or which does not lengthen life or improve quality over leaving treatment till symptoms develop
P12	Overdiagnosis means the detection, usually leading to overtreatment, of a condition, which if left undetected, would not have caused a problem in the person's lifetime	Unnecessary treatment of a condition, sometimes identified through overdiagnosis. The treatment may do harm (iatrogenic) and is wasteful of resources

Supplementary 2. Interview topic guide

Screening and diagnosis

So if we could start from the beginning for you, can you take me through how you came to be diagnosed with DCIS/breast cancer?

- How was the diagnosis described to you by your clinician(s)?
- If you can recall, could you describe your immediate thoughts and feelings in response to the diagnosis at the time?
- How do you feel about the diagnosis now?

Possibility of overdiagnosis

What is your understanding of 'overdiagnosis'? (*re-cap from survey*)

- How did you come to be aware of overdiagnosis?
- How did you feel when you first found out about overdiagnosis?
- What impact has that awareness of overdiagnosis had on you?
- Why have you thought about overdiagnosis in relation to your cancer?
- How does/did this make you feel? What have been the main effects of that possibility for you?

Treatment

- Did you resist or refuse any particular treatments?
    - Could you explain why you resisted/refused any treatment?
- What have been the main physical, psychological and social effects of treatment for you?
- Do you feel your cancer diagnosis was beneficial in any way?
- Do you think different treatment options could have been possible for you (eg, less aggressive?)

Reflections

- Given your experience, what would you say to other women who are about to undergo breast screening or who are considering whether to do so?

- How do you think information about overdiagnosis should be handled for women in the future?
- Should information on overdiagnosis be made available? – given if/when diagnosed or before?
- Is there anything that could be done better / have made it a better experience for you?

- What are your views about campaigns and advertisements that promote mammogram screening to women?

- Do you have any other comments on detection or diagnosis that you would like to tell us about? Is there anything important that we've missed?

Supplementary 3. Participants' suggestions for supporting women making breast screening decisions in the future

What's needed?	**Advice/recommendation – How to implement it**	**Illustrative quotes**
Individual level		
Prioritise patient preferences	Medical preferences quiz elicited by nurses or clinicians and incorporated into decision making about screening, diagnosis, and treatment	*It would be good if there was some way one could try to ascertain which women would welcome more information and which would not… and one thing I remember saying was that, if someone had looked at my medical history and the choices I had taken earlier in my life, they would have figured out that I was a person who wanted to know and was a little bit skeptical…if there was some way of, doing a quiz with women, or something, about what choices they would make in a parallel situation to kind of gauge, I think that would be really good.* (Participant 5)
Communicate screening harms; don't downplay overdiagnosis	Clinician communication training In surgical consultations, provide information about overdiagnosis and the harms of overdiagnosis including what that looks and feels like (Participant 6) – (e.g. having video testimonies of women, because 'people's risk perceptions are off')	*It's (overdiagnosis) a really difficult concept to get hold of actually…It's not intuitive…it is a difficult concept to explain…one part of me understands why the medical establishment doesn't want to complicate things…but at the same time…I think people should know* (Participant 5) *They downplay overdiagnosis. They don't think it even exists. They say you can't measure it. Like it does, like my story and all the women that feel this way, like---doesn't matter…you feel like you're…somewhat of a victim of our medical system, yet nobody's acknowledging that, except for a handful of people* (Participant 6) *Quite a lot of that could be done through training doctors better, how they communicate* (Participant 8) *I think that it's about managing expectations* (Participant 4)
Flexible care pathways, patient-preference-driven		*The other thing I think is absolutely crucial is that once you get the diagnosis there should not be an unambiguous set of steps that are always followed independent of the patient, what they want, and what matters to them at that time in their lives.* (Participant 1)
Medical profession / health system level		

Acknowledge limitations and uncertainty in current knowledge		*I think it's appropriate for people (medical professionals) to acknowledge what they know and acknowledge what they don't know* (Participant 10) *How do you talk to women that already – the problem for you is how do you say it in a way that doesn't offend all the women that went through all this crap including chemo and then you tell them it's for nothing. They're going to fight you* (Participant 7) *What's needed is a much clearer account of what the mammography screen, well any kind of screening, can and can't do. And also what the chances are that you'll get a really ambiguous outcome… like…a false positive…or DCIS* (Participant 1)
Opportunity for proper discussion before screening		*And I think… maybe it should be flagged up to women… that they can go and discuss screening with their GP before they go for it. That should be made more prominent.* (Participant 5)
Lower the anxiety dial	Build in more time between appointments, possibly with nurses	*If people just knew, something this size, this is probably taken 7 years to develop in you. Why can't we give you 30 days…Just to…make a decision? Why do we think that between finding it and doing something is going to like go poof, which it took 7 years to get to this tiny little spot. I hate that whole idea that we kind of assume, well now that you know, you have to do something. 'Cause otherwise you're being stupid…give them stuff to read …this is not a medical emergency* (Participant 3) *Take more time and not panic…everyone just pause…when you make decisions out of fear it can be life changing and you can't go back… I mean I'd just feel awful if someone didn't find out… that there is a controversy and there is a potential overdiagnosis* (Participant 6) *In other words to say look even if they find a small lump actually to say your body can get rid of these things naturally, you have an element of choice. I think to sort of lower the level of anxiety basically about the disease. ..I think if you lower the dial, it allows women to make more informed choices about their treatment and not go for the just give me everything I want to get rid of this* (Participant 8)

Address external factors that pressure women into screening	Remove/address screening incentives, targets, automatic invitations	*The whole system is set up to disempower you* (Participant 10) *I tried to argue that one should make the invitation more neutral it shouldn't be you've been given an appointment or mammogram at this time, because that means if you don't want to go you have to do something* (Participant 12) *And I think that what they should not do is send you a screening invitation for breast cancer screening with a date and a time and a place on it, because that kind of almost preempts your decision. I think it's wrong because I think it steers women towards having screening without them thinking too much about it.* (Participant 5) *It's very hard when you're trying to go around whatever the system is set up to do* (Participant 6)
Culture / Society level		
A shift in thinking about and labelling cancer		*Our culture is teaching us to get rid of this, get help. You've got this whole cultural thing to deal with …People want that from their Doctors, they want a take away and I think this is one of the reasons why people are perhaps over treated…I've got this, you told me I've got this and now I need something to deal with it. We've got to change a whole way of thinking which is not easy* (Participant 9) *You can see that people hate the idea of having a cancer. Oh my god, get rid of it. I can see that but that's because of the way we think of cancers… If the words around it, the language around it was gentler I think people wouldn't feel oh my god I've got to get rid of it. I think there is a lot of that…The whole cultural history of doing big things when it comes to breast cancer…I think that's something that perhaps lingers in people's minds…it's only really recently that we've been talking about quality of life* (Participant 9)

		I still don't think this is a true cancer as we know cancer…it's a mindset that for me shifted pretty quickly …The nature of DCIS, it's not a tumour, it's not like an invasive cancer. And this isn't really explained to women (Participant 6).

Supplementary 4. Case study 1.

Pam was in her early 50s when she had her second routine screening mammogram. She thought it was the sensible and right thing to do. She was called back for further testing and just thought it was a false alarm so didn't take her husband along with her to the appointment, where she had another mammogram and biopsies. Ten days later she was told that she had invasive ductal carcinoma, cancer that had spread beyond the milk ducts. She asked at the time of the diagnosis, *'do these things ever go away on their own?'* and recalled that her husband, the doctor, and the nurse looked at her *'as if I was nuts'.*

Three days later Pam started Googling to find out more about her diagnosis and *'it felt like an avalanche of information came back about the possibility of overdiagnosis'.* Her husband read some of the research papers with her and confirmed that they were good scientific studies. Pam explained that it was at that point that it became clear to her that she might have been caught unnecessarily by the screening program, and described feeling 'shocked' upon finding out about overdiagnosis.

She continued to research for another month and then went to see a breast cancer surgeon to discuss treatment options; this was an 'uncomfortable' exchange because she challenged the treatment options offered (a lumpectomy and possibly radiotherapy). She asked for a second opinion and saw another surgeon three weeks later, who listened to her concerns but didn't have anything different to offer. *'I did ask her about something like active monitoring, because I knew that was what was offered to men with prostate cancer',* where overdiagnosis is also an issue. She was told that (at the time) 'we just don't do that'. Pam 'reluctantly' agreed to a lumpectomy. In preparation, she had an ultrasound where more cancer was detected in the same breast (of the same low grade, both <1cm) after more biopsies and a mammogram. She was told then that a lumpectomy was no longer an option and a mastectomy was recommended.

By this point Pam was exhausted from weighing up all her options (it had been 2 months since her diagnosis). She agreed to have a mastectomy (but refused breast reconstruction) and had the surgery and a sentinel node biopsy soon afterwards. She made a good physical recovery. The result of the biopsy was clear, so no radiotherapy was needed, but this provided little in the way of reassurance, as it *'did nothing to convince me that I actually needed the surgery in the first place...I was left with that uncertainty...(and even years down the track), I still don't know if I actually ever needed that treatment'.* In the years that followed, Pam blamed herself for not paying better attention to information about overdiagnosis that may have been in the media and questioned her decisions. The treatment was not without consequence or burden; it brought on menopause and osteoporosis which limited her activities, still affects her choices about what she wears, and impacted on her travel insurance costs, in addition to the months of emotional turmoil that she endured from the decision making, surgery, drugs, and ongoing questioning about whether it was all in fact necessary. Pam acknowledged the difficulties for the medical profession to communicate overdiagnosis but, '*at the same time...I think people should know'.*

Supplementary 4. Case study 2.

When Jenny received her first invitation for a screening mammogram she wasn't interested in screening because she had *'heard with cancers that it's not always clear and I don't want to be in that situation'*. She was annoyed that an appointment had been made for her without asking her first, so didn't go. The breast screening service called her to ask why she hadn't gone and to rebook her in. She was cooking dinner at the time and wanted the call to end so agreed to go in, assuming that everything would be fine. She was called back and diagnosed with DCIS and advised that she would need surgery (a quadrantectomy). '*They were telling me I needed surgery for something that might never progress…I was put into that dilemma that I had decided I wanted to avoid'.*

Jenny declined the recommended surgery: *'you're telling me this might never progress you don't know whether it will or not and I'm not having surgery for that'*. She sought a second consultation because she thought that the care team hadn't answered all of her questions. At the next consultation she was told that if she didn't have the surgery she might die, because they were unsure whether she might have some invasive cancer (this was the first time that invasive cancer was mentioned); *'I didn't know what to think or how to digest that information. But it was enough to make me think oh god I might be on the brink of death, I've got two children, I have to do this, have the surgery'.* Jenny had a mastectomy, five 'tiny little cancers' were found, the largest 0.25cm (2.5mm). At the time, she believed that *'they had saved my life as we say'.*

It wasn't until a follow-up appointment 3 years later when she said to her surgeon, '*I know I was reluctant, but I would probably be dead by now'* and her surgeon said, *'probably not'* that she worked out *'that really we're talking on a much longer time scale here for the development of the cancer'.* She was filled with 'rage' that she'd not been told before screening and treatment that some invasive cancers are known not to progress, *'even three years later I had still thought although I'd found out a lot about overdiagnosis by then, I had still thought that in my case because invasive cancer had been found that my life had been saved'.* It *'was a process, a slow process of coming to understand what had happened after the event'.*

On reflection she felt that she had been *'utterly railroaded'* and frightened into having surgery when she wasn't ready and was very upset about not feeling fully informed prior to screening and treatment. *'If I had known then what I know now I would have walked away…They put the wind up me, they frightened me. I didn't have a good understanding of the statistics that were quoted'.* She believed that the screening program leaflet (which did not include information about overdiagnosis) had only told her half of the information that she needed to know, that's what hurt so much. She describes the experience as amongst the most painful experiences of her life and commented that she is 'marked by it forever'. '*They've given me as much (information) as they're giving, and I haven't got a right to anymore. That's what hurts a lot. The fact that they knew. It's like being the last woman in town to find out your husband is having an affair'. 'This was a very traumatic experience for me'.*

Supplementary 4. Case study 3.

Sally was aware that mammograms are not absolutely accurate in terms of what they show and thinks that she knew that mammograms can overdiagnose. Eventually she decided to go and have one, reasoning *'It's only information. You don't actually have to do anything about it'.* Sally was diagnosed with ductal carcinoma in situ. She had not heard of DCIS before but was told *'it's not cancer but you'll probably have a mastectomy'*; which she perceived as a 'ridiculous' recommendation, given that she had been told that she didn't have cancer, and may never have. The breast surgeon told her that DCIS will definitely develop into invasive cancer and could kill her if she didn't have the recommended mastectomy. Sally was '*looking for a conversation'* with her surgeon but left feeling *'utterly patronised…no autonomy…No right to have any decision about anything at all'.*

The surgeon that she went to for a second opinion also only offered mastectomy, but she contacted a breast surgeon that she had come across in the DCIS literature by email and said, *'I really wish I hadn't had that mammogram…do you know anyone…who would be prepared to even have a conversation about treatment that (isn't) so radical?'* Surgeon no.3. also said that he had to advise mastectomy but was willing to compromise with a lumpectomy - which she had (plus another to attend to margins) – and regular monitoring. Sally described the surgeon as *'worried the whole time, that he wasn't giving me the treatment…that he understood to be the gold standard'.* She independently read a lot of research to understand her diagnosis and options. Reflecting on her experience, Sally described it as *'frightening…when the people who did talk to me about DCIS talked about it, they talked about it as inevitably advancing to aggressive cancer. Inevitably'.* And described how *'incredibly difficult'* it was to push back against clinicians, one who asked what 'nonsense' she had been reading because she had decided not to have a mastectomy. The conversations she has with her current surgeon are open and supportive.

Sally felt that if she had gone through with the mastectomy and reconstruction she would be *very, very angry* now, because she's fine. She would have missed out on important career opportunities that have presented in that time, she suspects that she would have stopped working or at least reduced her workload, due to the physical consequences of surgery but also because '*you're turned into someone who can't make any decisions…and it's very hard to imagine how you could simultaneously have that identity and also have an identity of someone who's making decisions all the time in their workplace'. …'I have done the things that I really wanted to do in my professional and my personal life in a way that I would not have been able to do if, in my view, I'd had a mastectomy and reconstruction'.* Sally hoped that in future all women could be given a clearer account of what a screening mammogram can and cannot do, including the likelihood of getting an ambiguous outcome like DCIS, and for treating teams to consider patient preferences. She supposed that there are hundreds or thousands of women in positions like her who have had a mastectomy and moved on with their lives, '*they don't go through the…I created the angst for myself in a way, by finding out about it',* but she was aware of other women in her workplace who had undergone mastectomies and now think that they shouldn't have.

Supplementary 4. Case study 4.

Maureen went for a routine screening mammography, *'I just went and did it as you do and thought it would be fine'.* She was called back for a full assessment which she described as *'the worst morning of my life'.* She felt that none of the treating team showed any care for *'what was going on from my point of view…they just treated me like an object. I didn't feel like a person at all'.* Imaging showed a tumour in the whole lower quadrant of her breast. Maureen was interested to learn more about her diagnosis and its significance so asked some questions but was told *'oh you don't need to know that…so I didn't know what was going on, nobody was going to explain it and I got very patronising answers'.*

At the time of recall, Maureen did not know about overdiagnosis, and believes that she was *'one of the last in the UK to get the old-style invitation…It only gave the pluses of the screening not the negative',* rather than the current information that is included with screening invitations, which is 'more balanced about the harms of screening'. When she didn't receive answers to her questions, she asked, *'what would happen if I just walked away now? and he put his head back and just laughed…and then said, well you would be a fool because you won't know what's wrong with you…No one had used the phrase carcinoma, I didn't know there were different kinds of cancer at this stage, I was naïve'.*

Maureen ended up having 14 needle biopsies taken and a vacuum-assisted biopsy, from which she 'bled and bled and bled'. She was diagnosed with high-grade intraductal carcinoma in 8cm of breast tissue and advised that she would have a mastectomy: '*I think he should've been…not taking the forgone conclusion that I would be having a mastectomy.'* She undertook some research online and discovered the concept of overdiagnosis which was an 'eye opener', *'I gradually learned more and more about it and realised that for every life saved there are four overdiagnosis and that it was really serious'.* She learned, *'if you go for screening and have cancer diagnosed you then might have a life expectancy of 15 years whereas if you don't go for screening and then you develop symptoms you might only survive 10 years with cancer but you've already had five good years where you were pre cancer so you're no worse off really.'* On the basis of her own analysis of risk and the advice of some others, '*I ran the risk and kept my breast for another two years'.*

She described being treated as a 'difficult woman' when she asked for monitoring only but eventually the surgeon accepted her decision and she had a clinical breast examination every six months, but refused any further mammograms. Her friends thought she was 'mad', *'they were thinking I was going to drop dead. But I said it's not going to kill me anytime soon'.* Maureen did eventually get a mastectomy three years after her diagnosis, when she developed a symptom of invasive cancer (blood from nipple).

Maureen acknowledged that she '*probably would've got breast cancer eventually. I think if I hadn't gone for screening, I might have lived another three years quite cheerfully not knowing that I had it…not worrying about anything…once I had been to the biopsy, I lived with the fear of cancer coming'.* She explained that her management strategy was to acknowledge that the cancer was there, *'but at the same time to just enjoy life and not get fixated on it'.*

At the time of the interview, it had been 8 years since Maureen's diagnosis, and she was now *'going downhill quite fast'.* She said that she had had 8 good years, and *'I've got no*

regrets about my reaction I just wish that I hadn't been to the screening in the first place'. She believed that the cancer would have developed more slowly if her breast had not been damaged by the biopsy, *'I think I could've delayed the whole process really had I not been at the mammography screening'*. Maureen developed stage 4 (metastatic) cancer and died in 2021.