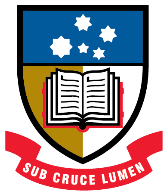

THE UNIVERSITY of ADELAIDE

Breast Density: Optimisation of Communication and Clinical Care

Dr. Avisak Bhattacharjee

Faculty of Health and Medical Science
Adelaide Medical School
The University of Adelaide

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Principal supervisor

Associate Professor Wendy Ingman
Discipline of Surgical Specialties
Adelaide Medical School
The University of Adelaide

Co-supervisors

Professor Deborah Turnbull
Chair of Psychology
School of Psychology
The University of Adelaide

Dr. Sarah J. White
Adjunct Senior Lecturer
School of Clinical Medicine
Discipline of General Practice
The University of New South Wales

Dedicated to

All women diagnosed as interval breast cancer who participated in regular breast screening.

Declaration

I certify that this work contains no material which has been accepted for the award of any other degree or diploma in my name, in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. In addition, I certify that no part of this work will, in the future, be used in a submission in my name, for any other degree or diploma in any university or other tertiary institution without the prior approval of the University of Adelaide and where applicable, any partner institution responsible for the joint-award of this degree.

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Dr. Avisak Bhattacharjee

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Summary

Knowledge is often regarded as power; however, the precise extent of knowledge required to wield such power remains undefined. In recent years, knowledge about breast density has become a topic of significant debate within the academic and medical communities. This discussion has gained particular prominence in Australia.

Breast density, also known as mammographic density, appears as the white and bright areas on a mammogram. The greater the proportion of these white and bright regions, the higher the breast density. Breast density is inversely associated with age and body mass index. Breast density is clinically significant as it is both an independent risk factor for breast cancer and a potential impediment to tumour detection in mammograms. Given these considerations, many argue that breast density information should be disclosed to women during routine screening mammograms.

However, there is concern that providing this information, particularly to women with high breast density, could lead to confusion, heightened anxiety and unnecessary additional test . Reflecting this apprehension, BreastScreen Australia has opted not to include breast density notification as a standard component of its screening program. Their position is grounded in the limited availability of research conclusively demonstrating that breast density notification does not cause harms such as anxiety. Without sufficient knowledge about breast density among women, the potential for anxiety following breast density notification remains a valid concern. Additionally, an effective and reassuring communication strategy is pivotal in clinical care that reduces anxiety successfully. However, there is no structured guideline for breast density communication in Australia.

This research aimed to (1) evaluate breast density knowledge of South Australian women, (2) assess the psychological impact of breast density notification, and (3) explore conversation themes in breast density telehealth consultations between breast surgeons and women attending hospital-based breast cancer screening.

This cross-sectional mixed methods study was conducted in women undergoing breast cancer screening at The Queen Elizabeth Hospital Breast/Endocrine outpatient department in South Australia with approval from the Central Adelaide Local Health Network Human Research Ethics Committee.

In Study 1, knowledge about breast density of South Australian women undergoing a screening mammogram was assessed by administering a questionnaire. Two-thirds of the participants were familiar with the term 'breast density' and more than half had 'some knowledge' about breast density. This study identified that prior breast density notification, awareness, younger age, and English as the language spoken at home were associated with increased breast density knowledge. However, the study also showed widespread misconceptions including the misunderstanding that breast density can be determined by touch. Interestingly, eighty two percent of women expressed their interest to know their own breast density.

In Study 2, the psychological impact of breast density notification was assessed using the State and Trait Anxiety Inventory (STAI) tool, which is a validated method used across the world for health-related anxiety measurement. State anxiety determines how the subject feels after receiving the disease-related distressful information; for this study, it is breast density information. On the other hand, trait anxiety determines how the subject generally feels. Therefore, the STAI tool assesses anxiety related to the health event on the backdrop of the subject's general anxiety status. This research suggested that state anxiety was not different between women notified they had dense breasts compared to those who were notified of non-

dense breasts. There was also no significant difference in trait anxiety. This study also asked women how they felt after being told their breast density. Eighty two percent of women reported positive or neutral reactions to breast density notification, with 17% of reactions being negative.

In Study 3, telehealth consultations between surgeons and patients who had been notified of their breast density were recorded and qualitatively analysed. Central themes of the consultation were addressing breast density knowledge gaps, placing breast density into the context of the patient's individual circumstance, providing reassurance, and exploring optimal breast screening management pathways. A key takeaway from this study was that doctors who initiated conversation with an open question such as "*What questions came to your mind when you got your breast density letter?*" were most effective in identifying patient misconceptions and inviting discussion about patient concerns. These findings will help healthcare practitioners to understand the type of dialogue and the diversity of concerns patients raise during breast density consultation.

Overall, this research identified that the general understanding of South Australian women about breast density is quite low. Despite this, they wish to know their own breast density to participate in a shared-decision making about their breast cancer screening. In notifying women of their breast density, consideration of women's knowledge, range of experiences, and circumstances is required. Existing misconceptions can be addressed in public awareness campaigns and in conversations between healthcare professionals and women. Negative reactions to breast density information can be mitigated through co-design of communication strategies with consumers and clinicians. The research in this thesis can be used to support development of future public awareness campaigns, communication strategies, and clinical guidance for management of women with high breast density. To support General Practitioners

in breast density consultations with their patients, comprehensive educational programs should be developed. These programs should focus on the clinical significance of breast density, evidence-based supplemental screening options, and effective communication strategies.

Table of Contents

Chapter One- Literature Review and Aims

Chapter Two- Materials and Methods

Chapter Five- Statement of authorship and publication 3

Chapter Six- Conclusion and future work

Chapter Seven- Appendices

Publications arising from this research

Journal articles (published in Cancers, Basel)

1. **Bhattacharjee, A.**, Walsh, D., Dasari, P., Hodson, L.J., Edwards, S., White, S.J., Turnbull, D., Ingman, W.V. Factors associated with increased knowledge about breast density in South Australian women undergoing breast cancer screening. Cancers 2024, 16, 893. https://doi.org/10.3390/ cancers16050893.

Journal articles (Published in International Journal of Breast Cancer)

2. **Bhattacharjee A**, Walsh D, Dasari P, Hodson LJ, Edwards S, White SJ, Turnbull, D., Ingman, W.V. The Impact of Breast Density Notification on Anxiety in South Australian Women Undergoing Breast Cancer Screening. Int J Breast Cancer. 2025;2025:9997077.

Journal articles (Submitted)

3. **Bhattacharjee, A.**; Walsh, D.; White, S.J.; Turnbull, D.; Ingman, W.V. A qualitative exploration of how breast density concerns are discussed during doctor-patient consultations

Awards and Honours

2021

- Best Clinical Oral Presentation, SA Breast Cancer Study Group (SABCSG)
- Full Fee Scholarship, University of Adelaide.

2022

- THRFG BHI Conference and Travel Award.
- THRF/FHMS University of Adelaide Scholarship

2023

- Adelaide Medical School Travel Award.
- Robinson Research Institute Career Development Award
- Three Minute Thesis Faculty Finalist, University of Adelaide

2024

- Adelaide Graduate Award, University of Adelaide

2025

- Outstanding Abstract Award at the 11th International Breast Density and Cancer Risk Assessment Workshop at Kaua'i, Hawaii, USA from 4th-6th June 2025

Media and Organisational Coverage of the Research

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- Should breast density become a compulsory component of breast cancer screening tests? News, Media release and Advocacy. The Royal Australasian College of Surgeons (RACS). Published on 3 May 2023. URL:https://www.surgeons.org/News/media-releases/Should-breast-density-become-a-compulsory-component-of-breast-cancer-screening-tests
- Breast density mystery to many by Brad Couch. The Advertiser. Published on 6 May 2023. URL: https://pages.pagesuite.com/c/4/c4b9b356-f8c0-44c7-a0ba-7bea1a9b4109/page.jpg
- Medical experts are calling for breast density to be included on mammogram reports, as breast density can potentially increase the risk of breast cancer. @JessHeatley10. Broadcasted on 10 News First Adelaide in 4 June 2023. URL:https://x.com/10NewsFirstAdl/status/1665264447361802240
- The best way to communicate the cancer risks of breast density. Latest news of The Hospital Research Foundation Group. Published on 7 June 2023. URL: https://hospitalresearch.org.au/news/latest-news/finding-the-best-way-to-communicate-the-cancer-risks-of-breast-density/?fbclid=IwY2xjawHoaEpleHRu -A2FlbQIxMQABHXe2Vi4AYoA2rPNZY_iXb-AxUeY7iIwrmrWmsiMdGgNe5bjS _Vw-GqHAug_aem_WL-pMgKErlZeBKp8t4ejZQ
- The best way to communicate the cancer risks of breast density. Latest news of the Australian Breast Cancer Research. Published on 7 June 2023. URL:https://australianbreastcancer.org.au/news-stories/latest-news/the-best-way-to-communicate-the-cancer-risks-of-breast-density/

2024

- Women’s knowledge about breast density is still patchy: new research. Central Adelaide Local Health Network (CALHN). Published on 13 June 2024.

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Abbreviations

ARIA	Accessibility/Remoteness Index of Australia
AUD	Australian Dollar
BCSC	Breast Cancer Surveillance Consortium
BCNA	Breast Cancer Network Australia
BD	Breast Density
BIRADS	Breast Imaging Reporting and Data System
BMI	Body Mass Index
BSSA	Breast Screen South Australia
BSWA	Breast Screen Western Australia
CALD	Culturally and Linguistically Diverse
CALHN	Central Adelaide Local Health Network
CI	Confidence Interval
FHMS	Faculty of Health and Medical Science
GP	General Practitioners
IBM	International Business Machines Corporation
ICDR	Incremental Cancer Detection Rates
INForMD	International Forum on Mammographic Density
LIBRA	Laboratory for Individualized Breast Radiology Assessment
NHMRC	National Statement on the Ethical Conduct of Human Research
NVIVO	Non-Versioned Information, Versatile Outcomes
OR	Odds Ratio
RCT	Randomized Controlled Trial
SA	South Australia
SD	Standard Deviation

SEIFA	Socio-Economic Index of Australia
SPSS	Statistical Package for Social Science
STAI	State and Trait Anxiety Inventory
THRF	The Hospital Research Foundation
TQEH	The Queen Elizabeth Hospital
US	United States
WA	Western Australia

CHAPTER ONE

Literature Review and Aims

1.1. Introduction:

Breast density, referred to as mammographic density in radiological discourse, stands as a distinct term and concept. It should not be conflated with the tactile firmness discernible during clinical breast examinations, as the two are unrelated (1, 2). The designation ‘breast density’ denotes the proportional presence of radio-opaque elements, appearing white, which signify the epithelial and stromal tissue components of the breast, in contrast to the radiolucent fatty tissue elements, which appear dark. Radiologists assess breast density either visually or quantitatively upon examination of the mammogram. Succinctly put, higher degrees of whiteness on the mammogram correspond to increased breast density.

In 1953, Leborgane initially delineated various parenchymal density patterns observable on X-ray mammograms (3). Subsequently, in 1976, John Wolfe introduced a categorization scheme for breast parenchymal density and identified breast density as a risk factor for breast cancer (4). In 1977, Egan and Mosteller described the masking effect of breast density (5). Multiple quantification systems for assessing breast density exist, the most widely used in the Breast Imaging Reporting and Data System (BI-RADS), devised by the American College of Radiology (ACR) (6). This system classifies breast density into four categories: Category A (mostly fatty), Category B (scattered fibroglandular tissue), Category C (heterogeneously dense), and Category D (extremely dense) (see Fig 1). The former two categories are at times amalgamated and labelled as 'non-dense', and the latter two categories can be grouped together and designated as 'dense'.

The BI-RADS classification system is subjective, and there can be considerable variability in breast density classification both within and between observers (7, 8). Approximately 13-19% of participants undergo re-classification as either 'dense' or 'non-dense' upon subsequent evaluations. Intriguingly, less variability has been noted among participants with 'extremely dense' breast tissue compared to those with 'heterogeneously dense' tissue (8, 9). Likewise, a

recent study estimates inter-observer agreement at 49%, with the highest accuracy observed for the 'mostly fatty' and 'extremely dense' categories (10). Significant debate persists regarding the reliability of density measurements (11), and critiques of the BI-RADS classification system in assessing breast density as a risk factor for breast cancer have identified visual assessment as a noteworthy limitation (12).

Figure 1: American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) classification system of 4 density categories: 'Mostly fatty', 'Scattered density', 'Heterogeneously dense', and 'Extremely dense'. Reproduced with permission from InforMD (www.informd.org.au).

Automated software offers a more objective avenue for breast density quantification. Among the array of available software applications, some operate on the basis of breast tissue area, while others rely on breast tissue volume. Volumetric measurement yields a more precise evaluation of dense breast tissue compared to area-based assessment (13). Leading software programs for volumetric breast density measurement include Volpara (version 1.5.3; Volpara Health Technologies, Wellington, New Zealand) (14) and Quantra (Hologic, Marlborough, Mass) (15). Conversely, the Laboratory for Individualized Breast Radiodensity Assessment

(LIBRA) software (16) has recently emerged as a recommended tool for area-based density assessment in numerous studies (13). Despite significant technological advancements in mammography, the optimal parameter for predicting breast cancer risk remains unclear, whether it be absolute density, percent density, or more complex measures of hyperdensity (17-19).

1.2. Why breast density is important

Following John Wolfe's assertion regarding breast density as a risk factor for breast cancer, subsequent years saw Egan and Mosteller challenging this notion, contending that Wolfe's observed breast cancer risk was in fact an artefact of masking. According to Egan and Mosteller, the presence of dense parenchymal patterns in the breast obscured pre-existing breast cancer, rather than indicating an increased risk (20). However, after three decades of extensive investigation and a burgeoning body of literature, it is firmly established that breast density holds significance for two distinct and independent reasons; high breast density is a factor contributing to reduced sensitivity of mammography to detect cancer, and it is a marker indicative of increased breast cancer risk (21, 22).

1.2.1. Masking effect

The sensitivity of mammography in radiologically detecting breast cancer exhibits its highest performance, ranging from 80% to 98%, in breasts categorized as 'mostly fatty' tissue, but diminishes as breast density increases (23). Specifically, sensitivity rates stand at 84% to 90%, 69% to 81%, and 57% to 71% in breasts classified as 'scattered density', 'heterogeneously dense', and 'extremely dense' respectively (24). This decline in sensitivity can be attributed to the fact that both cancerous lesions and dense tissue appear white on the mammogram, leading to breast density obscuring potential tumours. Consequently, there is a potential for delayed diagnosis, with cancers detected in dense breasts often being larger in comparison to those detected in non-dense breasts which can be associated with a poorer prognosis (25-27).

1.2.2. Breast density as a breast cancer risk factor

In addition to its masking effect, breast density is an independent risk factor for breast cancer (28). Women with breasts categorized as 'extremely dense' have a four- to six-fold greater likelihood of developing breast cancer compared to those with breasts classified as 'mostly fatty', when matched for age and body mass index (29). Breast density is incorporated into established breast cancer risk assessment tools such as the Breast Cancer Surveillance Consortium (BCSC) Risk Calculator and the Tyrer-Cuzick Risk Assessment Calculator (30).It has been estimated in a large population-based, case-control, cohort study that approximately 29% of premenopausal and 14% of postmenopausal breast cancers could be prevented if high breast density among women could be reduced to ‘scattered density’ (31) The case and control were matched on age, year of risk factor assessment and Breast Cancer Surveillance Consortium (BCSC) registry (31).

Significantly, a number of other risk factors for breast cancer are correlated with breast density. These include family history (32), nulliparity (68), and hormone replacement therapy (33, 34). However, a recent investigation suggested that the association between family history and breast density is restricted to women with first-degree affected relatives (35). Moreover, breast density and family history are recognised as distinct risk factors, or at times, they complement each other, in the context of breast cancer risk (35). A multinational study included 353 pairs of monozygotic and 246 pairs of dizygotic twins from Australian Twin Registry confirmed that 60% of breast density is attributable to genetic factors (32).

Alteration of breast density is possible depending on the presence of multiple factors including medication named Tamoxifen. Women with elevated breast density who show a notable response to Tamoxifen also concurrently experience a reduction in the risk of breast cancer recurrence (36). Intriguingly, carriers of BRCA1 and BRCA2 mutations do not display heightened breast density (37). Moreover, breast density exhibits variability with factors such

as age, body mass index, tamoxifen therapy, hormone replacement therapy, weight fluctuations, and dietary changes. A noteworthy observation is that a 'dense' breast may transition to a 'non-dense' state, or vice versa, in a subsequent mammogram one year later, following a significant alteration in any of these factors (see Fig 2). However, it is imperative to acknowledge that the risk associated with breast density remains independent of age and BMI, despite the potential impact of these factors on breast cancer risk.

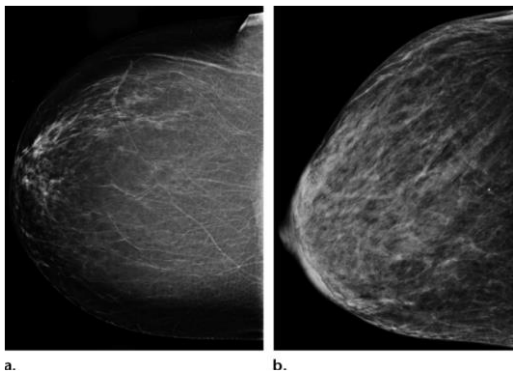

Figure 2: (a) A normal right craniocaudal screening mammogram of a 42-year-old woman exhibits scattered areas of fibroglandular density. (b) A subsequent right craniocaudal screening mammogram, obtained one year later following the patient's interval gastric bypass surgery and subsequent significant weight loss, displays breast tissue of extreme density (12).

1.2.3. Interval cancer

Due to the combined impact of the masking effect of breast density and the risk associated with high breast density, women with elevated breast density have a heightened likelihood of encountering an 'interval cancer' compared to those with lower breast density(23, 38). An interval cancer can be defined as the diagnosis of breast cancer between the scheduled screenings after a negative screening outcome (39).

Interval cancers can be categorised according to screening and diagnostic mammography and ultrasonography reports. These categories include: 1) True interval cancer (lacking signs on the screening mammogram), 2) Occult carcinoma (absence of suspicious findings on both screening and diagnostic mammograms, categorized as BI-RADS A or B, with cancer detection

relying on supplementary imaging such as ultrasonography), 3) Minimal signs (retrospectively discernible alterations in mammogram, yet lacking conspicuous configuration), 4) False-negative due to reporting confusion (cancer overlooked or missed during screening), and 5) False-negative due to technical error (cancer properties inadequately delineated during screening due to inadequate exposure or improper breast positioning) (40). This classification scheme effectively encapsulates the diverse scenarios wherein cancer may not be truly present at the time of initial screening, or may be missed, misunderstood, misdiagnosed, or overlooked in breast tissue with high density.

1.3. Breast density and breast cancer: biological perspective

1.3.1. Establishment of breast density in early life

Recent evidence suggests that early-life growth may influence breast density, yet the nature and consistency of this association remain under investigation. Breast development involves extensive fibroglandular tissue proliferation during childhood and adolescence, representing a critical period of vulnerability to hormonal and environmental exposures that may influence future breast cancer risk (41-43). Previous studies have suggested that sex steroid hormones and growth factors responsible for regulating somatic growth also modulate breast fibroglandular tissue development, potentially linking early growth patterns to later breast cancer susceptibility (44, 45).

While a 2014 review of epidemiologic studies revealed mixed findings—some studies identified an inverse association between childhood body size and adult breast density in premenopausal women aged 27 and 49 years, whereas others found no significant association (46)—more recent research supports an inverse relationship between adiposity in childhood or adolescence and adult breast density, measured both as percent and absolute dense volume (47-50).

Further, two studies have explored whether breast density mediates the relationship between early anthropometric characteristics and postmenopausal breast cancer risk. Anderson et al. found that adjusting for breast density reduced the strength of association between childhood BMI and overall breast cancer risk, although associations with birthweight and childhood height remained unchanged (51). Similarly, Rice et al. estimated that approximately 26% of the effect of childhood body size on postmenopausal breast cancer risk may be mediated through breast density (52).

Adding to this body of evidence, a recent longitudinal study demonstrated that early-life growth trajectories are prospectively associated with breast density in young adult women, reinforcing the notion that breast density may be established earlier in life than previously appreciated and may contribute to lifetime breast cancer risk (53).

These findings highlight the need for further longitudinal studies with robust early-life and imaging data to clarify the developmental origins of breast density and their potential role in mediating breast cancer risk.

1.3.2. Relationship between high breast density and cancer risk

High breast density is associated with biological changes that increase the risk of malignant transformation (54, 55). Most notably, alterations in the breast stroma microenvironment in dense tissue such as changes to the extracellular matrix (56) and immune cell activity (57) contribute to increased susceptibility to oncogenesis. Elevated levels of growth factors, including insulin-like growth factor 1 (IGF-1), insulin-like growth factor-binding protein-3 and growth hormone (GH) have been observed in women with high breast density. These growth factors can promote cell proliferation and survival, contributing to increased breast cancer risk. Furthermore, breast density also has a strong genetic component, with heritability estimates ranging from 30% to 60%. Genome-wide association studies have identified several genetic

loci associated with breast density, some of which are also linked to breast cancer risk, suggesting shared genetic pathways (58). High breast density is a multifaceted risk factor for breast cancer, influenced by stromal composition growth factors and genetics. Understanding the biological underpinnings of breast density can inform risk assessment, screening, and prevention strategies in clinical practice.

1.4. Breast density in different imaging modalities

Modern breast imaging has evolved to provide non-invasive, complementary tools for acquiring biological information about breast cancer, beyond traditional morphologic assessment (59). Conventional techniques such as full-field digital mammography and ultrasound have undergone significant advancements, leading to digital breast tomosynthesis, contrast-enhanced mammography, and automated breast ultrasound, each improving detection sensitivity and anatomical clarity. These structural methods are now complemented by functional imaging modalities. Magnetic Resonance Imaging techniques, including Diffusion-Weighted Imaging and Magnetic Resonance Spectroscopy, offer insights into cellular density and metabolic profiles. Additionally, Molecular Breast Imaging, utilizing Tc-99m sestamibi, enables detection of early metabolic and molecular alterations characteristic of malignant transformation—before visible structural or vascular changes occur.

Full-field digital mammograph remains the foundation of breast imaging, as it has been shown to significantly reduce mortality, despite its sensitivity being less than 50% in women with dense breast tissue and its inherent limitations due to the two-dimensional format (60). Over the past decade, the diagnostic accuracy of Full-field digital mammography has been enhanced by the advent of digital breast tomosynthesis, which overcomes the constraints of the two dimensional approach by generating a three-dimensional reconstruction of the breast, thereby

reducing the impact of tissue overlap and improving lesion detection (60, 61).Another promising diagnostic modality that has the potential to enhance the performance of full-field digital mammography is contrast-enhanced mammography (59). Contrast-enhanced mammography has demonstrated superior diagnostic accuracy compared to full-field digital mammography and is gradually gaining wider clinical acceptance (62, 63,64).

1.5. Breast density notification: perspective in Australia

1.5.1. BreastScreen Australian perspective

BreastScreen Australia acknowledges the importance of breast density and its potential impact on future screening methods (65). However, their current policy is to not notify women about the breast density as BreastScreen Australia feel that further research is required to better understand how breast density affects cancer risk for different groups of women, varies over time, and interacts with other known risk factors to impact on lifetime breast cancer risk. Moreover, there are significant shortage of information regarding options of reporting and notification of breast density, optimum, cost-effective, and appropriate screening protocols, and mental and physical health impact of such notifications.

The lack of post-screening follow-up subsequent to breast density notification has the potential to exacerbate patient anxiety (66). There is a lack of guidance in Australian clinical management for women with dense breasts, and limited research on women's psychological, social, and behavioural responses following awareness of their breast density status (67). Furthermore, routine notification may result in a shift of screening costs from Medicare to consumers, potentially creating disparities in access to breast cancer detection (68). It is worth acknowledging the ongoing inadequacies in supplemental imaging facilities, particularly in rural areas (69).

However, the BreastScreen Australia breast density position is currently under review and there have been recent practice changes in state-based BreastScreen programs and the Royal Australian and New Zealand College of Radiologists regarding reporting of breast density information (21, 70, 71). With these changes, there is an increasing number of Australian women being notified of their breast density when they have a mammogram.

BreastScreen Western Australia implements a practice of notifying participants if they have dense breasts, while also informing them of the reduced sensitivity of mammography to detect breast cancer (67). This screening program caters to approximately 125,000 women annually. This initiative enables women with dense breasts to consult their general practitioners, undergo physical breast examinations, and contemplate supplemental screening options at their discretion (72). However, this approach does not inform women that breast density is a risk factor for breast cancer (69), potentially conflicting with the core principle of breast density notification (73).

BreastScreen South Australia also commenced notifying women about their breast density from August 2023 after successful completion of a pilot study to learn about women's preferences regarding breast density notification (70). In their survey, they observed that 90% of their participants want to know own breast density after breast screening. Moreover, 65% of the participants confirmed that they feel informed after being told about their breast density. More recently, BreastScreen Victoria declared that they are going to inform their clients participating in the breast screen program state-wide about breast density from early 2025 (71).

The current BreastScreen Australia position statement on breast density, acknowledges that it *"will continue to work with women, BreastScreen Australia services and researchers to further develop the evidence base and to pilot notification, using emerging reporting tools and initiatives to ensure that valid, reliable and useful information is provided to women to inform*

future decision-making" (65). In line with this sentiment, there is an emerging wealth of research on breast density in Australia which may assist future national breast density notification policy.

1.5.2. Consumer perspective

Patient advocacy has played a vital role in raising public awareness about breast density and changes in clinical practice (74). In the United States, a surge of advocacy led by women diagnosed with interval cancers—tumours developing between "normal" mammograms—catalysed legislative reform for breast density notification. These women, often unaware that dense breast tissue both masks tumours and increases cancer risk, championed transparency in screening results. Led by Nancy Cappello, whose late-stage cancer followed a "normal" mammogram, advocates lobbied for informed consent and patient education. Their efforts resulted in Connecticut passing the first mandatory breast density notification law in 2009, followed by numerous states (75). This grassroots movement ultimately influenced the 2019 federal mandate for national breast density disclosure standards. Today, consumer groups' advocacy efforts in the US have led to the enactment of nearly 40 state "inform" laws and federal legislation which led the Food And Drug Administration to structure a national breast density reporting standard (74).

Consumer groups such as Breast Cancer Network Australia advocate in favour of breast density notification (76). They argue that "Australia's approach to population-based screening is not keeping pace with growing evidence that supports routine reporting of breast density to empower people to understand and manage their risk of breast cancer" (77). Furthermore, this information can potentially support informed decision-making between women and their healthcare providers regarding breast awareness, supplemental imaging modalities, and strategies aimed at reducing breast cancer risk.

When women undergo screening at a BreastScreen Australia facility, the mammogram is conducted within a clinical setting. However, the radiologist refrains from documenting or notifying the participant of their breast density status, a practice that contradicts recommendations from the Royal Australian and New Zealand College of Radiologists. A national stakeholder workshop that explored the ethical issues associated with breast density notification reported that women with dense breasts who encounter an interval cancer undetected through participation in the screening program may perceive themselves as deceived and betrayed, leading to a breakdown in trust between participants and healthcare providers—a situation with profoundly damaging consequences (69). The opportunity to engage in shared decision-making regarding how best to manage their breast health, and duty of care by the physician were also identified as ethical issues in favour of breast density notification (69).

Drawing from qualitative research conducted in New South Wales, many women express a strong desire to be informed about their breast density status, viewing it as their right to know information about their own bodies (78). Quantitative data also support this, with surveys consistently indicating that over 80% of Australian women want to know their breast density (79).

1.6. Breast density and awareness

A significant motivation behind informing women about their breast density is to empower them to take a more active role in decisions regarding breast cancer screening. To achieve this, women need to have an awareness of breast density and its implications for breast cancer screening.

A recent review comprising mostly USA-based cross-sectional studies found substantial variability in both general and personal awareness of breast density across different study

populations (80). Specifically, a scarcity of awareness mostly remains in socioeconomically disadvantaged communities. It is notable that most of the incorporated studies in this review were conducted after enactment of legislation for mandatory notification which indicates that the knowledge and support requirements of women were not adequately addressed in the United States before and in the years subsequent to the implementation of breast density legislation. However, these studies can provide insight into what is needed to adequately address awareness of breast density.

A recent study from the US suggested that education, screening history, and preferred language in a low-resource setting are significant predictors for breast density awareness among Latinas (81)**.** The factors contributing to insufficient awareness regarding breast cancer and associated health risks are likely multifaceted. These may encompass a scarcity of discourse about cancer screening within individuals' countries of origin (82-85), feelings of embarrassment or apprehension regarding a potential breast cancer diagnosis (86), as well as language barriers encountered in the United States, which could hinder discussions about breast cancer risk with English-speaking healthcare providers. Previous research has highlighted the efficacy of utilizing social support networks, such as peer counsellors, as an effective approach to medical education outreach within non-English speaking Latina communities (87-89).

Australian communities incorporate people from many different culturally and linguistically diverse backgrounds, and the barriers to breast density awareness identified by American research should be considered. These factors are being taken into consideration in Australian breast cancer screening. For example, BreastScreen SA recently provided information about breast screening services in twenty languages, although not all languages used by South Australian were covered in their project (90). Another initiative is the Sistas Shawl project in Queensland that provides modesty shawls to help First Nations women feel safe and comfortable during their breast cancer screening experience (91). Despite BreastScreen’s

progress in addressing linguistic and cultural barriers more broadly, there remains a critical gap in the provision of breast density information to diverse populations, highlighting an urgent need for targeted communication strategies. Consequently, further work is needed to optimally communicate breast density information to culturally diverse communities in Australia.

1.7. Breast density knowledge

Like awareness, the level of breast density knowledge also varies among different countries (92) and there exists both widely accepted facts as well as common misunderstandings. For example, among the main breast density facts are (i) the recognition of breast density as an independent risk factor for breast cancer, (ii) the masking effect it can exert on cancer detection, and (iii) the potential role of supplementary imaging for women with high breast density. Breast density misconceptions include (i) the notion that breast density can be assessed through touch and feel, as well as (ii) the belief that it is contingent upon breast size (93).

Knowledge of the initial two facts were assessed in Korean women and it was found that only 29.7% of the cohort had 'good knowledge', where the participants could answer correctly of both the facts. An additional noteworthy finding of this study is the substantial disparity in participants' understanding of breast density: while 64% recognized high breast density as a risk factor for breast cancer, only 38% were aware of its masking effect on breast detection. However, they did not assess the knowledge about misconceptions (94). A recent Croatian study revealed that women who were cognizant of breast density had significant understanding in comparison to the participants of another study in 2012 in terms of masking effect and cancer risk (95). Additionally, this study revealed higher knowledge status among their cohort in comparison to the afore-mentioned Korean cohort (94, 95). The pioneer breast density advocate and scientist Nancy Capello reported that women residing in states of the USA where breast density status is reported had better understanding that risk of developing breast cancer is more

among women with high breast density (96). Consequently, it was claimed that women who receive breast density notification tend to exhibit more knowledge and awareness regarding breast density (97).

Knowledge and awareness of breast density can influence the rate of subsequent breast screening attendance significantly (98). and it is now evident that breast density education is crucial (92). However, it must be more structured as a recent Western Australia study emphasized that breast density notification does not reduce rescreening rates in the target age group but may deter younger women (99). This highlights the need for tailored messaging, supportive counselling, and educational campaigns to sustain screening participation and guide effective policy.

Unfortunately, if the source of education is not properly understandable and authentic, women might gain some misunderstanding about breast density. Women exhibit diverse preferences regarding sources of information resourced mainly from healthcare professionals, social media, leaflets, TV program, and other women of community (92). Among them, healthcare professionals are emerging gradually as pivotal figures in disseminating this information. A recent study confirmed that the common sources of breast density knowledge are healthcare providers (71%), online search and research (14%), friends and family including colleagues (14%), print media (8%), patient advocacy groups (6%), electronic media (3%), and social media (2%) (96). However, participants often perceive healthcare professionals as the most trustworthy and reliable sources for acquiring information pertaining to various health-related matters (92). In this current age of information, people may gather knowledge from a wide spectrum of sources which may or may not be correct and therefore misconceptions can arise.

A qualitative study illustrated that women from different literacy levels and racial/ethnic backgrounds harboured misconceptions regarding the correlation between fatty tissue and

breast density (100). The authors also revealed several other misconceptions including the perception that breast density as indicative of their breast tissue being lumpier, that breast density pertains to the presence of cells or membranes within the breast tissue, that look or size of the breast determines breast density, and, that high density is an early stage of breast cancer (100). An important conclusion from this qualitative study was that women from diverse racial/ethnic and literacy backgrounds exhibit varying interpretations of the concept of breast density, findings which are not entirely elucidated by quantitative findings alone (100).

1.8. Breast density and anxiety

Anxiety can be defined as "an abnormal and overwhelming sense of apprehension and fear often marked by physical signs (such as tension, sweating, and increased pulse rate), by doubt concerning the reality and nature of the threat, and by self-doubt about one's capacity to cope with it" (101). State anxiety and trait anxiety represent two interconnected categories within the realm of anxiety (102). State anxiety manifests as transient feelings of apprehension, worry, and fear elicited by a specific stimulus (101). In contrast, trait anxiety denotes an individual's inherent tendency towards experiencing anxiety, constituting a deeply ingrained aspect of their personality (101). Trait anxiety is shaped by a multitude of factors including genetic predispositions, physiological mechanisms, hormonal influences, environmental contexts, cultural backgrounds, and societal influences (103-105). While trait anxiety can exacerbate and intensify state anxiety, it is important to recognize that these two forms of anxiety may also possess distinct characteristics and may evolve independently of one another (103). State anxiety can be evaluated in relation to particular stimuli, such as the impact of breast density notification (102). Nevertheless, an individual's level of trait anxiety can also influence their experience of state anxiety in response to such stimuli (102).

In a study conducted by BreastScreen Western Australia, it was found that approximately 21% of the study population confirmed that knowing their breast density made them feeling anxious (67). Anxiety in this study was measured by asking the participant whether they felt anxious after being told their breast density. Anxiety reported in this study can be categorized as 'fear of screening outcome' based on theoretical frameworks of anxiety related to breast screening (106). This aspect demonstrates a significant positive feedback loop, as it heightens participants' intention to engage in various types of screening related to breast health due to their perceived risk (101, 107). The findings from Western Australia also support this hypothesis, revealing that 50% of women notified of their high breast density took proactive steps to consult their general practitioners (78), and 96% expressed an intention to undergo re-screening at the appropriate time (67).

Currently, there is no research examining the psychological and behavioural effects of informing women that they have low breast density and, consequently, a lower risk of breast cancer. However, some insights can be gleaned from related studies. A study conducted among 1,420 Australian women assessed the effects of breast density notification and concluded a control group that did not receive any breast density information (67). This suggests that not receiving information about breast density may be associated with reduced psychological distress though it does not confirm that notification of low breast density will not have any psychological impact. In addition, understanding of breast density information may be crucial in instigating post-notification psychological stress. A US study claimed that understanding of breast density information varies across the ethnicity and level of literacy (108). Therefore, this study may also shed light on the reaction of notifying women about their low breast density.

An Australian randomized controlled trial provided evidence that a significantly higher proportion of participants who received a hypothetical dense breast notification reported experiencing anxiety (49%) compared to those who did not receive such a notification (14%)

(109). Similar to the Western Australian study, this study measured anxiety by asking participants if they would feel anxious. Although the differences were modest, a cross-sectional survey in Australia similarly demonstrated evidence that a lower proportion of controls strongly agreed or agreed with feeling anxious (8%) compared to women who were notified of having dense breasts for the first time (23%) (67). However, the majority of participants who received notifications did not experience anxiety or confusion (60%) (67). A cross-sectional survey conducted in the United States found no significant difference in the proportion of women reporting breast cancer anxiety between states that issued dense breast notifications and those without such legislation (45% and 44%, respectively; $p = 0.87$) (110).

Two studies have indicated that individuals from ethnic minority backgrounds experience more pronounced negative psychological reactions. A cross-sectional survey in the United States ($n = 457$) revealed that African-American women exhibited higher levels of anxiety and concern following breast density notifications compared to European American women. However, no evidence was found to suggest differences in levels of breast cancer worry between these groups (110).

Breast density notification serves as a catalyst for women and their healthcare providers to engage in an evaluation of their cancer risk and to devise personalized screening plans (111). In a study conducted in the United States, researchers conducted semi-structured interviews in both English and Spanish with 24 self-identified Hispanic women who had received breast density notifications in the state of New York (111). The majority of participants had little prior knowledge or experience regarding breast density and expressed uncertainty and apprehension regarding its significance. For several individuals, having dense breasts was perceived as a concerning and abnormal condition, evoking feelings of anxiety and vulnerability. Most participants expressed a strong desire to acquire further knowledge about breast density and emphasized the importance of adhering to timely and more comprehensive breast cancer

screening procedures. Moreover, it was observed that women with lower socioeconomic status, limited access to medical coverage, and heightened scepticism towards medical matters were less likely to fully comprehend the breast density information provided to them (111).

Regrettably however, all studies assessing anxiety following breast density notification to date have used a self-assessed measure of anxiety where leading question is frequently utilised. For instance, “How anxious do you think you would be if you were told you had dense breasts?” (112) or “Knowing my breast density makes me feel/ would make me feel--- <anxious>” (67) are leading questions which could be considered to provide an inaccurate result in the psychological literature (113). Additionally, the existing studies did not seem to have used psychometrically tested questions which again means that reliability and validity are compromised. Therefore, there is a scarcity of research investigating the impact of breast density notification on psychological measures of anxiety, such as state anxiety.

1.9. Knowledge status of Australian GPs about breast density and recommendations

A recent study revealed that Australian GPs possess inadequate knowledge about breast density due to the absence of formal training or guidelines on density management for GPs (115). However, Western Australia does provide information about breast density status to their participants' general practitioners (GPs). Unfortunately, there is a dearth of studies examining the perspectives, experiences, and knowledge of Australian GPs regarding breast density notification. Consequently, women in Western Australia undergoing breast screening and being informed of their high density do not receive the same standard of subsequent advice and management from their GPs.

The findings of an Australian study highlighted the urgent need for comprehensive training and support for GPs to effectively engage in discussions and manage care for women with

dense breasts, particularly if population-wide notification systems are introduced (116). The existing Australian studies on the knowledge status of GPs (115, 116), recommended to enhance the role of GPs in managing breast density information and notification. Firstly, implementing mandatory notification of breast density in Australia is recommended. This policy should ensure that patients with dense breast tissue are informed through their mammogram results, promoting transparency and informed decision-making.

1.10. Conclusion

There is a growing interest in Australia for widespread breast density notification as a routine part of mammography. However, to ensure optimal outcomes from breast density notification, further research assessing women's breast density knowledge and emotional responses to notification are needed, as well as exploration of how doctors can best to communicate this complex information with their patients.

1.12. Knowledge gap and Aims

Three areas of knowledge gap in the breast density -

i. What is currently known about the level of awareness and knowledge of Australian women regarding breast density?
ii. What is the psychological impact of breast density notification on Australian women?
iii. How do breast specialists communicate breast density information to their patients?

The areas of knowledge gap were investigated by addressing the following aims:

i. To evaluate breast density knowledge among South Australian women attending breast cancer screening in a public hospital outpatients department.
ii. To investigate the impact of breast density notification on anxiety using the state and trait anxiety inventory (STAI) tool in South Australian women undergoing breast cancer screening in a public hospital outpatients department.
iii. To explore conversation themes in telehealth consultations between breast surgeons and patients notified of their breast density.

Women attending The Queen Elizabeth Hospital for breast cancer screening will be recruited to the study. They will be asked to complete a questionnaire assessing their breast density knowledge while waiting for their mammogram (Aim 1). Subsequently, women who indicated on the questionnaire that they want to know their breast density and would like to be contacted for further studies, will be notified of their breast density by letter. Women's psychological and emotional response to breast density notification will be evaluated (Aim 2). Women in this cohort will also be invited to a telehealth consultation with a breast surgeon to explore the conversation themes that arise after breast density notification (Aim 3). The findings of this research will assist in developing future public awareness campaigns and clinical guidance for

doctors so women who have been notified of their breast density after they have had a mammogram can be optimally supported.

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CHAPTER TWO
Materials and Method

2.1. Approach

2.1.1. Study 1-Factors associated with increased knowledge about breast density in South Australian women undergoing breast cancer screening

This cross-sectional study was conducted in women attending the outpatient department of the Breast/Endocrine Surgical unit of The Queen Elizabeth Hospital between March 2022 and July 2023. The study was completed just prior to the introduction of breast density notification policy by BreastScreen South Australia, which was implemented in August 2023 (1). The declining cohort was not further assessed to identify the cause of non-participation.

The Queen Elizabeth Hospital is the second-largest tertiary healthcare institution in South Australia, addressing the medical needs of around 244,000 individuals spanning seventeen suburbs in the western region of the city. Of this population, 51% are female. The median weekly household income among residents in private accommodations is 1516 AUD and 68% of the inhabitants within the hospital's catchment area predominantly speak in English for household communication (2). The study population was selected with consideration for the design of subsequent investigations employing a validated psychological instrument to assess anxiety following breast density notification. Additionally, the study aimed to facilitate structured surgeon–patient consultations to address confusion and emotional distress related to breast density information. Notably, this represents the first Australian study to utilize a validated psychological assessment tool in this context. The absence of such tools in community-based screening programs is primarily attributable to limitations in their operational frameworks and concerns that the use of psychological measures might inadvertently heighten participant distress.

Survey Procedure

All women who attended the outpatient department for breast screening during the study period were invited to participate. Participants were provided with a questionnaire about breast density awareness and knowledge. The questionnaire was based on a questionnaire designed to assess breast density knowledge in a Western Australian cohort (3). In this questionnaire, the basic concept about breast density was incorporated in simple and understandable words just after initial two general questions. Thereafter, the core questions regarding facts and misconceptions were included to assess the breast density knowledge.

All the women in the waiting bay who were attending the clinic for a screening mammogram were actively engaged. Women who appeared to be distressed to the researcher (A.B) and those lacking the capability to provide informed consent were ineligible to participate. Sociodemographic and clinical data from the patient database were retrieved from the Electronic Medical Record. These data included age, suburb of residence (extracted to determine Accessibility/Remoteness Index of Australia-ARIA and Socio-Economic Index for Areas-SEIFA), screening frequency, and breast density status measured by Volpara software version 3.4. Language spoken at home was self-reported through the questionnaire. The questionnaire assessed recognition of the term ‘breast density’, prior screening and breast density notification, whether participants wanted to know their breast density, as well as five key questions that assessed knowledge about breast density (see the Supplementary File). Participants who answered one key knowledge question correctly or less were defined as having ‘low knowledge’; those who answered two and above correctly were defined as having ‘some knowledge’ about breast density. The categories of ‘low knowledge’ and ‘some knowledge’ were established by the research team following a discussion, where a consensus was reached that this approach would provide a sensible and pragmatic representation of women’s knowledge.

Statistical Analysis

The participants' sociodemographic characteristics including age, language spoken at home, Socio-Economic Index of Australia (SEIFA), Accessibility/Remoteness Index of Australia (ARIA), and clinical profile including number of mammograms in the last 3 years and breast density status within the cohort were expressed in frequency and percentages. The data regarding the women who had ever heard the term 'breast density' and 'who were told about their own breast density by any health professionals' were also calculated for descriptive representation. Both sociodemographic and clinical variables were tested as predictors of 'some knowledge' about breast density by multivariable binary logistic regression analysis. Response of the participants to each key question and their interest to know about own density was individually tested against the significant predictors of knowledge by multivariable binary logistic regression analysis. Missing data were managed using an imputation method. Specifically, in instances where categorical variables exhibited missing values, imputation was performed by substituting these values with the mode of the respective category. Categorical variables were presented using frequency and percentage, while continuous variables were summarised using mean and standard deviation. To evaluate the relationship between dependent and independent variables, odds ratios (OR) were employed. The precision of these estimates was further evaluated through the calculation of 95% confidence intervals (95% CI). Significance testing was conducted using Fisher's exact test and the chi-square test to determine the p-value (<0.05 being classed as statistically significant). All the determined p-values were adjusted using Benjamini–Hochberg method. Analyses were performed using IBM SPSS statistics version 28.

2.1.2. Study 2- The impact of breast density notification on anxiety in South Australian women undergoing breast cancer screening

Participant recruitment and selection

Female participants were recruited from an existing consecutive cohort who had participated in study 1 survey assessing knowledge of breast density (4).

Data collection and procedure

The following questions were asked in the initial study: *"You are waiting to have a mammogram at TQEH, and this will show your breast density. Would you like to be told your breast density?"* and *"The Queen Elizabeth Hospital is conducting a number of studies about breast density. If you are eligible for any studies, would you like a researcher to contact you?".*

Participants who answered 'yes' to the former question received the breast density notification letter by post from the consultant breast surgeon. The letter was co-designed by the authors and a representative from the Australian Breast Density Consumer Advisory Council. It contained a breast density assessment obtained by Volpara software version 3.4 employing the BI-RADS 5th edition breast composition classification. Participants were notified their breast density was Category A, B, C or D. The letter described the relevant breast density category using the descriptors provided by Volpara, with Category A and B being described as 'non-dense' and Category C and D being described as 'dense' (5), which was documented in the State's electronic medical record system (6).

Participants who also answered "yes" to the latter question, received either an anonymised online survey (Qualtrics software) or a hard-copy survey containing the 6 items from the Mind Garden© State and Trait Anxiety Inventory (STAI) that evaluates how the participant feels in the last 7 days and how they feel generally (7). The survey was sent 7 days after the notification letter. Reminders via phone and text message were sent after 48 hours of sending the survey.

Participants were required to respond to the survey within the next 7 days in order to be included in the study.

The following free-text, no word limit question was also included in the survey *"How do you feel after being told about your breast density?"*

Outcomes

State and Trait anxiety scores were calculated from the Mind Garden© manual, with the maximum anxiety score of either State or Trait anxiety being 80 (7). Participants were categorised as having State and Trait anxiety in the following ranges: "no or low anxiety" (scores between 20-37), "moderate anxiety" (scores between 38-44), and "severe anxiety" (scores between 45-80) (8). Outcomes were analysed in relation to participants' breast density status, with those receiving a letter notifying them of Category A and B being considered "non-dense", and those receiving a letter notifying them of Category C or D being considered "dense". These categories were used based on the descriptors provided in the breast density notification letter.

Data Analysis

Data from the STAI tool were analysed using IBM SPSS software version 28, with missing data managed using imputation method (mode of the respective category substituted for categorical data). Categorical data and continuous data were analysed respectively using the chi-square test or Mann-Whitney U test. Effect sizes were measured using Cohen's d (9) and P-values were considered statistically significant at <0.05.

Responses to the open-ended question were analysed by an iterative 3-step summative content analysis method (10) with the researchers (AB, DT, WI) blinded to breast density status of the participant. To enhance transparency and analytic rigor, the findings from the 6 unique themes

produced by this process were reviewed by a member of the research team who is also a mammographer employed by BreastScreen Australia (LH). The responses were then unblinded and categorised according to breast density status.

2.1.3. Study 3- A qualitative exploration of how breast density concerns are discussed during doctor-patient consultations

Design

This qualitative study explored talk during telehealth consultations between breast surgeons and patients after the patients had been notified of their breast density by letter. The purpose of the consultations was specifically for research and not a scheduled part of the patient's clinical management.

Participant recruitment and selection

The study was approved by the Central Adelaide Local Health Network Human Research Ethics Committee, approval number 17945. Doctor-participants and patient-participants were recruited to the study. Telehealth consultations were conducted between November 2023 to October 2024.

Doctor-participants were recruited from the Breast and Endocrine Surgery unit of The Queen Elizabeth Hospital. Four consultant surgeons, one fellow registrar, and two RMOs were approached. Among them, three consultant surgeons and one RMO expressed interest to participate. Subsequently, one was unable to schedule telehealth consultations in line with patients' preferences and did not participate. One participating surgeon was also a participant-investigator. Apart from these number of surgeons, there was only one senior consultant left who was the clinical lead of the Breast/Endocrine surgery unit of the Queen Elizabeth Hospital. According to the guideline of the research protocol of the Central Adelaide Local Health Network (CALHN), the clinical lead of the respective discipline who permits the research in his/her department will not be able to participate in the research. Though the clinical lead was highly interested in participating, we were unable to invite him as per guideline. Certainly, one

of the limitations of this research is that this was a single-centered study. Consequently, it was beyond scope to invite more surgeons to participate. Therefore, we have recommended to conduct the future study in multiple centers of different states and territories which is stated in chapter 6.

Patient-participants were recruited from an existing consecutive cohort who had participated in an earlier study assessing knowledge of breast density (4). Participants in the prior study were over 18 years of age and attending The Queen Elizabeth Hospital for a screening mammogram. As part of that study, participants were asked if they wanted to know their own breast density and whether they would like to be contacted about any future breast density studies. Participants who answered 'Yes' to both questions were notified of their breast density by a letter written by a consultant breast surgeon. A consecutive sample of 23 participants were invited for a telehealth consultation with a surgeon to consult about breast density from the above-mentioned cohort of prior study as a representative sample and 16 of them expressed their interest. The accepting and declining cohorts were not assessed to understand causes of action they had taken. Two were unable to participate due to technological difficulties and two more were unable to participate due to scheduling difficulties.

The booking and attendance of the telehealth consultation was regarded as consent for patients and doctors to participate in the study. In addition, at commencement of the telehealth consultation, doctor-participants were requested to obtain verbal consent from the patient-participants for recording and storage of the consultation, and for use of the de-identified recordings in publications and in conference presentations. This was recorded in the consent log, which was signed by the doctor-participants at the completion of each consultation.

Apart from the consent log, no structure was provided to the surgeons for the telehealth consultation. The surgeons were aware that the patients had been notified of their breast

density, and that they had indicated they were interested to speak to the surgeon as part of a study. The goal was to observe surgeons in as naturalistic a setting as possible without any guidelines or constraints.

Data collection and procedure

Scheduling, recording and verbatim transcription of the consultation was conducted using Teams software, with the entire consultation (scheduled for 15 minutes) being recorded. The transcripts were checked manually (by A.B.) and edits made to ensure they were an accurate reflection of the consultation. In total, 12 telehealth consultations were conducted by the three surgeon-participants, (6 by one doctor, 4 by another and 2 by another). Each video and related transcript was de-identified and subsequently referred to by doctor-participant number (01 to 03) and patient-participant number (01 to 12). For example, doctor-participant 01 consultation with patient-participant 03 was referred to as 01_03.

Analysis

Following initial discussion of the data (A.B., S.W., D.T., W.I.), an inductive analysis was conducted of the transcripts to identify and explore semantic themes using the 6-step process proposed by Braun and Clarke (11). This involved data familiarisation, generating initial codes, collating potential themes, review of themes, defining and naming themes, and finally, report writing. The conversations from the doctor perspective and patient perspective were considered and analysed separately. Conversations that related to discussion of the research project itself was not considered in this analysis.

Initial codes were generated by A.B. and S.W., and separately by W.I. before being combined. Potential themes were collated as thematic maps of doctor themes and patient themes (A.B., W.I.), were reviewed (A.B., S.W., W.I.), and further refining and naming of the themes was done in an iterative and collaborative manner (A.B., S.W., D.W., D.T., W.I.) (12).

2.2. Flowchart

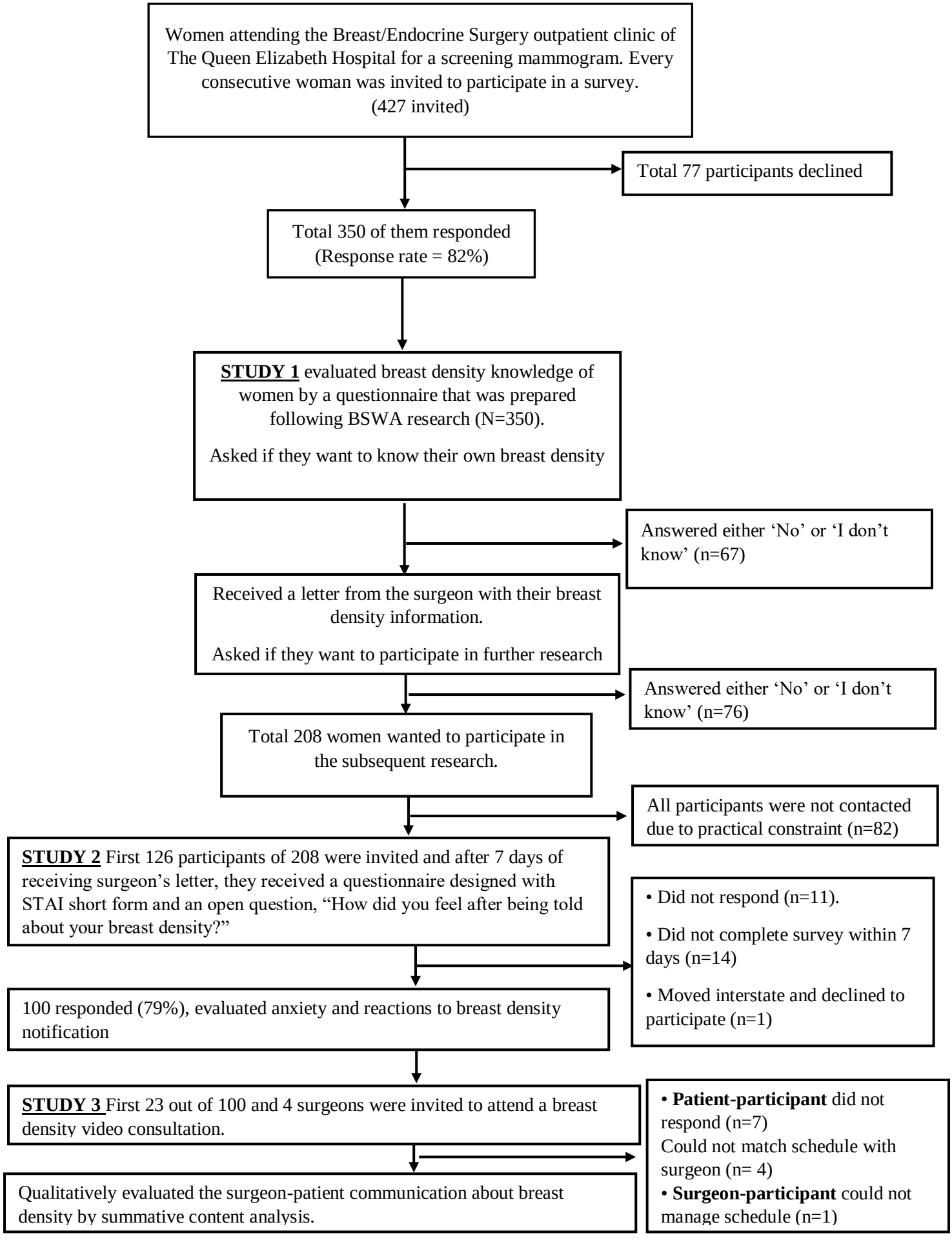

Figure 3: Overview of the investigations of knowledge status, anxiety status, and the communication strategy of breast density information.

2.3. Ethical clearance

2.3.1. Study 1: Factors associated with increased knowledge about breast density in south Australian women undergoing breast cancer screening

The study was conducted in accordance with the NHMRC National Statement on the Ethical Conduct of Human Research (2007), and approved by the Ethics Committee of Central Adelaide Local Health Network (protocol code 15630 approved 10 January 2021).

2.3.2. Study 2: The impact of breast density notification on anxiety in south Australian women undergoing breast cancer screening

The study was conducted in accordance with the NHMRC National Statement on the Ethical Conduct of Human Research (2007), and approved by the Ethics Committee of Central Adelaide Local Health Network (protocol code 16630 approved 01 November 2022).

2.3.3. Study 3: A qualitative exploration of how breast density concerns are discussed during doctor-patient consultations

The study was conducted in accordance with the NHMRC National Statement on the Ethical Conduct of Human Research (2007), and approved by the Ethics Committee of Central Adelaide Local Health Network (protocol code 17945 approved 30 May 2023).

2.4. Tools used in this study

To address the research questions, this study used different tools throughout the research. They are –

1. Breast density knowledge assessment questionnaire developed by the researchers of the University of Western Australia and used to assess the awareness and knowledge of women undergoing screening under BreastScreen Western Australia (3). In this survey, two additional questions were also added where the participants were asked if they want to know their own breast density and subsequently, if they want to participate in a future relevant study. Those who answered affirmatively both these additional questions were invited for the second study.
2. Subsequent survey questionnaire was designed using State and Trait Anxiety Inventory (STAI) short form psychological tool to determine and measure the anxiety status after breast density notification (13). To utilise this copyright tool with proper guideline, appropriate permission and manual has been obtained from Mind Garden (7). In this questionnaire, another additional open question was added where the participants were asked how did they feel after being told about their own breast density. The response of this later component of the questionnaire was used understand their reaction towards breast density information.

All the participants of the initial study who wanted to participate in the future research were invited for the breast density video consultation via Team Meeting with the breast and endocrine surgeons of The Queen Elizabeth Hospital.

2.5. References

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CHAPTER THREE

STATEMENT OF AUTHORSHIP AND PUBLICATION 1

Statement of Authorship

Title of Paper	**Factors Associated with Increased Knowledge about Breast Density in South Australian Women Undergoing Breast Cancer Screening**
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Principal Author

Name of Principal Author (Candidate)	**Avisak Bhattacharjee**		
Contribution to the Paper	Participated by conceptualization, development of methodology, validation, investigation, formal analysis, resource management, funding acquisition, and writing including original draft preparation, review, and editing. Administered the overall project.		
Overall percentage (%)	90%		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	06/01/2025

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);

ii. permission is granted for the candidate in include the publication in the thesis; and

iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	**David Walsh**

Contribution to the Paper	Participated by conceptualization, development of methodology, validation, resource management, and writing including review and editing.		
Signature		Date	06/01/2025
Name of Co-Author	**Pallave Dasari**		
Contribution to the Paper	Participated by conceptualization, development of methodology, and writing including review and editing.		
Signature		Date	06/01/2025
Name of Co-Author	**Leigh J. Hodson**		
Contribution to the Paper	Participated by conceptualization, development of methodology, and project administration.		
Signature		Date	06/01/2025
Name of Co-Author	**Suzanne Edwards**		
Contribution to the Paper	Participated by formal data analysis, and data curation.		
Signature		Date	06/01/2025
Name of Co-Author	**Sarah J White**		
Contribution to the Paper	Participated by conceptualization, validation, co-supervision, and critical review, and editing of the manuscript.		
Signature		Date	06/01/2025
Name of Co-Author	**Deborah Turnbull**		
Contribution to the Paper	Participated by conceptualization, validation, co-supervision, and critical review, and editing of the manuscript.		
Signature		Date	06/01/2025
Name of Co-Author	**Wendy V. Ingman**		
Contribution to the Paper	Participated by conceptualization, development of methodology, validation, resource management, funding acquisition, project administration, principal supervision, and critical review, and editing of the manuscript.		
Signature		Date	06/01/2025

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Factors Associated with Increased Knowledge about Breast Density in South Australian Women Undergoing Breast Cancer Screening

Avisak Bhattacharjee [1 2], David Walsh [1], Pallave Dasari [1 2], Leigh J Hodson [1 2], Suzanne Edwards [3], Sarah J White [4], Deborah Turnbull [5], Wendy V Ingman [1 2]

Affiliations

[1]Discipline of Surgical Specialties, Adelaide Medical School, The Queen Elizabeth Hospital, University of Adelaide, Woodville South, SA 5011, Australia.
[2]Robinson Research Institute, University of Adelaide, Adelaide, SA 5006, Australia.
[3]School of Public Health, University of Adelaide, Adelaide, SA 5005, Australia.
[4]Centre for Social Impact, University of New South Wales, Sydney, NSW 2052, Australia.
[5]School of Psychology, University of Adelaide, Adelaide, SA 5005, Australia.

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Simple Summary

Breast density is an independent risk factor for breast cancer and can impede detection of cancer by mammography. There is growing awareness of breast density in Australia and globally, but it is unclear whether this awareness is increasing knowledge of what breast density is and what it means to have dense breasts. This study was conducted to investigate South Australian women's knowledge of the common facts and misconceptions about breast density. This study reports that women who had previously heard the term breast density had increased knowledge compared to those who had not, suggesting that current efforts to raise awareness are leading to better knowledge. Despite this, the study shows that there are widespread misconceptions that must be actively dispelled, including the misunderstanding that breast density can be determined by touch.

Abstract

Background: There is growing awareness of breast density in women attending breast cancer screening; however, it is unclear whether this awareness is associated with increased knowledge. This study aims to evaluate breast density knowledge among Australian women attending breast cancer screening.

Method: This cross-sectional study was conducted on women undergoing breast cancer screening at The Queen Elizabeth Hospital Breast/Endocrine outpatient department. Participants were provided with a questionnaire to assess knowledge, awareness, and desire to know their own breast density.

Result: Of the 350 women who participated, 61% were familiar with 'breast density' and 57% had 'some knowledge'. Prior breast density notification (OR = 4.99, 95% CI = 2.76, 9.03; p = 0.004), awareness (OR = 4.05, 95% CI = 2.57, 6.39; p = 0.004), younger age (OR = 0.97, 95% CI = 0.96, 0.99; p = 0.02), and English as the language spoken at home (OR = 3.29, 95% CI = 1.23, 8.77; p = 0.02) were independent predictors of 'some knowledge' of breast density. A significant proportion of participants (82%) expressed desire to ascertain their individual breast density.

Conclusions: While knowledge of breast density in this Australian cohort is generally quite low, we have identified factors associated with increased knowledge. Further research is required to determine optimal interventions to increase breast density knowledge.

Keywords: breast cancer risk; breast cancer screening; breast density; knowledge; mammographic density; mammography.

1. Introduction

Breast density, also known as mammographic density, refers to the radiological appearance of the breast on an X-ray mammogram. High breast density appears on a mammogram as white areas and signifies a high abundance of fibroglandular tissue in the breast in proportion to the abundance of adipose tissue. Breast density is typically quantified as 'percent mammographic density', calculated as the ratio of the area of dense breast tissue to the total area of breast tissue (1,2). Breast density impacts upon both breast cancer risk and the early detection of breast cancer on a mammogram and has become a major focus of interest within the medical, scientific, and broader community (3,4). Given the clinical implications, there is ongoing consideration of how best to incorporate breast density into screening recommendations for organised breast screening programs (5). The American College of Radiology defines four categories of breast density in the 5th edition of Breast Imaging-Reporting Data System (BI-RADS): Category A (Mostly fatty), Category B (Scattered density), Category C (Heterogeneously dense), and Category D (Extremely dense) (6). Within this classification, the 'Heterogeneously dense' and 'Extremely dense' categories are sometimes grouped together as 'dense breasts', although the studies that have informed current recommendations about risk and screening focus on the extremely dense category and are not generalizable to those with heterogeneously dense breast tissue (7). Approximately 8% of women within the age range of 40 to 74 have breast tissue categorised as extremely dense and 35% have heterogeneously dense tissue (8). The BI-RADS classification system is subjective and leads to inconsistencies in measurement (9), which is why new methods for quantitative assessment of breast density are now available, including Volpara and Quantra software (10). The sensitivity of mammography to detect cancer among individuals with dense breast tissue is reduced compared to those with low density. A recent study, employing the Incremental Cancer Detection Rates (ICDR), estimated that approximately 267,000 mammographically occult

undetected tumours may be present among women with dense breast tissue who participated in a population-based screening program in 2021 in the United States (11). A tumour missed in a dense breast could result in unfavourable consequences such as an interval cancer, which is a breast cancer diagnosis after a negative screening mammogram and before the next mammogram is due (12). Conceivably, this cancer might have been pre-existing during the unremarkable mammogram, concealed beneath the more radiopaque and whiter background of high breast density. Up to fifty percent of cancers detected through mammography may evade detection due to the masking influence exerted by extremely dense breast tissue (13). In addition to causing reduced sensitivity of mammography to detect cancer, breast density is also an independent risk factor for breast cancer. Women categorised with extremely dense breasts have a 4–6-fold greater risk of breast cancer compared to those categorised with mostly fatty breasts when matched with age and BMI (14–16). Up to 35% of pre-menopausal breast cancer and 16% of post-menopausal breast cancers can be attributed to breast density (17). Moreover, while not conclusively established (18), breast density may also increase breast cancer-specific mortality (19). Considering the significance of breast density in risk and detection of breast cancer, the Food and Drug Administration, in a statement dated 9 March 2023, announced the revision of its mammography regulations, necessitating the incorporation of breast density information into facility reports (20). The European Union Society of Breast Imaging recently released screening recommendations for women with extremely dense breasts, stating that "women should be appropriately informed about their individual breast density... and on the diagnostic and prognostic implications of having dense breasts" (21). In Australia, breast cancer screening is conducted largely within the BreastScreen Australia public screening program. The policies of both BreastScreen Australia and the Royal Australian and New Zealand College of Radiologists are to not report breast density within the population-based screening program (3,22,23). However, BreastScreen Western Australia, BreastScreen South

Australia, and the majority of private screening providers currently incorporate breast density notification into their screening protocol. For over a decade, BreastScreen Western Australia has notified women who have dense breasts. The notification includes an explanation about how high density can potentially impede cancer detection and provides participants with a website link with further explanation of breast density, encompassing its potential associated risks (3,24). More recently, BreastScreen South Australia commenced notification of breast density to all screening participants commencing August 2023, following the successful execution of a pilot study (25). However, breast density notification may not achieve the intended positive outcomes if there exists a lack of understanding about what breast density is. Furthermore, there may be common misconceptions about breast density that impede people's knowledge. Currently, there is limited research on the knowledge of Australian women about breast density. One study evaluated knowledge in women attending BreastScreen Western Australia, finding that, among the cohort of breast density notified women, 85% knew about the reduced sensitivity of detecting cancer on a mammogram due to breast density, a significant contrast to the non-notified group, where 54% knew about this reduced sensitivity (24). Furthermore, 25% of notified women were cognizant of the increased breast cancer risk associated with dense breasts, which stands in contrast to the 13.2% knowledge rate observed in the non-notified group. In the present study, we aimed to assess awareness and knowledge about breast density in a South Australian cohort, and investigate whether women want to know their breast density. This study was conducted prior to the recent change in policy by BreastScreen South Australia and may serve as a baseline for future investigations assessing the impact of widespread notification on breast density knowledge.

2. Materials and Methods

This cross-sectional study was conducted in women attending the outpatient department of the Breast/Endocrine Surgical unit of The Queen Elizabeth Hospital between March 2022 and July 2023 (CALHN Ethics approval reference number 15681). The study was completed just prior to the introduction of breast density notification policy by BreastScreen South Australia, which was implemented in August 2023 (25). The Queen Elizabeth Hospital is the second-largest tertiary healthcare institution in South Australia, addressing the medical needs of around 244,000 individuals spanning seventeen suburbs in the western region of the city. Of this population, 51% are female. The median weekly household income among residents in private accommodations is 1516 AUD and 68% of the inhabitants within the hospital's catchment area predominantly speak in English for household communication (26).

2.1. Survey Procedure

All women who attended the outpatient department for breast screening during the study period were invited to participate. Participants were provided with a questionnaire about breast density awareness and knowledge. The questionnaire was based on a questionnaire designed to assess breast density knowledge in a Western Australian cohort (24). In this questionnaire, the basic concept about breast density was incorporated in simple and understandable words just after initial two general questions. Thereafter, the core questions regarding facts and misconceptions were included to assess the breast density knowledge.

All the women in the waiting bay who were attending the clinic for a screening mammogram were actively engaged. Every consecutive attendee was approached with the explanation about the objectives, implications, and required time to fill out the survey (5-7 min). The declining cohort were not further assessed to discover the actual cause of decline. Additionally, women

from diverse ethnicity including who were identified as indigenous were not separately assessed.

Women who appeared to be distressed to the researcher (AB) and those lacking the capability to provide informed consent were ineligible to participate. Sociodemographic and clinical data from the patient database were retrieved from the Electronic Medical Record. These data included age, suburb of residence (extracted to determine Accessibility/Remoteness Index of Australia-ARIA and Socio-Economic Index for Areas-SEIFA), screening frequency, and breast density status measured by Volpara software version 3.4. Language spoken at home was self-reported through the questionnaire. The questionnaire assessed recognition of the term 'breast density', prior screening and breast density notification, whether participants wanted to know their breast density, as well as five key questions that assessed knowledge about breast density (see the Supplementary File). Participants who answered one key knowledge question correctly or less were defined as having 'low knowledge'; those who answered two and above correctly were defined as having 'some knowledge' about breast density. The categories of 'low knowledge' and 'some knowledge' were established by the research team following a discussion, where a consensus was reached that this approach would provide a sensible and pragmatic representation of women's knowledge.

2.2. Statistical Analysis

The participants' sociodemographic characteristics including age, language spoken at home, Socio-Economic Index of Australia (SEIFA), Accessibility/Remoteness Index of Australia (ARIA), and clinical profile including number of mammograms in the last 3 years and breast density status within the cohort were expressed in frequency and percentages. The data regarding the women who had ever heard the term 'breast density' and 'who were told about their own breast density by any health professionals' were also calculated for descriptive

representation. Both sociodemographic and clinical variables were tested as predictors of 'some knowledge' about breast density by multivariable binary logistic regression analysis. Response of the participants to each key question and their interest to know about own density was individually tested against the significant predictors of knowledge by multivariable binary logistic regression analysis. Missing data were managed using an imputation method. Specifically, in instances where categorical variables exhibited missing values, imputation was performed by substituting these values with the mode of the respective category. Categorical variables were presented using frequency and percentage, while continuous variables were summarised using mean and standard deviation. To evaluate the relationship between dependent and independent variables, odds ratios (OR) were employed. The precision of these estimates was further evaluated through the calculation of 95% confidence intervals (95% CI). Significance testing was conducted using Fisher's exact test and the chi-square test to determine the p-value (<0.05 being classed as statistically significant). All the determined p-values were adjusted using Benjamini–Hochberg method. Analyses were performed using IBM SPSS statistics version 28.

3. Results

Overall, 427 women were invited to participate, with 346 women providing immediate responses. Six women opted to take the questionnaire home to complete at their convenience and subsequently mail it back; however, only four of them returned the questionnaire. In sum, 350 ultimately responded to the questionnaire, yielding a response rate of 82%. Table 1 provides a comprehensive summary of the baseline characteristics encompassing sociodemographic variables and knowledge status, prior awareness of the term 'breast density', and desire to know their breast density. The mean age of the respondents was 61 years (SD 11.45). Seventy percent of respondents were in the current Australian breast screening target age group of 50–74 years, with 17% aged between 40–49 years, and 13% aged 75 and older.

Most respondents reported English as their primary language (94%). A substantial 97% of the cohort resided in major cities, according to the Accessibility/Remoteness Index of Australia (ARIA), signifying they were located in highly accessible, accessible, or moderately accessible areas (Table 1). Table 2 provides a synopsis of the factors associated with 'some knowledge' about breast density, defined as a score of two or more out of five questions answered correctly. Younger age, English as the language spoken at home, prior awareness of the term 'breast density', and prior notification of one's own breast density were significant predictors of some knowledge about breast density.

Table 1 Characteristics of the study participants.

Variables	Frequency
Age (years)	
Mean (SD)	61.10 (±11.45)
Language spoken at home	
English	330 (94%)
Other	20 (6%)
Heard of breast density before	
Heard about breast density	215 (61%)
Never heard about breast density	135 (39%)
Accessible/Remoteness Index of Australia	
Highly accessible/Accessible/Moderately accessible	341 (97%)
Remote/Very remote	9 (3%)
Ever been told own breast density by any health professionals	
Yes	90 (26%)
No/Don't know	260 (74%)
Breast density status	
High density (C/D)	234 (67%)
Low density (A/B)	116 (33%)
Want to know their own breast density	
Yes	286 (82%)
No/Don't know	64 (18%)
Breast density knowledge status	
Low knowledge (Score 0–1)	151 (43%)
Some knowledge (Score 2 and above)	199 (57%)

Table 2. Multivariable binary logistic regression analysis for independent predictors associated with 'some knowledge' about breast density.

Independent Predictors	Comparison	OR (95% CI)	Global p-Value *
Age		0.97 (0.96, 0.99)	0.02 *
Language at home	English vs. Others	3.29 (1.23, 8.77)	0.02 *
Heard of breast density before	Yes vs. no/don't know	4.05 (2.57, 6.39)	0.004 *
Ever been told about own breast density	Yes vs. no/don't know	4.99 (2.76, 9.03)	0.004 *
SEIFA [a] decile		1.02 (0.94, 1.11)	0.95
ARIA [b]	Accessible vs. Remote	1.06 (0.28, 4.00)	0.95
Number of previous mammograms [c]		1.01 (0.82, 1.23)	0.95
Breast density status	High (C, D) vs. Low (A, B)	1.06 (0.67, 1.66)	0.95

Binary logistic regression modelling 'some knowledge' as response and 'low knowledge' as reference.
a. SEIFA- Socio Economic Index,
b. ARIA-Accessibility/Remoteness Index of Australia,
c. in last 3 years.
* Significant *p*-value after Benjamini–Hochberg adjustment.
OR, odds ratio;
CI, confidence interval.

Table 3 delineates the extent to which predictors associated with 'some knowledge' contributed to knowledge of specific factual information about breast density. Younger age, prior notification of breast density, and prior awareness of the term 'breast density' were significant predictors for knowing that breast density can mask cancer on a mammogram. With regard to knowledge about the potential requirement for further tests in women with high breast density, younger age, English as a language spoken at home, prior notification of breast density, and prior awareness of the term 'breast density' all demonstrated significance. However, only prior notification of breast density and prior awareness of the term 'breast density' significantly contributed to knowledge that high breast density is a risk factor for breast cancer.

Table 3. Multivariable binary logistic regression analysis for independent predictors of knowledge associated with common facts about breast density.

Independent predictors	Do you think dense breast tissue makes it more difficult to see cancer on a mammogram?		Do you think that, after a mammogram, sometimes women may require further tests because they have dense breast tissue?		Do you think having breasts that are mostly dense on a mammogram puts you at increased risk for breast cancer?	
	Frequency (%)	OR (95% CI) p-value	Frequency (%)	OR (95% CI) p-value	Frequency (%)	OR (95% CI) p-value
Age		0.97 (0.95,0.99) 0.001*		0.96 (0.94,0.98) <0.001*		0.99 (0.97,1.02) 0.55
Language at home						
English	158/330 (48%)	1.71 (0.66,4.38) 0.27	202/330 (61%)	2.93 (1.14,7.54) 0.03*	77/330 (23%)	1.73 (0.49,6.04) 0.52
Others	7/20 (35%)		7/20 (35%)		3/20 (15%)	
Ever been told about breast density by any health professionals						
Yes	73/90 (81%)	7.84 (4.37, 14.09) 0.001*	72/90 (80%)	3.59 (2.03, 6.36) 0.001*	35/90 (39%)	3.040(1.79,5.18) 0.004*
No/ Don't know	92/260 (35%)		137/260 (53%)		45/260 (17%)	
Heard of breast density before						
Yes	131/215 (61%)	4.64 (2.88, 7.45) 0.001*	148/215 (69%)	2.68 (1.72, 4.18) 0.001*	60/215 (28%)	2.23 (1.27,3.90) 0.02*
No/ Don't know	34/135 (25%)		61/135 (45%)		20/115 (17%)	

Binary logistic regression modelling correct answer as response and wrong answer as reference.

* Significant P-value after Benjamini-Hochberg adjustment.

OR, Odds Ratio;

CI, Confidence interval

Table 4 shows the degree to which factors predicted knowledge about common misconceptions related to breast density. English as a language spoken at home, prior breast density notification, and prior awareness of the term 'breast density' were predictive of participants' knowledge that breast density is not related to how breasts look or feel. Similarly, the latter two predictors were associated with knowledge that breast density is not related to breast size.

Table 4. Multivariable binary logistic regression analysis for independent predictors of knowledge associated with common misconceptions about breast density.

Independent predictors	Do you think breast density can be determined by feel or touch?		Do you think women with large breasts are more likely to have dense breast tissue than women with small breasts?	
	Frequency (%)	OR (95% CI) p-value	Frequency (%)	OR (95% CI) p-value
Age		0.99 (0.97, 1.01) 0.28		0.98 (0.97, 1.02) 0.69
Language at home				
English	101/330 (31%)	3.97 (0.90, 17.43) 0.09	91/330 (28%)	2.37 (0.83, ∞) 0.004*
Others	2/20 (10%)		0/20 (0%)	
Ever been told own breast density by any health professionals				
Yes	36/90 (40%)	1.92(1.16, 3.18) 0.02*	33/90 (37%)	2.11(1.20, 3.39) 0.01*
No/Don't know	67/267 (25%)		58/260 (22%)	
Heard of breast density before				
Yes	78/215 (36%)	2.51 (1.50, 4.20) 0.004*	68/215 (32%)	2.25 (1.32, 3.84) 0.004*
No/Don't know.	25/135 (19%)		23/135 (17%)	

Binary logistic regression modelling correct answer as response and wrong answer as reference.
* Significant P-value after Benjamini-Hochberg adjustment
OR, Odds Ratio;
CI, Confidence interval.

Table 5 shows that eighty two percent of respondents expressed their interest in knowing their own breast density. Age, language spoken at home, and awareness of breast density were not predictors of whether women wanted to know their density.

Table 5. Multivariable binary logistic regression analysis for independent predictors of interest to know own breast density.

Variables	You are waiting to have a mammogram at TQEH, and this will show your breast density. Would you like to be told your breast density?	
	Frequency (%)	OR (95% CI) p-value
Age		0.99 (0.96, 1.01) 0.28
Language at home		
English	271/330 (82%)	1.53 (0.54, 4.38)
Others	15/20 (75%)	0.43
Ever been told about breast density by any health professionals		
Yes	80/90 (89%)	2.09 (1.02, 4.32)
No/Don't know	206/260 (79%)	0.14
Heard of breast density before		
Yes	182/215 (85%)	1.64 (0.95, 2.84)
No/Don't know	104/135 (77%)	0.14

Binary logistic regression modelling 'want to know' as response and do not want to know as reference.

P-value after Benjamini-Hochberg adjustment.

OR, Odds Ratio;

CI, Confidence interval.

4. Discussion

This study provides insight into awareness and knowledge about breast density among women in Australia. The findings reveal a significant deficit in fundamental knowledge of breast density, even though many of the participants were familiar with the term 'breast density'.

Moreover, women were largely unaware that breast density is a risk factor for breast cancer, despite many possessing knowledges about the masking effect. This study elucidates the factors that contribute to increased breast density knowledge, including younger age, English language spoken at home, prior breast density notification, and breast density awareness. With ongoing discussion both in Australia and internationally as to the need for notification of breast density, this study highlights the informational needs of women to support accurate knowledge of breast density and the high degree of preference for knowing such information. Notably, South Australia is the second state in Australia, following Western Australia, to implement breast density notification as an integral component of the population-based screening program (3,20,21,25). The Australian context differs from the United States, given that, by April 2015, a total of 22 states had enacted legislation mandating to notify women about breast density (27). Likewise, information pertaining to breast density is distributed across the six jurisdictions in Canada in a comprehensive manner. Among them, five inform specifically women classified under category D directly, while one provides information to their respective physicians (28). As notification in BreastScreen South Australia was commenced subsequent to the closing of this study, it is worth mentioning that the study cohort had not been generally exposed to density notification at the screening program before participating here. Regarding awareness among the study cohort, sixty percent of respondents had heard the term ‘breast density’ before. The level of awareness among South Australian women is notably lower compared to Western Australian women (>80%), where breast density notification has been more widespread (24). The questionnaire revealed that approximately one-quarter of the study cohort had been notified of their own breast density, a finding that aligns with the results of a prior study conducted in the United States during a period when breast density notification was not mandated by legislation (29). Less than 60% of participants correctly answered two or more questions out of five about breast density. Younger age and English language spoken at home

were predictors of some knowledge, suggesting that targeting information to older women and those not fluent in English may provide opportunities to increase South Australian women's knowledge about breast density. These findings underscore a fundamental knowledge deficit about breast density among Australian women. At the same time, awareness of breast density was a predictor of knowledge, suggesting that efforts in Australia to raise awareness have had an impact on knowledge. Similar findings were observed in a recent study conducted in Croatia (30). This is in contrast with recent studies conducted in the United States. Variables including education, screening history, and preferred language were found to play a role in disparities in awareness but did not exert significant impact on knowledge levels (31). Another US study reported that density notification may increase overall awareness; however, it may not have a discernible impact on increasing knowledge concerning the masking effect and the risk associated with breast cancer (32). Further research is required to establish optimal approaches for raising awareness about breast density that leads to increased knowledge. In the current investigation, only 23% of women were aware that high breast density is a risk factor for breast cancer. This figure is nearly three times lower than that reported in a prior U.S. study, where breast density notification is mandated by law (33). A European study suggests that awareness of breast cancer risk can have a favourable impact on breast screening rates (30). Considering these findings, it is imperative to devise strategies for enhancing this important knowledge among women, aiming to promote greater participation in healthy lifestyles, breast awareness, and screening programs. Several states within the United States have already demonstrated positive outcomes by incorporating breast density notification into their population-based screening programs, leading to enhanced knowledge and awareness of breast density among women and increased participation in subsequent screening (33). However, the exclusion of breast density information in breast cancer screening in Australia is viewed by consumers as failing to adequately address women's 'right to know' and the enablement of their involvement

in shared decision-making processes (3,34). Interestingly, eighty-two percent of the respondents indicated a desire to ascertain their individual breast density, regardless of their level of awareness or whether they had been previously told their breast density by a health professional. This outcome reflects a broad interest in knowing one's density, and is similar to the results observed in a pilot study conducted by BreastScreen South Australia (25). Regrettably, there exists the risk of common misconceptions that may taint genuine knowledge. Common misconceptions regarding breast density, such as the belief that it can be diagnosed through touch or is associated with breast size, are prevalent. Notably, the current study identifies the key predictors dispelling these prevalent misconceptions among women. In this context, both prior breast density notification and breast density awareness play pivotal roles. While the current study suggests that awareness and notification is associated with increased knowledge about breast density, more communication is required to comprehensively dispel common misconceptions. Websites (35) and factsheets (36) that provide breast density information should be aware of these common misconceptions and actively seek to dispel them. For the most comprehensive information, personalised counselling within a dedicated radiologist-run breast density consultation may foster better understanding among women about breast density and augment their participation in shared decision-making (37).

However, radiologist consultation regarding breast density is not practical within population-based breast screening. The inclusion of general practitioners (GPs) and breast care nurses in this context could afford a more cost-effective and efficient support system for women with dense breasts. Given the inherent diversity in women's knowledge levels and individual risk, we posit that personalised, one-on-one consultations is preferred, as a 'one size fits all' approach may not suffice. Given the limited understanding of mammographic density among Australian GPs (22), it is also imperative to explore approaches for enhancing their education and training. Well-structured and comprehensive training to GPs and breast care nurses could

empower them with the requisite knowledge and competencies to guide women about critical information concerning breast density. This approach would empower women to be actively involved in making decisions on how best to manage their breast cancer risk and breast cancer screening in line with the National Women's Health Strategy 2020–2030 of Australia (38) and Women's Health Strategy for England 2022 (39).

This study addresses critical gaps within the extant literature, notwithstanding certain limitations. We enrolled women from a single centre and generalisability may be limited. Moreover, we did not collect data on the literacy status of women, despite its considerable influence on breast density awareness status (31). This study cohort included only 6% of participants reporting speaking a language other than English at home. While there was a statistically significant difference in the odds of having some knowledge about breast density between the two language groups, the wide confidence interval may reflect the low proportion of participants speaking another language at home. Another constraint is our inability to elucidate the reasons for study non-participation among non-respondent women. It is plausible to speculate that non-participation might be influenced by factors such as coming from culturally and linguistically diverse (CALD) backgrounds and the need for interpreters for clinical appointments. The proportion of participation of women coming from CALD backgrounds was lower than the expected population from The Queen Elizabeth Hospital catchment area. A drawback of this kind of questionnaire for non-English speaking participants is the reliance on hospital interpreters, whose principal role is assisting patients in the context of their clinical consultation, not completing a research questionnaire. Interestingly, the majority of responses we received from CALD participants were when a family member proficient in English was present to assist, rather than a professional interpreter. To increase participation in women from CALD backgrounds, the study questionnaire should be translated into different languages.

The primary merit of this study is its capacity to discriminatively pinpoint influential predictors of common factual knowledge and misconceptions about breast density. Another notable strength of this study is its high response rate of 82%, which exceeds that of prior studies with similar (29) and even larger cohorts (24,33).

5. Conclusions

While knowledge of breast density in this Australian cohort is generally quite low, we have identified factors associated with increased knowledge. Women who had previously heard the term breast density had increased knowledge compared to those who had not, suggesting that current efforts to raise awareness are leading to better knowledge. Despite this, there are widespread misconceptions that must be actively dispelled, including the misunderstanding that breast density can be determined by touch. These findings support further efforts to raise awareness and promote education about breast density for women attending breast cancer screening.

6. Author Contributions

Conceptualization, all authors; methodology, W.V.I., A.B., L.J.H., D.W. and P.D.; software, A.B.; validation, W.V.I., D.W., D.T. and S.J.W.; formal analysis, A.B. and S.E.; investigation, A.B.; resources, A.B., D.W. and W.V.I.; data curation, S.E.; writing—original draft preparation, A.B.; writing—review and editing, all authors; supervision, W.V.I., D.T. and S.J.W.; project administration, W.V.I., A.B. and L.J.H.; funding acquisition, W.V.I. and A.B. All authors have read and agreed to the published version of the manuscript.

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8. Institutional Review Board Statement:

The study was conducted in accordance with the NHMRC National Statement on the Ethical Conduct of Human Research (2007), and approved by the Ethics Committee of Central Adelaide Local Health Network (protocol code 15630 approved 10 January 2021).

9. Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

10. Data Availability Statement Data will be made available upon request.

11. Conflicts of Interest: The authors declare no conflicts of interest.

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CHAPTER FOUR
STATEMENT OF AUTHORSHIP AND PUBLICATION 2

Statement of Authorship

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Principal Author

Name of Principal Author (Candidate)	**Avisak Bhattacharjee**		
Contribution to the Paper	Participated by conceptualization, development of methodology, validation, investigation, formal analysis, resource management, funding acquisition, and writing including original draft preparation, review, and editing. Administered the overall project.		
Overall percentage (%)	95%		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	28/02/2025

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that: the candidate's stated contribution to the publication is accurate (as detailed above); permission is granted for the candidate in include the publication in the thesis; and the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	**David Walsh**		
Contribution to the Paper	Participated by conceptualization, development of methodology, validation, resource management, and writing including review and editing.		
Signature		Date	28/02/2025

Name of Co-Author	**Pallave Dasari**		
Contribution to the Paper	Participated by conceptualization, development of methodology, and writing including review and editing.		
Signature		Date	28/02/2025

Name of Co-Author	**Leigh J. Hodson**		
Contribution to the Paper	Participated by conceptualization, development of methodology, and project administration.		
Signature		Date	28/02/2025

Name of Co-Author	**Suzanne Edwards**		
Contribution to the Paper	Participated by formal data analysis, and data curation.		
Signature		Date	28/02/2025

Name of Co-Author	**Sarah J White**		
Contribution to the Paper	Participated by conceptualization, validation, co-supervision, and critical review, and editing of the manuscript.		
Signature		Date	28/02/2025s

Name of Co-Author	**Deborah Turnbull**		
Contribution to the Paper	Participated by conceptualization, validation, co-supervision, and critical review, and editing of the manuscript.		
Signature		Date	28/02/2025

Name of Co-Author	**Wendy V. Ingman**		
Contribution to the Paper	Participated by conceptualization, development of methodo1ogy, validation, resource management, funding acquisition, project administration, principal supervision, and critical review, and editing of the manuscript.		
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The Impact of Breast Density Notification on Anxiety in South Australian Women undergoing Breast Cancer Screening

Avisak Bhattacharjee[1,2], David Walsh[1], Pallave Dasari[1,2], Leigh J. Hodson[1,2], Suzanne Edwards[3], Sarah J. White[4], Deborah Turnbull[5] and Wendy V. Ingman[1,2]

1. Discipline of Surgical Specialties, Adelaide Medical School, The Queen Elizabeth Hospital, University of Adelaide, Woodville South, SA 5011, Australia;
2. Robinson Research Institute, University of Adelaide, Adelaide, SA 5006, Australia
3. School of Public Health, University of Adelaide, Adelaide, SA 5005, Australia;
4. School of Clinical Medicine, UNSW Medicine, University of New South Wales, Sydney, NSW 2052, Australia;
5. School of Psychology, University of Adelaide, Adelaide, SA 5005, Australia.

Abstract

Purpose: To investigate the impact of breast density notification on anxiety using the State and Trait Anxiety Inventory (STAI) tool in South Australian women undergoing breast cancer screening.

Methods: A survey based cross-sectional mixed method study was conducted in women attending breast cancer screening at The Queen Elizabeth Hospital Breast/Endocrine outpatients department (n=100). The women had participated in a previous study assessing their general knowledge of breast density and had indicated they wanted to know their own breast density. Breast density was assessed using Volpara software and participants were notified by letter. The STAI tool was administered with an additional question asking how participants felt after being told their breast density. State and Trait anxiety were compared between those receiving notification of dense breasts and those notified of non-dense breasts.

Results: State anxiety scores were not different between women notified they had dense breasts (n=34, mean state anxiety±SD; 36.65±13.03) and those who had non-dense breasts (n=66, 35.17±13.60, p=0.51). Severe trait anxiety was observed in 8 of 34 (23%) and 13 of 66 (20%) women in the dense and non-dense groups respectively, and there were no significant

differences. Qualitative analysis of 122 coded responses revealed the majority of reactions to breast density notification were positive or neutral, with 17% being negative.

Conclusion: Notification of dense breasts was not associated with elevated anxiety when compared to notification of non-dense breasts. Breast density notification approaches need to be considerate of the significant proportion of women with severe underlying anxiety.

1. Introduction:

Breast density is related to the proportion of fibroglandular tissue to fatty tissue in the breast; dense tissue is predominantly fibroglandular tissue and appears white, and non-dense fatty tissue appears dark (1). Breast density is an independent risk factor for breast cancer and can mask cancers on a mammogram (2, 3). While notifying women of their breast density when they have a mammogram cancer can assist in decision-making around how best to manage their breast health, there are several concerns with this practice (4). One concern is the potential for increased anxiety and confusion among women. Studies have suggested that women notified of their breast density can report feelings of anxiety, worry, and confusion regarding their breast health (5-7).

Despite these concerns, there is a growing number of women being notified of their breast density when they have a mammogram. Breast density notification was legislated by the USA Food and Drug Administration in 2023 (8). The European Union Society of Breast Imaging also recommend informing women about their individual breast density and breast MRI for women with high breast density (9). A number of jurisdictions in Canada also notify women of their breast density as part of community-based screening programs (10). In Australia, the Royal Australian and New Zealand College of Radiologists updated their position statement in favour of notification in 2023 (10, 11). BreastScreen Australia, the national umbrella organisation for breast screening does not record or report breast density to clients (11), although notification has been implemented in three different state-based BreastScreen programs (12-14).

Anxiety can be defined as “an abnormal and overwhelming sense of apprehension and fear often marked by physical signs (such as tension, sweating, and increased pulse rate), by doubt concerning the reality and nature of the threat, and by self-doubt about one’s capacity to cope

with it" (15). State anxiety manifests as transient feelings of apprehension, worry, and fear elicited by a specific stimulus, while trait anxiety denotes an individual's inherent tendency towards experiencing anxiety, constituting a deeply ingrained aspect of their personality (15). Trait anxiety is shaped by a multitude of factors including genetic predisposition, physiological mechanisms, hormonal influences, environmental context, cultural background, and societal influences (16-18). While trait anxiety can exacerbate and intensify state anxiety, it is important to recognise that these two forms of anxiety may also possess distinct characteristics and may evolve independently of one another (17).

Women's psychological constructs and attitudes to breast density notification remain underexplored (6). Studies that investigate anxiety associated with breast density notification within community-based public screening cohorts have typically relied on self-reported anxiety measures, not validated psychological tools (5, 19). This is primarily due to limitations in the study setting and the possibility for the psychological tool to escalate the psychological stress of the participant.

The principal aim of this study was to investigate anxiety status and the reaction of Australian women to breast density notification using the State and Trait Anxiety Inventory (STAI) tool. The study was conducted within the setting of breast cancer screening in a large public hospital, which enabled a more probing investigation of anxiety measures compared to those conducted in the setting of community-based screening.

2. Methods

2.1.Study design and setting

A cross-sectional mixed methods survey was conducted between February and October, 2023 at the Breast and Endocrine public outpatient services of The Queen Elizabeth Hospital (TQEH), in Adelaide, South Australia **(Figure 1)**.

2.2.Participant recruitment and selection

Female participants were recruited from an existing consecutive cohort who had participated in an earlier study assessing knowledge of breast density (20). The cohort for this initial study was over 18 years of age, not suspected to have breast cancer, and attending TQEH for a screening mammogram. Women were excluded if they were unable to provide informed consent and/or appeared to the researcher to be distressed. All participants provided informed consent for the study. The demographics of the women who declined to participate was not able to be captured as they did not consent to the study.

2.3.Data collection and procedure

The following questions were asked in the initial study: "You are waiting to have a mammogram at TQEH, and this will show your breast density. Would you like to be told your breast density?" and "The Queen Elizabeth Hospital is conducting a number of studies about breast density. If you are eligible for any studies, would you like a researcher to contact you?". Participants who answered "yes" to the former question received the breast density notification letter by post from the consultant breast surgeon (DW). The letter was co-designed by the authors and a representative from the Australian Breast Density Consumer Advisory Council. It contained a breast density assessment obtained by Volpara software version 3.4 employing the BI-RADS 5th edition breast composition classification. Participants were notified their breast density was Category A, B, C or D. The letter described the relevant breast density category using the descriptors provided by Volpara, with Category A and B being described as non-dense and Category C and D being described as dense (21).

Participants who also answered "yes" to the latter question, received either an anonymised online survey (Qualtrics software) or a hard-copy survey containing the 6 items from the Mind Garden© State and Trait Anxiety Inventory (STAI) that evaluates how the participant feels in the last 7 days and how they feel generally (15). The survey was sent 7 days after the notification letter. Reminders via phone and text message were sent after 48 hours of sending

the survey. Participants were required to respond to the survey within the next 7 days in order to be included in the study.

The following free-text, no word limit question was also included in the survey "How do you feel after being told about your breast density?".

2.4.Outcomes

State and Trait anxiety scores were calculated from the Mind Garden© manual, with the maximum anxiety scores of both State and Trait anxiety being 80 (15). Participants were categorised as having state and trait anxiety in the following ranges: "no or low anxiety" (scores between 20-37), "moderate anxiety" (scores between 38-44), and "severe anxiety" (scores between 45-80) (22). Outcomes were analysed in relation to participants' breast density status, with those receiving a letter notifying them of Category A and B being considered "non-dense", and those receiving a letter notifying them of Category C or D being considered "dense". These categories were used based on the descriptors provided in the breast density notification letter.

1.1.Data Analysis

Data from the STAI tool were analysed using IBM SPSS software version 28, with missing data managed using imputation method (mode of the respective category substituted for categorical data). Categorical data and continuous data were analysed respectively using the chi-square test or Mann-Whitney U test. Effect sizes were measured using Cohen's d (23) and P-values were considered statistically significant at <0.05.

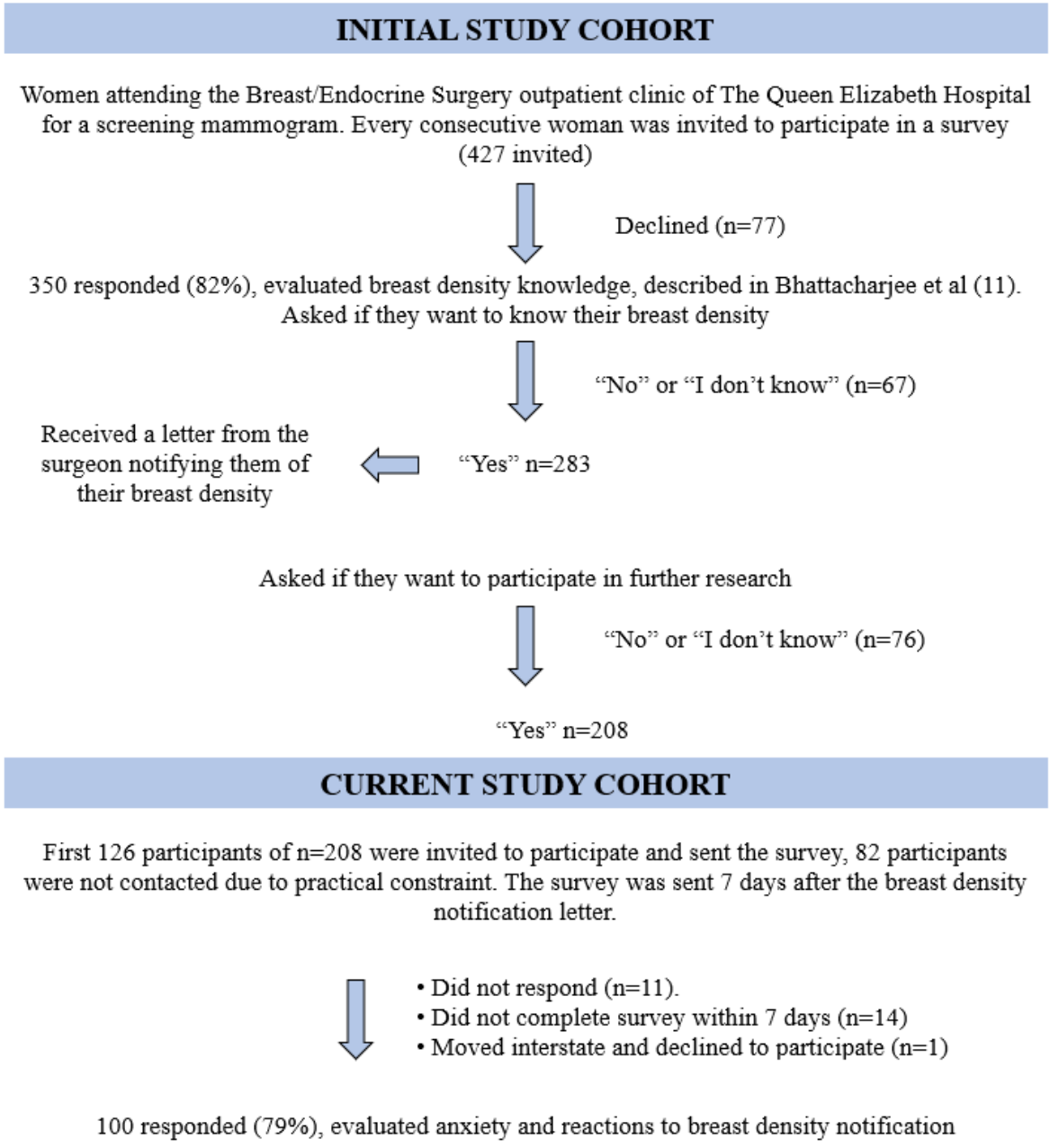

Figure 1: Flowchart of participation in breast density studies. The cohort for the current study was a subset of the initial cohort who had participated in a study assessing breast density knowledge.

Responses to the open-ended question were analysed by an iterative 3-step summative content analysis method (24) with the researchers (AB, DT, WI) blinded to breast density status of the participant. To enhance transparency and analytic rigor, the findings from the 6 unique themes produced by this process were reviewed by a member of the research team who is also a mammographer employed by BreastScreen Australia (LH). The responses were then unblinded and categorised according to breast density status.

1.2.Ethics approval

The study was conducted in accordance with the NHMRC National Statement on the Ethical Conduct of Human Research (2007), and approved by the Human Research Ethics Committee of Central Adelaide Local Health Network (protocol #16630 approved 01 November 2022).

2. Results

2.1.Sample

A total of 427 women were originally identified as eligible for the initial research and were invited to participate. Of these, 350 (81.9%) women took part in the earlier study (25) and 208 (59%) wanted to know their breast density and wanted to be contacted about future research studies **(Figure 1)**. Due to time constraints and practical considerations, only the first 126 were sent questionnaires, of whom 100 (79%) replied within the pre-specified period of 7 days after being sent the survey. Of these, 34 women had been notified they had dense breasts and 66 had been notified they had non-dense breasts **(Table 1)**. Women had a mean age of about 60 years. All participants identified as speaking English at home. Nearly half of the participants were from the most disadvantaged areas in terms of the SEIFA and two-thirds had had three or more mammograms in the last 3 years.

Table 1: Sociodemographic variables of the participants

Variables	Dense breast (n=34) n, (%)	Non-dense breast (n=66) n, (%)	Overall in current study (N=100)	Overall in prior study (N=350)[25]
Age (Mean±SD)	59.60±10.89	61.09±9.53	60.58±9.98	61.10 (±11.45)
Marital status				
Married de Facto	20 (59)	45 (68)	65 (65)	215 (61)
Never married	6 (18)	8 (12)	14 (14)	46 (13)
Separated/Divorced	6 (18)	9 (14)	15 (15)	63 (18)
Widowed	2 (6)	4 (6)	6 (6)	26 (7)
Language spoken at home				
English	34 (100)	66 (100)	100 (100)	330 (94)
Others	0 (0)	0 (0)	0 (0)	20 (6)
SEIFA				
Most disadvantaged (Lowest third of decile)	14 (41)	34 (51)	48 (48)	180 (51)
Moderately advantaged (Middle third of decile)	15 (44)	22 (33)	37 (37)	111 (32)
Highly advantaged area (Highest third of decile)	5 (15)	10 (15)	15 (15)	59 (17)
Mammogram in last 3 years				
1-2	9 (26)	21(31)	30 (30)	136 (39)
>=3	25 (74)	45 (68)	70 (70)	214 (61)

2.2.State and Trait Anxiety

We found no statistically significant or clinically relevant differences in average state and trait anxiety scores of women in the dense and non-dense breast groups **(Table 2)**. Average scores were in the vicinity of no or low anxiety and Cohen's d indicated negligible to small differences between dense and non-dense groups. There were no statistically significant differences in the two groups in categorical scores for both state and trait anxiety. About a half of women in the dense breast group and 61% in the non-dense group scored in the no or low state anxiety range, and about one quarter of women in both groups had scores in the severe state anxiety range **(Table 3)**. The distribution was similar for trait anxiety.

Table 2: Average STAI Scores according to breast density (N=100)

Anxiety types	Dense breast (n=34)		Non-dense breast (n=66)		p-value	Cohen's d
	Variability	95% CI	Variability	95% CI		
STATE						
Mean (SD)	36.65 (13.03)	32.10, 41.20	35.17 (13.60)	31.83, 38.51	0.51	0.11
Median (IQR)	37 (22.25,47.75)		33 (20,47)			
TRAIT						
Mean	37.62 (11.44)	33.63, 41.61	35.19(12.51)	32.11,38.27	0.26	0.19
Median (IQR)	37 (29.25,44)		33 (26,43)			

p value is significant at <0.05.
p value is determined by Mann Whitney U test.

Table 3: Distribution of participants based on anxiety and breast density types (N=100)

Anxiety types	Dense breast (n=34) (n,%)	Non-dense breast (n=66) (n,%)	p-value
STATE			
No or Low	18 (53)	40 (61)	0.69
Moderate	6 (18)	8 (12)	
Severe	10 (29)	18 (27)	
TRAIT			
No or Low	18 (53)	40 (60)	0.76
Moderate	8 (23)	13 (20)	
Severe	8 (23)	13 (20)	

p value is significant at <0.05.
p value is determined by chi square test.

2.3. Perception after receiving breast density status

The summative content analysis produced 122 discrete codable statements generating 6 themes across the single open-ended question, "How do you feel after being told about your breast density?" **(Table 4)**. The responses were on average 14 words long (range 1-107 words). The most common response was of a favourable nature indicating women felt informed, interested or curious in women from both dense and non-dense groups (42% and 39% of responses respectively). More responses from women in the dense breast group were unfavourable, indicating feelings of concern or disappointment, compared to the non-dense group (19% and 5% respectively). Conversely, fewer responses from women in the dense group indicated a feeling of gratitude, relief or reassurance compared to the non-dense group (7% and 15% respectively). About 10% of responses in both groups indicated that they felt 'okay' after being told about their breast density. When coded in terms of positive, negative and neutral reactions, about half of comments from both groups were coded as positive and there were no significant

differences between the dense and non-dense group **(Table 5)**. However, more reactions from women in the dense breast group were negative compared to reactions in the non-dense group (26% and 13% respectively).

Table 4: Distribution of preliminary themes according to the density status (N=122)

Themes	Dense Breast (n=43)* n, (%)	Non-dense breast (n=79)** n, (%)	Overall (N=122) n, (%)	Example
Favourable response/Informed /Interested/Curious	18 (42)	31(39)	49 (40)	"Very pleased to know my risk and the need to be vigilant"
Gratitude/Feels relieved /Feels reassured	3 (7)	12 (15)	15 (12)	"Its good to know my density as it puts my mind at rest."
Unfavourable response/ Disappointed	8 (19)	4 (5)	12 (10)	"A bit concerned that a cancer may be missed on mammograms due to breast density----."
Confused	3(7)	6 (8)	9 (7)	"---with it, not quite sure I understood it all-----"
Neutral	6 (14)	18 (23)	24 (20)	"Don't affect me at all."
Okay	5 (11)	8 (10)	13 (11)	"Ok with it----------"
Total	43 (100)	79 (100)	122 (100)	

*Total response from 34 dense breast women is 30. Missing responses number is 3 and one is contextual response. Total 30 complete responses were coded as 43 coded responses.
** Total response from 66 dense breast women is 59. Missing responses number is 5 and two are contextual responses. Total 59 complete responses were coded as 79 coded responses.

Table 5: Final arrangement of themes according to the density status (N=122)

Themes	Dense Breast (n=43)* n, (%)	Non-dense breast (n=79)** n, (%)	p-value	Overall (N=122)
Negative reaction±	11 (26)	10 (13)		21 (17)
Positive reaction*	21 (48)	43(54)	0.19	64 (52)
Neutral reaction**	11 (26)	26 (33)		37 (30)
Total	43 (100)	79 (100)		122 (100)

p-value has been determined by chi square test. P-value is significant at <0.05.
± Negative reaction consists 'Confused' and 'Disappointed/Negative reaction' codes from table 2.
*positive reaction consists of 'Positive reaction/informed /Interested/Curious' and 'Gratitude/Feels relieved /. Feels reassured' codes from table 2.
** Neutral reaction consists of 'Neutral' and 'Okay' codes from table 2.

3. Discussion:

The current study provides critical insights into the psychological impact of breast density notification among Australian women attending breast cancer screening in a public hospital setting, and provides a complimentary approach to other studies that assessed self-reported anxiety within community-based breast screening settings. Here, we use a validated psychological tool to assess anxiety following notification of dense breasts, using women notified of non-dense breasts as a comparator group. Through assessing both state and trait anxiety, the impact of breast density notification can be considered against the backdrop of the underlying tendency of participants towards anxiety.

State anxiety after notification of dense breasts was not different to state anxiety following notification of non-dense breasts, suggesting that psychological measures of anxiety are not affected by breast density notification. Although the sample size of 100 participants might be considered modest, this sample size is well-accepted within the psychology literature where previous studies that employed the STAI tool to measure anxiety after a stressful health event have used similar or smaller sample sizes (22, 26, 27). The smaller effect size determined by

Cohen's d between the dense and non-dense groups in case of state (0.11) and trait (0.19) anxiety suggest that a larger sample size would not yield different results.

In this study, 20% of women who participated were identified as having severe trait anxiety. This finding is in agreement to a recent survey (2021-2022) that reported that 21% of Australian women had experienced an anxiety disorder in the last 12 months (28). A substantial number of Australian women are suffering from high underlying anxiety in their day-to-day life and this has the potential to affect their response to any health information, including how they respond to being notified of their breast density, whether they have dense or non-dense breasts. Overall, 42% of this study cohort was identified as having state anxiety in the 7 days following breast density notification in the moderate or severe range. This is higher than other Australian study findings where 20% participants self-reported anxiety following breast density notification (5) or reported they were likely to feel anxious if told they had dense breasts (6, 29). This difference is likely to be associated with how anxiety was measured. The STAI tool does not ask participants to assess their own anxiety, but rather measures the psychological manifestations of anxiety such as the extent of feelings of tension, worry, and calm. The high frequency of state anxiety, irrespective of whether the participant received a letter notifying them of dense or non-dense breasts, might be attributed to the high level of underlying trait anxiety in the cohort.

Women who received breast density notification generally respond neutrally or positively, as reflected in the themes identified from the qualitative analysis of the open-ended question concerning how the women felt after being told their breast density. These results are similar to themes described in previous studies (5, 29). Approximately half of the reactions were positive and reflected the participants feeling informed, relieved, reassured, and grateful. An additional 30% were neutral, with a common response being "Okay" or a statement that they were not affected by the information. Negative reactions occurred in around 20% of responses,

and included confusion about breast density information and concerns about breast cancer being missed.

It may not be surprising that women notified of dense breasts would experience negative reactions, given they are receiving the news that they have an increased risk for breast cancer (30) and reduced sensitivity of a mammogram to detect cancer (31). These negative reactions could be mitigated through co-design of health communication strategies with consumers has significant potential to increase community engagement and information uptake (32-34). Trial of an interactive computer-animated agent co-designed with consumers that explains what women want to know about breast density suggests this approach can increase breast density knowledge and reduce self-reported anxiety (35). Further work to improve breast density communication and mitigate negative reactions would benefit from engagement with consumer organisations such as the Australian Breast Density Consumer Advisory Council that assisted in the current study.

4. Limitations:

Limitations of this study include data collection from a single site and the potential for selection bias. The cohort was recruited from a prior study, who had specified their preference to be informed of their breast density and contacted for future studies, so the experience of those who did not want to know was not captured. Moreover, the participants were attending the public hospital-based breast service for routine mammographic screening or follow-up rather than attending community-based breast cancer screening. Women showing signs of distress at the time of their breast screening were excluded from the study, so their experiences of breast density notification were not captured. Furthermore, there was a lack of uptake of the survey by non-English-speaking women, which limits the generalizability of the study.

This study used women notified on non-dense breasts as a comparator group, however it's possible that the notification letter could have increased state anxiety in the non-dense group.

Furthermore, this study did not distinguish between women's responses to being notified of Category C or Cate-gory D breast density, and it is possible that notification of Category D may have a greater psychological impact than Category C. Ideally, state anxiety could be measured before and after breast density notification, however this was not possible in this study. The opportune time to measure state anxiety before notification would be when participants were recruited to the study, prior to the mammogram and their breast density measurement. However, breast screening may in itself cause some anxiety which would have affected the baseline measure (36). Another approach would be to randomise women with dense breasts to receiving or not receiving breast density notification.

Investigation of how a participant feels on the day they receive the notification letter and in-person interviews seeking to understand how participants feel after breast density notification may have revealed more in-depth findings than the current study. In addition, the readability of the surgeons' letters and the level of health literacy of the participants were also not assessed in this study.

5. Conclusion:

With more and more women being notified of their breast density when they have a mammogram, it is important to understand the psychological impact of this information. This study has used a validated psychological tool and suggests that notification of high breast density is not associated with an escalation in anxiety. While women's reactions to breast density notification are overall positive or neutral, negative reactions including confusion and concern can also occur. Breast density notification approaches need to be considerate of the significant proportion of women with severe underlying anxiety. Co-design of communication strategies with consumers may help mitigate negative reactions to breast density notification.

6. Ethical clearance

The study was conducted in accordance with the NHMRC National Statement on the Ethical Conduct of Human Research (2007), and approved by the Ethics Committee of Central Adelaide Local Health Network (protocol code 16630 approved 01 November 2022).

7. Competing interests

No relevant disclosure.

8. Acknowledgement

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9. Author contribution

Conceptualization, all authors; methodology, W.V.I., A.B., L.J.H., D.W. and P.D.; software, A.B.; validation, W.V.I., D.W., D.T. and S.J.W.; formal analysis, A.B. and S.E.; investigation, A.B.; resources, A.B., D.W. and W.V.I.; data curation, S.E.; writing—original draft preparation, A.B.; writing—review and editing, all authors; supervision, W.V.I., D.T. and S.J.W.; project administration, W.V.I., A.B. and L.J.H.; funding acquisition, W.V.I. and A.B. All authors have read and agreed to the published version of the manuscript.

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CHAPTER FIVE
STATEMENT OF AUTHORSHIP AND PUBLICATION 3

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Principal Author

Name of Principal Author (Candidate)	**Avisak Bhattacharjee**		
Contribution to the Paper	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
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Signature		Date	7/04/2025

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that: the candidate's stated contribution to the publication is accurate (as detailed above); permission is granted for the candidate in include the publication in the thesis; and the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	**David Walsh**		
Contribution to the Paper	Participated by conceptualization, development of methodology, validation, resource management, and writing including review and editing.		
Signature		Date	28/02/2025

Name of Co-Author	**Sarah J White**		
Contribution to the Paper	Participated by conceptualization, validation, co-supervision, and critical review, and editing of the manuscript.		
Signature		Date	28/02/2025

Name of Co-Author	**Deborah Turnbull**		
Contribution to the Paper	Participated by conceptualization, validation, co-supervision, and critical review, and editing of the manuscript.		
Signature		Date	28/02/2025

Name of Co-Author	**Wendy V. Ingman**		
Contribution to the Paper	Participated by conceptualization, development of methodo1ogy, validation, resource management, funding acquisition, project administration, principal supervision, and critical review, and editing of the manuscript.		
Signature		Date	28/02/2025

A Qualitative Exploration of How Breast Density Concerns are Discussed during Doctor-Patient Consultations

Avisak Bhattacharjee[1,2], David Walsh[1], Sarah J. White[3], Deborah Turnbull[4] and Wendy V. Ingman[1,2]

1. Discipline of Surgical Specialties, Adelaide Medical School, The Queen Elizabeth Hospital, University of Adelaide, Woodville South, SA 5011, Australia;
2. Robinson Research Institute, University of Adelaide, Adelaide, SA 5006, Australia
3. School of Clinical Medicine, UNSW Medicine, University of New South Wales, Sydney, NSW 2052, Australia;
4. School of Psychology, University of Adelaide, Adelaide, SA 5005, Australia.

Abstract

Background: Policy changes are prompting Australian women to be notified of their breast density following a mammogram. Despite women being encouraged to discuss breast density with their doctor, little is known of how conversations about breast density are managed during the consultation. This study explored how breast surgeons and patients discuss breast density following breast density notification.

Methods: This qualitative study analysed 15-minute telehealth consultations between three doctors in the Breast and Endocrine surgery unit of The Queen Elizabeth Hospital and 12 patients who had been notified of their breast density by letter (n=12). An inductive semantic analysis was conducted of the transcripts to identify and explore themes.

Results: Doctors prompted conversation through asking questions, which assisted them to identify patient concerns, misconceptions and feelings. They discussed actions that can be taken and worked to provide reassurance. Patients provided context for their breast density concerns which was often combined with other factors such as family and personal history. They described knowledge about breast density, as well as actions taken, all of which affected whether they felt positive or negative towards their breast density. They also provided personal perspectives which were often pragmatic.

Conclusion: Our results suggest that doctors preparing for consultations following breast density notification might anticipate the discussion of a broad range of issues, even in brief telehealth formats. As breast density notification becomes a more common practice, it is hoped that studies like this might contribute to the development of communication guidelines.

1. Introduction

Effective communication is central to clinicians' ability to provide care to patients (1, 2). It can improve patient quality of life, shared decision-making, and the ability of patients to cope with their health condition through de-escalation of anxiety (1, 3-5). Conversely poor communication can lead to diminished patient trust, dissatisfaction, and adverse health outcomes (1, 3). For consultations involving complex medical information such mammographic breast density, clear and compassionate communication can potentially be challenging (6).

Mammographic breast density is a radiological finding relating to the white and bright areas on an x-ray mammogram (7). High breast density can reduce cancer detection by mammography and is also an independent risk factor for breast cancer (7). The USA Food and Drug Administration legislated breast density notification in 2023 (8). The European Union Society of Breast Imaging also recommend informing women about their individual breast density and breast MRI for women with high breast density (9). In Australia, the Royal Australian and New Zealand College of Radiologists recently updated their position statement in favour of notification (10, 11). BreastScreen Australia, the national umbrella organisation for breast screening does not record or report breast density to clients, although notifcation has been implemented in BreastScreen WA, SA and Victoria (12-14). Due to these policies, there is a growing number of women being notified of their breast density when they have a mammogram.

Breast density is a complex issue that affects both breast cancer risk and breast cancer screening (15). Receiving breast density notification can be confusing; appropriate clinical management for individual circumstances may be unclear, and common misconceptions exist (16). For these reasons, women notified of their breast density are encouraged to discuss the findings with their doctor to support shared decision-making on clinical management (10, 12).

The doctor-patient consultation following breast density notification can be critical to shaping a patient's understanding of breast density, deciding on the most suitable management pathway, and addressing their concerns. Indeed, it can be challenging for Australian clinicians to have discussions with women with dense breasts to help manage risk as there is no current education, support, and evidence-based guidelines to guide the conversation (17). Understanding existing strategies of breast surgeons regarding breast density conversations is a first step in informing policymakers in designing optimised breast density communication guidelines for clinicians. Thus, the aim of this study was to explore the nature of the conversation between breast surgeons and patients in a consultation following breast density notification.

2. Methods

2.1.Design

This qualitative study explored talk during telehealth consultations between breast surgeons and patients after the patients had been notified of their breast density by letter. The purpose of the consultations was specifically for research and not a scheduled part of the patient's clinical management.

2.2.Participant recruitment and selection

The study was approved by the Central Adelaide Local Health Network Human Research Ethics Committee, approval number 17945. Doctor-participants and patient-participants were recruited to the study. Telehealth consultations were conducted between November 2023 to October 2024.

Doctor-participants were recruited from the Breast and Endocrine Surgery unit of The Queen Elizabeth Hospital. Four consultant surgeons, one fellow registrar, and two RMOs were approached. Among them, three consultant surgeons and one RMO expressed interest to

participate. Subsequently, one was unable to schedule telehealth consultations in line with patients' preferences and did not participate. One participating surgeon was also a participant-investigator.

Patient-participants were recruited from an existing consecutive cohort who had participated in an earlier study assessing knowledge of breast density (18). Participants in the prior study were over 18 years of age and attending The Queen Elizabeth Hospital for a screening mammogram. As part of that study, participants were asked if they wanted to know their own breast density and whether they would like to be contacted about any future breast density studies. Participants who answered 'Yes' to both questions were notified of their breast density by a letter written by a consultant breast surgeon. A consecutive sample of 23 participants were invited for a telehealth consultation with a surgeon to consult about breast density from the above-mentioned cohort of prior study as a representative sample and 16 of them expressed their interest. The accepting and declining cohorts were not assessed to understand causes of action they had taken. Two were unable to participate due to technological difficulties and two more were unable to participate due to scheduling difficulties.

The booking and attendance of the telehealth consultation was regarded as consent for patients and doctors to participate in the study. In addition, at commencement of the telehealth consultation, doctor-participants were requested to obtain verbal consent from the patient-participants for recording and storage of the consultation, and for use of the de-identified recordings in publications and in conference presentations. This was recorded in the consent log, which was signed by the doctor-participants at the completion of each consultation.

Apart from the consent log, no structure was provided to the surgeons for the telehealth consultation. The surgeons were aware that the patients had been notified of their breast density, and that they had indicated they were interested to speak to the surgeon as part of a

study. The goal was to observe surgeons in as naturalistic a setting as possible without any guidelines or constraints.

2.3.Data collection and procedure

Scheduling, recording and verbatim transcription of the consultation was conducted using Teams software, with the entire consultation (scheduled for 15 minutes) being recorded. The transcripts were checked manually (by A.B.) and edits made to ensure they were an accurate reflection of the consultation. In total, 12 telehealth consultations were conducted by the three surgeon-participants, (6 by one doctor, 4 by another and 2 by another). Each video and related transcript was de-identified and subsequently referred to by doctor-participant number (01 to 03) and patient-participant number (01 to 12). For example, doctor-participant 01 consultation with patient-participant 03 was referred to as 01_03.

2.4.Analysis

Following initial discussion of the data (A.B., S.W., D.T., W.I.), an inductive analysis was conducted of the transcripts to identify and explore semantic themes using the 6-step process proposed by Braun and Clarke (19). This involved data familiarisation, generating initial codes, collating potential themes, review of themes, defining and naming themes, and finally, report writing. The conversations from the doctor perspective and patient perspective were considered and analysed separately. Conversations that related to discussion of the research project itself was not considered in this analysis.

Initial codes were generated by A.B. and S.W., and separately by W.I. before being combined. Potential themes were collated as thematic maps of doctor themes and patient themes (A.B., W.I.), were reviewed (A.B., S.W., W.I.), and further refining and naming of the themes was done in an iterative and collaborative manner (A.B., S.W., D.W., D.T., W.I.) (20).

3. Results and Discussion

The three doctor-participants included two consultant surgeons (both male) and one trainee surgeon (female). Characteristics of patient-participants are shown in Table 1. The final thematic map identified four doctor themes (Figure 1): questions, knowledge, clinical management, and reassurance. Four patient themes were identified (Figure 2): knowledge, context/concerns, actions taken, and feelings/perspective.

3.1.Doctor Themes

Questions

In many cases, but not all, the doctor commenced the consultation by asking the patient about their breast density notification letter and what details they remembered. In some cases, the doctor asked the patient what questions they had about breast density. These open-ended questions tended to lead to very broad conversations that were directed by the answer the patients provided.

> *What questions came to your mind when you got your breast density letter?* ***(Transcript 01_06)***

Open-ended questions are an effective approach to facilitate more comprehensive patient responses, thereby enhancing the quality of the medical information obtained (21). However, some contend that open-ended questions may overwhelm healthcare providers, complicating diagnosis, and that a balanced integration of open and structured inquiries is essential for optimising patient interactions and data collection (22, 23).

Doctors also prompted patients to discuss how they felt about their breast density and whether they were satisfied with the clinical management of their situation. This led to conversations

about those feelings and also broader discussion about the actions that were being taken and patient perspectives of their situation.

> *I mean, do you find that there's less anxiety now that you've got all these plans in place?* ***(Transcript 03_11)***

Previous research suggests that patient ethnicity and literacy level affect the likelihood of doctors enquiring about breast density worries or concerns (24). However, understanding the individual concerns a patient may have is an important aspect of determining the most appropriate clinical management through shared decision-making.

Knowledge

The consultation was an opportunity for doctors to explain concepts of breast density and improve patient understanding. The explanations included descriptions of breast density which were factual and similar to what would be described within radiology literature or on a patient fact sheet, and also descriptions that were more colourful.

> *It's a bit like if you've got a night time, you've got a very cloudy sky and you can't see through that cloudy overcast sky. A clear night when there's no cloud cover, you'll see all the stars you know, shimmering in the night and it's a little bit like that with mammography, So when you have very dense mammograms, it's like that overcast sky and it might, you know, be concealing something beyond that.* ***(Transcript 03_10)***

Doctors also addressed patient misconceptions about breast density. Past studies have shown that misconceptions, such as the belief that breast density is related to the feel of breasts or their size, are common amongst Australian breast screening participants (18), and these misconceptions were revealed during these consultations. A recent study suggests that

Australian General Practitioners may not have adequate knowledge of breast density (21), and this knowledge is required in order for doctors to ensure patient misconceptions can be addressed during the consult. There may be significant knowledge gaps including legal awareness, cancer risk comprehension, discussion confidence, management consensus, and notification process understanding (25). Bridging of these gaps is crucial for enhancing patient care and outcomes.

In the present study, doctors only directly addressed misconceptions when they were affecting the patient's decisions or feelings about their breast density. One misconception that was revealed by this study is the idea that non-dense breasts, which are sometimes described as "mostly fatty", are bad, as the term "fatty" was considered as unhealthy by some participants.

> *Okay, so I might be able to help you right there and say that if you've got a level A and you've got fatty breast tissue, your mammogram works extremely well. So in terms of finding breast cancers, category A is the best.* ***(Transcript 01_05)***

Clinical management

Discussion on clinical management for women with dense breasts included regular screening, supplementary screening, and medication. As the consultations were scheduled for research purposes and not part of clinical management, doctors did not prescribe specific management pathways. However, they did discuss the management strategies currently in place and provided further information that the patient could follow up at their next scheduled consultation.

> *Just to tell you that you can potentially go on to lower doses of that medication [tamoxifen] which carry less side effects. So you might want to revisit that.* ***(Transcript 03_11)***

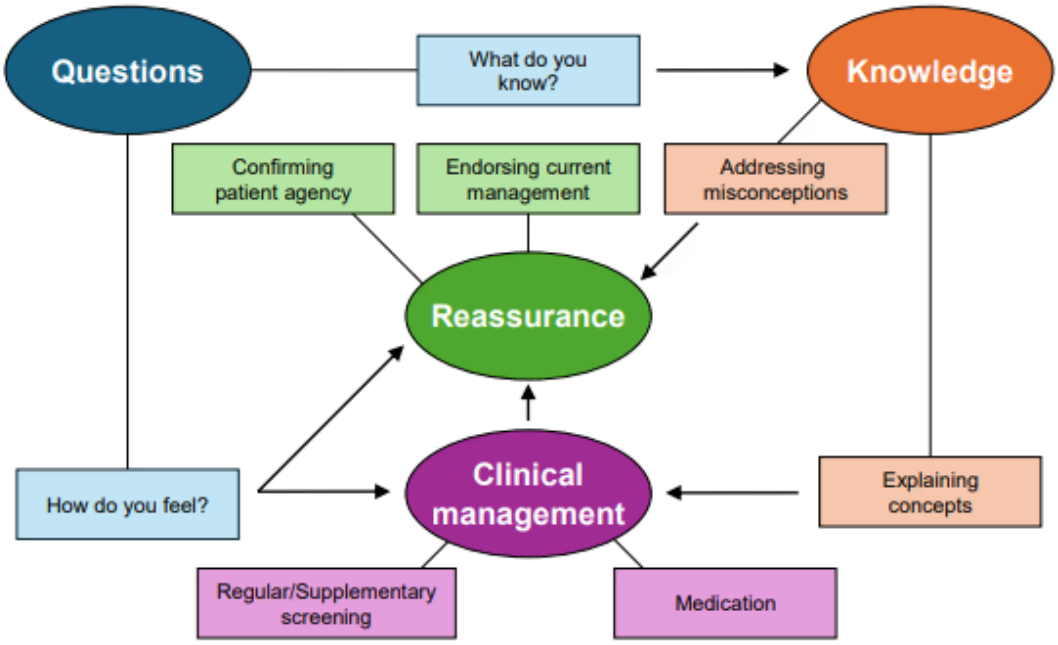

Figure 1: Thematic map showing themes from doctors' perspective. The map is colour-coded, with four central themes of questions (blue), knowledge (orange), clinical management (purple), and reassurance (green). Arrows represent codes within one theme linked to a different theme.

Reassurance

A significant focus of the consultation was the reassurance doctors provided to patients. Clinical management for women with dense breasts is affected by many contributing variables, including other breast cancer risk factors, access to screening services and individual preferences (26). It can be important for patients to feel in control of the situation and supported by their clinical team. Conventional reassurance strategies used by some clinicians, such as emphasising the mildness of the condition, may be ineffective due to divergent perspectives between patients and doctors (27). Instead, listening to and validating patients' views and

experiences is essential for providing effective reassurance (27, 28). Doctors provided reassurance during the consultation through both confirming patient agency and endorsing the patient's current clinical management.

> *And I think you're doing all the right things and you know you've been, you've been given that extra little bit to help reassure you about that. So that's excellent. And I'm sure you know you're being well looked after.* ***(Transcript 03_09)***

3.2.Patient themes

Knowledge

Patients described their knowledge during the consultation, often in response to questions by the doctor, with both correct and incorrect information being expressed. Some patients said they did not understand what was meant by the concept of breast density, while others demonstrated a good understanding.

> *The more dense your breasts are, the more difficult it is for the radiographer to find any breast cancers in your breast.* ***(Transcript 01_04)***

Patients also referred to sharing their breast density notification and knowledge of breast density with family and friends.

> *I told others when I was told, but my sisters have also gone on to have testing done and they're the same.* ***(Transcript 03_12)***

Table 1: Characteristics of the patient-participants (N=12)

Mean age (±SD) (in years)	58±8.55
Language spoken at home (n,%)	
English	11 (92%)
Others	1 (8%)
Accessibility/Remoteness Index of Australia (ARIA)	
Highly accessible	7 (58%)
Accessible	3 (25%)
Moderately accessible	2 (17%)
Socio-Economic Indexes for Areas (SEIFA) decile	
Lower third	8 (67%)
Middle third	3 (25%)
Upper third	1 (8%)
Breast density	
Category 'A'	2 (17%)
Category 'B'	4 (33%)
Category 'C'	4 (33%)
Category 'D'	2 (17%)

Concerns/Context

Patient concerns about breast density were embedded in a wider context of concerns related to breast cancer risk and breast cancer screening. This context was provided by patients without specific prompting from the doctors and included concerns about personal and family history of breast cancer as well as benign breast conditions.

> *Look, my history and the reason as to why I have imaging every year is mum died of breast cancer.* ***(Transcript 02_08)***

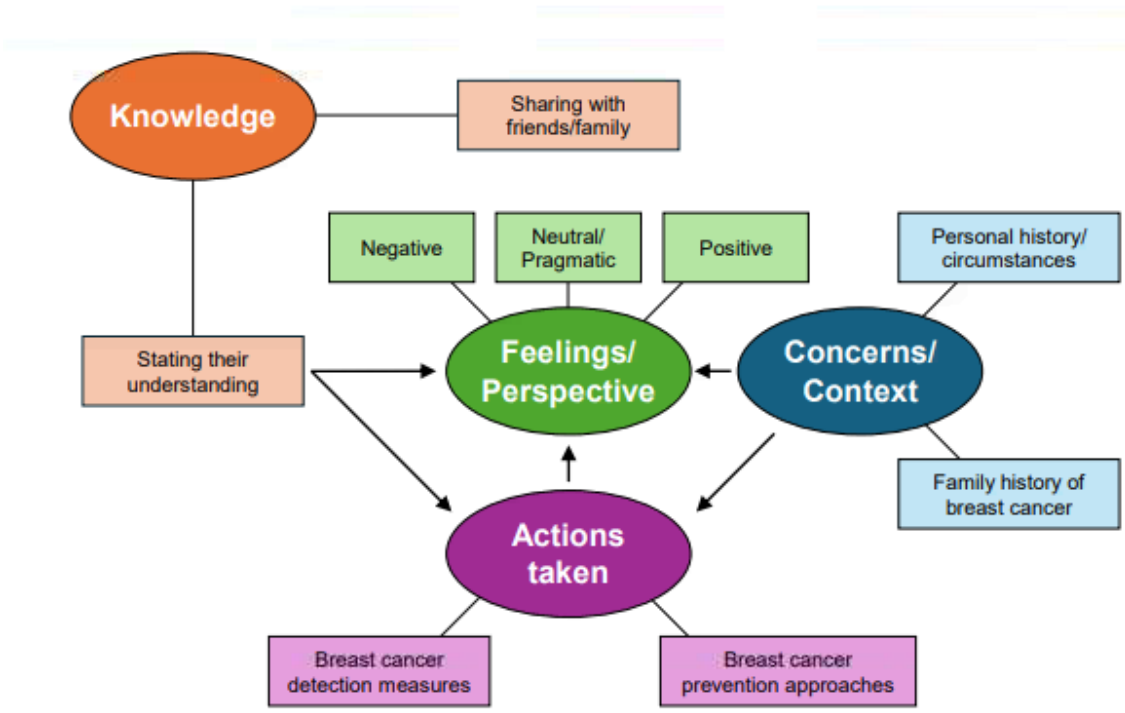

Figure 2: Thematic map showing themes from patients' perspective. The map is colour-coded, with four central themes of knowledge (orange), concerns/context (blue), actions taken (purple), and feelings/perspective (green). Arrows represent codes within one theme linked to a different theme.

They also described concerns in relation to their personal history and circumstances, highlighting the potential desirability for the development of individual management pathways.

> *I've suffered with cysts in my breasts for quite a lot of years and about four years ago they really flared up, which started this whole journey of finding out about the breast density. But my surgeon was really good, so he explained. With the cysts and a bit higher risk now, and not being able to see things quite visible on them. And because I*

live in [rural area]. So he said not to have the mammograms here or anything 'cause the machines in [urban area] were a lot better. ***(Transcript 03_11)***

This study was conducted in a screening cohort attending a public hospital outpatients department, and therefore the context of their concerns will differ from women attending a community-based screening program such as BreastScreen. Regardless of the cohort, decision-making in breast screening can be complex, and not only driven by knowledge, but also by personal values shaped by emotion, past experience, and instinct (29). If risk-based screening models become adopted as part of community screening programs in the future, nuanced conversations about the context of individual concerns may feature more prominently in shared decision-making (30).

Feelings/Perspective

Patients expressed negative feelings of anxiety and concern about their breast density, which was often associated with other factors such as personal or family history of breast cancer or benign conditions. Patients who revealed living with anxiety associated with breast cancer risk often described it as a motivating factor in their actions. Similarly, women notified they have dense breasts can report feelings of anxiety which is associated with increased intention to participate in breast screening (16).

I am a little more anxious only because you know the one lump that I did have removed. While I couldn't say it was completely benign, they could say, well, it wasn't malignant yet. So because I couldn't feel that, I think I'm a little anxious. So I'm very strict on making sure I have my ultrasound and mammogram booked in after I've had my last one. I'll book in my next one just so that I don't forget. ***(Transcript 03_12)***

Patients also expressed positive feelings about their breast density and breast cancer screening. Women notified of low breast density often described feeling reassured, relieved, and confident that mammography would be effective for them and that they did not need to worry about the risk associated with high breast density. Women with high breast density, although largely expressing negative feelings discussed above, also expressed positive feelings such as satisfaction and reassurance regarding how their breast cancer screening was being managed. In this regard, it is worth mentioning that a common theme from a survey of Australian women about breast density notification was that women believed being better informed could help with alleviating anxiety (31).

> *I am happy that I get the 12 monthly check ups because as I say I don't feel lumps and that just helps my concerns.* ***(Transcript 03_09)***

Some patients expressed a neutral or pragmatic perspective to their breast density and to the implications for their chance of developing breast cancer. These included comments around it being just another challenge, the need to get on with life, and that as long as they have all the systems in place they are doing all that they can.

> *The more we know about it, the better. And at my age, I sort of think, if it happens and this is, this in a way it's been my bottom line, I can't stop it from happening.* ***(Transcript 02_08)***

> ***Actions taken***

Patients in this cohort were recruited from the Breast and Endocrine surgery unit outpatients department of The Queen Elizabeth Hospital, and therefore were already taking a number of actions in regards to their breast cancer risk and/or breast cancer screening. These actions included breast awareness, regular mammograms, supplementary screening and medication.

The actions taken by patients were motivated by the multifaceted context of their concerns as well as their feelings towards it. The actions taken were at times described as being part of how patients alleviate their concerns, as described above.

The public hospital-based screening cohort in this study were receiving guidance from breast surgeons, which is a different scenario to the guidance that may be provided to women attending community-based screening. The intention to take action in this public hospital cohort is primarily driven by factors such as a personal or family history, which significantly influences the decision to pursue supplementary screening (32). Women attending community-based screening who are concerned or confused after receiving their breast density information may require more information (16).

General practitioners and breast care nurses may benefit from these findings in their conversations with patients about breast density. Asking open-ended questions can assist in exploring patient concerns and any misunderstandings. The conversation may cover supplementary screening, lifestyle factors that affect breast cancer risk, concerns about family members, and potential medications. Further studies are needed to develop a structured guideline for GPs and breast care nurses to optimally support women with high breast density.

Conclusion

Breast density is at times a misapprehended concept, and patient concerns can be shaped by a spectrum of factors. A nuanced and patient-centred approach is required to effectively address these concerns. Despite this complexity, the conversations between breast surgeons and patients were reasonably straightforward and positive, and perhaps benefited from the surgeons' experience and background knowledge about breast density.

The data suggest that brief doctor-patient consultations that begin with an open-ended question designed to ascertain a patient's existing knowledge of breast density provide a foundation for broad ranging communication. This approach allows patients to express the context of their concerns, their existing knowledge and feelings about breast density notification, and can provide the opportunity for doctors to clarify misconceptions.

Studies such as this can be used to inform doctors about the type of dialogue they might anticipate with patients and together with other evidence, might form the basis for the development of communication guidelines. Such guidelines might be increasingly useful if breast density notification becomes a more regular practice.

4. Disclosure statement:

There is no conflict of interest.

5. Ethical clearance

The study was conducted in accordance with the NHMRC National Statement on the Ethical Conduct of Human Research (2007), and approved by the Ethics Committee of Central Adelaide Local Health Network (protocol code 17945 approved 30 May 2023).

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7. Author contribution

Conceptualization, all authors; methodology, W.V.I., A.B., L.J.H., D.W. and P.D.; software, A.B.; validation, W.V.I., D.W., D.T. and S.J.W.; formal analysis, A.B. and S.E.; investigation, A.B.; resources, A.B., D.W. and W.V.I.; data curation, S.E.; writing—original draft preparation, A.B.; writing—review and editing, all authors; supervision, W.V.I., D.T. and

S.J.W.; project administration, W.V.I., A.B. and L.J.H.; funding acquisition, W.V.I. and A.B. All authors have read and agreed to the published version of the manuscript.

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CHAPTER SIX
CONCLUSION AND FUTURE WORK

These research findings contribute to the field of breast density research and policy development in Australia. Three issues were addressed, namely evaluation of breast density knowledge among South Australian women attending the hospital-based breast cancer screening, investigation of the emotional impact of breast density notification using a validated psychological tool, and exploration of conversation themes in telehealth consultations between breast surgeons and patients notified of their breast density. It does not give answers to all of the questions; however, the knowledge generated provides versatile directions for future breast density research that can assist in rolling out of a national approach to breast density notification.

6.1. Considerations for Australian breast density notification

Australia continues to grapple with establishing clear guidelines for breast density notification, despite advocacy from several groups urging that BreastScreen Australia participants be informed of their breast density and its potential impact on the accuracy of screening results. Currently, routine assessment of breast density is feasible using a range of automated and validated tools. Furthermore, such data would be valuable for the monitoring and evaluation of screening programs (1). However, there is no consensus among BreastScreen Australia programs across all states and territories regarding the notification of women about their breast density, as ongoing debates among experts persist.

A clear guideline for breast density notification with a defined pathway for the clinical management of women with dense breasts has yet to be established. Although efforts to evaluate screening protocols based on breast density and other risk factors are ongoing, there remains a paucity of evidence regarding the relative benefits and risks of breast density notification when specific screening protocols are not provided. In other contexts, such practices have led to an increase in supplemental screening (2). In Australia, this would entail

transferring screening costs to Medicare and to clients, thereby creating inequities in access to population screening (2).

To obtain maximum benefit from breast density notification using standard resources it is important to consider ethical, legal, and financial aspects. This requires careful planning, monitoring, and evaluating how the guidelines are put into practice. However, the challenges associated with privately-funded supplemental screening and its impact on women and the healthcare system are likely to persist. It is essential to closely monitor cancer diagnoses and the rates of imaging and biopsy in benign cases outside the BreastScreen program to obtain comprehensive information about the benefits, harms, and costs of screening (1).

In development of a national consensus on breast density notification, it would be important to consider how screening participants receive this information, and what happens when they speak to their primary health provider. The research in this thesis can be used to support development of future public awareness campaigns, communication strategies, and clinical guidance for management of women with high breast density.

6.2. Improving communication about breast density

Despite being first described in 1976 (3), breast density is a relatively new term in the public understanding of breast cancer screening and breast cancer risk. The research in this thesis reports that in women attending breast screening at a public hospital, 40% were not familiar with the term ‘breast density’. Furthermore, we assessed breast density knowledge, distinguishing between commonly held facts and myths, and discovered a reasonably high level of misconception. Notifying women of their breast density when many have never heard the term before, or do not understand its significance, may lead to confusion that could be avoided with increased public knowledge of breast density.

The predictors of breast density knowledge that were identified in this study, such as age and language spoken at home, might be used in the future to target educational campaigns to

increase breast density knowledge in the community. Furthermore, the common misconceptions identified in this study can be addressed through prioritising dissemination of facts that counter these, such as highlighting that breast density is not related to how breasts look or feel.

To progress and monitor community knowledge of breast density across Australia, a comparative multi-centered commonwealth study could be designed to compare the knowledge and awareness of women dwelling in the notifying and non-notifying states and territories. Several strategies could be planned and executed to address misconceptions; the most contentious issue discovered by this research. Availability of appropriate information by breast density notification will not only increase knowledge, but also help women to participate in shared clinical decisions about their own breast health.

In addition to improving public understanding of breast density, it is also important to consider how women may feel after being notified they have dense breasts. To the best of our knowledge, the research in this thesis is the first to use a scientifically validated and reliable psychological tool to quantify and categorise state anxiety among women after being told their breast density. Moreover, the current study also considered how the participants 'generally feel' through assessment of trait anxiety. This study compared anxiety between women notified of non-dense versus dense breasts and found similar levels of anxiety in both groups. Of significance, was the finding that 20% of women in this cohort had severe underlying anxiety, regardless of their breast density. This is important because women with severe anxiety may react differently to breast density notification compared to those without underlying anxiety.

Studies on the impact of women notified they have low breast density are limited, and this research is the first to explore reactions to notification of non-dense breasts. As the majority of reactions in this group were positive, it can be considered that notification of non-dense breasts

is generally well-received. However, it is worth mentioning the concerns of one woman who was notified of low density. The description of Category A breast density supplied in the letter, and often used in literature, is “mostly fatty”, and this led the individual to be concerned about the health status of her breasts. Although this misunderstanding was addressed by the consultant surgeon in Study 3, it highlights the importance of increasing the community’s general knowledge about breast density and providing clear information that does not cause confusion.

Different notification strategies may elicit different responses in screening participants (4) and it is important to develop communication strategies that will have the least negative impact on all. This study lays the groundwork for future community-based research to develop breast density notification strategies cognizant of the range of experiences and emotions of the people receiving the information.

6.3. Clinical guidance for health professionals

Women notified of dense breasts may seek advice from their general practitioners who may be ill-equipped to have these discussions as there is no structured framework of training, education, and support regarding breast density patient management. The current study provides some insight into what breast surgeons and patients discuss after the patient has been notified of their breast density. This contribution may help to develop structured guidance for optimised clinician-patient communication.

The findings of an Australian study highlighted the urgent need for comprehensive training and support for GPs to effectively engage in discussions and manage care for women with dense breasts, particularly if population-wide notification systems are introduced (5). The existing Australian studies on the knowledge status of GPs (5, 6) recommended to enhance the role of GPs in managing breast density information and notification.

The research in this thesis may assist in development of clinical communication guidelines for health professionals. It is challenging to communicate complex information such as breast density; it is not a 'One size fits all' approach to communication, as many factors need to be considered. For example, patient's readability capacity, literacy level, underlying anxiety status for other events of life might be considered. Our research suggests that consultations that commence with an open-ended question that enables a patient to provide their own understanding and context to their concerns can be an effective approach.

Furthermore, clear guidelines for supplemental screening should be established, considering individual risk factors and best practices. This will help GPs make informed decisions about recommending additional screening for patients with dense breasts. Interdisciplinary collaboration between GPs, radiologists, and other healthcare professionals should be encouraged to ensure a cohesive approach to breast density notification and management. Future studies can be designed to devise a consultation structure to cover all areas whilst maintaining flexibility to be adjusted to the individual patient. This would ideally be tailored for use by GPs. At this moment, considering there is no such resource, the consultation strategies of the surgeons exhibited in this study could be directly deployed into clinical practice, or a clinical trial can be planned that investigates whether a structured conversation can improve patient outcomes.

To support GPs in this role, comprehensive educational programs should be developed. These programs should focus on the clinical significance of breast density, evidence-based supplemental screening options, and effective communication strategies. Providing GPs with up-to-date scientific evidence summaries, informational pamphlets for patients, and professional college educational programs will be crucial in enhancing their knowledge and confidence in discussing breast density.

Finally, ongoing research and evaluation of breast density notification practices should be promoted. GPs should be encouraged to participate in research to contribute to the development of evidence-based policies and communication strategies. This will ensure that the approach to breast density notification remains effective and responsive to new evidence and patient needs.

6.4. Limitations

This research has some limitations which are largely discussed within each chapter of the thesis. However, it is important to also consider this study as a whole, and how the clinical setting of the study and the cultural background of the study participants may have affected the findings.

Only a small fraction (6%) of the participants belong to Non-English-speaking background. Overall, this study cohort is not representative of the Australian community unlike the previous Western Australian study (7). Additionally, the reasons for non-participation of non-responding cohort is unclear. However, it can be speculated that coming from non-English speaking background or different cultures, and dependency on interpreters for clinical appointments can be the plausible reasons of non-participation.

This study was conducted in a tertiary care hospital on a single site, and therefore, generalizability of the study report is challenging. Due to the hospital setting, participants were undergoing breast screening as per their breast surgeon's advice. While this setting may not be directly comparable to a community-based setting such as a cohort attending the BreastScreen Australia program, it does provide information complimentary to community-based settings. For example, the psychological tool used to assess anxiety would be difficult to implement in the BreastScreen setting, as without the individualised support of the clinical team, there is a risk that the psychological tool itself may escalate anxiety. However, it needs to be considered that the findings of this research represent a hospital-based cohort, not a community-based cohort.

6.5. Recommendations for change in practice

Chapter	Publication status	Recommendations for changes in practice
3.	Published in Cancers (Basel) (8)	Raise awareness and promote education about breast density for women attending breast cancer screening.
4.	Published in International Journal of Breast Cancer (9)	Breast density notification approaches need to be considerate of the significant proportion of women with severe underlying anxiety. Co-design of communication strategies with consumers may help mitigate negative reactions to breast density notification.
5.	Submitted to/unpublished	A nuanced and patient-centred approach is required to effectively address breast density concerns in doctor-patient consultations. Commencing doctor-patient consultations with an open-ended question designed to ascertain a patient's existing knowledge of breast density can provide a foundation for broad ranging communication and addressing patient misconceptions.

6.6. Conclusion

Significant changes of Australia's approach to breast density notification are currently underway while pressure is gradually mounting to notify women about their breast density. This study provides a foundation for development of public awareness campaigns, research on improved communication strategies, and development of clinical guidance that supports optimal communication between doctors and patients.

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CHAPTER SEVEN
APPENDICES

Appendix I

Published article

cancers

MDPI

Article

Factors Associated with Increased Knowledge about Breast Density in South Australian Women Undergoing Breast Cancer Screening

Avisak Bhattacharjee [1,2], David Walsh [1], Pallave Dasari [1,2], Leigh J. Hodson [1,2], Suzanne Edwards [3], Sarah J. White [4], Deborah Turnbull [5] and Wendy V. Ingman [1,2,*]

[1] Discipline of Surgical Specialties, Adelaide Medical School, The Queen Elizabeth Hospital, University of Adelaide, Woodville South, SA 5011, Australia; avisak.bhattacharjee@adelaide.edu.au (A.B.); david.walsh2@sa.gov.au (D.W.); pallave.dasari@adelaide.edu.au (P.D.); leigh.hodson@adelaide.edu.au (L.J.H.)
[2] Robinson Research Institute, University of Adelaide, Adelaide, SA 5006, Australia
[3] School of Public Health, University of Adelaide, Adelaide, SA 5005, Australia; suzanne.edwards@adelaide.edu.au
[4] Centre for Social Impact, University of New South Wales, Sydney, NSW 2052, Australia; sarah.white@unsw.edu.au
[5] School of Psychology, University of Adelaide, Adelaide, SA 5005, Australia; deborah.turnbull@adelaide.edu.au
* Correspondence: wendy.ingman@adelaide.edu.au; Tel.: +61-88222-6141

Simple Summary: Breast density is an independent risk factor for breast cancer and can impede detection of cancer by mammography. There is growing awareness of breast density in Australia and globally, but it is unclear whether this awareness is increasing knowledge of what breast density is and what it means to have dense breasts. This study was conducted to investigate South Australian women's knowledge of the common facts and misconceptions about breast density. This study reports that women who had previously heard the term breast density had increased knowledge compared to those who had not, suggesting that current efforts to raise awareness are leading to better knowledge. Despite this, the study shows that there are widespread misconceptions that must be actively dispelled, including the misunderstanding that breast density can be determined by touch.

Abstract: Background: There is growing awareness of breast density in women attending breast cancer screening; however, it is unclear whether this awareness is associated with increased knowledge. This study aims to evaluate breast density knowledge among Australian women attending breast cancer screening. **Method:** This cross-sectional study was conducted on women undergoing breast cancer screening at The Queen Elizabeth Hospital Breast/Endocrine outpatient department. Participants were provided with a questionnaire to assess knowledge, awareness, and desire to know their own breast density. **Result:** Of the 350 women who participated, 61% were familiar with 'breast density' and 57% had 'some knowledge'. Prior breast density notification (OR = 4.99, 95% CI = 2.76, 9.03; p = 0.004), awareness (OR = 4.05, 95% CI = 2.57, 6.39; p = 0.004), younger age (OR = 0.97, 95% CI = 0.96, 0.99; p = 0.02), and English as the language spoken at home (OR = 3.29, 95% CI = 1.23, 8.77; p = 0.02) were independent predictors of 'some knowledge' of breast density. A significant proportion of participants (82%) expressed desire to ascertain their individual breast density. **Conclusions:** While knowledge of breast density in this Australian cohort is generally quite low, we have identified factors associated with increased knowledge. Further research is required to determine optimal interventions to increase breast density knowledge.

Keywords: breast density; mammographic density; knowledge; mammography; breast cancer screening; breast cancer risk

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1. Introduction

Breast density, also known as mammographic density, refers to the radiological appearance of the breast on an X-ray mammogram. High breast density appears on a mammogram as white areas and signifies a high abundance of fibroglandular tissue in the breast in proportion to the abundance of adipose tissue. Breast density is typically quantified as 'percent mammographic density', calculated as the ratio of the area of dense breast tissue to the total area of breast tissue [1,2]. Breast density impacts upon both breast cancer risk and the early detection of breast cancer on a mammogram and has become a major focus of interest within the medical, scientific, and broader community [3,4]. Given the clinical implications, there is ongoing consideration of how best to incorporate breast density into screening recommendations for organised breast screening programs [5].

The American College of Radiology defines four categories of breast density in the 5th edition of Breast Imaging-Reporting Data System (BI-RADS): Category A (Mostly fatty), Category B (Scattered density), Category C (Heterogeneously dense), and Category D (Extremely dense) [6]. Within this classification, the 'Heterogeneously dense' and 'Extremely dense' categories are sometimes grouped together as 'dense breasts', although the studies that have informed current recommendations about risk and screening focus on the extremely dense category and are not generalizable to those with heterogeneously dense breast tissue [7]. Approximately 8% of women within the age range of 40 to 74 have breast tissue categorised as extremely dense and 35% have heterogeneously dense tissue [8]. The BI-RADS classification system is subjective and leads to inconsistencies in measurement [9], which is why new methods for quantitative assessment of breast density are now available, including Volpara and Quantra software [10].

The sensitivity of mammography to detect cancer among individuals with dense breast tissue is reduced compared to those with low density. A recent study, employing the Incremental Cancer Detection Rates (ICDR), estimated that approximately 267,000 mammographically occult undetected tumours may be present among women with dense breast tissue who participated in a population-based screening program in 2021 in the United States [11]. A tumour missed in a dense breast could result in unfavourable consequences such as an interval cancer, which is a breast cancer diagnosis after a negative screening mammogram and before the next mammogram is due [12]. Conceivably, this cancer might have been pre-existing during the unremarkable mammogram, concealed beneath the more radiopaque and whiter background of high breast density. Up to fifty percent of cancers detected through mammography may evade detection due to the masking influence exerted by extremely dense breast tissue [13].

In addition to causing reduced sensitivity of mammography to detect cancer, breast density is also an independent risk factor for breast cancer. Women categorised with extremely dense breasts have a 4–6-fold greater risk of breast cancer compared to those categorised with mostly fatty breasts when matched with age and BMI [14–16]. Up to 35% of pre-menopausal breast cancer and 16% of post-menopausal breast cancers can be attributed to breast density [17]. Moreover, while not conclusively established [18], breast density may also increase breast cancer-specific mortality [19].

Considering the significance of breast density in risk and detection of breast cancer, the Food and Drug Administration, in a statement dated 9 March 2023, announced the revision of its mammography regulations, necessitating the incorporation of breast density information into facility reports [20]. The European Union Society of Breast Imaging recently released screening recommendations for women with extremely dense breasts, stating that "women should be appropriately informed about their individual breast density... and on the diagnostic and prognostic implications of having dense breasts" [21].

In Australia, breast cancer screening is conducted largely within the BreastScreen Australia public screening program. The policies of both BreastScreen Australia and the Royal Australian and New Zealand College of Radiologists are to not report breast density within the population-based screening program [3,22,23]. However, BreastScreen Western Australia, BreastScreen South Australia, and the majority of private screening providers

currently incorporate breast density notification into their screening protocol. For over a decade, BreastScreen Western Australia has notified women who have dense breasts. The notification includes an explanation about how high density can potentially impede cancer detection and provides participants with a website link with further explanation of breast density, encompassing its potential associated risks [3,24]. More recently, BreastScreen South Australia commenced notification of breast density to all screening participants commencing August 2023, following the successful execution of a pilot study [25].

However, breast density notification may not achieve the intended positive outcomes if there exists a lack of understanding about what breast density is. Furthermore, there may be common misconceptions about breast density that impede people's knowledge. Currently, there is limited research on the knowledge of Australian women about breast density. One study evaluated knowledge in women attending BreastScreen Western Australia, finding that, among the cohort of breast density notified women, 85% knew about the reduced sensitivity of detecting cancer on a mammogram due to breast density, a significant contrast to the non-notified group, where 54% knew about this reduced sensitivity [24]. Furthermore, 25% of notified women were cognizant of the increased breast cancer risk associated with dense breasts, which stands in contrast to the 13.2% knowledge rate observed in the non-notified group. In the present study, we aimed to assess awareness and knowledge about breast density in a South Australian cohort, and investigate whether women want to know their breast density. This study was conducted prior to the recent change in policy by BreastScreen South Australia and may serve as a baseline for future investigations assessing the impact of widespread notification on breast density knowledge.

2. Materials and Methods

This cross-sectional study was conducted in women attending the outpatient department of the Breast/Endocrine Surgical unit of The Queen Elizabeth Hospital between March 2022 and July 2023 (CALHN Ethics approval reference number 15681). The study was completed just prior to the introduction of breast density notification policy by BreastScreen South Australia, which was implemented in August 2023 [25]. The Queen Elizabeth Hospital is the second-largest tertiary healthcare institution in South Australia, addressing the medical needs of around 244,000 individuals spanning seventeen suburbs in the western region of the city. Of this population, 51% are female. The median weekly household income among residents in private accommodations is 1516 AUD and 68% of the inhabitants within the hospital's catchment area predominantly speak in English for household communication [26].

2.1. Survey Procedure

All women who attended the outpatient department for breast screening during the study period were invited to participate. Participants were provided with a questionnaire about breast density awareness and knowledge. The questionnaire was based on a questionnaire designed to assess breast density knowledge in a Western Australian cohort [24]. All the women in the waiting bay who were attending the clinic for a screening mammogram were actively engaged. Women who appeared to be distressed to the researcher (AB) and those lacking the capability to provide informed consent were ineligible to participate.

Sociodemographic and clinical data from the patient database were retrieved from the Electronic Medical Record. These data included age, suburb of residence (extracted to determine Accessibility/Remoteness Index of Australia-ARIA and Socio-Economic Index for Areas-SEIFA), screening frequency, and breast density status measured by Volpara software version 3.4. Language spoken at home was self-reported through the questionnaire.

The questionnaire assessed recognition of the term 'breast density', prior screening and breast density notification, whether participants wanted to know their breast density, as well as five key questions that assessed knowledge about breast density (see the Supplementary File). Participants who answered one key knowledge question correctly or less were defined as having 'low knowledge'; those who answered two and above correctly were defined as

having 'some knowledge' about breast density. The categories of 'low knowledge' and 'some knowledge' were established by the research team following a discussion, where a consensus was reached that this approach would provide a sensible and pragmatic representation of women's knowledge.

2.2. Statistical Analysis

The participants' sociodemographic characteristics including age, language spoken at home, Socio-Economic Index of Australia (SEIFA), Accessibility/Remoteness Index of Australia (ARIA), and clinical profile including number of mammograms in the last 3 years and breast density status within the cohort were expressed in frequency and percentages. The data regarding the women who had ever heard the term 'breast density' and 'who were told about their own breast density by any health professionals' were also calculated for descriptive representation.

Both sociodemographic and clinical variables were tested as predictors of 'some knowledge' about breast density by multivariable binary logistic regression analysis. Response of the participants to each key question and their interest to know about own density was individually tested against the significant predictors of knowledge by multivariable binary logistic regression analysis.

Missing data were managed using an imputation method. Specifically, in instances where categorical variables exhibited missing values, imputation was performed by substituting these values with the mode of the respective category. Categorical variables were presented using frequency and percentage, while continuous variables were summarised using mean and standard deviation. To evaluate the relationship between dependent and independent variables, odds ratios (OR) were employed. The precision of these estimates was further evaluated through the calculation of 95% confidence intervals (95% CI). Significance testing was conducted using Fisher's exact test and the chi-square test to determine the p-value (<0.05 being classed as statistically significant). All the determined p-values were adjusted using Benjamini–Hochberg method. Analyses were performed using IBM SPSS statistics version 28.

3. Results

Overall, 427 women were invited to participate, with 346 women providing immediate responses. Six women opted to take the questionnaire home to complete at their convenience and subsequently mail it back; however, only four of them returned the questionnaire. In sum, 350 ultimately responded to the questionnaire, yielding a response rate of 82%.

Table 1 provides a comprehensive summary of the baseline characteristics encompassing sociodemographic variables and knowledge status, prior awareness of the term 'breast density', and desire to know their breast density. The mean age of the respondents was 61 years (SD 11.45). Seventy percent of respondents were in the current Australian breast screening target age group of 50–74 years, with 17% aged between 40–49 years, and 13% aged 75 and older. Most respondents reported English as their primary language (94%). A substantial 97% of the cohort resided in major cities, according to the Accessibility/Remoteness Index of Australia (ARIA), signifying they were located in highly accessible, accessible, or moderately accessible areas (Table 1).

Table 2 provides a synopsis of the factors associated with 'some knowledge' about breast density, defined as a score of two or more out of five questions answered correctly. Younger age, English as the language spoken at home, prior awareness of the term 'breast density', and prior notification of one's own breast density were significant predictors of some knowledge about breast density.

Table 1. Characteristics of the study participants.

Variables	Frequency
Age (years)	
Mean (SD)	61.10 (±11.45)
Language spoken at home	
English	330 (94%)
Other	20 (6%)
Heard of breast density before	
Heard about breast density	215 (61%)
Never heard about breast density	135 (39%)
Accessible/Remoteness Index of Australia	
Highly accessible/Accessible/Moderately accessible	341 (97%)
Remote/Very remote	9 (3%)
Ever been told own breast density by any health professionals	
Yes	90 (26%)
No/Don't know	260 (74%)
Breast density status	
High density (C/D)	234 (67%)
Low density (A/B)	116 (33%)
Want to know their own breast density	
Yes	286 (82%)
No/Don't know	64 (18%)
Breast density knowledge status	
Low knowledge (Score 0–1)	151 (43%)
Some knowledge (Score 2 and above)	199 (57%)

Table 2. Multivariable binary logistic regression analysis for independent predictors associated with 'some knowledge' about breast density.

Independent Predictors	Comparison	OR (95% CI)	Global *p*-Value *
Age		0.97 (0.96, 0.99)	0.02 *
Language at home	English vs. Others	3.29 (1.23, 8.77)	0.02 *
Heard of breast density before	Yes vs. no/don't know	4.05 (2.57, 6.39)	0.004 *
Ever been told about own breast density	Yes vs. no/don't know	4.99 (2.76, 9.03)	0.004 *
SEIFA [a] decile		1.02 (0.94, 1.11)	0.95
ARIA [b]	Accessible vs. Remote	1.06 (0.28, 4.00)	0.95
Number of previous mammograms [c]		1.01 (0.82, 1.23)	0.95
Breast density status	High (C, D) vs. Low (A, B)	1.06 (0.67, 1.66)	0.95

Binary logistic regression modelling 'some knowledge' as response and 'low knowledge' as reference. a. SEIFA-Socio Economic Index, b. ARIA-Accessibility/Remoteness Index of Australia, c. in last 3 years. * Significant *p*-value after Benjamini–Hochberg adjustment. OR, odds ratio; CI, confidence interval.

Table 3 delineates the extent to which predictors associated with 'some knowledge' contributed to knowledge of specific factual information about breast density. Younger age, prior notification of breast density, and prior awareness of the term 'breast density' were significant predictors for knowing that breast density can mask cancer on a mammogram. With regard to knowledge about the potential requirement for further tests in women with high breast density, younger age, English as a language spoken at home, prior notification of breast density, and prior awareness of the term 'breast density' all demonstrated significance. However, only prior notification of breast density and prior awareness of the term

'breast density' significantly contributed to knowledge that high breast density is a risk factor for breast cancer.

Table 3. Multivariable binary logistic regression analysis for independent predictors of knowledge associated with common facts about breast density.

Independent Predictors	Do You Think Dense Breast Tissue Makes It More Difficult to See Cancer on a Mammogram?		Do You Think That, after a Mammogram, Sometimes Women May Require Further Tests because They Have Dense Breast Tissue?		Do You Think Having Breasts That Are Mostly Dense on a Mammogram Puts You at Increased Risk for Breast Cancer?	
	Frequency (%)	**OR (95% CI) *p*-Value**	**Frequency (%)**	**OR (95% CI) *p*-Value**	**Frequency (%)**	**OR (95% CI) *p*-Value**
Age		0.97 (0.95, 0.99) 0.001 *		0.96 (0.94, 0.98) <0.001 *		0.99 (0.97, 1.02) 0.55
Language at home						
English	158/330 (48%)	1.71 (0.66, 4.38) 0.27	202/330 (61%)	2.93 (1.14, 7.54) 0.03 *	77/330 (23%)	1.73 (0.49, 6.04) 0.52
Others	7/20 (35%)		7/20 (35%)		3/20 (15%)	
Ever been told about breast density by any health professionals						
Yes	73/90 (81%)	7.84 (4.37, 14.09) 0.001 *	72/90 (80%)	3.59 (2.03, 6.36) 0.001 *	35/90 (39%)	3.040 (1.79, 5.18) 0.004 *
No/Don't know	92/260 (35%)		137/260 (53%)		45/260 (17%)	
Heard of breast density before						
Yes	131/215 (61%)	4.64 (2.88, 7.45) 0.001 *	148/215 (69%)	2.68 (1.72, 4.18) 0.001 *	60/215 (28%)	2.23 (1.27, 3.90) 0.02 *
No/Don't know	34/135 (25%)		61/135 (45%)		20/115 (17%)	

Binary logistic regression modelling correct answer as response and wrong answer as reference. * Significant *p*-value after Benjamini-Hochberg adjustment. OR, Odds Ratio; CI, Confidence interval.

Table 4 shows the degree to which factors predicted knowledge about common misconceptions related to breast density. English as a language spoken at home, prior breast density notification, and prior awareness of the term 'breast density' were predictive of participants' knowledge that breast density is not related to how breasts look or feel. Similarly, the latter two predictors were associated with knowledge that breast density is not related to breast size.

Table 4. Multivariable binary logistic regression analysis for independent predictors of knowledge associated with common misconceptions about breast density.

Independent Predictors	Do You Think Breast Density Can Be Determined by Feel or Touch?		Do You Think Women with Large Breasts Are More Likely to Have Dense Breast Tissue Than Women with Small Breasts?	
	Frequency (%)	**OR (95% CI) *p*-Value**	**Frequency (%)**	**OR (95% CI) *p*-Value**
Age		0.99 (0.97, 1.01) 0.28		0.98 (0.97, 1.02) 0.69
Language at home				
English	101/330 (31%)	3.97 (0.90, 17.43) 0.09	91/330 (28%)	2.37 (0.83, ∞) 0.004 *
Others	2/20 (10%)		0/20 (0%)	
Ever been told own breast density by any health professionals				
Yes	36/90 (40%)	1.92 (1.16, 3.18) 0.02 *	33/90 (37%)	2.11 (1.20, 3.39) 0.01 *
No/Don't know	67/267 (25%)		58/260 (22%)	
Heard of breast density before				
Yes	78/215 (36%)	2.51 (1.50, 4.20) 0.004 *	68/215 (32%)	2.25 (1.32, 3.84) 0.004 *
No/Don't know.	25/135 (19%)		23/135 (17%)	

Binary logistic regression modelling correct answer as response and wrong answer as reference. * Significant *p*-value after Benjamini–Hochberg adjustment OR, odds ratio; CI, confidence interval.

Table 5 shows that eighty two percent of respondents expressed their interest in knowing their own breast density. Age, language spoken at home, and awareness of breast density were not predictors of whether women wanted to know their density.

Table 5. Multivariable binary logistic regression analysis for independent predictors of interest to know own breast density.

Variables	You Are Waiting to Have a Mammogram at TQEH, and This Will Show Your Breast Density. Would You like to Be Told Your Breast Density?	
	Frequency (%)	**OR (95% CI)** ***p*-Value**
Age		0.99 (0.96, 1.01) 0.28
Language at home		
English	271/330 (82%)	1.53 (0.54, 4.38)
Others	15/20 (75%)	0.43
Ever been told about breast density by any health professionals		
Yes	80/90 (89%)	2.09 (1.02, 4.32)
No/Don't know	206/260 (79%)	0.14
Heard of breast density before		
Yes	182/215 (85%)	1.64 (0.95, 2.84)
No/Don't know	104/135 (77%)	0.14

Binary logistic regression modelling 'want to know' as response and do not want to know as reference. *p*-value after Benjamini–Hochberg adjustment. OR, odds ratio; CI, confidence interval.

4. Discussion

This study provides insight into awareness and knowledge about breast density among women in Australia. The findings reveal a significant deficit in fundamental knowledge of breast density, even though many of the participants were familiar with the term 'breast density'. Moreover, women were largely unaware that breast density is a risk factor for breast cancer, despite many possessing knowledge about the masking effect. This study elucidates the factors that contribute to increased breast density knowledge, including younger age, English language spoken at home, prior breast density notification, and breast density awareness.

With ongoing discussion both in Australia and internationally as to the need for notification of breast density, this study highlights the informational needs of women to support accurate knowledge of breast density and the high degree of preference for knowing such information. Notably, South Australia is the second state in Australia, following Western Australia, to implement breast density notification as an integral component of the population-based screening program [3,20,21,25]. The Australian context differs from the United States, given that, by April 2015, a total of 22 states had enacted legislation mandating to notify women about breast density [27]. Likewise, information pertaining to breast density is distributed across the six jurisdictions in Canada in a comprehensive manner. Among them, five inform specifically women classified under category D directly, while one provides information to their respective physicians [28]. As notification in BreastScreen South Australia was commenced subsequent to the closing of this study, it is worth mentioning that the study cohort had not been generally exposed to density notification at the screening program before participating here.

Regarding awareness among the study cohort, sixty percent of respondents had heard the term 'breast density' before. The level of awareness among South Australian women is notably lower compared to Western Australian women (>80%), where breast density notification has been more widespread [24].

The questionnaire revealed that approximately one-quarter of the study cohort had been notified of their own breast density, a finding that aligns with the results of a prior study conducted in the United States during a period when breast density notification

was not mandated by legislation [29]. Less than 60% of participants correctly answered two or more questions out of five about breast density. Younger age and English language spoken at home were predictors of some knowledge, suggesting that targeting information to older women and those not fluent in English may provide opportunities to increase South Australian women's knowledge about breast density. These findings underscore a fundamental knowledge deficit about breast density among Australian women.

At the same time, awareness of breast density was a predictor of knowledge, suggesting that efforts in Australia to raise awareness have had an impact on knowledge. Similar findings were observed in a recent study conducted in Croatia [30]. This is in contrast with recent studies conducted in the United States. Variables including education, screening history, and preferred language were found to play a role in disparities in awareness but did not exert significant impact on knowledge levels [31]. Another US study reported that density notification may increase overall awareness; however, it may not have a discernible impact on increasing knowledge concerning the masking effect and the risk associated with breast cancer [32]. Further research is required to establish optimal approaches for raising awareness about breast density that leads to increased knowledge.

In the current investigation, only 23% of women were aware that high breast density is a risk factor for breast cancer. This figure is nearly three times lower than that reported in a prior U.S. study, where breast density notification is mandated by law [33]. A European study suggests that awareness of breast cancer risk can have a favourable impact on breast screening rates [30]. Considering these findings, it is imperative to devise strategies for enhancing this important knowledge among women, aiming to promote greater participation in healthy lifestyles, breast awareness, and screening programs.

Several states within the United States have already demonstrated positive outcomes by incorporating breast density notification into their population-based screening programs, leading to enhanced knowledge and awareness of breast density among women and increased participation in subsequent screening [33]. However, the exclusion of breast density information in breast cancer screening in Australia is viewed by consumers as failing to adequately address women's 'right to know' and the enablement of their involvement in shared decision-making processes [3,34]. Interestingly, eighty-two percent of the respondents indicated a desire to ascertain their individual breast density, regardless of their level of awareness or whether they had been previously told their breast density by a health professional. This outcome reflects a broad interest in knowing one's density, and is similar to the results observed in a pilot study conducted by BreastScreen South Australia [25].

Regrettably, there exists the risk of common misconceptions that may taint genuine knowledge. Common misconceptions regarding breast density, such as the belief that it can be diagnosed through touch or is associated with breast size, are prevalent. Notably, the current study identifies the key predictors dispelling these prevalent misconceptions among women. In this context, both prior breast density notification and breast density awareness play pivotal roles. While the current study suggests that awareness and notification is associated with increased knowledge about breast density, more communication is required to comprehensively dispel common misconceptions. Websites [35] and factsheets [36] that provide breast density information should be aware of these common misconceptions and actively seek to dispel them. For the most comprehensive information, personalised counselling within a dedicated radiologist-run breast density consultation may foster better understanding among women about breast density and augment their participation in shared decision-making [37].

However, radiologist consultation regarding breast density is not practical within population-based breast screening. The inclusion of general practitioners (GPs) and breast care nurses in this context could afford a more cost-effective and efficient support system for women with dense breasts. Given the inherent diversity in women's knowledge levels and individual risk, we posit that personalised, one-on-one consultations is preferred, as a 'one size fits all' approach may not suffice. Given the limited understanding of mammo-

graphic density among Australian GPs [22], it is also imperative to explore approaches for enhancing their education and training. Well-structured and comprehensive training to GPs and breast care nurses could empower them with the requisite knowledge and competencies to guide women about critical information concerning breast density. This approach would empower women to be actively involved in making decisions on how best to manage their breast cancer risk and breast cancer screening in line with the National Women's Health Strategy 2020–2030 of Australia [38] and Women's Health Strategy for England 2022 [39].

This study addresses critical gaps within the extant literature, notwithstanding certain limitations. We enrolled women from a single centre and generalisability may be limited. Moreover, we did not collect data on the literacy status of women, despite its considerable influence on breast density awareness status [31]. This study cohort included only 6% of participants reporting speaking a language other than English at home. While there was a statistically significant difference in the odds of having some knowledge about breast density between the two language groups, the wide confidence interval may reflect the low proportion of participants speaking another language at home. Another constraint is our inability to elucidate the reasons for study non-participation among non-respondent women. It is plausible to speculate that non-participation might be influenced by factors such as coming from culturally and linguistically diverse (CALD) backgrounds and the need for interpreters for clinical appointments. The proportion of participation of women coming from CALD backgrounds was lower than the expected population from The Queen Elizabeth Hospital catchment area. A drawback of this kind of questionnaire for non-English speaking participants is the reliance on hospital interpreters, whose principal role is assisting patients in the context of their clinical consultation, not completing a research questionnaire. Interestingly, the majority of responses we received from CALD participants were when a family member proficient in English was present to assist, rather than a professional interpreter. To increase participation in women from CALD backgrounds, the study questionnaire should be translated into different languages.

The primary merit of this study is its capacity to discriminatively pinpoint influential predictors of common factual knowledge and misconceptions about breast density. Another notable strength of this study is its high response rate of 82%, which exceeds that of prior studies with similar [29] and even larger cohorts [24,33].

5. Conclusions

While knowledge of breast density in this Australian cohort is generally quite low, we have identified factors associated with increased knowledge. Women who had previously heard the term breast density had increased knowledge compared to those who had not, suggesting that current efforts to raise awareness are leading to better knowledge. Despite this, there are widespread misconceptions that must be actively dispelled, including the misunderstanding that breast density can be determined by touch. These findings support further efforts to raise awareness and promote education about breast density for women attending breast cancer screening.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/cancers16050893/s1, study questionnaire.

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Research Article

The Impact of Breast Density Notification on Anxiety in South Australian Women Undergoing Breast Cancer Screening

Avisak Bhattacharjee,[1,2] **David Walsh**,[1] **Pallave Dasari**,[1,2] **Leigh J. Hodson**,[1,2] **Suzanne Edwards**,[3] **Sarah J. White**,[4] **Deborah Turnbull**,[5] **and Wendy V. Ingman**[1,2]

[1]*Discipline of Surgical Specialties, Adelaide Medical School, The Queen Elizabeth Hospital, University of Adelaide, Woodville South, South Australia, Australia*
[2]*Robinson Research Institute, University of Adelaide, Adelaide, South Australia, Australia*
[3]*School of Public Health, University of Adelaide, Adelaide, South Australia, Australia*
[4]*School of Clinical Medicine, University of New South Wales, Sydney, New South Wales, Australia*
[5]*School of Psychology, University of Adelaide, Adelaide, South Australia, Australia*

Correspondence should be addressed to Wendy V. Ingman; wendy.ingman@adelaide.edu.au

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Purpose: The purpose was to investigate the impact of breast density notification on anxiety using the State and Trait Anxiety Inventory (STAI) tool in South Australian women undergoing breast cancer screening.
Methods: A survey-based cross-sectional mixed method study was conducted in women attending breast cancer screening at the Queen Elizabeth Hospital Breast/Endocrine outpatient department ($n = 100$). The women had participated in a previous study assessing their general knowledge of breast density and had indicated they wanted to know their own breast density. Breast density was assessed using Volpara software, and the participants were notified by letter. The STAI tool was administered with an additional question asking how participants felt after being told their breast density. State and trait anxiety levels were compared between those receiving notification of dense breasts and those notified of nondense breasts.
Results: State anxiety scores were not different between women notified they had dense breasts ($n = 34$, mean state anxiety ± SD; 36.65 ± 13.03) and those who had nondense breasts ($n = 66$, 35.17 ± 13.60, $p = 0.51$). Severe trait anxiety was observed in 8 of 34 (23%) and 13 of 66 (20%) women in the dense and nondense groups, respectively, and there were no significant differences. Qualitative analysis of 122 coded responses revealed the majority of reactions to breast density notification were positive or neutral, with 17% being negative.
Conclusion: Notification of dense breasts was not associated with elevated anxiety when compared to the notification of nondense breasts. Breast density notification approaches need to be considerate of the significant proportion of women with severe underlying anxiety.

1. Introduction

Breast density is related to the proportion of the fibroglandular tissue to fatty tissue in the breast; the dense tissue is predominantly fibroglandular tissue and appears white, and nondense fatty tissue appears dark [1]. Breast density is an independent risk factor for breast cancer and can mask cancers on a mammogram [2, 3]. While notifying women of their breast density when they have a mammogram cancer can assist in decision-making around how best to manage their breast health, there are several concerns with this practice [4]. One concern is the potential for increased anxiety and confusion among women. Studies have suggested that women notified of their breast density can report feelings of anxiety, worry, and confusion regarding their breast health [5–7].

Despite these concerns, there is a growing number of women being notified of their breast density when they have

a mammogram. Breast density notification was legislated by the US Food and Drug Administration in 2023 [8]. The European Union Society of Breast Imaging also recommend informing women about their individual breast density and breast MRI for women with high breast density [9]. A number of jurisdictions in Canada also notify women of their breast density as part of community-based screening programs [10]. In Australia, the Royal Australian and New Zealand College of Radiologists updated their position statement in favour of notification in 2023 [10, 11]. BreastScreen Australia, the national umbrella organisation for breast screening does not record or report breast density to clients [11], although notification has been implemented in three different state-based BreastScreen programs [12–14].

Anxiety can be defined as "an abnormal and overwhelming sense of apprehension and fear often marked by physical signs (such as tension, sweating, and increased pulse rate), by doubt concerning the reality and nature of the threat, and by self-doubt about one's capacity to cope with it" [15]. State anxiety manifests as transient feelings of apprehension, worry, and fear elicited by a specific stimulus, while trait anxiety denotes an individual's inherent tendency towards experiencing anxiety, constituting a deeply ingrained aspect of their personality [15]. Trait anxiety is shaped by a multitude of factors including genetic predisposition, physiological mechanisms, hormonal influences, environmental context, cultural background, and societal influences [16–18]. While trait anxiety can exacerbate and intensify state anxiety, it is important to recognise that these two forms of anxiety may also possess distinct characteristics and may evolve independently of one another [17].

Women's psychological constructs and attitudes to breast density notification remain underexplored [6]. Studies that investigate anxiety associated with breast density notification within community-based public screening cohorts have typically relied on self-reported anxiety measures, not validated psychological tools [5, 19]. This is primarily due to limitations in the study setting and the possibility for the psychological tool to escalate the psychological stress of the participant.

The principal aim of this study was to investigate anxiety status and the reaction of Australian women to breast density notification using the State and Trait Anxiety Inventory (STAI) tool. The study was conducted within the setting of breast cancer screening in a large public hospital, which enabled a more probing investigation of anxiety measures compared to those conducted in the setting of community-based screening.

2. Methods

2.1. Study Design and Setting. A cross-sectional mixed methods survey was conducted between February and October, 2023 at the Breast and Endocrine public outpatient services of the Queen Elizabeth Hospital (TQEH), in Adelaide, South Australia (Figure 1).

2.2. Participant Recruitment and Selection. Female participants were recruited from an existing consecutive cohort who had participated in an earlier study assessing knowledge of breast density [20]. The cohort for this initial study was over 18 years of age, not suspected to have breast cancer, and attending TQEH for a routine mammogram. The participants were not part of the community-based BreastScreen Australia screening program, rather they were a hospital-based cohort attending the Breast and Endocrine outpatient department at regular intervals for routine mammograms. They did not have any breast cancer symptoms at the time of the mammogram. There are several indications for undergoing hospital-based routine mammography including previous breast cancer or benign condition, strong family history, or a genetic predisposition. Therefore, this cohort may be more concerned about their breast health in comparison to those attending community-based screening. Women were excluded if they were unable to provide informed consent and/or appeared to the researcher to be distressed. All participants provided informed consent for the study.

2.3. Data Collection and Procedure. The following questions were asked in the initial study: "You are waiting to have a mammogram at TQEH, and this will show your breast density. Would you like to be told your breast density?" and "The Queen Elizabeth Hospital is conducting a number of studies about breast density. If you are eligible for any studies, would you like a researcher to contact you?"

Participants who answered "yes" to the former question received the breast density notification letter by post from the consultant breast surgeon (D.W.). The letter was codesigned by the authors and a representative from the Australian Breast Density Consumer Advisory Council. It contained a breast density assessment obtained by Volpara software version 3.4 employing the BI-RADS 5th edition breast composition classification. Participants were notified their breast density was Category A, B, C, or D. The letter described the relevant breast density category using the descriptors provided by Volpara, with Category A and B being described as nondense and Category C and D being described as dense [21].

Participants who also answered "yes" to the latter question, received either an anonymised online survey (Qualtrics software) or a hard-copy survey containing the 6 items from the Mind Garden STAI that evaluates how the participant feels in the last 7 days and how they feel generally [15]. The survey was sent 7 days after the notification letter. Reminders via phone and text message were sent after 48 h of sending the survey. Participants were required to respond to the survey within the next 7 days in order to be included in the study.

The following free-text, no word limit question was also included in the survey "How do you feel after being told about your breast density?"

2.4. Outcomes. State and trait anxiety scores were calculated from the Mind Garden manual, with the maximum anxiety scores of both state and trait anxiety being 80 [15]. Participants were categorised as having state and trait anxiety in the following ranges: "no or low anxiety" (scores between

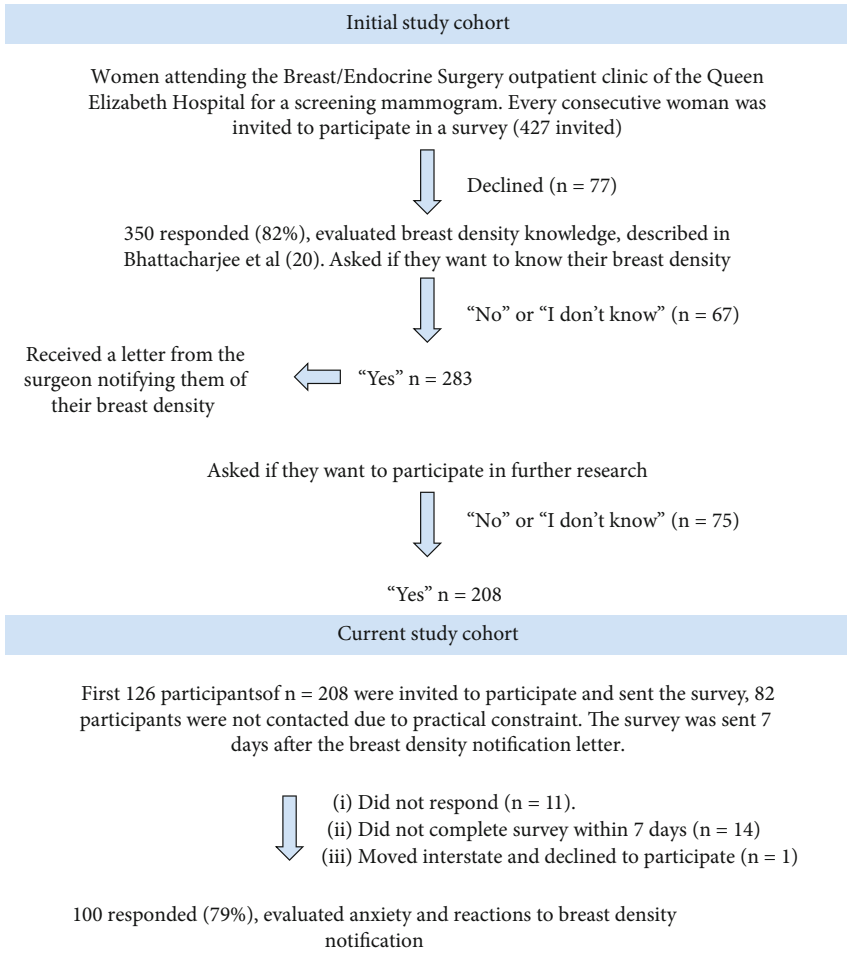

Figure 1: Flowchart of participation in breast density studies. The cohort for the current study was a subset of the initial cohort who had participated in a study assessing breast density knowledge.

20 and 37), "moderate anxiety" (scores between 38 and 44), and "severe anxiety" (scores between 45 and 80) [22]. Outcomes were analysed in relation to participants' breast density status, with those receiving a letter notifying them of Category A and B being considered "nondense," and those receiving a letter notifying them of Category C or D being considered "dense." These categories were used based on the descriptors provided in the breast density notification letter.

2.5. Data Analysis. Data from the STAI tool were analysed using IBM SPSS software version 28, with missing data managed using imputation method (mode of the respective category substituted for categorical data). Categorical data and continuous data were analysed, respectively, using the chi-square test or Mann–Whitney U test. Effect sizes were measured using Cohen's d [23], and p values were considered statistically significant at < 0.05.

Responses to the open-ended question were analysed by an iterative 3-step summative content analysis method [24] with the researchers (A.B., D.T., and W.V.I.) blinded to breast density status of the participant. To enhance transparency and analytic rigor, the findings from the six unique themes produced by this process were reviewed by a member of the research team who is also a mammographer employed by BreastScreen Australia (L.J.H.). The responses were then unblinded and categorised according to breast density status.

2.6. Ethics Approval. The study was conducted in accordance with the NHMRC National Statement on the Ethical Conduct of Human Research (2007) and approved by the Human Research Ethics Committee of Central Adelaide Local Health Network (protocol #16630 approved 01 November 2022).

3. Results

3.1. Sample. A total of 427 women who were attending the Breast/Endocrine outpatients department for routine mammography were identified as eligible for the initial research and were invited to participate. Of these, 350 (81.9%) women took part in the earlier study and 208 (59%) wanted to know their breast density and wanted to be contacted about future research studies (Figure 1). Due to time constraints and practical considerations, only the first 126 were

TABLE 1: Sociodemographic variables of the participants.

Variables	Dense breast ($n = 34$) n (%)	Nondense breast ($n = 66$) n (%)	Overall in current study ($N = 100$)	Overall in prior study ($N = 350$) [20]
Age (mean ± SD)	59.60 ± 10.89	61.09 ± 9.53	60.58 ± 9.98	61.10 (±11.45)
Marital status				
Married de facto	20 (59)	45 (68)	65 (65)	215 (61)
Never married	6 (18)	8 (12)	14 (14)	46 (13)
Separated/divorced	6 (18)	9 (14)	15 (15)	63 (18)
Widowed	2 (6)	4 (6)	6 (6)	26 (7)
Language spoken at home				
English	34 (100)	66 (100)	100 (100)	330 (94)
Others	0 (0)	0 (0)	0 (0)	20 (6)
SEIFA				
Most disadvantaged (lowest third of decile)	14 (41)	34 (51)	48 (48)	180 (51)
Moderately advantaged (middle third of decile)	15 (44)	22 (33)	37 (37)	111 (32)
Highly advantaged area (highest third of decile)	5 (15)	10 (15)	15 (15)	59 (17)
Mammogram in last 3 years				
1–2	9 (26)	21 (31)	30 (30)	136 (39)
≥ 3	25 (74)	45 (68)	70 (70)	214 (61)

TABLE 2: Average STAI scores according to breast density ($N = 100$).

Anxiety types	Dense breast ($n = 34$)		Nondense breast ($n = 66$)		p value	Cohen's d
	Variability	95% CI	Variability	95% CI		
State						
Mean (SD)	36.65 (13.03)	32.10, 41.20	35.17 (13.60)	31.83, 38.51	0.51	0.11
Median (IQR)	37 (22.25, 47.75)		33 (20, 47)			
Trait						
Mean (SD)	37.62 (11.44)	33.63, 41.61	35.19 (12.51)	32.11,38.27	0.26	0.19
Median (IQR)	37 (29.25, 44)		33 (26,43)			

Note: p value is significant at < 0.05. p value is determined by the Mann–Whitney U test.

sent questionnaires, of whom 100 (79%) replied within the prespecified period of 7 days after being sent the survey. Of these, 34 women had been notified they had dense breasts and 66 had been notified they had nondense breasts (Table 1). Women had a mean age of about 60 years. All participants identified as speaking English at home. Nearly half of the participants were from the most disadvantaged areas in terms of the SEIFA and two-thirds had had three or more mammograms in the last 3 years.

3.2. State and Trait Anxiety. We found no statistically significant or clinically relevant differences in average state and trait anxiety scores of women in the dense and nondense breast groups (Table 2). Average scores were in the vicinity of no or low anxiety and Cohen's d indicated negligible to small differences between the dense and nondense groups. There were no statistically significant differences in the two groups in categorical scores for both state and trait anxiety. About a half of women in the dense breast group and 61% in the nondense group scored in the no or low state anxiety range, and about one-quarter of women in both groups had scores in the severe state anxiety range (Table 3). The distribution was similar for trait anxiety.

3.3. Perception After Receiving Breast Density Status. The summative content analysis produced 122 discrete codable statements generating 6 themes across the single open-ended question, "How do you feel after being told about your breast density?" (Table 4). The responses were on average 14 words long (range 1–107 words). The most common response was of a favourable nature indicating women felt informed, interested, or curious in women from both the dense and nondense groups (42% and 39% of responses, respectively). More responses from women in the dense breast group were unfavourable, indicating feelings of concern or disappointment, compared to the nondense group (19% and 5%, respectively). Conversely, fewer responses from women in the dense group indicated a feeling of gratitude, relief or reassurance compared to the nondense group (7% and 15%, respectively). About 10% of responses in both

TABLE 3: Distribution of participants based on anxiety and breast density types ($N = 100$).

Anxiety types	Dense breast ($n = 34$) (n, %)	Nondense breast ($n = 66$) (n, %)	p value
State			
No or low	18 (53)	40 (61)	
Moderate	6 (18)	8 (12)	0.69
Severe	10 (29)	18 (27)	
Trait			
No or low	18 (53)	40 (60)	0.76
Moderate	8 (23)	13 (20)	
Severe	8 (23)	13 (20)	

Note: p value is significant at < 0.05. p value is determined by the chi-square test.

groups indicated that they felt 'okay' after being told about their breast density. When coded in terms of positive, negative and neutral reactions, about half of comments from both groups were coded as positive and there were no significant differences between the dense and nondense group (Table 5). However, more reactions from women in the dense breast group were negative compared to reactions in the nondense group (26% and 13%, respectively).

4. Discussion

The current study provides critical insights into the psychological impact of breast density notification among Australian women attending breast cancer screening in a public hospital setting and provides a complimentary approach to other studies that assessed self-reported anxiety within community-based breast screening settings. Here, we use a validated psychological tool to assess anxiety following notification of dense breasts, using women notified of nondense breasts as a comparator group. Through assessing both state and trait anxiety, the impact of breast density notification can be considered against the backdrop of the underlying tendency of participants towards anxiety.

State anxiety after notification of dense breasts was not different to state anxiety following notification of nondense breasts, suggesting that psychological measures of anxiety are not affected by breast density notification. Although the sample size of 100 participants might be considered modest, this sample size is well-accepted within the psychology literature where previous studies that employed the STAI tool to measure anxiety after a stressful health event have used similar or smaller sample sizes [22, 25, 26]. The smaller effect size determined by Cohen's d between the dense and nondense groups in case of state (0.11) and trait (0.19) anxiety suggest that a larger sample size would not yield different results.

In this study, 20% of women who participated were identified as having severe trait anxiety. This finding is in agreement to a recent survey (2021–2022) that reported that 21% of Australian women had experienced an anxiety disorder in the last 12 months [27]. A substantial number of Australian women are suffering from high underlying anxiety in their day-to-day life and this has the potential to affect their response to any health information, including how they respond to being notified of their breast density, whether they have dense or nondense breasts.

Overall, 42% of this study cohort was identified as having state anxiety in the 7 days following breast density notification in the moderate or severe range. This is higher than other Australian study findings where 20% participants self-reported anxiety following breast density notification [5] or reported they were likely to feel anxious if told they had dense breasts [6, 28]. This difference is likely to be associated with how anxiety was measured. The STAI tool does not ask participants to assess their own anxiety, but rather measures the psychological manifestations of anxiety such as the extent of feelings of tension, worry, and calm. The high frequency of state anxiety, irrespective of whether the participant received a letter notifying them of dense or nondense breasts, might be attributed to the high level of underlying trait anxiety in the cohort.

Women who received breast density notification generally respond neutrally or positively, as reflected in the themes identified from the qualitative analysis of the open-ended question concerning how the women felt after being told their breast density. These results are similar to themes described in previous studies [5, 28]. Approximately half of the reactions were positive and reflected the participants feeling informed, relieved, reassured, and grateful. An additional 30% were neutral, with a common response being "Okay" or a statement that they were not affected by the information. Negative reactions occurred in around 20% of responses and included confusion about breast density information and concerns about breast cancer being missed.

It may not be surprising that women notified of dense breasts would experience negative reactions, given they are receiving the news that they are have an increased risk for breast cancer [29] and reduced sensitivity of a mammogram to detect cancer [30]. These negative reactions could be mitigated through codesign of health communication strategies with consumers, which has significant potential to increase community engagement and information uptake [31–33]. Trial of an interactive computer-animated agent codesigned with consumers that explains what women want to know about breast density suggests this approach can increase breast density knowledge and reduce self-reported anxiety [34]. Further work to improve breast density communication and mitigate negative reactions would benefit from engagement with consumer organisations such as the Australian Breast Density Consumer Advisory Council that assisted in the current study.

4.1. Limitations. Limitations of this study include data collection from a single hospital site and the potential for selection bias. The cohort was recruited from a prior study, who had specified their preference to be informed of their breast density and contacted for future studies, so the experience of those who did not want to know was not captured. Moreover, the participants were attending the public hospital-based breast service for routine mammographic screening

TABLE 4: Distribution of preliminary themes according to the density status ($N = 122$).

Themes	Dense breast ($n = 43$)[a] n (%)	Nondense breast ($n = 79$)[b] n (%)	Overall ($N = 122$) n (%)	Example
Favourable response/informed/ interested/curious	18 (42)	31 (39)	49 (40)	"Very pleased to know my risk and the need to be vigilant"
Gratitude/feels relieved/feels reassured	3 (7)	12 (15)	15 (12)	"Its good to know my density as it puts my mind at rest."
Unfavourable response/disappointed	8 (19)	4 (5)	12 (10)	"A bit concerned that a cancer may be missed on mammograms due to breast density——."
Confused	3 (7)	6 (8)	9 (7)	"—with it, not quite sure I understood it all.———"
Neutral	6 (14)	18 (23)	24 (20)	"Do not affect me at all."
Okay	5 (11)	8 (10)	13 (11)	"Ok with it——————————————————"
Total	43 (100)	79 (100)	122 (100)	

[a]Total response from 34 dense breast women is 30. The number of missing responses is 3, and one is contextual response. Total 30 complete responses were coded as 43 coded responses.
[b]Total response from 66 dense breast women is 59. The number of missing responses is 5, and two are contextual responses. Total 59 complete responses were coded as 79 coded responses.

TABLE 5: Final arrangement of themes according to the density status ($N = 122$).

Themes	Dense breast ($n = 43$) n (%)	Nondense breast ($n = 79$) n (%)	p value	Overall ($N = 122$)
Negative reaction[a]	11 (26)	10 (13)	0.19	21 (17)
Positive reaction[b]	21 (48)	43 (54)		64 (52)
Neutral reaction[c]	11 (26)	26 (33)		37 (30)
Total	43 (100)	79 (100)		122 (100)

Note: p value has been determined by the chi-square test. p value is significant at < 0.05.
[a]Negative reaction consists "confused" and "disappointed/negative reaction" codes from Table 4.
[b]Positive reaction consists of "positive reaction/informed /interested/curious" and "gratitude/feels relieved/feels reassured" codes from Table 4.
[c]Neutral reaction consists of "neutral" and "okay" codes from Table 4.

or follow-up rather than attending community-based breast cancer screening. Women showing signs of distress at the time of their breast screening were excluded from the study, so their experiences of breast density notification were not captured. Furthermore, there was a lack of uptake of the survey by non-English-speaking women, which limits the generalizability of the study.

This study used women notified on nondense breasts as a comparator group, however it is possible that the notification letter could have increased state anxiety in the nondense group. Furthermore, this study did not distinguish between women's responses to being notified of Category C or Category D breast density, and it is possible that notification of Category D may have a greater psychological impact than Category C. Ideally, state anxiety could be measured before and after breast density notification; however, this was not possible in this study. The opportune time to measure state anxiety before notification would be when participants were recruited to the study, prior to the mammogram and their breast density measurement. However, breast screening may in itself cause some anxiety which would have affected the baseline measure [35]. Another approach would be to randomise women with dense breasts to receiving or not receiving breast density notification.

Investigation of how a participant feels on the day they receive the notification letter and in-person interviews seeking to understand how participants feel after breast density notification may have revealed more in-depth findings than the current study. In addition, the readability of the surgeons' letters and the level of health literacy of the participants were also not assessed in this study.

5. Conclusion

With more and more women being notified of their breast density when they have a mammogram, it is important to understand the psychological impact of this information. This study has used a validated psychological tool and suggests that notification of high breast density is not associated with an escalation in anxiety. While women's reactions to breast density notification are overall positive or neutral, negative reactions including confusion and concern can also occur. Breast density notification approaches need to be considerate of the significant proportion of women with severe underlying anxiety. Codesign of communication strategies with consumers may help mitigate negative reactions to breast density notification.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Conflicts of Interest

The authors declare no conflicts of interest.

Funding

This research was funded by the Hospital Research Foundation PhD scholarship awarded to A.B.

Acknowledgments

The authors would like to thank Mrs. Lyn Moore, from the Australian Breast Density Consumer Advisory Council, for assistance in developing the breast density notification letter.

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Appendix II

Ethical clearance

Government of South Australia
Health
Central Adelaide Local Health Network

Central Adelaide Local Health Network
Research Services

Tel: 08 7117 2224

Postal Address:
Royal Adelaide Hospital
Clinical Trial Centre
Level 3, Wayfinder 3D460.02
Port Road
ADELAIDE SA 5000

Health.CALHNResearchLNR@sa.gov.au
www.health.sa.gov.au

ABN: 96 269 526 412

Authorisation Date: 10 January 2022

A/Prof Wendy Ingman
Surgical Science Department
The University of Adelaide

Dear A/Prof Ingman

CALHN Reference Number: 15681

Project Title: Assessing Patients' Knowledge about Breast Density

Thank you for submitting the above proposal for review. This project has undergone ethics and governance review via the expedited processes of the Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee (HREC) and CALHN Research Services.

I am pleased to advise that your project has been granted full ethics approval and meets the requirements of the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research 2007* incorporating all updates. The project is **authorised** by CALHN Research Services for conduct at The Queen Elizabeth Hospital.

The CALHN HREC is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research* (2007).

Documents reviewed and approved:

Document	Version	Date
Ethics and Governance Application (EGA) Form	-	10 November 2021
Protocol	4	10 January 2022
Participant Information Consent Form (PICF)	4	10 January 2022
Data Collection Spreadsheet – Questionnaire	4	10 January 2022

Sites covered by CALHN HREC approval:

Site	State	Principal Investigator
The Queen Elizabeth Hospital	SA	Wendy Ingman

Project authorisation is valid for **one (1) year** from **10 January 2022 to 10 January 2023.** An annual progress report requesting an extension must be submitted if the duration of the project continues beyond this period.

GENERAL TERMS AND CONDITIONS OF PROJECT AUTHORISATION:

1. The CALHN HREC is the South Australian (SA) 'lead HREC' for the purpose of this ethics approval. Any study sites that are not listed on this letter are not covered by the CALHN HREC approval.
2. The study must be conducted in accordance with the standards outlined in the National Statement on Ethical Conduct in Human Research (2007), the Australian Code for the Responsible Conduct of Research (2018), and SA Health policies.
3. Adequate record keeping must be maintained in accordance with Good Clinical Practice, and the NHMRC, state, and national guidelines. The duration of record retention for all low risk research data is five years from the date of publication.
4. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing ethical acceptability of the project and/or the site acceptability of the project must to be submitted to CALHN Research Services. Researchers are required to immediately report anything which might warrant review of ethical approval of the study, including:
   a) Adverse events which warrant protocol change or notification to research participants;
   b) Changes to the protocol;
   c) Changes to the safety or efficacy of the investigational product, device or method;

   d) Matters that may affect the conduct of the project;
   e) Premature termination of the study.
   5. Confidentiality of the research participants must be maintained at all times as required by law.
6. A report of the progress of the project at least annually, and related to the degree of risk to participants. The report is due on the anniversary of project authorisation. Continuation of approval is contingent on submission of this report, due within 14 days of the approval anniversary. Failure to comply may result in suspension of the project
7. A final report if the outcome of the project must be submitted on completion of the project. A copy of any published material must also be provided with the report, or following when available.
8. A copy of this letter should also be maintained on file by the Coordinating Principal Investigator as evidence of project authorisation.
9. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements. **A copy of compliance confirmation must be forwarded to CALHN Research Services upon receipt.**

You are reminded that this letter constitutes ethical approval only and governance authorisation for CALHN sites.

Should you have any queries about the consideration of your project, please contact Health.CALHNResearchLNR@sa.gov.au.

All future correspondence regarding this study must include the CALHN reference number in the subject header.

We wish you every success in your research.

Yours sincerely,

Ian Tindall
Chair, CALHN Human Research Ethics Committee

Bernadette Swart
Manager, CALHN Research Services

17 January 2022

Government of South Australia
Health
Central Adelaide Local Health Network

Central Adelaide Local Health Network
Research Services

Tel: 08 7117 2224

Postal Address:
Royal Adelaide Hospital
Clinical Trial Centre
Level 3, Wayfinder 3D460.02
Port Road
ADELAIDE SA 5000

Health.CALHNResearchLNR@sa.gov.au
www.health.sa.gov.au

ABN: 96 269 526 412

Authorisation Date: 01 November 2022

A/Prof Wendy Ingman
Breast Endocrine Department
The Queen Elizabeth Hospital

Dear A/Prof Ingman,

CALHN Reference Number: 16630

Project Title: Assessing the Impact of Breast Density Notification in Women

Thank you for submitting the above proposal for review. This project has undergone ethics and governance review via the expedited processes of the Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee (HREC) and CALHN Research Services.

I am pleased to advise that your project has been granted full ethics approval and meets the requirements of the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research 2007* incorporating all updates. The project is **authorised** by CALHN Research Services for conduct at The Queen Elizabeth Hospital.

The CALHN HREC is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research* (2007).

Documents reviewed and approved:

Document	Version	Date
Ethics and Governance Application (EGA) Form	-	06 June 2022
Protocol	3	06 October 2022
Participant Information Consent Form (PICF)	3	06 October 2022
Questionnaire	3	06 October 2022
Email Template to Participants	2	20 June 2022

Sites covered by CALHN HREC approval:

Site	State	Principal Investigator
The Queen Elizabeth Hospital	SA	A/Prof Wendy Ingman

Project authorisation is valid for **one (1) year** from **01 November 2022 to 01 November 2023**. An annual progress report requesting an extension must be submitted if the duration of the project continues beyond this period.

GENERAL TERMS AND CONDITIONS OF PROJECT AUTHORISATION:

1. The CALHN HREC is the South Australian (SA) 'lead HREC' for the purpose of this ethics approval. Any study sites that are not listed on this letter are not covered by the CALHN HREC approval.
2. The study must be conducted in accordance with the standards outlined in the National Statement on Ethical Conduct in Human Research (2007), the Australian Code for the Responsible Conduct of Research (2018), and SA Health policies.
3. Adequate record keeping must be maintained in accordance with Good Clinical Practice, and the NHMRC, state, and national guidelines. The duration of record retention for all low risk research data is five years from the date of publication.
4. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing ethical acceptability of the project and/or the site acceptability of the project must to be submitted to CALHN Research Services. Researchers are required to immediately report anything which might warrant review of ethical approval of the study, including:

a) Adverse events which warrant protocol change or notification to research participants;
b) Changes to the protocol;
c) Changes to the safety or efficacy of the investigational product, device or method;
d) Matters that may affect the conduct of the project;
e) Premature termination of the study.
5. Confidentiality of the research participants must be maintained at all times as required by law.

6. A report of the progress of the project at least annually, and related to the degree of risk to participants. The report is due on the anniversary of project authorisation. Continuation of approval is contingent on submission of this report, due within 14 days of the approval anniversary. Failure to comply may result in suspension of the project
7. A final report if the outcome of the project must be submitted on completion of the project. A copy of any published material must also be provided with the report, or following when available.
8. A copy of this letter should also be maintained on file by the Coordinating Principal Investigator as evidence of project authorisation.
9. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements. **A copy of compliance confirmation must be forwarded to CALHN Research Services upon receipt.**

You are reminded that this letter constitutes ethical approval only and governance authorisation for CALHN sites.

Should you have any queries about the consideration of your project, please contact Health.CALHNResearchLNR@sa.gov.au.

All future correspondence regarding this study must include the CALHN reference number in the subject header.

We wish you every success in your research.

Yours sincerely,

Ian Tindall
Chair, CALHN Human Research Ethics Committee

Bernadette Swart
Manager, CALHN Research Services

4 November 2022

Government of South Australia
Health
Central Adelaide Local Health Network

Authorisation Date: 30 May 2023

Central Adelaide Local Health Network
Research Services

Tel: 08 7117 2224

Postal Address:
Royal Adelaide Hospital
Clinical Trial Centre
Level 3, Wayfinder 3D460.02
Port Road
ADELAIDE SA 5000

Health.CALHNResearchLNR@sa.gov.au
www.health.sa.gov.au

ABN: 96 269 526 412

A/Prof Wendy Ingman
University of Adelaide

Dear A/Prof Wendy Ingman,

CALHN Reference Number: 17945

Project Title: How Doctors Communicate Breast Density Information with their Patients

Thank you for submitting the above proposal for review. This project has undergone ethics and governance review via the expedited processes of the Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee (HREC) and CALHN Research Services.

I am pleased to advise that your project has been granted full ethics approval and meets the requirements of the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research 2007* incorporating all updates. The project is **authorised** by CALHN Research Services for conduct at The Queen Elizabeth Hospital.

The CALHN HREC is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research* (2007).

Documents reviewed and approved:

Document	Version	Date
Ethics and Governance Application (EGA) Form	-	11 May 2023
Protocol	3	25 May 2023
Participant Information Sheet	3	25 May 2023
Participant Information Consent Form (PICF)- Consent Log for Surgeons	3	25 May 2023
Participant Information Consent Form (PICF)- Surgeon	3	25 May 2023
CARE Patient Feedback Measure Survey	3	25 May 2023
Data Collection Spreadsheet	-	-

Sites covered by CALHN HREC approval:

Site	State	Principal Investigator
The Queen Elizabeth Hospital	SA	A/Prof Wendy Ingman

Project authorisation is valid for **one (1) year** from **30 May 2023 to 30 May 2024**. An annual progress report requesting an extension must be submitted if the duration of the project continues beyond this period.

GENERAL TERMS AND CONDITIONS OF PROJECT AUTHORISATION:

1. The CALHN HREC is the South Australian (SA) 'lead HREC' for the purpose of this ethics approval. Any study sites that are not listed on this letter are not covered by the CALHN HREC approval.
2. The study must be conducted in accordance with the standards outlined in the National Statement on Ethical Conduct in Human Research (2007), the Australian Code for the Responsible Conduct of Research (2018), and SA Health policies.
3. Adequate record keeping must be maintained in accordance with Good Clinical Practice, and the NHMRC, state, and national guidelines. The duration of record retention for all low risk research data is five years from the date of publication.
4. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing

ethical acceptability of the project and/or the site acceptability of the project must to be submitted to CALHN Research Services. Researchers are required to immediately report anything which might warrant review of ethical approval of the study, including:
   a) Adverse events which warrant protocol change or notification to research participants;
   b) Changes to the protocol;
   c) Changes to the safety or efficacy of the investigational product, device or method;
   d) Matters that may affect the conduct of the project;
   e) Premature termination of the study.
   5. Confidentiality of the research participants must be maintained at all times as required by law.
6. A report of the progress of the project at least annually, and related to the degree of risk to participants. The report is due on the anniversary of project authorisation. Continuation of approval is contingent on submission of this report, due within 14 days of the approval anniversary. Failure to comply may result in suspension of the project
7. A final report if the outcome of the project must be submitted on completion of the project. A copy of any published material must also be provided with the report, or following when available.
8. A copy of this letter should also be maintained on file by the Coordinating Principal Investigator as evidence of project authorisation.
9. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements. **A copy of compliance confirmation must be forwarded to CALHN Research Services upon receipt.**

You are reminded that this letter constitutes ethical approval only and governance authorisation for CALHN sites. You must not commence this research project at [Site/s] until governance authorisation at that site has been obtained.

Should you have any queries about the consideration of your project, please contact Health.CALHNResearchLNR@sa.gov.au.

All future correspondence regarding this study must include the CALHN reference number in the subject header.

We wish you every success in your research.

Yours sincerely,

Ian Tindall
Chair, CALHN Human Research Ethics Committee

Bernadette Swart
Manager, CALHN Research Services

30 May 2023

Appendix III

Permission and Copyright Certificate of Mind Garden for STAI

State-Trait Anxiety Inventory for Adults™

Instrument and Scoring Key

License to Administer

Developed by Charles D. Spielberger
in collaboration with R.L. Gorsuch, R. Lushene, P.R. Vagg, & G.A. Jacobs

Published by Mind Garden, Inc.
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Permission Letter

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To Whom It May Concern,

The above-named person has made a license purchase from Mind Garden, Inc. and has permission to administer the following copyrighted instrument up to that quantity purchased:

State-Trait Anxiety Inventory for Adults

The license holder has permission to administer the complete instrument in their research, however, only four sample items from this instrument as specified below may be included in the research write-up, thesis, or dissertation. Any other use must receive prior written permission from Mind Garden. The entire instrument form may not be included or reproduced at any time in any other published material. Please understand that disclosing more than we have authorized will compromise the integrity and value of the test.

Citation of the instrument must include the applicable copyright statement listed below.

Sample Items:

I feel at ease
I feel upset
I lack self-confidence
I am a steady person

Sincerely,

Robert Most
Mind Garden, Inc.
www.mindgarden.com

Conditions for Online Use

You agree to:

- Administer this Mind Garden instrument for research purposes only.
- Control access to the instrument. The instrument may not be made available via the open web, nor sent in the message body or as an attachment to survey participants.
- Avoid using copyrighted items from this instrument on the survey landing page. You should put other items on this landing page, e.g., demographics or informed consent.
- Put the instrument copyright statement on every page containing questions/items from this instrument. The copyright statement is provided in the enclosed permission letter.
- Track your license use. Each time a participant opens the survey and has access to the copyrighted items is considered one administration.
- Compensate Mind Garden, Inc. for each administration.
- Purchase a license for any additional administrations over the initial purchase quantity, or close the survey.
- Remove this online survey at the conclusion of your data collection and you will personally confirm that it cannot be accessed.

Caution: If you do not require a unique login for each respondent, the survey method you use may elicit a large number of responses to your survey. You are responsible for compensating Mind Garden for every administration, regardless of circumstances.

Distributing an entire instrument in either the text of an email or as an email attachment is strictly prohibited.

For Dissertation and Thesis Appendices

This license permits you to administer the complete instrument in your research, however, only the four pre-authorized sample items from this instrument as provided by Mind Garden may be included in the research write-up, thesis, dissertation, or appendices, and only when accompanied by the instrument copyright statement. Detailed information on these requirements is provided in the enclosed permission letter.

For Results Reporting and Publications

This research license is for data collection, and it permits you to collect and disclose item scores, scale scores, and scores statistics (group average, group standard deviation, T-scores, etc.). You may not include the complete instrument in results reporting or publications -- you may include only the four pre-authorized sample items and with copyright language and attribution: see the enclosed permission letter.

This license is for research only and not for providing individual feedback to survey participants. Please understand that disclosing more than we have authorized will compromise the integrity and value of the test.

Note: the list above illustrates some permitted and prohibited uses of the instrument and is not meant to be comprehensive.

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Appendix IV

Supplementary Materials

PARTICIPANT INFORMATION SHEET

Non-Interventional Study

Breast/Endocrine Surgical Unit - The Queen Elizabeth Hospital

Title:	Assessing Patients' Knowledge about Breast Density
Protocol Number:	15681
Protocol Number:	Associate Professor Wendy Ingman, Dr Avisak Bhattacharjee, Dr Pallave Dasari, Dr David Walsh, and Ms Leigh Hodson.

PART 1: What does my participation involve?

1. Introduction

You are invited to take part in this research project, "Assessing Patients' Knowledge about Breast Density." The research project is aiming to understand the knowledge and awareness status of common Australian women about breast density as an influential risk factor for breast cancer.

You are eligible to participate in this project because you are a woman who is attending the Breast/Endocrine Clinic at The Queen Elizabeth Hospital and undergoing a mammogram.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. You will be given a copy of this Participant Information Sheet to keep.

2. What is the purpose of this research?

The purpose of this study is to develop a standardised breast density protocol and assess what women know about breast density. This research is headed by the Principal Investigator A/Prof Wendy Ingman, Head of the Breast Biology and Cancer Unit, University of Adelaide and The Queen Elizabeth Hospital (email: wendy.ingman@adelaide.edu.au), as part of doctoral training for Dr Avisak Bhattacharjee.

3. What does participation in this research involve?

If you agree to participate you must first sign a consent form before any research happens. This project requires you fill out a questionnaire about breast density. We will require permission to access to the information you are providing and your breast/endocrine surgeons to check your clinical details. No other procedures are required.

4. Do I have to take part in this research project?

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

This is a research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced.

Your participation in this study shall not affect any other right you may have to compensation under common law.

5. What are the possible benefits of taking part?

Although there will be no clear benefit to you from your participation in this research, the outcomes of this research are expected to generate new scientific understanding of awareness of breast density.

6. What are the possible risks and disadvantages of taking part?

There are no risks for you for participating in this study since this is a survey.

PART 2: How is the research project being conducted?

7. What will happen to my survey answers? How will my confidentiality be protected – will the information and results remain anonymous?

Only researchers directly involved in the study (both CALHN and non-CALHN employed researchers) will have access to identifiable data. Every questionnaire will be given an anonymous code and the data compiled for analysis. This code will be stored separately to your information. At the end of the study, the results will be pooled, analysed and published in scientific articles with no identifying information. Researchers who are not employed by CALHN will not be able to view data on your Electronic Medical Record (EMR). Additionally, researchers who are not using their CALHN capacity for this research project will also not have access to the EMR.

8. Will I be informed about the results of the study?

The results of this research study will not provide any immediate or meaningful insights into your current health status. If you wish to find out about the outcomes of this research you can contact the researcher who will provide the information at the completion of the study.

9. How long will my information be stored for?

Your personal information will be stored for a minimum period of 15 years. This confidential material will be stored securely in the Basil Hetzel Institute for Translational Health Research at The Queen Elizabeth Hospital using secure information technology systems operated by the University of Adelaide which require password protection and two-factor authentication.

10. Who is organising and funding the research?

This research has been initiated by the Associate Professor Wendy Ingman, Dr Avisak Bhattacharjee, Dr David Walsh, and their research team at The Queen Elizabeth Hospital and the University of Adelaide. The research study and its outcomes belong to The University of Adelaide.

There are no costs associated with participating in this research project, nor will you be paid.

If knowledge acquired through this research leads to discoveries that are of commercial value to the University of Adelaide, the study doctors or their institutions, there will be no financial benefit to you or your family for these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project apart from their normal wages.

11. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the CALHN Human Research Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

12. Further information and who to contact

For participants to obtain additional information about this study, please contact A/Prof Wendy Ingman (ph 8222 6141 or email: wendy.ingman@adelaide.edu.au) at The University of Adelaide.

If you wish to speak to someone not associated with the study about your rights as a participant or to make a complaint about the conduct of the study, you may contact The Executive Officer of the CALHN Human Research Ethics Committee

Complaints Contact

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	Executive Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

CONSENT FORM

Non-Interventional Study

Breast/Endocrine Surgical Unit - The Queen Elizabeth Hospital

Title:	Assessing Patients' Knowledge about Breast Density
Protocol Number:	TBD
Protocol Number:	Associate Professor Wendy Ingman, Dr Avisak Bhattacharjee, Dr Pallave Dasari, Dr David Walsh, and Ms Leigh Hodson.

Declaration by Participant

By filling out this survey, I give consent to participating in this study voluntarily.

I understand that a copy of the Participant Information Sheet for this study will be provided for my personal records.

Name of Participant _____

Signature _____ Date _____

What is your date of birth: _____

Government of South Australia
SA Health

THE UNIVERSITY of ADELAIDE

QUESTIONNAIRE

Breast/Endocrine Surgical Unit - The Queen Elizabeth Hospital

Title:	Assessing Patients' Knowledge about Breast Density
Protocol Number:	15681
Principal Investigator(s):	Associate Professor Wendy Ingman, Dr Avisak Bhattacharjee, Dr Pallave Dasari, Dr David Walsh, and Ms Leigh Hodson

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- What language do you speak at home?

  English Other

Please specify _____

- Are you being assisted by an interpreter today?

  Yes No Don't know

Breast density is a measure of how white the breasts appear on a mammogram. Breasts that appear mostly dark on a mammogram are low density, breasts that appear mostly white on a mammogram are high density.

- Before now, had you ever heard of breast density?

  Yes No Don't know

- Do you think women with large breasts are more likely to have dense breast tissue than women with small breasts?

  No, strongly disagree No, disagree Unsure Yes, agree Yes, strongly agree

- Do you think breast density can be determined by feel or touch?

  No, strongly disagree No, disagree Unsure Yes, agree Yes, strongly agree

- Do you think dense breast tissue makes it more difficult to see cancer on a mammogram?

  No, strongly disagree No, disagree Unsure Yes, agree Yes, strongly agree

Please complete both sides of the page.

- Do you think that, after a mammogram, sometimes women may require further tests because they have dense breast tissue?

  No, strongly disagree No, disagree Unsure Yes, agree Yes, strongly agree

- Do you think having breasts that are mostly dense on a mammogram puts you at increased risk for breast cancer?

  No, strongly disagree No, disagree Unsure Yes, agree Yes, strongly agree

- Have you ever been told by a health professional that your breast tissue is dense?

  Yes No Don't know

- If yes, who told you? A GP, BreastScreen, Radiologist, other, please specify_____

- Have you ever had a mammogram before?

  Yes No Don't know

- You are waiting to have a mammogram at TQEH, and this will show your breast density. Would you like to be told your breast density?

  Yes No

- The Queen Elizabeth Hospital is conducting a number of studies about breast density. If you are eligible for any studies, would you like a researcher to contact you?

  Yes No

PARTICIPANT INFORMATION SHEET

Non-Interventional Study

Breast/Endocrine Surgical Unit - The Queen Elizabeth Hospital

Title:	Assessing the Impact of Breast Density Notification in Women
HREC Reference Number:	16630
Protocol Number:	Associate Professor Wendy Ingman, Dr Avisak Bhattacharjee, Professor Deborah Turnbull, Dr David Walsh, and Leigh Hodson.
CPI/PI:	**A/P Wendy Ingman** Surgical specialities Adelaide Medical School The University of Adelaide
Location:	The Queen Elizabeth Hospital

1. Introduction

You are invited to take part in this research project, "Assessing the Impact of Breast Density Notification in Women". The research project is aiming to understand how breast density affects women. You are eligible to participate in this project because you were notified your breast density after having a mammogram breast density to be noticed.

This Participant Information Sheet/Consent Form tells you about the research project. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

2. What is the purpose of this research?

The purpose of this study is to understand how women react to being told their breast density

3. Who is undertaking this research?

Associate Professor Wendy Ingman from the Surgical specialties of Adelaide Medical School of the University of Adelaide is the principal investigator of this research project. Dr Avisak Bhattacharjee under her supervision is working for this project as the PhD student from the same institution.

Professor Deborah Turnbull, chair of the school of Psychology, is contributing in this research as the expert psychologist and co-supervisor of Dr. Avisak Bhattacharjee.

Dr. David Walsh, a consultant Breast surgeon of The Queen Elizabeth Hospital is collaborating the project as the concerned clinician.

Leigh Hodson, a research officer of The University of Adelaide, is working here to develop the project and analyse the results.

4. Do I have to take part in this research project?

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

This is a research project and you do not have to be involved. If you do not wish to participate, your medical care/[employment] will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced.

5. What does participation in this research involve?

If you agree to participate, please click on the link in the email or in text message to complete the survey. The survey will take about 5 minutes to complete. If required the survey can be completed as a paper copy, and posted back to the researcher. One of the research team members will call you/send you text message (according to your availability over phone) as a reminder on the 2nd day and 5th day of receiving this mail/text. If applicable, we can offer to fill out the survey on your next appointment day with the surgeon at the Breast/Endocrine Clinic of The Queen Elizabeth Hospital.

This project requires no further procedures to be undertaken. We will require permission to access to the information you are providing and the breast/endocrine surgeons need the consent to check your clinical details that you have already given.

6. What do I have to do?

No additional activities are required except filling out the survey following the survey link provided to you in the email.

7. What are the possible benefits of taking part?

Although there will be no clear benefit to you from your participation in this research, the outcomes of this research are expected to generate new scientific understanding of how best to communicate with women about their breast density.

8. What are the possible risks and disadvantages of taking part?

There are no risks for you for participating in this study since this is a survey.

9. Can I have other treatments during this research project?

Yes, you can continue your usual treatment while you are participating in this research project.

10. What will happen to information about me? Confidentiality and data security.

Every survey will be personalized and it will be given an anonymous code inside its link and the data compiled for analysis. This code will be stored separately to your information. During the study period, the research team will be able to identify individual participant. At the end of the study, the results from all participants will be pooled, analysed and published. This will be done so no individual patient's information can be traced.

Data security will be strictly ensured by the Australian Code for the Responsible Conduct of Research. Additional and specific advices regarding data storage and security will be sought from the experts of FHMS. Data will be stored on a shared departmental drive like the university computers in the Basil Hetzel Research Institute and the computers of CALHN in The Queen Elizabeth Hospital with password protection only accessible for the study team. Unidentifiable data will be shown to the researcher in the 'Qualtrics' online platform, though participants can be identifiable if require. The re-identification will only be done by the CALHN employed study team members whom are acting in their CALHN capacity for the duration of this project. Data storage and security will ensure the requirements of ethics secretariat.

Data will be stored for the highest 15 years and after that data will be deleted forever from all the departmental password protected confidential storage. If any hard copies of data will be made, they will be destroyed after the mentioned period.

The results of the study will be published in the-
(1) Referred journals.
(2) Scholarly conferences such as the International Conference on Communication in Healthcare;
(3) Public engagement through social media and professional organisations.

In any type of study results, publications and discussion, the participants will never be identifiable. Your data will be received in the 'Qualtrics' software as the coded data/anonymous data that can only be re-identified (if necessary) by the surgeon and clinical collaborator of the research team, Dr. David Walsh. However, participating in this survey you are consenting the principal investigator A/P Wendy Ingman to get access your identifiable CALHN participant data during the study period.

11. What happens if I withdraw from the research?

Your participation in this study shall not affect any other right to compensation you may have under common law. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

12. Complaints and contacts (Investigators and Ethics Committee)

For participants to obtain additional information about this study, please contact A/Prof Wendy Ingman (ph 8222 6141) at The University of Adelaide.

The project will be carried out according to the National Statement on Ethical conduct in Human Research (2007) incorporating all updates. This statement has been developed to protect the interest of people who agree to participate in human research studies.

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC). If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC chairperson, on 71172229.

Reviewing HREC approving this research, HREC Executive officer details and Complaints Contact

HREC name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC support officer
Telephone	(08) 71172229
Email	Health.CALHNResearchEthics@sa.gov.au

Government of South Australia

Health
Central Adelaide
Local Health Network

To Date: _____
Ms._____
Address: _____

Subject: Breast density letter

Thank you for your recent interest in your Breast Density Research Project

I am writing to inform you that your recent mammogram showed a density level of A/B/C/D.

The following is some background information on breast density levels.

A. Low tissue density, almost all fatty tissue
Your mammogram displays mostly fatty tissue, which appears as dark grey, combined with minor areas of white and light grey fibroglandular tissue. Your breasts are not considered dense. About 10% of female breasts fit category “a”. They are referred to as “fatty breasts”.

B. Low-mid tissue density, scattered dense tissue
Your mammogram displays mostly fatty tissue, which appears as dark grey, combined with scattered areas of white and light grey fibrograndular tissue. Your breasts are not considered dense. About 40% of female breasts fit category “b”. They are referred to as “scattered fibroglandular breasts”.

C. Mid-high tissue density, mixed dense & fatty tissue
Your mammogram displays mostly dense, fibroglandular tissue, which appears white and light grey, combined with lesser areas of dark grey fatty tissue. Your breasts are considered dense. About 40% of female breasts fit category “c”. They are referred to as “heterogeneously dense breasts”.

D. High tissue density, extremely dense tissue
Your mammogram displays mostly dense, fibroglandular tissue, which appears white and light grey, combined with very little dark-grey fatty tissue. The large amount of white areas makes it difficult for a radiologist to confidently rule out that cancer is not present. About 10% of female breasts fit category “d”. They are referred to as “extremely dense breasts”.

Thanks again for your interest in for research.

Surgeon’s name & signature: _____
Consultant Breast Surgeon CALHN

PARTICIPANT INFORMATION SHEET

Non-Interventional Study

Breast/Endocrine Surgical Unit - The Queen Elizabeth Hospital

Title:	How Doctors Communicate Breast Density Information with their Patients.
Protocol Number:	17945
Protocol Number:	Associate Professor Wendy Ingman, Dr Avisak Bhattacharjee, Dr Sarah J. White, Dr David Walsh, Professor Deborah Turnbull and Ms Leigh Hodson.

PART 1: What does my participation involve?

1. Introduction

You are invited to take part in this research project, **"How Doctors Communicate Breast Density Information with their Patients."** The research project is aiming to determine the existing surgeon-patient communication strategies through telehealth consultations.

You are eligible to participate in this project because you are a woman who attended the Breast/Endocrine Clinic at The Queen Elizabeth Hospital. You completed a survey on breast density and expressed your interest to attend the relevant future research of the hospital.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. You will be given a copy of this Participant Information Sheet to keep.

2. What is the purpose of this research?

The purpose of this study is to determine the existing surgeon-patient communication strategies through telehealth consultations. This research is headed by the Principal Investigator A/Prof Wendy Ingman, Head of the Breast Biology and Cancer Unit, University of Adelaide (email: wendy.ingman@adelaide.edu.au), as part of doctoral training for Dr Avisak Bhattacharjee.

3. Who is undertaking this research?

The investigators for this research are as follows- 1) Associate professor Wendy Ingman, Head, Breast Biology and Cancer Unit, The University of Adelaide, 2) Dr. Avisak Bhattacharjee, a PhD researcher of the University of Adelaide, 3) Dr Sarah J White, Senior Lecturer, Center for Social Impact, The University of New South Wales, 4) Dr. David Walsh, Consultant surgeon of Breast and Endocrine Surgery Department of The Queen Elizabeth Hospital, SA Health 5) Professor Deborah Turnbull, Chair of School of Psychology, The University of Adelaide, 6) Ms. Leigh Hodson, Research assistant, Breast Biology and Cancer Unit, Basil Hetzel Institute

4. Do I have to take part in this research?

This is a research project and you do not have to be involved. If you do not wish to participate, your medical care/[employment] will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced.

5. What does participation in this research involve?

If you agree to participate please let us know your decision within 2 weeks by post, email or over phone. Thereafter, the hospital staffs will help you to book an appointment for telehealth consultation with a breast/endocrine surgeon as a part of this research. Your contact to participate will be regarded as your consent. However, your verbal consent will be recorded during telehealth consultation. If requires, you can cancel or rescheduling the appointment any time before the day of consultation. The consultation will be to discuss your breast density, and will take around 15 minutes. In this tenure, you can discuss about any queries about breast density and you can share your feelings you experienced after knowing your breast density. The whole video consultation will be recorded. After consultation is over, you will receive a quick survey form that you need to fill out to let us know your feedback about your experience of consultation. It is to be confirmed that only breast/endocrine surgeon will get access to your identifiable data from the Electronic Medical Record if necessary. It is noteworthy that you will not enjoy any financial benefit for participating in this research.

6. What do I have to do?

You need not to perform any additional activities or restrictions for participating in this research.

7. What are the possible benefits of taking part?

The benefit you will enjoy is the consultation with the breast/endocrine surgeon free of cost as a part of research project and will come to know the necessary information about breast density. The outcomes of this research are expected to generate new scientific understanding of how the surgeon-patient conversation are conducted, providing information to improve training for effective communication with patients.

8. What are the possible risks and disadvantages of taking part?

Your conversation with surgeon will be recorded and the risk of re-recording will be mitigated by storing the audio clips in a highly secured university device protected by password. There is no foreseeable risk so far.

9. Can I have other treatments during the research project?

It is to be clear that participation in this research will not make any change of your ongoing medical management and care.

10. What will happen to information about me? Confidentiality and data security.

Only researchers with CALHN capacity will have access to identifiable data. Your face will be blurred and the recording will be saved using an anonymous code to de-identify your data before hand over it to the non-CALHN researchers. The data will be stored in the secured box folder of The University of Adelaide in audio.wav, video.wav (unidentifiable), transcripts.dox, metadata.xlsx. All the researchers mentioned here will have access to your un-identifiable data. Your un-identifiable data will be stored in the University box folder and secured cabinet (printed copy of the transcript) for 15 years under responsibility of A/P Wendy Ingman. Data destruction will be ensured by deleting the Box folders from the university storage and trashing the hard copies in the confidential bin of the Basil Hetzel Institute.

Research findings will be disseminated through: (1) Refereed journals – with an aim to publish in journals with high clinician readership; (2) Scholarly conferences such as the International Conference on Communication in Healthcare; (3) Public engagement through social media and professional organisations; (4) Training workshops, using Conversation Analytic Roleplay Method, to disseminate findings directly to participating healthcare professionals. And you will not be identified in any form of these disseminations.

Statement on Privacy:

'In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.'

11. What will happen to my test samples?

It is to be ensured that you need not give any test samples as a part of this study. This study is all about your conversation with the breast/endocrine surgeon.

12. What happens if I withdraw from the research?

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

This is a research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced. In that case, your all collected data will be destroyed by deleting from the storage and disposing in the confidential bin of the institute.

13. What happens if I am injured from taking part in this study?

Your participation in this study shall not affect any other right to compensation you may have under common law.

14. Complaints and contacts (Investigators and Ethics Committee)

For participants to obtain additional information about this study, please contact A/Prof Wendy Ingman (phone 8222 6141 or email: wendy.ingman@adelaide.edu.au / breast_density@adelaide.edu.au) at The University of Adelaide.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The study has been approved by the Human Research Ethics Committee of The Queen Elizabeth Hospital. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the Chairperson, Research Ethics Committee, The Queen Elizabeth Hospital on 8222 6910.

Reviewing HREC approving this research, HREC Executive Officer details and Complaints Contact

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Support Officer
Telephone	(08) 71172229
Email	Health.CALHNResearchEthics@sa.gov.au

The study investigator details:

Name	Wendy Ingman
Position	Associate Professor of University of Adelaide
Phone	(08) 82226141
Email	Wendy.ingman@adelaide.edu.au / breast_density@adelaide.edu.au

PARTICIPANT INFORMATION SHEET & CONSENT LOG FOR SURGEONS

Non-Interventional Study

Breast/Endocrine Surgical Unit - The Queen Elizabeth Hospital

Title:	How Doctors Communicate Breast Density Information with their Patients.
Protocol Number:	17945
Protocol Number:	Associate Professor Wendy Ingman, Dr Avisak Bhattacharjee, Dr Sarah J. White, Dr David Walsh, Professor Deborah Turnbull and Ms Leigh Hodson.

Participant consent log template – verbal consent:

Project title:

Script for staff: A research team from the University of Adelaide is conducting research into communication in consultations. This research is a part of the Ph.D. project of Dr. Avisak Bhattacharjee.

The investigators for this research are as follows- 1) Associate professor Wendy Ingman, Head, Breast Biology and Cancer Unit, The University of Adelaide, 2) Dr. Avisak Bhattacharjee, a PhD researcher of the University of Adelaide, 3) Dr Sarah J White, Senior Lecturer, Centre for Social Impact, The University of New South Wales, 4) Dr. David Walsh, Consultant surgeon of Breast and Endocrine Surgery Department of The Queen Elizabeth Hospital, SA Health 5) Professor Deborah Turnbull, Chair of School of Psychology, The University of Adelaide, 6) Ms. Leigh Hodson, Research assistant, Breast Biology and Cancer Unit, Basil Hetzel Institute

Would you be interested in participating?

If yes, then:

Do you or will you have another person with you for the call? If so, could you please allow them during video consultation. By participating in the project, your consultation (audio) will be recorded and analysed by members of the research team, who will be looking at the way in which patients and clinicians talk in consultations conducted via telehealth. Clips and transcripts of these (both with personal information removed) will be used during the analytic process. De-identified and anonymised clips and transcripts may be used in training, publications, and presentations. You may also choose to allow recordings and transcripts to be stored for an indefinite period in a secure database of recorded healthcare interactions for future research and education aimed at improving clinical communication and safe patient care. Participation or non-participation will have no bearing on the treatment. Participation is voluntary and you can withdraw your consent at any time by emailing the CI. We will email or text you a letter with the details of the study and of the CI.

Q1. Do you consent to your consultation being recorded for this research project?

Q2. Do you consent to that recording to be stored in a database for future analysis and/or teaching?

Consent Log

Code no.	Time	Date	Consent to record	Consent to store recording	Consent to show in publications and conference as unidentifiable record	Email or mobile no. for sending survey	Admin initial

Complaints and contacts (Investigators and Ethics Committee)

For participants to obtain additional information about this study, please contact A/Prof Wendy Ingman (phone 8222 6141 or email: wendy.ingman@adelaide.edu.au / breast_density@adelaide.edu.au) at The University of Adelaide.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The study has been approved by the Human Research Ethics Committee of The Queen Elizabeth Hospital. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the Chairperson, Research Ethics Committee, The Queen Elizabeth Hospital on 8222 6910.

Reviewing HREC approving this research, HREC Executive Officer details and Complaints Contact

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Support Officer
Telephone	(08) 71172229
Email	Health.CALHNResearchEthics@sa.gov.au

The study investigator details:

Name	Wendy Ingman
Position	Associate Professor of University of Adelaide
Phone	(08) 82226141
Email	Wendy.ingman@adelaide.edu.au / breast_density@adelaide.edu.au