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Improving breast cancer outcomes for Aboriginal women: a mixed-methods study protocol

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Manuscripts

Breast Cancer Protocol Outline

Title:

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study protocol

Authors:

Christie V (1,2), Rice M (3), Dracakis J (3), Green D (4), Amin J (1), Littlejohn K (5), Pyke C (5), McCowen D (4), and Gwynne K (1)

Affiliations

1. Faculty of Medicine Health and Human Sciences, Macquarie University
2. Poche Centre for Indigenous Health, The University of Sydney
3. Faculty of Medicine and Health, The University of Sydney
4. Armajun Aboriginal Health Service
5. Foundation for Breast Cancer Care

Abstract:

Breast cancer is the most commonly diagnosed cancer affecting Australian women, and the second highest cause of cancer death in Australian women. While the incidence of breast cancer is lower in Aboriginal women than non-Aboriginal women, the mortality rate for Aboriginal women is higher, with Aboriginal women 1.2 times more likely to die from the disease. In NSW, Aboriginal women are 69% more likely to die from their breast cancer than non-Aboriginal women.

Co-design is a research method recognized to enhance collaboration between those doing the research and those impacted by the research. Co-design has been used to significant effect in research with Aboriginal communities, ensuring research and services are relevant, culturally competent and empower communities as co-researchers. We report the development of a new protocol using co-design methods to improve breast cancer outcomes for Aboriginal women.

Methods and analysis: This is an iterative quantitative and qualitative study consisting of five main phases. In the Planning phase, we will ensure appropriate governance of the project. Following consultation with the community, we will begin Phase 2, inviting community members to attend modified screening for breast cancer events. In Phase 3, the research team will collect data on the outcomes of the modified screening events and the outcomes for the women who have and have not participated. The data shall be analyzed quantitatively and thematically in Phase 4 with Aboriginal community representatives and reported back to community. Lastly, in Phase 5 we evaluate the co-design process and adapt our protocol for use in partnership with other communities.

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3 Discussion: Without culturally safe access to screening and treatment opportunities, the gap
4 in health outcomes between Aboriginal and non-Aboriginal women will continue to widen.
5 Led by a team of experienced Aboriginal and non-Aboriginal investigators and community
6 representatives, we have developed this protocol using co-design methods.
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10 **'Strengths and limitations of this study'**

- 13 • This study aims to engage Aboriginal women to design and implement a
14 framework for improving participation in breast cancer screening, diagnostic,
15 treatment, and post-treatment services
- 17 • The study will be designed and implemented with a local Aboriginal community-
18 controlled health service and Aboriginal co-investigators
- 20 • The study employs a mixed-methods design with descriptive statistical analysis of
21 quantitative data on service utilisation as well as qualitative analysis drawn from
22 focus groups and in-depth interviews regarding user satisfaction
- 24 • Strengths: The collective action co-design methodology strengthens community
25 engagement by sharing power, knowledge and skill with community members
26 and health services
- 28 • Limitations: Small study size limits scalability of the research design

30 **Introduction:**

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33 Breast cancer is the most commonly diagnosed cancer in Australia, representing 28% of all
34 cancer incidence in women and the second highest number of deaths(1). Mortality due to
35 breast cancer has declined significantly over recent decades. This coincides with improved
36 rates of early detection following introduction of national population-based mammography
37 screening programs(2). Yet, Aboriginal and Torres Strait Islander women in Australia
38 continue to face high mortality rates, despite an incidence of breast cancer on par with or
39 less than non-Indigenous women(3). Between 1998 and 2013, there was no significant
40 decrease in the Indigenous mortality rates for breast cancer in comparison to a significant
41 decline for non-Indigenous women(3). When looking at the overall picture, tumour biology
42 is shown to play only a minimal role in the disparity of survival outcomes as compared with
43 preventable causes relating to delayed diagnosis and treatment(4).
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50 Uptake of screening has increased over time among both non-Indigenous and Indigenous
51 populations in Australia, however a significant gap remains. Australia's national population-
52 based screening program BreastScreen offers free 2-yearly mammograms targeting women
53 aged 50-74 years. In 2019, 41% of Aboriginal and Torres Strait Islander women in this age
54 group participated compared with 54% of non-Indigenous women(5). As a consequence of
55 the gap, Aboriginal and Torres Strait Islander women are more likely to be diagnosed at an
56 advanced stage, experiencing worse disease outcomes and lower rates of survival(5-7).
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3 While age is the greatest risk factor for breast cancer, Aboriginal women are more likely to
4 be younger than non-Aboriginal women at the time of diagnosis(8). Aboriginal women are
5 more likely to receive more invasive surgical treatment compared with their non-Aboriginal
6 counterparts(9). This is likely due to perception of difficulty in engaging Aboriginal women
7 for regular and timely follow-up monitoring and care.
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10
11 There is evidently a demonstrable need for improved screening, diagnostic and care
12 pathways for Aboriginal women in Australia(10). The literature identifies numerous enabling
13 factors and barriers which contribute to ease, or not, of access, timeliness, and quality of
14 care for Aboriginal women with regard to breast cancer screening and services(11) (12-14)
15 (15, 16) (17-19).
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18
19 Overwhelmingly, barriers are related to the lack of cultural safety within health services.
20 Aboriginal women are apprehensive about utilising services due to recent or historical
21 experiences of racism, lack of culturally safe care and a deficit of resources featuring
22 culturally-appropriate educational and health promotion messages. Initiatives which
23 focused on resourcing community-led initiatives to raise awareness facilitated increased
24 uptake and provided culturally safe care(13, 14, 17, 20-22). This care involved Aboriginal
25 Health Workers and highlights the importance of primary health care following diagnosis
26 (23). Furthermore, individuals were less likely to engage in services as a consequence of
27 previous experiences or the experiences of women they knew with mammography and
28 breast cancer. Feelings of shame or stigma were also cited, as was the impact of financial
29 barriers and geographical remoteness.
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36 There is a body of evidence surrounding initiatives aimed at increasing breast screening
37 among Aboriginal women which indicates that success is highest where there are
38 partnerships with Aboriginal community-controlled organisations(18). These initiatives
39 implemented culturally-appropriate engagement strategies to address a range of social,
40 cultural, personal and economic factors. An expanding evidence base supports the use of
41 'co-design' as a research methodology for the design, implementation, and evaluation of
42 successful, cost-effective and sustainable strengths-based solutions to health challenges
43 among Aboriginal communities(24).
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48 Application of a rigorous, co-design methodology to enhancing breast cancer screening and
49 care has been evidenced in the literature(25-29) but not extensively. There is a need for
50 more translational research utilising co-design methodology that partners with Aboriginal
51 women, their communities and community-controlled health organisations to develop
52 comprehensive ecological framework for addressing barriers and improving women's
53 engagement in screening as well as follow-up diagnostic and breast cancer care services.
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57 This study will develop and evaluate, using codesign methods, a culturally safe breast
58 screening, diagnostic, treatment and follow up pathway for Aboriginal women in selected
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3 regions. The findings of this work will inform policy and practice aimed at reducing the rates
4 of mortality of Aboriginal women from breast cancer.
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7 **Aims and Objectives:**

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10 Primary objectives:

11 In one region in NSW Australia we will:

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- 13
- 14 • Increase breast cancer health literacy among Aboriginal people.
- 15 • Co-design and evaluate a pathway for timely and culturally safe diagnostic,
16 treatment and post-treatment services for Aboriginal women.
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18 **Methods and analysis**

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20 A preliminary mapping process co-designed with the communities in 2018 has informed this
21 research. The Community Mapping Project (CMP) consisted of interviews with Aboriginal
22 breast cancer survivors from local communities, staff from the local Aboriginal Health
23 Service (AHS), and other breast cancer care providers. The CMP explored experiences,
24 priorities and preferences, particularly from the survivors' perspectives. It was a
25 comprehensive mapping of existing screening, diagnosis, treatment and post treatment
26 service delivery, resulting in co-designed recommendations (Figures 1,2,3,4) to adjust the
27 existing services and improve the pathway for Aboriginal women in the area.
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37 **Patient and Public Involvement**

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39 The development of the research question and outcome measures was informed by
40 patients' priorities, experience, and preferences during the Mapping Project which took
41 place in 2018. Members of the community who had suffered or were suffering from breast
42 cancer were interviewed and asked about their experience and also their opinions on how
43 the system could be improved.
44
45 No patients were involved in the recruitment to this study and it is yet to be conducted. The
46 results be disseminated to study participants via formal and informal avenues. There will be
47 community events held to disseminate the results and there will be publications available
48 for those who have participated but choose not to attend an event.
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Figures 1-4 Flowchart mapping the screening, diagnosis, treatment and post-treatment services

Figure 1 Screening services

(attached as Image file)

Figure 2 Diagnostic services

(attached as Image file)

Figure 3 Treatment services

(attached as Image file)

Figure 4 Post treatment services

Governance

With these recommendations, further co-design took place with breast cancer survivors and AHS staff to inform the development of the research question, the aims and the outcome measures for this study. This process also determined how the local community wanted to be involved in the design, recruitment, implementation and evaluation of the study. Through the co-design process the community were able to assess the burden of the intervention, including time and resource commitments, in order to inform a sustainable approach.

Local community members, breast cancer survivors and AHS staff will have continued input throughout the study as part of the iterative co-design process. An Aboriginal Advisory Group will inform the project and AHS staff who self-nominate will be investigators on the study. The research team will continue to hold community meetings regarding the progress and outcomes of the process, and community members will be given the option to receive a copy of the completed study and its outcomes and be invited to attend community meetings/workshops organised to disseminate the results of the study. The Aboriginal Advisory Group and AHS staff will be involved in designing the dissemination process.

Ethics

This project has ethics approval from the Aboriginal Health and Medical Research Council of NSW, Ref: 1525/19.

Design

The study will use a mixed-methods design, utilising both qualitative and quantitative research methods. Qualitative methods will include semi-structured, in-depth interviews

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3 and focus group discussions. Quantitative methods will include a structure questionnaire to
4 assess participant satisfaction, as well as analysis of demographic and clinical cohort data
5 from BreastScreen NSW. The target population for this study is Aboriginal women living in
6 the study region. The expected duration of this study is approximately three years, in which
7 time the BreastScreen van will have visited these areas at least twice.
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10 11 Target population

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13
14 Seven percent of the local population in the Armidale region identify as Aboriginal
15 and/Torres Strait Islander (ABS 2016 census data). Four specific study sites have been
16 selected by convenience sampling on the basis of a pre-existing relationship with the local
17 AHS which services the region. The communities expressed interest in working with the AHS
18 in this capacity. The study will rely on voluntary sampling of individuals who fit the criteria
19 of target population: Aboriginal women, >30 years and willing to receive care through the
20 AHS.
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24 25 Phases of implementation

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27 The process of implementation is shown in Figure 5.
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29

30 31 Phase 1: Preparation phase

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33 The core research team will work with Breast Screen NSW to gather the pre-intervention
34 data to use as a baseline to measure quantitative outcomes. Data collected will include:
35 number of women who attended the Breast Screen van in Armidale and the surrounding
36 regions in 2018 and 2019 (2020 data has been affected by Covid-19 and therefore is not
37 representative), and how many of these women identified as Aboriginal and/or Torres Strait
38 Islander. The team will also work closely with the AHS (one of the team is a staff member
39 and second is the CEO of the AHS) in planning for the screening event and staffing the van
40 with an Aboriginal Health Worker for several days during its visit to the area. This work will
41 be done in consultation with Breast Screen NSW.
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47 The team will also work on development of resources for patrons of the local health
48 services, including information on the different stages of the treatment journey and on the
49 local support services for these different stages. This will include working with the local
50 Oncology unit to ensure that culturally safe spaces are offered and welcoming for Aboriginal
51 women in the area.
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57 Figure 5. Process of implementation

58
59 (attached as an Image file)
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Phase 2: Community information

The local AHS staff and research team member will reach out to communities in the region to inform them of the screening day event and presence of an Aboriginal Health Worker in the Breast Screen van in 2021, and the inclusion of additional support services such as transport and child-minding. Outreach will include several forms of communication such as phone calls, emails, flyers and community visits, and will include reminders 1 week out from the screening day date.

Screening and follow up will be undertaken according the procedures described in Figures 1-4. The AHS will be offer risk assessments for women between 30-39 years and who will be referred on for screening if they present as high risk. For women who are 40-49 years old, letters will be sent out 6 weeks prior to screening dates and then two follow up calls will be placed 4 weeks prior and 1 week prior to the screening dates. For women who qualify for a reminder sent out by the government (50-74 years old) reminder phone calls will be placed 4 weeks prior and 1 week prior to the screening dates. For the women who are referred for further diagnosis and/or treatment there will be Aboriginal Health Workers acting as support staff on the days to inform them of the resources on offer and the treatment pathways suggested. All participants involved will be given a participant information sheet that outlines what the study is about; who is carrying out the study; what the study involves; information about how they can withdraw from the study; information about the risks and benefits of the study; and information on how to contact the researchers if needed.

Phase 3: Data Collection

All participants who complete the satisfaction questionnaire, participate in the in-depth interviews, or participate in the focus group discussions will need to sign a consent form. This consent form will allow the study to use the information provided and the participants will be advised the information they provide will be de-identified. Women participating in the in-depth interviews and focus group discussions will be advised that these will be recorded. These recordings will be transcribed, de-identified, and then destroyed. All Aboriginal women in the community will be allowed to access any of the adjustments being implemented, regardless of participation in the study. This will ensure equitable access to all services provided and will not negatively impact Aboriginal women who do not feel comfortable participating in the study.

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3 The Aboriginal Health Worker will manage the consent process and consents will be held by
4 the AHS. Consents will be gathered prior to participation in screening, in-depth interviews
5 and focus groups.
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9 The quantitative data (numbers of attendees who identify as Aboriginal and Torres Strait
10 Islander and satisfaction questionnaires) will be collected at the modified screening events.
11 The qualitative data will be gathered during the in-depth interviews (held at the modified
12 screening days where possible and after the event where not) and in-depth interviews held
13 between two and four weeks after the event. The focus groups will be organised by and
14 held at the local AHS and will include a shared meal over which a series of questions will be
15 asked (see Appendix 1) and responses collected. The discussions will be audio recorded and
16 transcribed with the consent of the participants.
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21 **Phase 4: Outcomes**

22 The study will quantitatively measure:

- 23 • the participation rates of Aboriginal women in breast cancer screening
- 24 • the participation rates of Aboriginal women in timely and culturally safe diagnostic,
25 treatment and post-treatment services
- 26 • satisfaction levels among Aboriginal women in the local community who go through
27 the screening, diagnostic, treatment, and post-treatment process
- 28 • breast cancer health literacy among Aboriginal women in the local community

29
30 To determine the change in rates, study outcomes will be compared to the baseline
31 participation of Aboriginal women in breast screening service, defined as the number of
32 women who attended the BreastScreen van in the chosen area and the surrounding regions
33 in the 3 years preceding and how many of these identified as Aboriginal and/or Torres Strait
34 Islander.
35

36 To establish baseline satisfaction levels all women will be asked to about satisfaction for
37 each of the 4 stages (screening, diagnosis, treatment and follow-up). For each stage , the
38 sub set of women who have previously accessed that stage will be asked if there is any
39 change in their level of satisfaction. Questionnaires will also be completed by Aboriginal
40 women who have not accessed the BreastScreen van previously, asking them why they have
41 not.
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44 Qualitative and quantitative data analysis will be used to establish whether the additional
45 adjustments implemented were successful in improving attendance and satisfaction levels
46 in breast cancer outcomes among Aboriginal women in the Armidale region.
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49 Participation rates will be measured during the screening day event and at the clinics which
50 have an Aboriginal Health Worker present and will be compared to data ascertained from
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3 Breast Screen Van during 2018-2019. Participation in diagnostic, treatment and post-
4 treatment services will be tracked in the six months post screening event via the AHS, which
5 will follow up with the local treatment services and with the women who have received
6 advice to go for further screening and treatment.
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10 To establish whether there was an improvement in satisfaction levels regarding screening,
11 diagnostic, treatment, and post-treatment services available to Aboriginal women
12 questionnaires will be completed by those who accessed the screening van in 2021, both
13 during normal operation and the screening day event. Questionnaires will also be
14 completed by women who accessed diagnostic, treatment and/or post-treatment services
15 for breast cancer following the attending a screening in 2021.
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20 Semi-structured interviews will also be conducted to gather more in-depth, qualitative data
21 with women who visited the Breast Screen van when it was running typically, those who
22 visited during the screening day event and also those who knew about the event but chose
23 not to attend. In addition, 2-hour focus groups will be conducted with 8-10 women who
24 attended while it was running typically and 8-10 women who attended the Screening day
25 event.
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30 The Australian Commission on Safety and Quality in Health Care definition of Health literacy
31 is “about how people understand information about health and health care, and how they
32 apply that information to their lives, use it to make decisions and act on it. Health literacy is
33 important because it shapes people’s health and the safety and quality of health care.”(30)
34 The way this study will assess health literacy will be through increase in participation of
35 services and also a self-reported increase in understanding about breast cancer and the
36 options for screening, diagnosis, treatment and follow up care.
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41 Safety considerations

42 Safety of the participants and anyone involved in the research is a priority of the study. Any
43 adverse events during the study will be recorded and reported, and a follow-up of the event
44 will be completed. The AHS will be available to assist and refer.
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48 **Phase 5: Data analysis and dissemination**

49 Data analysis plan

50
51 Quantitative data gathered through screening events will be analyzed through descriptive
52 statistics. For the qualitative data gathered through focus groups and in-depth interviews,
53 we will perform an inductive thematic analysis using NVivo11 to organize participant’s
54 responses into key themes. Coding and thematic analysis of qualitative data will be carried
55 out by two members of the study team and checked by an Aboriginal author who is also a
56 member of the community, following best practices for enhancing validity in qualitative
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3 methods(31, 32). The core research team will meet to review the findings and identify
4 outstanding or representative quotes for future presentation of the results. Preliminary
5 findings will be discussed with AHS and Aboriginal Advisory Group.
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8 Returning results to the community

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11 Results of the co-design study will be disseminated into the local Aboriginal community
12 through community meetings, social media and printed research summaries (including
13 Plain English summaries). We will work in collaboration with AHS to hold community
14 meetings and information evenings, which both participants and non-participants of the
15 study can attend. Community members will be encouraged to provide feedback and
16 comments on the process.
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21 Results will be published in peer reviewed journals and presented at professional
22 conferences. The AHS participating in the study will be invited to contribute to these
23 publications and presentations. We will acknowledge the sources of information and
24 those who have contributed to the research through authorship and acknowledgement in
25 resulting publications, meetings with community members and conference presentations.
26 We will also acknowledge the cultural property rights of Aboriginal peoples in relation to
27 knowledge, ideas, cultural expressions and cultural materials by including AHS
28 representatives as research team members.
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33 **Corresponding author:**

34 Vita Christie

35 E: vita.christie@sydney.edu.au

36 T: 0403 709 178 F: 02 9351 3196

37 A: 225 Edward Ford Building A27, The University of Sydney NSW 2006
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41

42 **Authors' contributions:**

43 Conception and design of the study - KG, DG, DM, MR, VC

44 Governance and scientific advice – KG, CP, JA DM, DG, VC

45 Drafting the Manuscript – VC, MR, KG, JD

46 Review and approval of the manuscript – all authors
47
48
49

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53
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56

57 **Competing interests statement.**

58 None
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10 **Key for Figures 1-4**

11
12 **Key** Blue boxes show the current process Orange boxes show the proposed additions to the process.
13

14 GP = General Practitioner / AMS = Aboriginal Medical Service / AHS = Aboriginal Health Service / CC = carbon copy (copied in)
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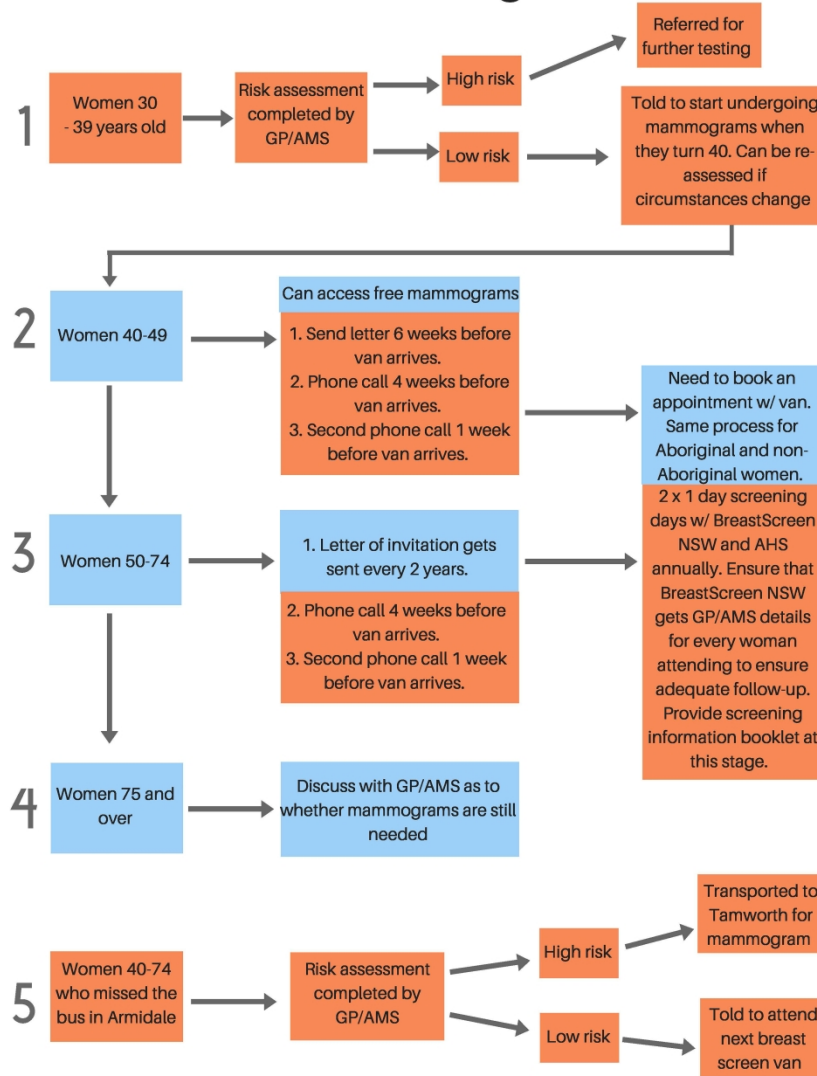
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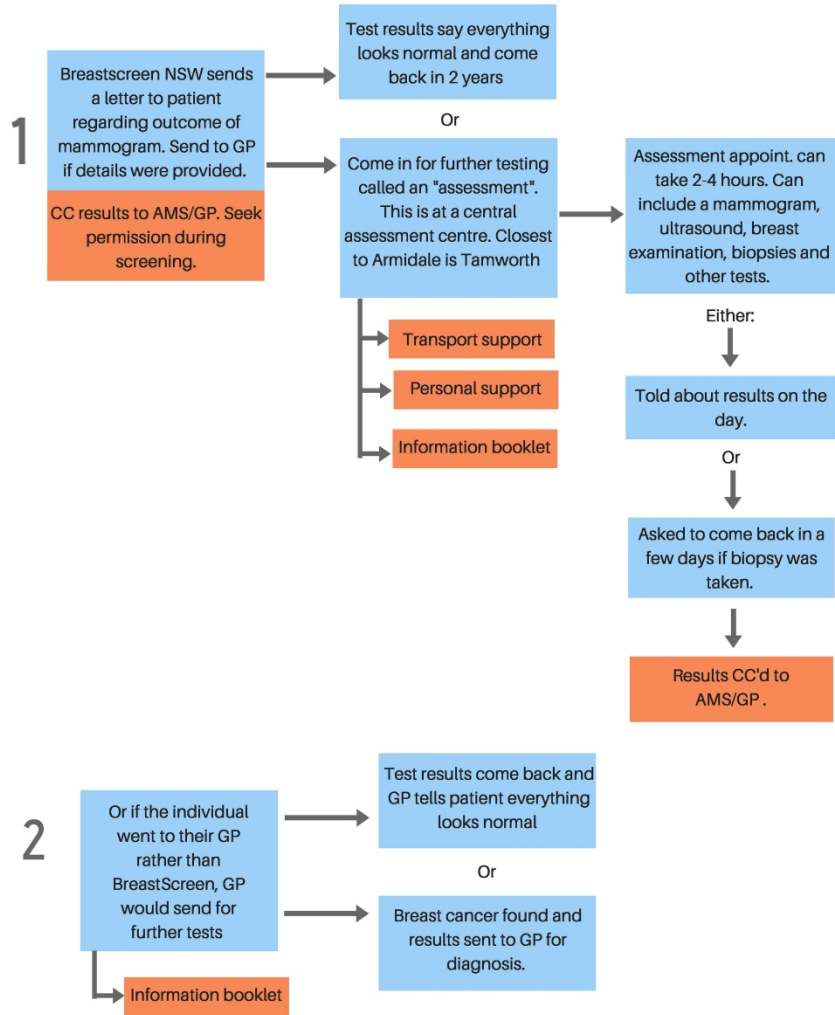
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Screening



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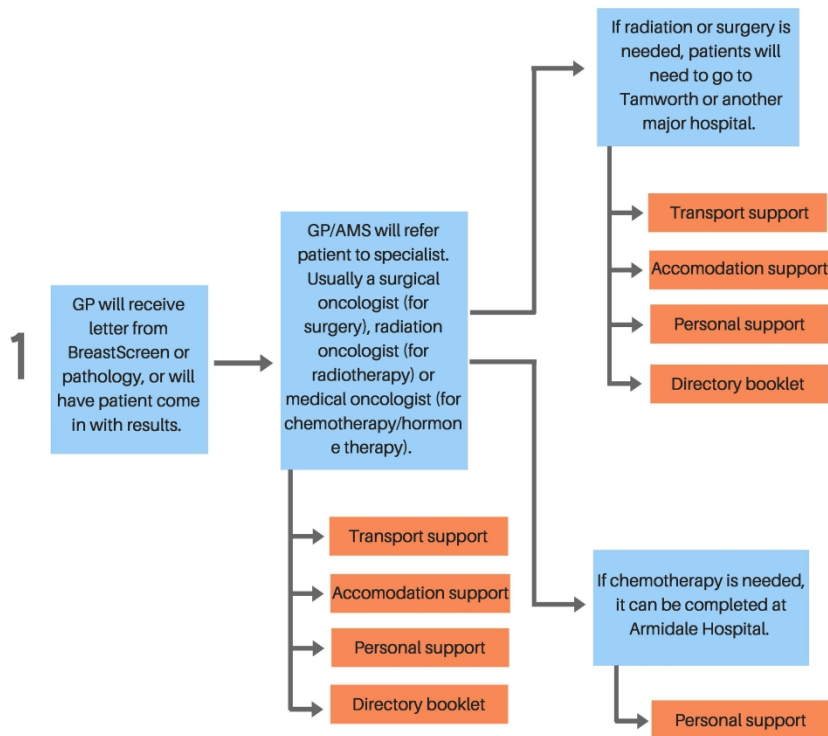
Diagnosis



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Treatment



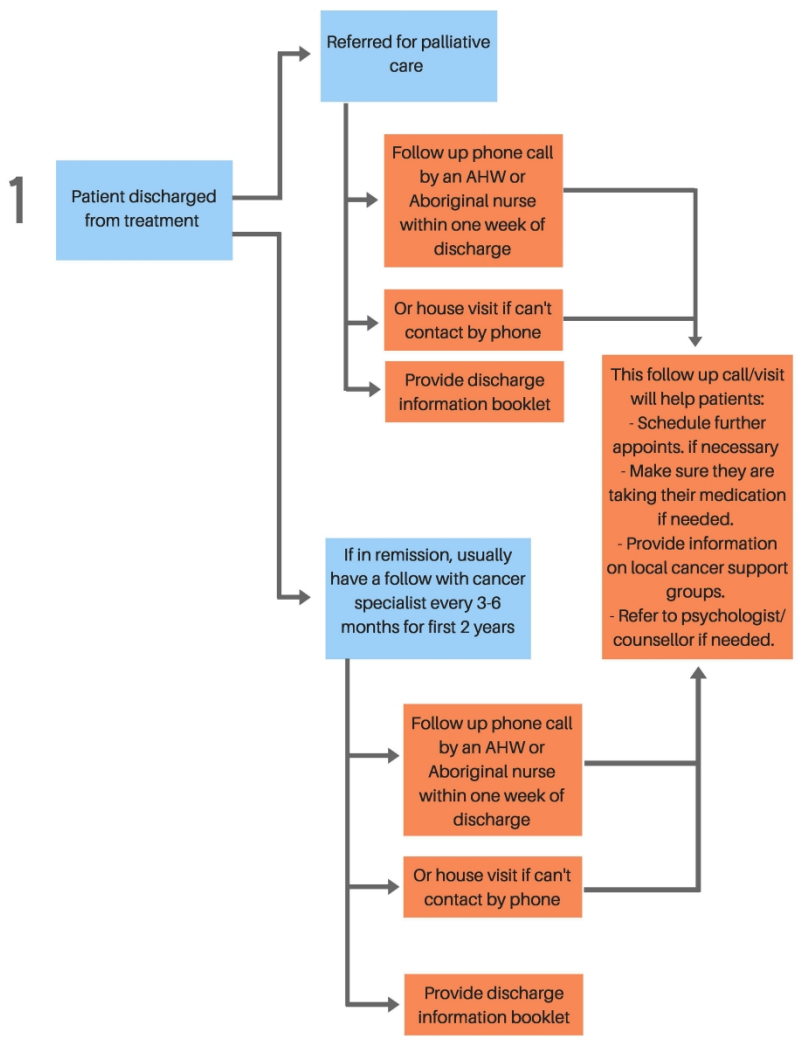
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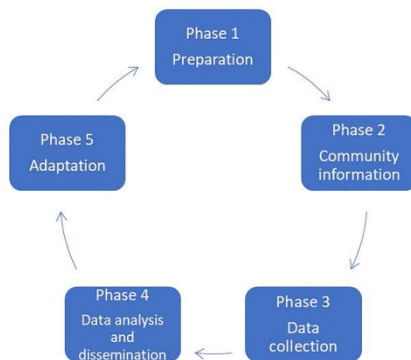
Post Treatment



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Figure 5



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Appendix 1

Questions for focus groups

1. Do you feel that you can discuss breast cancer openly in your community? If so, why? If not, why not?
2. In some Indigenous cultures there is a reported silence around breast cancer and cancer in general- do you think it is the same in your community?
3. What do you think this silence is about?
4. What is your attitude to screening and diagnosis of breast cancer?
5. What do you think gets in the way for a lot of women when it comes to screening and diagnosis?
6. Do you feel you understand how breast cancer affects Indigenous women in Australia? If not, why not?
7. How much trust do you have in the medical system when it comes to breast cancer? Why?
8. How does your community view breast cancer?
9. Do you think this is different from non-Indigenous culture? If so, why?
10. Who are the main supports for women suffering from breast cancer in your community?
11. How important is it for family and community to be involved in the journey? What difference do they make?
12. What did you think of the screening day events? If there was something you could change about them, what would it be?

BMJ Open

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study protocol

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Manuscripts

Breast Cancer Protocol Outline

Title:

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study protocol

Authors:

Christie V (1,2)*, Rice M (3), Dracakis J (3), Green D (4), Amin J (1), Littlejohn K (5), Pyke C (5), McCowen D (4), and Gwynne K (1)

*Corresponding author: contact vita.christie@sydney.edu.au

Affiliations

1. Faculty of Medicine Health and Human Sciences, Macquarie University
2. Poche Centre for Indigenous Health, The University of Sydney
3. Faculty of Medicine and Health, The University of Sydney
4. Armajun Aboriginal Health Service
5. Foundation for Breast Cancer Care

Abstract:

Introduction

Breast cancer is the most commonly diagnosed cancer affecting Australian women, and the second highest cause of cancer death in Australian women. While the incidence of breast cancer is lower in Aboriginal women than non-Aboriginal women, the mortality rate for Aboriginal women is higher, with Aboriginal women 1.2 times more likely to die from the disease. In NSW, Aboriginal women are 69% more likely to die from their breast cancer than non-Aboriginal women.

Co-design is a research method recognized to enhance collaboration between those doing the research and those impacted by the research. Co-design has been used to significant effect in research with Aboriginal communities, ensuring research and services are relevant, culturally competent and empower communities as co-researchers. We report the development of a new protocol using co-design methods to improve breast cancer outcomes for Aboriginal women.

Methods and analysis: Through a Community Mapping Project (CMP) in 2018, we co-designed with Aboriginal women an iterative quantitative and qualitative study consisting of 5 phases. In Phase 1, we will establish a governance framework for the project. In Phase 2 we will provide information to community members regarding the modified parts of the screening, diagnosis, treatment and follow up processes and invite them to partake. In Phase 3, the research team will collect data on the outcomes of the modified processes and the outcomes for the women who have and have not participated. The data shall be analyzed quantitatively and thematically in Phase 4 with Aboriginal community representatives and reported back to community. Lastly, in Phase 5 we evaluate the co-design process and adapt our protocol for use in partnership with other communities.

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3 42 Ethics and dissemination: Without culturally safe access to screening and treatment
4 43 opportunities, the gap in health outcomes between Aboriginal and non-Aboriginal women
5 44 will continue to widen. Led by a team of experienced Aboriginal and non-Aboriginal
6 45 investigators and community representatives, we have developed this protocol using co-
7 46 design methods.

10 47 **'Strengths and limitations of this study'**

- 13 48
- 14 49 • This study aims to engage Aboriginal women to design and implement a
15 50 framework for improving participation in breast cancer screening, diagnostic,
16 51 treatment, and post-treatment services
 - 17 52 • The study will be designed and implemented with a local Aboriginal community-
18 53 controlled health service and Aboriginal co-investigators
 - 19 54 • The study employs a mixed-methods design with descriptive statistical analysis of
20 55 quantitative data on service utilisation as well as qualitative analysis drawn from
21 56 focus groups and in-depth interviews regarding user satisfaction
 - 22 57 • Strengths: The collective action co-design methodology strengthens community
23 58 engagement by sharing power, knowledge and skill with community members
24 59 and health services
 - 25 60 • Limitations: Small study size limits the generalisability of the research findings

31 60 **Introduction:**

32 61
33 62 Breast cancer is the most commonly diagnosed cancer in Australia, representing 28% of all
34 63 cancer incidence in women and the second highest number of deaths(1). Mortality due to
35 64 breast cancer has declined significantly over recent decades. This coincides with improved
36 65 rates of early detection following introduction of national population-based mammography
37 66 screening programs(2). Yet, Aboriginal and Torres Strait Islander women in Australia
38 67 continue to face high mortality rates, despite an incidence of breast cancer on par with or
39 68 less than non-Indigenous women(3). Between 1998 and 2013, there was no significant
40 69 decrease in the Indigenous mortality rates for breast cancer in comparison to a significant
41 70 decline for non-Indigenous women(3). When looking at the overall picture, tumour biology
42 71 is shown to be only part of the picture in the disparity of survival outcomes; preventable
43 72 causes relating to delayed diagnosis and treatment are also substantial contributors (4).

44 73 Uptake of screening has increased over time among both non-Indigenous and Indigenous
45 74 populations in Australia, however a significant gap remains. Australia's national population-
46 75 based screening program BreastScreen offers free 2-yearly mammograms targeting women
47 76 aged 50-74 years. In 2019, 41% of Aboriginal and Torres Strait Islander women in this age
48 77 group participated compared with 54% of non-Indigenous women(5). As a consequence of
49 78 the gap, Aboriginal and Torres Strait Islander women are more likely to be diagnosed at an
50 79 advanced stage, experiencing worse disease outcomes and lower rates of survival(5-7).

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3 80 While age is the greatest risk factor for breast cancer, Aboriginal women are more likely to
4 81 be younger than non-Aboriginal women at the time of diagnosis(8). Aboriginal women are
5 82 more likely to receive more invasive surgical treatment compared with their non-Aboriginal
6 83 counterparts(9). This likely contributes to difficulty in engaging Aboriginal women in regular
7 84 and timely follow-up monitoring and care.

10
11 85 There is a demonstrable need for improved screening, diagnostic and care pathways for
12 86 Aboriginal women in Australia(10). The literature identifies numerous enabling factors and
13 87 barriers which contribute to ease, or not, of access, timeliness, and quality of care for
14 88 Aboriginal women with regard to breast cancer screening and services (11-21) .

17
18 89 Overwhelmingly, barriers are related to the lack of cultural safety within health services.
19 90 Aboriginal women are apprehensive about utilising services due to recent or historical
20 91 experiences of racism, lack of culturally safe care and a deficit of resources featuring
21 92 culturally-appropriate educational and health promotion messages. Initiatives which have
22 93 focused on resourcing community-led initiatives to raise awareness found to facilitate
23 94 increased uptake and provide culturally safe care.(12, 13, 16, 17, 19, 22) This care involved
24 95 Aboriginal Health Workers and highlights the importance of primary health care following
25 96 diagnosis. Furthermore, individuals were less likely to engage in services as a consequence
26 97 of previous experiences or the experiences of women they knew with mammography and
27 98 breast cancer. Feelings of shame or stigma were also cited, as was the impact of financial
28 99 barriers and geographical remoteness. (23)

33
34 100 There is a body of evidence surrounding initiatives aimed at increasing breast screening
35 101 among Aboriginal women which indicates that success is highest where there are
36 102 partnerships with Aboriginal community-controlled organisations(21). These initiatives
37 103 implemented culturally-appropriate engagement strategies to address a range of social,
38 104 cultural, personal and economic factors. An expanding evidence base supports the use of
39 105 'co-design' as a research methodology for the design, implementation, and evaluation of
40 106 successful, cost-effective and sustainable strengths-based solutions to health challenges
41 107 among Aboriginal communities(24).

44
45
46 108 Application of a rigorous, co-design methodology to enhance breast cancer screening and
47 109 care has been evidenced in the literature(25-29) but not extensively. There is a need for
48 110 more translational research utilising co-design methodology that partners with Aboriginal
49 111 women, their communities and community-controlled health organisations to develop
50 112 comprehensive ecological framework for addressing barriers and improving women's
51 113 engagement in screening as well as follow-up diagnostic and breast cancer care services.

54
55
56 114 A preliminary mapping process co-designed with the communities in 2018 has informed this
57 115 research. The Community Mapping Project (CMP) consisted of interviews with Aboriginal
58 116 breast cancer survivors from local communities, staff from the local Aboriginal Health
59 117 Service (AHS), and other breast cancer care providers. The CMP explored experiences,

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3 118 priorities and preferences, particularly from the survivors' perspectives. It was a
4 119 comprehensive mapping of existing screening, diagnosis, treatment and post treatment
5 120 service delivery, resulting in co-designed recommendations (Figures 1,2,3,4) to adjust the
6 121 existing services and improve the pathway for Aboriginal women in the area.
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10 122
11 123 This study will use the information garnered through the CMP to develop and evaluate,
12 124 using co-design methods, a culturally safe breast screening, diagnostic, treatment and
13 125 follow up pathway for Aboriginal women in selected regions. The findings of this work will
14 126 inform policy and practice aimed at reducing the rates of mortality of Aboriginal women
15 127 from breast cancer.
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19 128 20 129 **Aims and Objectives:**

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22 131 Primary objective:

23 132 In one region in NSW Australia we will:

- 24
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26 133
 - Co-design and evaluate a pathway for timely and culturally safe screening,

27 134 diagnostic, treatment and post-treatment services for Aboriginal women.

28 29 30 135 **Methods and analysis**

31 136

32 137 **Co-design**

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35 138 Co-design is a process of developing something with or alongside stakeholders or intended
36 139 recipients or beneficiaries(24, 30).
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39 140

40 141 The design of the study has been based on recommendations provided by the CMP from
41 142 2018. The CMP was a collaboration between the Foundation for Breast Cancer Care, the
42 143 Poche Centre for Indigenous Health and Armajun Aboriginal Health Service. The CMP
43 144 included consultation with Aboriginal survivors of breast cancer, Aboriginal women in the
44 145 target age range for breast cancer prevention and early intervention, and Aboriginal Health
45 146 Workers as well as local service providers in four towns of one central northern rural region
46 147 of NSW. The CMP informed this protocol. The development of the research question and
47 148 outcome measures were informed by patients' and healthcare providers' priorities,
48 149 experience, and preferences

49
50 150 The CMP guided the development of this iterative mixed methods study consisting of five
51 151 main phases which makes adjustments to the present processes of screening, diagnosis,
52 152 treatment and post treatment follow up to enhance cultural safety and promote
53 153 engagement of Aboriginal women. The planned start date for this study is May 2021 and
54 154 end date is May 2022.
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59 155 **Patient and Public Involvement**

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3 156 Fundamental to the co-design model is patient and public involvement. This study was
4 157 developed using co-design methods with community organisations and Aboriginal survivors
5 158 of breast cancer. The research will be conducted with patient and public involvement end to
6 159 end.

10 160 **Co-designed assessment and treatment pathway**

11
12 161 The current screening, diagnosis, treatment and post-treatment services respectively and
13 162 describe the adjustments and additions created through the CMP are shown in Figures 1-4.

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15
16 163 Key to figures: (attached as an Image file) **Key: Blue boxes show the current process Orange boxes show**
17 164 **the proposed additions to the process.**

18
19 165 Figure 1 Screening services

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21 166 (attached as Image file)

22
23 167 Figure 2 Diagnostic services

24 168
25 169 (attached as Image file)

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27 170 Figure 3 Treatment services

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29 172 (attached as Image file)

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31 173 Figure 4 Post treatment services

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33 34 35 175 **Governance**

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38 176 Through the CMP it was determined how the local community wanted to be involved in the
39 177 design, recruitment, implementation and evaluation of the study. Through the co-design
40 178 process the community were able to assess the burden of the research, including time and
41 179 resource commitments, in order to inform a sustainable approach.

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45 181 Local community members, breast cancer survivors and AHS staff will have continued input
46 182 throughout the study as part of the iterative co-design process. An Aboriginal Advisory
47 183 Group will inform the study and its progress and AHS staff who self-nominate will be
48 184 investigators on the study. The Aboriginal Advisory Group will meet every month and the
49 185 Investigators Group every eight weeks. Data will be collected and owned and managed by
50 186 the AHS and will be shared with Investigator group. Any publication will need to be
51 187 approved by the Aboriginal Advisory Group and the AHMRC ethics committee. Members of
52 188 the Investigators Group will continue to participate in community meetings regarding the
53 189 progress and outcomes of the process, and community members will be given the option to
54 190 receive a copy of the completed study and its outcomes and be invited to attend community

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3 191 meetings/workshops organised to disseminate the results of the study. The Aboriginal
4 192 Advisory Group and AHS staff will be involved in designing the dissemination process.

7 193 **Ethics**

9 194 This project has ethics approval from the Aboriginal Health and Medical Research Council of
11 195 NSW, Ref: 1525/19.

13 196 **Design**

15 197 The study will use a mixed-methods design. Qualitative methods will include semi-
17 198 structured, in-depth interviews and focus group discussions. Structured quantitative and
18 199 qualitative questionnaires will be used to assess participant satisfaction, as well as collect
20 200 information about demographics, patient journey and clinical data.

22 201 **Target population**

23 202
25 203 The target population for this study is Aboriginal women living in the study region. The
26 204 expected duration of this study is approximately three years, in which time the BreastScreen
28 205 van will have visited these areas at least twice.

30 206 The area we are working with is a regional and rural location situated in the Central North of
31 207 New South Wales. Seven percent of the local population in the region identify as Aboriginal
33 208 and/or Torres Strait Islander (ABS 2016 census data) which calculates as a possible sample
34 209 size of 631 Aboriginal women above the age of 30. Four specific study sites have been
36 210 selected by convenience sampling on the basis of a pre-existing relationship with the local
37 211 AHS which services the region. The communities expressed interest in working with the AHS
38 212 in this capacity. The study will rely on voluntary sampling of individuals who fit the criteria
40 213 of target population: Aboriginal women, >30 years and willing to receive care through the
41 214 AHS.

43 215

44 216 **Phases of implementation**

46 217 The process of implementation is shown in Figure 5.

47 218

49 219 **Phase 1: Preparation**

50 220

52 221 The Investigator team will work with Breast Screen NSW to gather the pre-intervention data
53 222 to use as a baseline to measure quantitative outcomes. Data collected will include:
55 223 retrospective data through the AHS related to participation as referral data is not available;
56 224 number of women who attended the Breast Screen van in Armidale and the surrounding
58 225 regions in 2018 and 2019 (2020 data has been affected by Covid-19 and therefore is not
59 226 representative), and how many of these women identified at Aboriginal and/or Torres Strait

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3 227 Islander. The team will also work closely with the AHS (one of the investigator team is a staff
4 228 member and second is the CEO of the AHS) in planning for a screening event, which is a
5 229 fixed period of time where the van is reserved for Aboriginal women only and, additionally,
6 230 staffing the van with an Aboriginal Health Worker for several extra days during its visit to
7 231 the area. This work will be done in consultation with Breast Screen NSW.
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10 232

11 233 The team will also work on development of resources for patrons of the local health
12 234 services, including information on the different stages of the treatment journey and on the
13 235 local support services for these different stages. This will include working with the local
14 236 oncology unit to ensure that welcoming and culturally safe spaces are offered to Aboriginal
15 237 women in the area.
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21 240 Figure 5. Process of implementation

22 241

23 242 (attached as an Image file)

24 243

25 244 **Phase 2: Community information**

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27 246 In our co-design process, 'community information' refers to both promoting the culturally
28 247 safe screening events and providing relevant information to potential participants regarding
29 248 the study. The local AHS staff and Investigator team member will reach out to communities
30 249 in the region to inform them of the screening day event and presence of an Aboriginal
31 250 Health Worker in the Breast Screen van in 2021, and the inclusion of additional support
32 251 services such as transport and child-minding. Outreach will include several forms of
33 252 communication such as phone calls, emails, flyers and community visits, and will include
34 253 written reminders 1 week out from the screening day date.
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42 255 Screening and follow up will be undertaken according the procedures described in Figures 1-
43 256 4. The AHS will be offer risk assessments for women between 30-39 years who will be
44 257 referred on for screening and MRI if they are found to meet high risk criteria. For women
45 258 who are 40-49 years old, letters will be sent out 6 weeks prior to screening dates and then
46 259 two follow up calls will be placed 4 weeks prior and 1 week prior to the screening dates. For
47 260 women who qualify for a reminder sent out by the government (50-74 years old), reminder
48 261 phone calls will be placed 4 weeks prior and 1 week prior to the screening dates. For the
49 262 women who are referred for further diagnosis, resources will be given to and support from
50 263 the local Aboriginal Health Workers on next steps.
51

52 264 Additionally there will be Aboriginal Health Workers acting as support staff if treatment is
53 265 suggested, to inform affected women of the resources on offer and treatment pathways
54 266 suggested. Women who partake in any part of the modified screening, diagnosis, treatment
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3 267 of follow up processes will be invited to join the study but will be no consequences for their
4 268 treatment or support if they elect not to participate.
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7 270 **Phase 3: Data Collection and outcome measurement**

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9 272 All participants involved in the study will be given a participant information sheet (PIS- see
10 273 Appendix 1) that outlines what the study is about; who is carrying out the study; what the
11 274 study involves; information about how they can withdraw from the study; information
12 275 about the risks and benefits of the study; and information on how to contact the
13 276 researchers if needed.

14 277 All participants who complete the satisfaction questionnaire, participate in the in-depth
15 278 interviews, or participate in the focus group discussions will need to sign a consent form.
16 279 This consent form will allow the study to use the information provided and the participants
17 280 will be advised the information they provide will be de-identified. The consent process will
18 281 be managed by the AHS. Women participating in the in-depth interviews and focus group
19 282 discussions will be advised that these will be recorded. These recordings will be transcribed,
20 283 de-identified, and then destroyed.

21 284 All Aboriginal women in the community will be allowed to access any of the additional
22 285 services/modifications being implemented, regardless of participation in the study. This will
23 286 ensure equitable access to all services provided and will not negatively impact Aboriginal
24 287 women who do not feel comfortable participating in the study.
25

26 288

27 289 The Aboriginal Health Worker will manage the consent process and consents will be held by
28 290 the AHS. Consents will be gathered prior to participation in screening, in-depth interviews
29 291 and focus groups.
30

31 292

32 293 The quantitative data (numbers of attendees who identify as Aboriginal and Torres Strait
33 294 Islander) will be collected by the AHS at the culturally safe screening events and satisfaction
34 295 questionnaires will be supplied after the event via the AHS. The qualitative data will be
35 296 gathered during the in-depth interviews conducted by the AHS at a location acceptable to
36 297 the participants between two and four weeks after the event so as to capture the
37 298 experience when it is fresh in the minds of the participants. The focus groups will be
38 299 organised by and held at the local AHS and will include a shared meal over which a series of
39 300 questions will be asked (see Appendix 2) and responses collected. The discussions will be
40 301 audio recorded and transcribed with the consent of the participants.
41

42 302

43 303 Further qualitative data will be collected from women engaging in the diagnosis, treatment
44 304 and follow up processes. This data aims to capture level of satisfaction with the
45 305 modifications outlined in the flow charts.

46 306 The AHS will also follow up with the participants to review their wellbeing after focus groups
47 307 and interviews.
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4 309 The study will quantitatively measure:

- 7 310 • the participation rates of Aboriginal women in breast cancer screening (over a 10
- 8 311 week period)
- 10 312 • the participation rates of Aboriginal women in timely and culturally safe diagnostic,
- 11 313 treatment and post-treatment services (over a one year period)
- 13 314 • satisfaction levels among Aboriginal women in the local community who go through
- 14 315 the screening, diagnostic, treatment, and post-treatment process (over a one year
- 15 316 period)
- 17 317 • breast cancer health literacy among Aboriginal women in the local community (over
- 18 318 a one year period)

20
21 319 To determine the change in rates, study outcomes will be compared to the baseline
22 320 participation of Aboriginal women in breast screening service, defined as the number of
23 321 women who attended the BreastScreen van in the chosen area and the surrounding regions
24 322 in the 2-3 years preceding and how many of these identified as Aboriginal and/or Torres
25 323 Strait Islander.

26 324

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29 325 To establish baseline satisfaction levels all women will be asked about satisfaction for each
30 326 of the 4 stages (screening, diagnosis, treatment and follow-up). For each stage, the sub set
31 327 of women who have previously accessed that stage will be asked if there is any change in
32 328 their level of satisfaction. Questionnaires will also be completed by Aboriginal women who
33 329 have not accessed the BreastScreen van previously, asking them why they have not.

34 330

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37 331 Qualitative and quantitative data analysis will be used to establish whether the additional
38 332 adjustments implemented were successful in improving attendance and satisfaction levels
39 333 in breast cancer outcomes among Aboriginal women in the Armidale region.

40 334

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42 335 Participation rates will be measured during the screening day event and at the clinics which
43 336 have an Aboriginal Health Worker present and will be compared to data ascertained from
44 337 Breast Screen Van during 2018-2019. Participation in diagnostic, treatment and post-
45 338 treatment services will be tracked in the six months post screening event via the AHS, which
46 339 will follow up with the local treatment services and with the women who have received
47 340 advice to go for further screening and treatment. This will entail a phone call and welfare
48 341 check and further referrals and advice as indicated.

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53 343 To establish whether there was an improvement in satisfaction levels regarding screening,
54 344 diagnostic, treatment, and post-treatment services available to Aboriginal women
55 345 questionnaires will be completed by those who accessed the screening van in 2021, both
56 346 during normal operation and the screening day event(see Appendix 3). Questionnaires will

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3 347 also be completed by women who accessed diagnostic, treatment and/or post-treatment
4 348 services for breast cancer in 2021.

5 349
6 350 Semi-structured interviews will also be conducted to gather more in-depth, qualitative data
7 351 with women who visited the Breast Screen van when it was running typically, those who
8 352 visited during the screening day event and also those who knew about the event but chose
9 353 not to attend. In addition, 2-hour focus groups will be conducted with 8-10 women who
10 354 attended while it was running typically and 8-10 women who attended the Screening day
11 355 event.

12 356
13 357 The Australian Commission on Safety and Quality in Health Care definition of Health literacy
14 358 is “about how people understand information about health and health care, and how they
15 359 apply that information to their lives, use it to make decisions and act on it. Health literacy is
16 360 important because it shapes people’s health and the safety and quality of health care.”(31)
17 361 The way this study will assess health literacy will be through increase in participation of
18 362 services and also a self-reported increase in understanding about breast cancer and the
19 363 options for screening, diagnosis, treatment and follow up care.

20 364
21 365 Safety considerations
22 366 Safety of the participants and anyone involved in the research is a priority of the study. Any
23 367 adverse events during the study will be recorded and reported, and a follow-up of the event
24 368 will be completed. The AHS will be available to assist and refer.

25 369 26 370 **Phase 4: Data analysis and dissemination**

27 371
28 372 Data analysis plan
29 373 Quantitative data gathered through screening events and de-identified reports via the AHS
30 374 primary healthcare software system and will be analyzed through descriptive statistics. For
31 375 the qualitative data gathered through focus groups and in-depth interviews, we will perform
32 376 an inductive thematic analysis using NVivo11 to organize participant’s responses into key
33 377 themes. Coding and thematic analysis of qualitative data will be carried out by two
34 378 members of the study team and checked by an Aboriginal author who is also a member of
35 379 the community, following best practices for enhancing validity in qualitative methods(32,
36 380 33). The core research team will meet to review the findings and identify outstanding or
37 381 representative quotes for future presentation of the results. Preliminary findings will be
38 382 discussed with AHS and Aboriginal Advisory Group.

39 383 40 384 Returning results to the community

41 385 Results of the co-design study will be disseminated into the local Aboriginal community
42 386 through community meetings, social media and printed research summaries (including

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3 387 Plain English summaries). We will work in collaboration with AHS to hold community
4 388 meetings and information evenings, which both participants and non-participants of the
5 389 study can attend. Community members will be encouraged to provide feedback and
6 390 comments on the process.
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10 391 Results will be published in peer reviewed journals and presented at professional
11 392 conferences. The AHS participating in the study will be invited to contribute to these
12 393 publications and presentations. We will acknowledge the sources of information and
13 394 those who have contributed to the research through authorship and acknowledgement in
14 395 resulting publications, meetings with community members and conference presentations.
15 396 We will also acknowledge the cultural property rights of Aboriginal peoples in relation to
16 397 knowledge, ideas, cultural expressions and cultural materials by including AHS
17 398 representatives as research team members.
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22 399 **Phase 5: Adaptation**

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25 400 In this phase we will evaluate the co-design process to evaluate whether it can be adapted
26 401 to other similar health issues in the Aboriginal community.
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34 406 **Corresponding author:**

35 407 Vita Christie

36 408 E: vita.christie@sydney.edu.au

37 409 T: 0403 709 178 F: 02 9351 3196

38 410 A: 225 Edward Ford Building A27, The University of Sydney NSW 2006
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44 411

45 412 **Authors' contributions:**

46 413 Conception and design of the study - KG, DG, DM, MR, VC

47 414 Planning- VC, KG, JD, DG

48 415 Governance and scientific advice – KG, CP, JA DM, DG, VC

49 416 Conduct and reporting: VC, KG, DG

50 417 Drafting the Manuscript – VC, MR, KG, JD

51 418 Review and approval of the manuscript – VC, KG, JA, DG, KL, CP, DM, JD
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58 422 (Macquarie University)
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4 424 **Competing interests statement.**

5 425 None
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7 426

8
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10 428 Foundation for Breast Cancer Care, Armajun Aboriginal Health Service, Poche Centre for
11 429 Indigenous Health (Dr John Skinner and Associate Professor Lynette Riley)

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Flow chart mapping the screening, diagnosis, treatment and post-treatment process

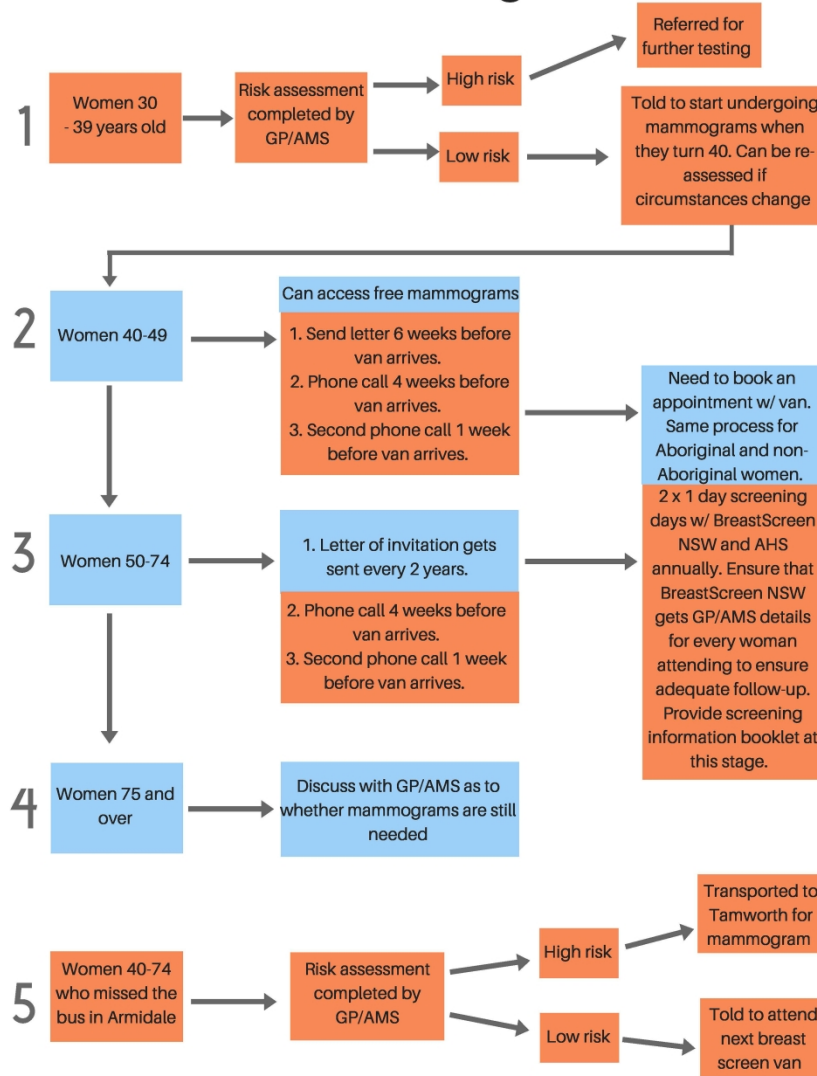
Blue boxes show the current process

Orange boxes show proposed additions to the process

Key to figures

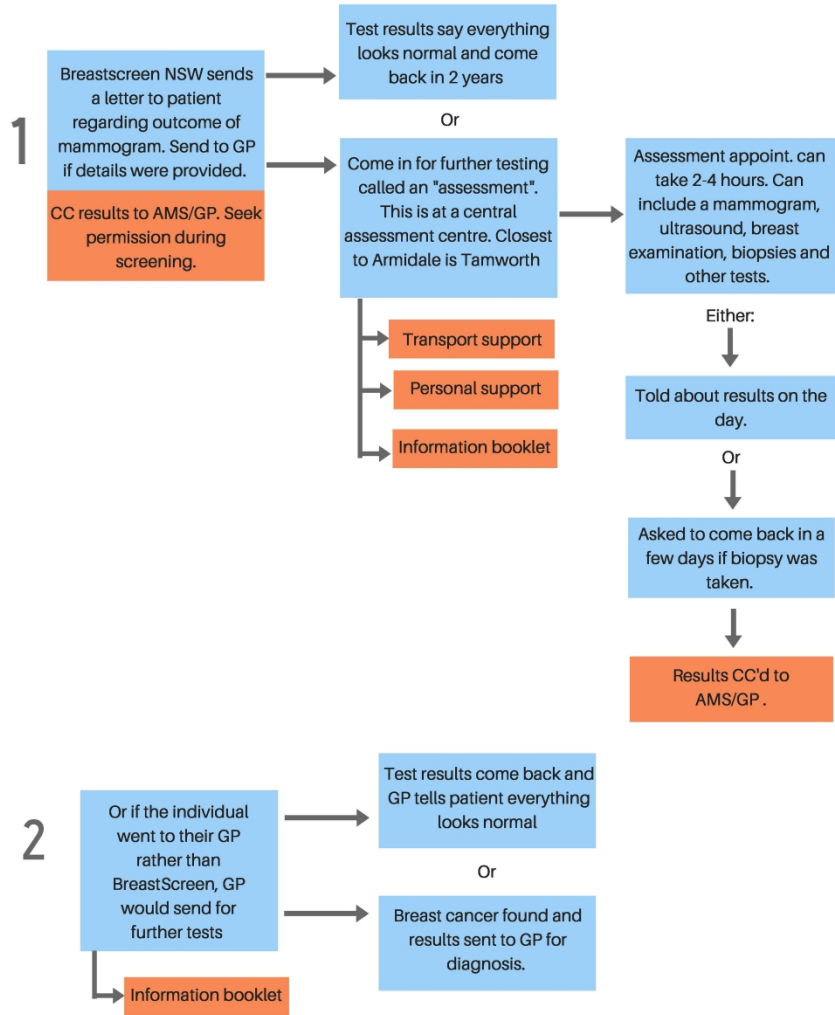
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Screening



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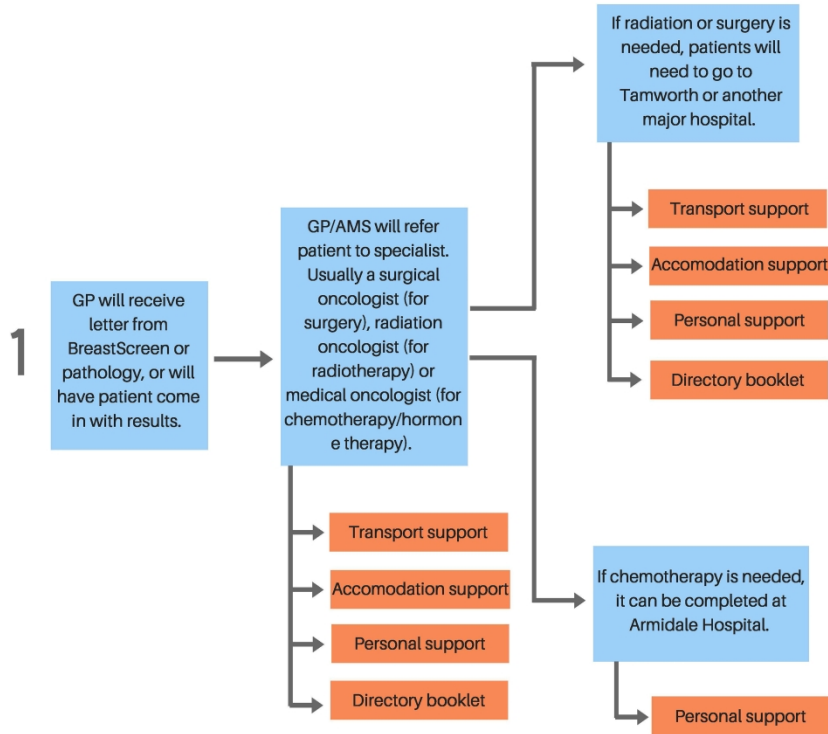
Diagnosis



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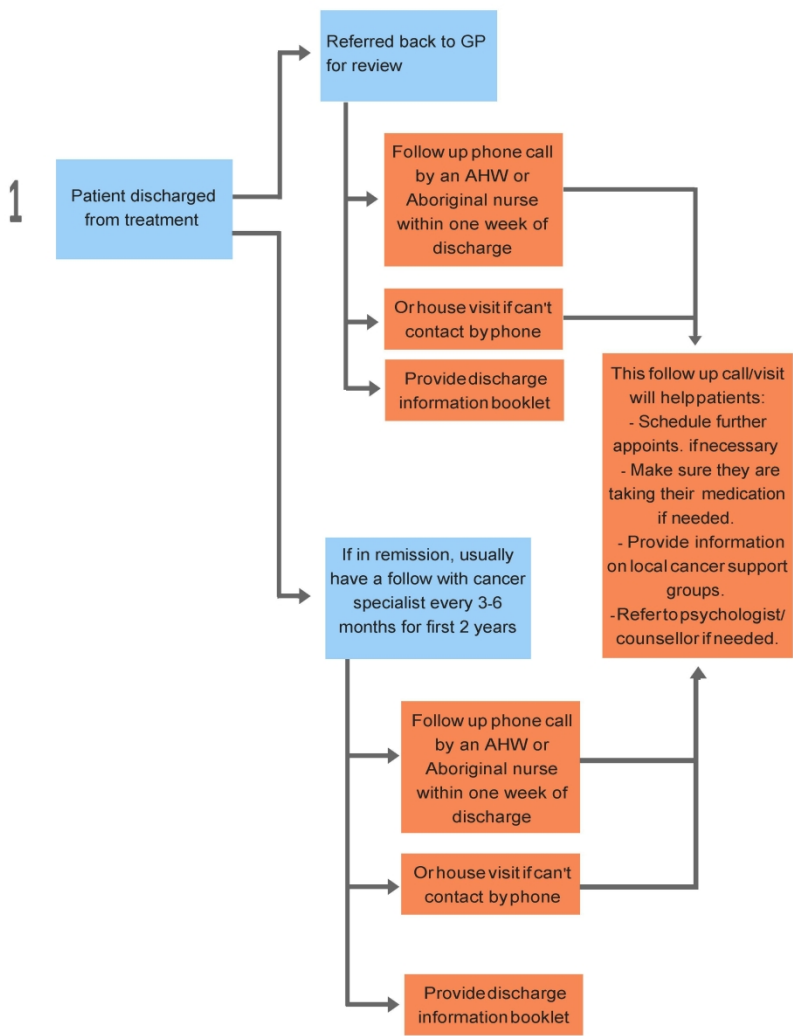
Treatment



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Post Treatment

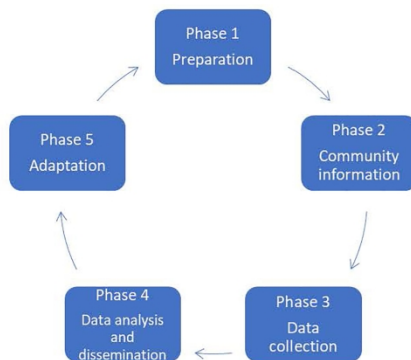


revised Figure 4

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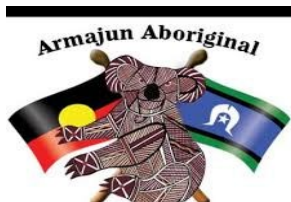
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Figure 5



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MACQUARIE
University
SYDNEY · AUSTRALIA

Adjunct Assoc Prof Kylie Gwynne

Macquarie University
Sydney, NSW
Telephone: +61 448 483 348
Email: kylie.gwynne@mq.edu.au

PARTICIPANT INFORMATION STATEMENT

Purpose of the study

This is an invitation to participate in a study by researchers at Macquarie University, Armajun Aboriginal Health Service and the Poche Centre for Indigenous Health, University of Sydney. The purpose of the research is to investigate whether the implementation of additional, culturally appropriate adjustments to the current breast cancer screening, diagnostic, treatment and post treatment services available to Aboriginal women in Armidale improves both the screening participation rates and the disease outcomes of Indigenous women living in the area. The study calls upon all Aboriginal women aged 30 years or older, living in Armidale or surrounding towns. Participants can be already be a breast cancer patient at Armajun Aboriginal Health Service (AHS) or choose to participate when they attend the screening day event.

This study acknowledges the factors influencing access to the current health care services in rural or remote communities in Australia. Preliminary research was undertaken with Armajun Aboriginal Health Service (AHS) to map the breast cancer screening, diagnostic and treatment services currently available to Aboriginal women in Armidale and identified numerous barriers that prevent access to these services effectively. The study will explore the impact of adjustments made to current stages of breast cancer services that aim to break down these barriers and allow for greater participate rates. Implementation and outcomes of the study are guided by Armajun and the local Aboriginal community of Armidale in which this study will take place, to ensure that the exact social and cultural needs of the local Aboriginal community are considered during the process.

The study is being conducted by Adjunct Assoc Prof Kylie Gwynne(Macquarie University). Other members of the research team members include Vita Christie, Debbie Green, Deb McCowen.

What does the study involve?

If you choose to take part in this study you will be asked to take part in in-depth interviews and focus group discussions with members of the research team to evaluate the quality of services provided to you. You may also be asked to complete questionnaires to assess your satisfaction of your experience with the screening and treatment services and may be recorded using Audio Recordings. The interview will assess the various types of adjustments being implemented and perceptions and experiences you've encountered within services provided. Both qualitative and quantitative data will be utilised to evaluate whether the additional adjustments were successful in improving the journey of breast cancer as well as the service satisfaction levels among Aboriginal women in Armidale. The interviews and discussion groups will be held at a location convenient to you. All recordings will be transcribes and then destroyed after being evaluated.

Your involvement in the study is entirely voluntary and you may choose to withdraw at any time from the study. You may also choose to withdraw any data that was collected from you up until that point. Please note no penalties will be given if you choose to withdraw from the study.

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study.

While there is little risk involved in this research study, talking about specific health issues and experiences may make you feel uncomfortable at times. Please know that if you want to discontinue talking about these topics, let the interviewer or head of discussion group know that you would like a break and if need be can assist you in a referral for additional emotional support. There is also the possibility that results from a mammogram can contain diagnosis of Breast Cancer and therefore can be a traumatic event for the participant to endure. However, personal and emotional support will be given to ensure the greatest care of the patient.

Can I withdraw from the study?

Participation in this study is entirely up to you. You can choose to decline participation in the study or refuse to continue *at any time* as you are under no obligation to remain in it. Your decision will not result in any penalties or benefits in which you are otherwise entitled to. You also have the right to not answer any questions or experiences that make you feel uncomfortable talking about at any time during the process. You are also entitled to request information collected during the research period to not be included in the study. Please note that this will not affect your relationship or current treatment with Armajun AHS, the Poche Centre or any other party involved.

How can I withdraw?

The participant can verbally confirm with the researcher that they no longer wish to participate in the study. At that time no further questions will be asked.

Will anyone else know the results?

There will be a summary of completed study and its results at the conclusion of the study – you will be given the option to receive a copy of these outcomes. Results of interviews will be strictly confidential and only accessed by researchers. The publication of the results of the study will be available to the local Aboriginal community through a communal meetings and printed summaries which both participants and non-participants can attend. A report of the study will also be published in peer reviewed journals however, all individual participants will not be identified in the final publication.

Can I tell others about the study?

Yes, if you wish to tell others about the study you may. If others are interested in being a part of the study themselves they can express interest by contact researches in charge of conducting the study.

What if I need further information about the study or my involvement in it?

After you have read and understood this sheet, the head researcher can answer any questions you have and is able to discuss it with you in further depth.

If you would like to know more, please feel free to contact *Adjunct Assoc Prof Kylie Gwynne* (+61 448483348) or kylie.gwynne@mq.edu.au) or *Vita Christie* (0403 709 178 or vita.christie@sydney.edu.au) or *Debbie Green* (02 6772 5258 or dgreen@armajun.org.au)

What if I have a complaint or any concerns?

If you have any problems or concerns as a result of your participation in the study please feel free to contact Debbie Green at Armajun Aboriginal Health Service at dgreen@armajun.org.au or on 02 6772 5258.

This information sheet is for you to keep

Appendix 1

Questions for focus groups

1. Do you feel that you can discuss breast cancer openly in your community? If so, why? If not, why not?
2. In some Indigenous cultures there is a reported silence around breast cancer and cancer in general- do you think it is the same in your community?
3. What do you think this silence is about?
4. What is your attitude to screening and diagnosis of breast cancer?
5. What do you think gets in the way for a lot of women when it comes to screening and diagnosis?
6. Do you feel you understand how breast cancer affects Indigenous women in Australia? If not, why not?
7. How much trust do you have in the medical system when it comes to breast cancer? Why?
8. How does your community view breast cancer?
9. Do you think this is different from non-Indigenous culture? If so, why?
10. Who are the main supports for women suffering from breast cancer in your community?
11. How important is it for family and community to be involved in the journey? What difference do they make?
12. What did you think of the screening day events? If there was something you could change about them, what would it be?

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5 Questions for community members
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- 9 1. Do you now feel that you can discuss breast cancer openly in your community? If so, why? If
10 not, why not?
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 - 15 2. How was your experience in the breast screen van today?
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 - 20 3. Is there anything that could have improved it?
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 - 26 4. What are your thoughts generally about the breast screening process?
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 - 32 5. Do you feel you understand better now how breast cancer affects Indigenous women in
33 Australia?
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 - 38 6. How does your community now view breast cancer?
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 - 43 7. Who are the main supports for women suffering from breast cancer in your community?
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 - 49 8. Do you have any other comments?
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 - 56 9. Would you be interested in joining a focus group discussion or one on one interview in 2-3
57 weeks' time?
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BMJ Open

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-048003.R2
Article Type:	Protocol
Date Submitted by the Author:	04-Aug-2021
Complete List of Authors:	Christie, Vita; Macquarie University; The University of Sydney Faculty of Medicine and Health, Poche Centre for Indigenous Health Rice, MacKenzie; The University of Sydney Dracakis, Jocelyn; The University of Sydney Faculty of Medicine and Health Green, Deb; Armajun Aboriginal Health Service Amin, Janaki; University of New South Wales, Department of Health Systems and Populations Littlejohn, Karen; Foundation for Breast Cancer Care Pyke, Christopher; Foundation for Breast Cancer Care McCowen, Debbie; Armajun Aboriginal Health Service Gwynne, Kylie; Macquarie University
Primary Subject Heading:	Public health
Secondary Subject Heading:	Health services research
Keywords:	PUBLIC HEALTH, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Breast tumours < ONCOLOGY, Adult oncology < ONCOLOGY

SCHOLARONE™
Manuscripts

Breast Cancer Protocol Outline

Title:

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study protocol

Authors:

Christie V (1,2)*, Rice M (3), Dracakis J (3), Green D (4), Amin J (1), Littlejohn K (5), Pyke C (5), McCowen D (4), and Gwynne K (1)

*Corresponding author: contact vita.christie@sydney.edu.au

Affiliations

1. Faculty of Medicine Health and Human Sciences, Macquarie University
2. Poche Centre for Indigenous Health, The University of Sydney
3. Faculty of Medicine and Health, The University of Sydney
4. Armajun Aboriginal Health Service
5. Foundation for Breast Cancer Care

Abstract:

Introduction

Breast cancer is the most commonly diagnosed cancer affecting Australian women, and the second highest cause of cancer death in Australian women. While the incidence of breast cancer is lower in Aboriginal women than non-Aboriginal women, the mortality rate for Aboriginal women is higher, with Aboriginal women 1.2 times more likely to die from the disease. In NSW, Aboriginal women are 69% more likely to die from their breast cancer than non-Aboriginal women.

Co-design is a research method recognized to enhance collaboration between those doing the research and those impacted by the research. Co-design has been used to significant effect in research with Aboriginal communities, ensuring research and services are relevant, culturally competent and empower communities as co-researchers. We report the development of a new protocol using co-design methods to improve breast cancer outcomes for Aboriginal women.

Methods and analysis: Through a Community Mapping Project (CMP) in 2018, we co-designed an iterative quantitative and qualitative study consisting of 5 phases. In Phase 1, we will establish a governance framework. In Phase 2 we will provide information to community members regarding the modified parts of the screening, diagnosis, treatment and follow up processes and invite them to partake. In Phase 3, the research team will collect data on the outcomes of the modified processes and the outcomes for the women who have and have not participated. The data shall be analyzed quantitatively and thematically in Phase 4 with Aboriginal community representatives and reported back to community. Lastly, in Phase 5 we evaluate the co-design process and adapt our protocol for use in partnership with other communities.

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3 42 Ethics and dissemination: This study has ethics approval of the Aboriginal Health and
4 43 Medical Research Council ref:1525/19. The findings will be published in the literature,
5 44 presented at conferences and short summaries will be issued via social media.
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8 45 **'Strengths and limitations of this study'**

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- 11 47 • This study aims to engage Aboriginal women to design and implement a
12 48 framework for improving participation in breast cancer screening, diagnostic,
13 49 treatment, and post-treatment services and will be designed and implemented
14 50 with a local Aboriginal community-controlled health service and Aboriginal co-
15 51 investigators
 - 16 52 • The study employs a mixed-methods design with descriptive statistical analysis of
17 53 quantitative data on service utilisation as well as qualitative analysis drawn from
18 54 focus groups and in-depth interviews regarding user satisfaction
 - 19 55 • Strengths: The collective action co-design methodology strengthens community
20 56 engagement by sharing power, knowledge and skill with community members
21 57 and health services
 - 22 58 • Limitations: Small study size limits the generalisability of the research findings
 - 23 59 • The author team appreciate completion by Aboriginal women often falls below
24 60 optimum. Whereas others have documented that the completion rates for
25 61 prescribed cancer treatment amongst Aboriginal cohorts is sub-optimal, this
26 62 study is to identify milestones and barriers along the cancer treatment pathway.
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34 62 35 63 **Introduction:**

36 64
37 65 Breast cancer is the most commonly diagnosed cancer in Australia, representing 28% of all
38 66 cancer incidence in women and the second highest number of deaths(1). Mortality due to
39 67 breast cancer has declined significantly over recent decades. This coincides with improved
40 68 rates of early detection following introduction of national population-based mammography
41 69 screening programs(2). Yet, Aboriginal and Torres Strait Islander women in Australia
42 70 continue to face high mortality rates, despite an incidence of breast cancer on par with or
43 71 less than non-Indigenous women(3). Between 1998 and 2013, there was no significant
44 72 decrease in the Indigenous mortality rates for breast cancer in comparison to a significant
45 73 decline for non-Indigenous women(3). When looking at the overall picture, tumour biology
46 74 is shown to be only part of the picture in the disparity of survival outcomes; preventable
47 75 causes relating to delayed diagnosis and treatment are also substantial contributors (4).

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54 76 Uptake of screening has increased over time among both non-Indigenous and Indigenous
55 77 populations in Australia, however a significant gap remains. Australia's national population-
56 78 based screening program BreastScreen offers free 2-yearly mammograms targeting women
57 79 aged 50-74 years. In 2019, 41% of Aboriginal and Torres Strait Islander women in this age
58 80 group participated compared with 54% of non-Indigenous women(5). As a consequence of

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3 81 the gap, Aboriginal and Torres Strait Islander women are more likely to be diagnosed at an
4 82 advanced stage, experiencing worse disease outcomes and lower rates of survival(5-7).

6
7 83 While age is the greatest risk factor for breast cancer, Aboriginal women are more likely to
8 84 be younger than non-Aboriginal women at the time of diagnosis(8). Aboriginal women are
9 85 more likely to receive more invasive surgical treatment compared with their non-Aboriginal
10 86 counterparts(9). This likely contributes to difficulty in engaging Aboriginal women in regular
11 87 and timely follow-up monitoring and care.

14
15 88 There is a demonstrable need for improved screening, diagnostic and care pathways for
16 89 Aboriginal women in Australia(10). The literature identifies numerous enabling factors and
17 90 barriers which contribute to ease, or not, of access, timeliness, and quality of care for
18 91 Aboriginal women with regard to breast cancer screening and services (11-21) .

21
22 92 Overwhelmingly, barriers are related to the lack of cultural safety within health services.
23 93 Aboriginal women are apprehensive about utilising services due to recent or historical
24 94 experiences of racism, lack of culturally safe care and a deficit of resources featuring
25 95 culturally-appropriate educational and health promotion messages. Initiatives which have
26 96 focused on resourcing community-led initiatives to raise awareness found to facilitate
27 97 increased uptake and provide culturally safe care.(12, 13, 16, 17, 19, 22) This care involved
28 98 Aboriginal Health Workers and highlights the importance of primary health care following
29 99 diagnosis. Furthermore, individuals were less likely to engage in services as a consequence
30 100 of previous experiences or the experiences of women they knew with mammography and
31 101 breast cancer. Feelings of shame or stigma were also cited, as was the impact of financial
32 102 barriers and geographical remoteness. (23)

37
38 103 There is a body of evidence surrounding initiatives aimed at increasing breast screening
39 104 among Aboriginal women which indicates that success is highest where there are
40 105 partnerships with Aboriginal community-controlled organisations(21). These initiatives
41 106 implemented culturally-appropriate engagement strategies to address a range of social,
42 107 cultural, personal and economic factors. An expanding evidence base supports the use of
43 108 'co-design' as a research methodology for the design, implementation, and evaluation of
44 109 successful, cost-effective and sustainable strengths-based solutions to health challenges
45 110 among Aboriginal communities(24).

49
50 111 Application of a rigorous, co-design methodology to enhance breast cancer screening and
51 112 care has been evidenced in the literature(25-29) but not extensively. There is a need for
52 113 more translational research utilising co-design methodology that partners with Aboriginal
53 114 women, their communities and community-controlled health organisations to develop
54 115 comprehensive ecological framework for addressing barriers and improving women's
55 116 engagement in screening as well as follow-up diagnostic and breast cancer care services.

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3 117 A preliminary mapping process co-designed with the communities in 2018 has informed this
4 118 research. The Community Mapping Project (CMP) consisted of interviews with Aboriginal
5 119 breast cancer survivors from local communities, staff from the local Aboriginal Health
6 120 Service (AHS), and other breast cancer care providers. The CMP explored experiences,
7 121 priorities and preferences, particularly from the survivors’ perspectives. It was a
8 122 comprehensive mapping of existing screening, diagnosis, treatment and post treatment
9 123 service delivery, resulting in co-designed recommendations to adjust the existing services
10 124 and improve the pathway for Aboriginal women in the area. An important aspect of co-
11 125 design is engaging with communities at the point the research is being conceptualised. This
12 126 is well prior to ethics approval. The AHMRC requires letters of support from Aboriginal
13 127 Community Controlled Health Services. The way we obtain these letters of support is by
14 128 engaging in a process, in this case the CMP, to literally co-design the protocol. Once the
15 129 protocol is approved by communities and then the AHMRC, we proceed to implementation
16 130 of the research. It is not possible therefore to report the detailed discussions, interviews
17 131 and process of the CMP beyond the output, shown in Figures 1-4, because ethics approval
18 132 was obtained after the co-design process of the CMP was completed.

133 Table 1: Key findings of the Community Mapping Project

	Key recommendations
1	Screening days for Aboriginal women, staffed by Aboriginal women
2	An Aboriginal health worker present at screening van for agreed periods of time (outside of screening days)
3	Provide transport to and from screening van
4	Community spokespeople promoting screening and extra support offered for diagnosis, treatment and follow up care
5	Directory booklets for women who are receiving treatment
6	Directory booklets for health services in order to ensure they are equipped with up to date information for women
7	Culturally appropriate area in local oncology department to increase comfort for Aboriginal patients
8	GP management plans prior to treatment
9	Follow up care plans post treatment
10	Follow up phone call/visit from an Aboriginal health Worker to check in and work through options
11	Local Aboriginal cancer support group formed

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135
136 This study will use the information garnered through the CMP to develop and evaluate a
137 culturally safe breast screening, diagnostic, treatment and follow up pathway for Aboriginal
138 women in selected regions. The findings of this work will inform policy and practice aimed at
139 reducing the rates of mortality of Aboriginal women from breast cancer.

140
141 **Aims and Objectives:**

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143 Primary objective:

144 In one region in NSW Australia we will:

- 145 • Co-design and evaluate a pathway for timely and culturally safe screening,
146 diagnostic, treatment and post-treatment services for Aboriginal women.

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3 147 **Aim:** improve communication and reduce anxiety and stress as screening transitions into
4 148 treatment to improve initial treatment uptake.

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7 149 **Methods and analysis**

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10 151 **Co-design**

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12 152 Co-design is a process of developing something with or alongside stakeholders or intended
13 153 recipients or beneficiaries(24, 30).

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16 154

17 155 The design of the study has been based on recommendations provided by the CMP from
18 156 2018. The CMP was a collaboration between the Foundation for Breast Cancer Care, the
19 157 Poche Centre for Indigenous Health and Armajun Aboriginal Health Service. The CMP
20 158 included consultation with Aboriginal survivors of breast cancer, Aboriginal women in the
21 159 target age range for breast cancer prevention and early intervention, and Aboriginal Health
22 160 Workers as well as local service providers in a regional and rural location situated in the
23 161 Central North of New South Wales.. The CMP informed this protocol. The development of
24 162 the research question and outcome measures were informed by patients' and healthcare
25 163 providers' priorities, experience, and preferences.

26 164 The CMP guided the development of this iterative mixed methods study consisting of five
27 165 main phases which makes adjustments to the present processes of screening, diagnosis,
28 166 treatment and post treatment follow up to enhance cultural safety and promote
29 167 engagement of Aboriginal women. The planned time period for data collection is one year:
30 168 2021-2022.. The study commenced when ethics approval was granted in 2019 and will
31 169 conclude 2022.

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37 170 **Patient and Public Involvement**

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40 171 Fundamental to the co-design model is patient and public involvement. This study was
41 172 developed using co-design methods with community organisations and Aboriginal survivors
42 173 of breast cancer. The research will be conducted with patient and public involvement end to
43 174 end.

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46 175 **Co-designed assessment and treatment pathway**

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48
49 176 The current screening, diagnosis, treatment and post-treatment services respectively and describe
50 177 the adjustments and additions created through the CMP are shown in Figures 1-4.

51
52 178 Key to figures: (attached as an Image file) **Key:** Blue boxes show the current process Orange boxes show
53 179 the proposed additions to the process.

54
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56 180 Figure 1 Screening services

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58 181 (attached as Image file)

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60 182 Figure 2 Diagnostic services

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3 183
4 184 (attached as Image file)

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6 185 Figure 3 Treatment services
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8 187 (attached as Image file)

9
10 188 Figure 4 Post treatment services
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12 13 14 190 **Governance**

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16 191 Through the CMP it was determined how the local community wanted to be involved in the
17 192 design, recruitment, implementation and evaluation of the study. Through the co-design
18 193 process the community were able to assess the burden of the research, including time and
19 194 resource commitments, in order to inform a sustainable approach.

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23 196 Local community members, breast cancer survivors and AHS staff will have continued input
24 197 throughout the study as part of the iterative co-design process. An Aboriginal Advisory
25 198 Group will inform the study and its progress and AHS staff who self-nominate will be
26 199 investigators on the study. The Aboriginal Advisory Group will meet every month and the
27 200 Investigators' Group every eight weeks. Data will be collected and owned and managed by
28 201 the AHS and will be shared with Investigator group. Any publication will need to be
29 202 approved by the Aboriginal Advisory Group and the AHMRC ethics committee. Members of
30 203 the Investigators Group will continue to participate in community meetings regarding the
31 204 progress and outcomes of the process, and community members will be given the option to
32 205 receive a copy of the completed study and its outcomes and be invited to attend community
33 206 meetings/workshops organised to disseminate the results of the study. The Aboriginal
34 207 Advisory Group and AHS staff will be involved in designing the dissemination process.

35 36 37 38 39 208 **Ethics**

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43 209 This project has ethics approval from the Aboriginal Health and Medical Research Council of
44 210 NSW, Ref: 1525/19.

45 46 47 211 **Design**

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49 212 The study will use a mixed-methods design. Qualitative methods will include semi-
50 213 structured, in-depth interviews and focus group discussions. Structured quantitative and
51 214 qualitative questionnaires will be used to assess participant satisfaction, as well as collect
52 215 information about demographics, patient journey and clinical data.

53 54 55 216 **Target population**

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3 218 The target population for this study is Aboriginal women living in the study region. The
4 219 expected duration of this study is approximately three years, in which time the BreastScreen
5 220 van will have visited these areas at least twice.
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8 221 The area we are working with is a regional and rural location situated in the Central North of
9 222 New South Wales. Seven percent of the local population in the region identify as Aboriginal
10 223 and/or Torres Strait Islander (ABS 2016 census data) which calculates as a possible sample
11 224 size of 631 Aboriginal women above the age of 30. Four specific study sites have been
12 225 selected by convenience sampling on the basis of a pre-existing relationship with the local
13 226 AHS which services the region. The communities expressed interest in working with the AHS
14 227 in this capacity. The study will rely on voluntary sampling of individuals who fit the criteria
15 228 of target population: Aboriginal women, >30 years and willing to receive care through the
16 229 AHS.
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22 231 **Phases of implementation**

23 232 The process of implementation is shown in Figure 5.
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26 233

27 234 **Phase 1: Preparation**

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29 236 The Investigator team will work with Breast Screen NSW to gather the pre-intervention data
30 237 to use as a baseline to measure quantitative outcomes. Data collected will include:
31 238 retrospective data through the AHS related to participation as referral data is not available;
32 239 number of women who attended the Breast Screen van in the region in 2018 and 2019
33 240 (2020 data has been affected by Covid-19 and therefore is not representative), and how
34 241 many of these women identified at Aboriginal and/or Torres Strait Islander. The team will
35 242 also work closely with the AHS (one of the investigator team is a staff member and second is
36 243 the CEO of the AHS) in planning for a screening event, which is a fixed period of time where
37 244 the van is reserved for Aboriginal women only and, additionally, staffing the van with an
38 245 Aboriginal Health Worker for several extra days during its visit to the area. This work will be
39 246 done in consultation with Breast Screen NSW.
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47 248 The team will also work on development of resources for patrons of the local health
48 249 services, including information on the different stages of the treatment journey and on the
49 250 local support services for these different stages. This will include working with the local
50 251 oncology unit to ensure that welcoming and culturally safe spaces are offered to Aboriginal
51 252 women in the area.
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56 255 Figure 5. Process of implementation

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58 257 (attached as an Image file)
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5 **Phase 2: Community information**

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8 261 In our co-design process, 'community information' refers to both promoting the culturally
9 262 safe screening events and providing relevant information to potential participants regarding
10 263 the study. The local AHS staff and Investigator team member will reach out to communities
11 264 in the region to inform them of the screening day event and presence of an Aboriginal
12 265 Health Worker in the Breast Screen van in 2021, and the inclusion of additional support
13 266 services such as transport and child-minding. Outreach will include several forms of
14 267 communication such as phone calls, emails, flyers and community visits, and will include
15 268 written reminders 1 week out from the screening day date.

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20 270 Screening and follow up will be undertaken according to the procedures described in
21 271 Figures 1-4. The AHS will be offer risk assessments for women between 30-39 years who will
22 272 be referred on for screening and MRI if they are found to meet high risk criteria. For women
23 273 who are 40-49 years old, letters will be sent out 6 weeks prior to screening dates and then
24 274 two follow up calls will be placed 4 weeks prior and 1 week prior to the screening dates. For
25 275 women who qualify for a reminder sent out by the government (50-74 years old), reminder
26 276 phone calls will be placed 4 weeks prior and 1 week prior to the screening dates. For the
27 277 women who are referred for further diagnosis, resources will be given to and support from
28 278 the local Aboriginal Health Workers on next steps.

29 279 Additionally there will be Aboriginal Health Workers acting as support staff if treatment is
30 280 suggested, to inform affected women of the resources on offer and treatment pathways
31 281 suggested. Women who partake in any part of the modified screening, diagnosis, treatment
32 282 of follow up processes will be invited to join the study but will be no consequences for their
33 283 treatment or support if they elect not to participate.

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41 **Phase 3: Data Collection and outcome measurement**

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45 287 All participants involved in the study will be recruited via the AHS. The AHS will contact each
46 288 prospective participant personally and explain the study to them. They will explain the
47 289 Participant Information Sheet and seek informed consent (PIS) (PIS- see Appendix 1). The
48 290 PIS outlines what the study is about; who is carrying out the study; what the study involves;
49 291 information about how they can withdraw from the study; information about the risks and
50 292 benefits of the study; and information on how to contact the researchers if needed.

51 293 All participants who complete the satisfaction questionnaire, participate in the in-depth
52 294 interviews, or participate in the focus group discussions will need to sign a consent form.

53 295 This consent form will allow the study to use the information provided and the participants
54 296 will be advised the information they provide will be de-identified. The consent process will
55 297 be managed by the AHS. Women participating in the in-depth interviews and focus group

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3 298 discussions will be advised that these will be recorded. These recordings will be transcribed,
4 299 de-identified, and then destroyed.

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6 300 All Aboriginal women in the community will be allowed to access any of the additional
7 301 services/modifications being implemented, regardless of participation in the study. This will
8 302 ensure equitable access to all services provided and will not negatively impact Aboriginal
9 303 women who do not feel comfortable participating in the study.

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13 305 The Aboriginal Health Worker will manage the consent process and consents will be held by
14 306 the AHS. Consents will be gathered prior to participation in screening, in-depth interviews
15 307 and focus groups.

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19 309 The quantitative data (numbers of attendees who identify as Aboriginal and Torres Strait
20 310 Islander) will be collected by the AHS at the culturally safe screening events and satisfaction
21 311 questionnaires will be supplied after the event via the AHS. The qualitative data will be
22 312 gathered during the in-depth interviews conducted by the AHS at a location acceptable to
23 313 the participants between two and four weeks after the event so as to capture the
24 314 experience when it is fresh in the minds of the participants. The focus groups will be
25 315 organised by and held at the local AHS and will include a shared meal over which a series of
26 316 questions will be asked (see Appendix 2) and responses collected. The discussions will be
27 317 audio recorded and transcribed with the consent of the participants.

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31 319 Further qualitative data will be collected from women engaging in the diagnosis, treatment
32 320 and follow up processes via focus groups and interviews. This data aims to capture level of
33 321 satisfaction with the modifications outlined in the flow charts.

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35 322 The AHS will also follow up with the participants to review their wellbeing after focus groups
36 323 and interviews.

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40 325 The study will quantitatively measure:

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- 44 327 • the participation rates of Aboriginal women in breast cancer screening (over a 10
45 328 week period)
 - 46 329 • the participation rates of Aboriginal women in timely and culturally safe diagnostic,
47 330 treatment and post-treatment services (over a one year period)
 - 48 331 • satisfaction levels among Aboriginal women in the local community who go through
49 332 the screening, diagnostic, treatment, and post-treatment process (over a one year
50 333 period)
 - 51 334 • breast cancer health literacy among Aboriginal women in the local community (over
52 335 a one year period)

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55 335 To determine the change in rates, study outcomes will be compared to the baseline
56 336 participation of Aboriginal women in breast screening service, defined as the number of
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3 337 women who attended the BreastScreen van in the chosen area and the surrounding regions
4 338 in the 2-3 years preceding and how many of these identified as Aboriginal and/or Torres
5 339 Strait Islander.
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9 341 To establish baseline satisfaction levels all women will be asked about satisfaction for each
10 342 of the 4 stages (screening, diagnosis, treatment and follow-up). For each stage, the sub set
11 343 of women who have previously accessed that stage will be asked if there is any change in
12 344 their level of satisfaction. Questionnaires will also be completed by Aboriginal women who
13 345 have not accessed the BreastScreen van previously, asking them why they have not.
14 346

15
16 347 Qualitative and quantitative data analysis will be used to establish whether the additional
17 348 adjustments implemented were successful in improving attendance and satisfaction levels
18 349 in breast cancer outcomes among Aboriginal women in the region.
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21 351 Participation rates will be measured during the screening day event and at the clinics which
22 352 have an Aboriginal Health Worker present and will be compared to data ascertained from
23 353 Breast Screen Van during 2018-2019. Participation in diagnostic, treatment and post-
24 354 treatment services will be tracked in the six months post screening event via the AHS, which
25 355 will follow up with the local treatment services and with the women who have received
26 356 advice to go for further screening and treatment. This will entail a phone call and welfare
27 357 check and further referrals and advice as indicated.
28 358

29 359 To establish whether there was an improvement in satisfaction levels regarding screening,
30 360 services available to Aboriginal women questionnaires will be completed by those who
31 361 accessed the screening van in 2021, both during normal operation and the screening day
32 362 event (see Appendix 3). Questionnaires and in depth interviews will also be completed by
33 363 women who accessed diagnostic, treatment and/or post-treatment services for breast
34 364 cancer in 2021.
35 365

36 366 Semi-structured interviews will be conducted to gather more in-depth, qualitative data with
37 367 women who visited the Breast Screen van when it was running typically, those who visited
38 368 during the screening day event and also those who knew about the event but chose not to
39 369 attend. In addition, 2-hour focus groups will be conducted with 8-10 women who attended
40 370 while it was running typically and 8-10 women who attended the Screening day event.
41 371

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43 372 The Australian Commission on Safety and Quality in Health Care definition of Health literacy
44 373 is “about how people understand information about health and health care, and how they
45 374 apply that information to their lives, use it to make decisions and act on it. Health literacy is
46 375 important because it shapes people’s health and the safety and quality of health care.”(31)
47 376 The way this study will assess health literacy will be through increase in participation of
48 377 services (quantitative data collection) and also a self-reported increase in understanding
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3 378 about breast cancer and the options for screening, diagnosis, treatment and follow up care
4 379 (via qualitative focus group discussion).

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7 381 Safety considerations

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9 382 Safety of the participants and anyone involved in the research is a priority of the study. Any
10 383 adverse events during the study will be recorded and reported, and a follow-up of the event
11 384 will be completed. The AHS will be available to assist and refer.

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15 386 **Phase 4: Data analysis and dissemination**

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17 388 Data analysis plan

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19 389 Quantitative data gathered through screening events and de-identified reports via the AHS
20 390 primary healthcare software system and will be analyzed through descriptive statistics. For
21 391 the qualitative data gathered through focus groups and in-depth interviews, we will perform
22 392 an inductive thematic analysis using NVivo11 to organize participant's responses into key
23 393 themes. Coding and thematic analysis of qualitative data will be carried out by two
24 394 members of the study team and checked by an Aboriginal author who is also a member of
25 395 the community, following best practices for enhancing validity in qualitative methods(32,
26 396 33). The core research team will meet to review the findings and identify outstanding or
27 397 representative quotes for future presentation of the results. Preliminary findings will be
28 398 discussed with AHS and Aboriginal Advisory Group.

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31 400 Returning results to the community

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34 401 Results of the co-design study will be disseminated into the local Aboriginal community
35 402 through community meetings, social media and printed research summaries (including
36 403 Plain English summaries). We will work in collaboration with AHS to hold community
37 404 meetings and information evenings, which both participants and non-participants of the
38 405 study can attend. Community members will be encouraged to provide feedback and
39 406 comments on the process.

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41 407 Results will be published in peer reviewed journals and presented at professional
42 408 conferences. The AHS participating in the study will be invited to contribute to these
43 409 publications and presentations. We will acknowledge the sources of information and
44 410 those who have contributed to the research through authorship and acknowledgement in
45 411 resulting publications, meetings with community members and conference presentations.
46 412 We will also acknowledge the cultural property rights of Aboriginal peoples in relation to
47 413 knowledge, ideas, cultural expressions and cultural materials by including AHS
48 414 representatives as research team members.

49 415 **Phase 5: Adaptation**

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3 416 In this phase we will evaluate the co-design process to evaluate whether it can be adapted
4 417 to similar health issues in Aboriginal communities elsewhere in Australia. We will do this
5 418 by sharing the findings of the study widely across AHSs and social media and inviting AHSs
6 419 to work with us to see if the protocol could be adapted with them for their community.
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15 424 **Corresponding author:**

16 425 Vita Christie

17 426 E: vita.christie@sydney.edu.au

18 427 T: 0403 709 178 F: 02 9351 3196

19 428 A: 225 Edward Ford Building A27, The University of Sydney NSW 2006

20 429

21 430 **Authors' contributions:**

22 431 Conception and design of the study - KG, DG, DM, MR, VC

23 432 Planning- VC, KG, JD, DG

24 433 Governance and scientific advice – KG, CP, JA DM, DG, VC

25 434 Conduct and reporting: VC, KG, DG

26 435 Drafting the Manuscript – VC, MR, KG, JD

27 436 Review and approval of the manuscript – VC, KG, JA, DG, KL, CP, DM, JD

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32 441

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34 443 None

35 444

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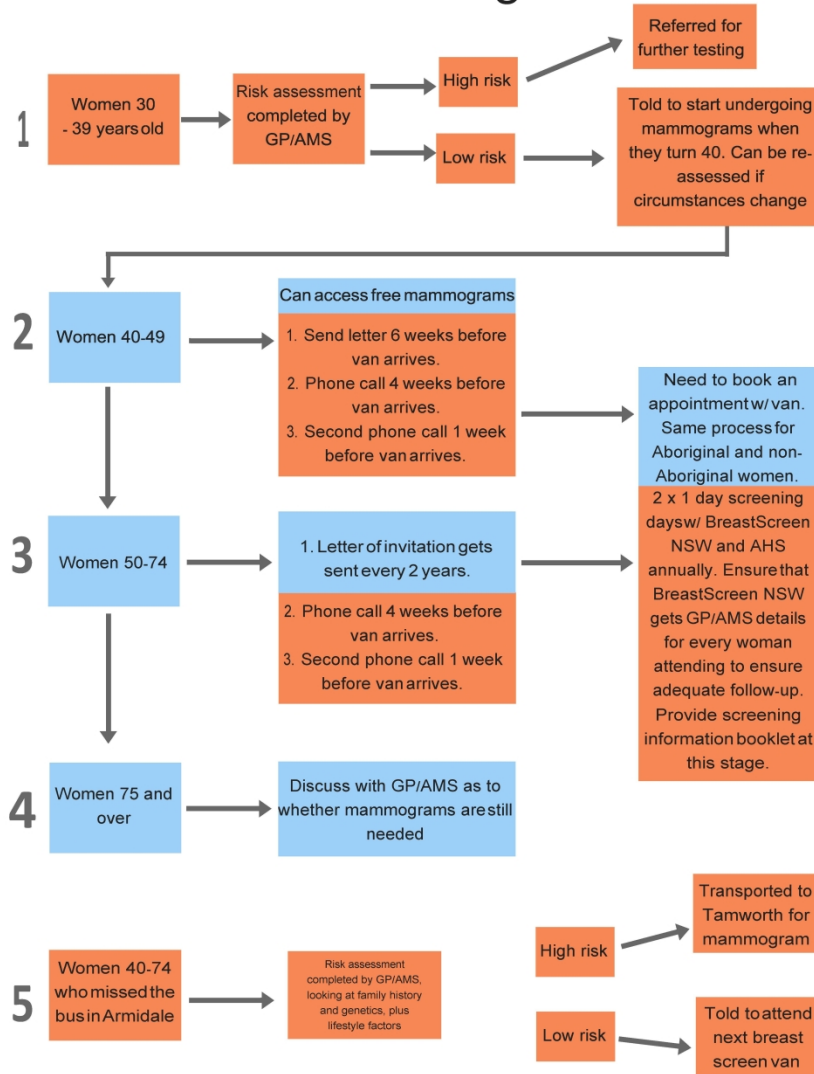
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For peer review only

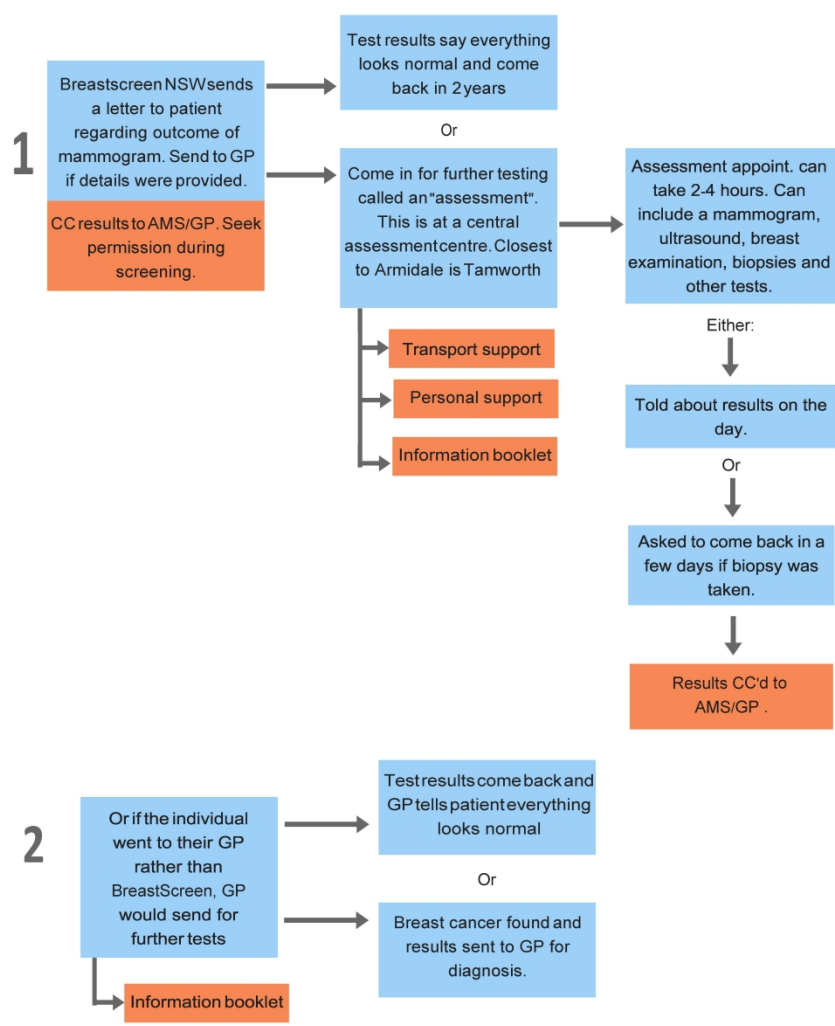
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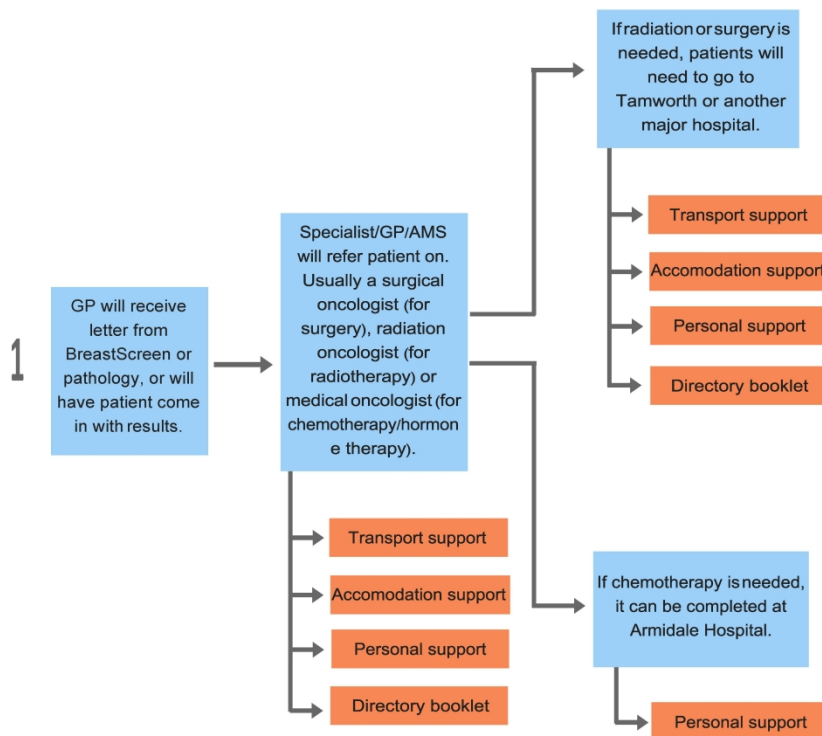
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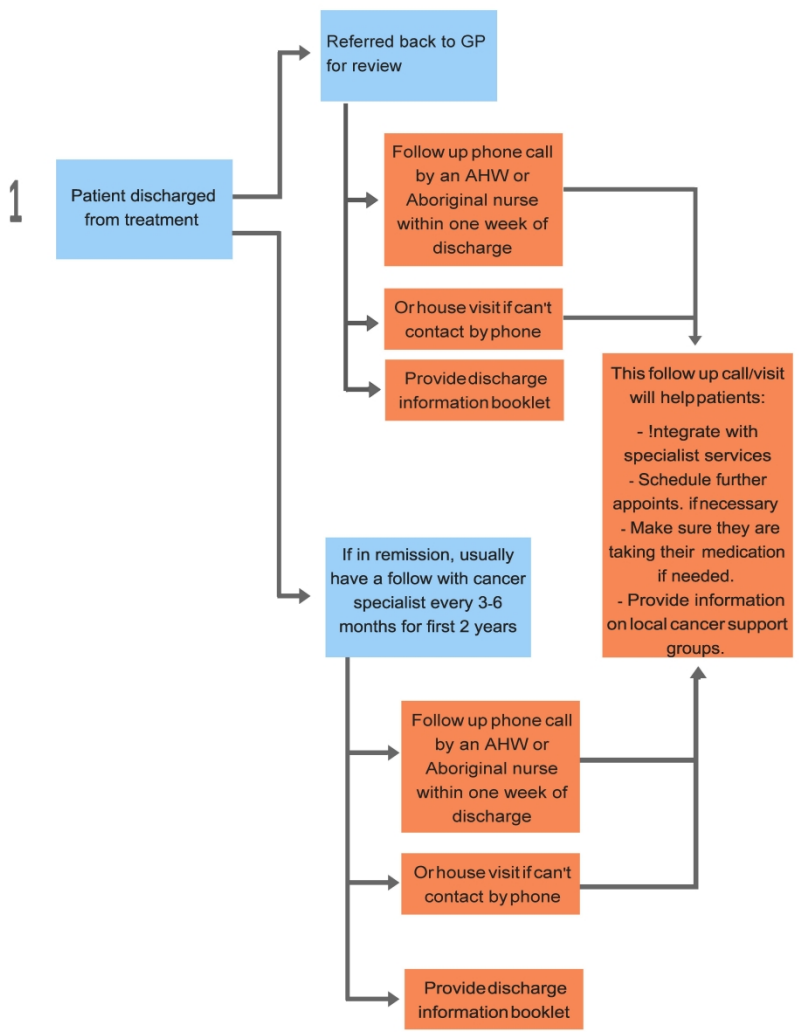


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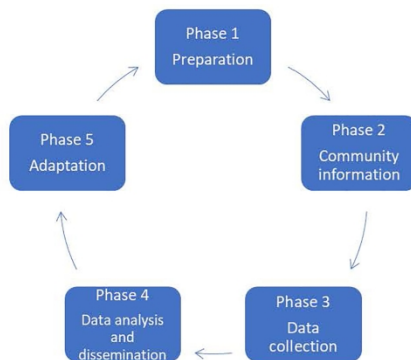
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Post Treatment



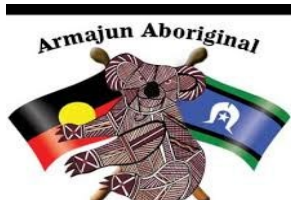
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Figure 5



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Adjunct Assoc Prof Kylie Gwynne

Macquarie University
Sydney, NSW
Telephone: +61 448 483 348
Email: kylie.gwynne@mq.edu.au

PARTICIPANT INFORMATION STATEMENT

Purpose of the study

This is an invitation to participate in a study by researchers at Macquarie University, Armajun Aboriginal Health Service and the Poche Centre for Indigenous Health, University of Sydney. The purpose of the research is to investigate whether the implementation of additional, culturally appropriate adjustments to the current breast cancer screening, diagnostic, treatment and post treatment services available to Aboriginal women in Armidale improves both the screening participation rates and the disease outcomes of Indigenous women living in the area. The study calls upon all Aboriginal women aged 30 years or older, living in Armidale or surrounding towns. Participants can be already be a breast cancer patient at Armajun Aboriginal Health Service (AHS) or choose to participate when they attend the screening day event.

This study acknowledges the factors influencing access to the current health care services in rural or remote communities in Australia. Preliminary research was undertaken with Armajun Aboriginal Health Service (AHS) to map the breast cancer screening, diagnostic and treatment services currently available to Aboriginal women in Armidale and identified numerous barriers that prevent access to these services effectively. The study will explore the impact of adjustments made to current stages of breast cancer services that aim to break down these barriers and allow for greater participate rates. Implementation and outcomes of the study are guided by Armajun and the local Aboriginal community of Armidale in which this study will take place, to ensure that the exact social and cultural needs of the local Aboriginal community are considered during the process.

The study is being conducted by Adjunct Assoc Prof Kylie Gwynne(Macquarie University). Other members of the research team members include Vita Christie, Debbie Green, Deb McCowen.

What does the study involve?

If you choose to take part in this study you will be asked to take part in in-depth interviews and focus group discussions with members of the research team to evaluate the quality of services provided to you. You may also be asked to complete questionnaires to assess your satisfaction of your experience with the screening and treatment services and may be recorded using Audio Recordings. The interview will assess the various types of adjustments being implemented and perceptions and experiences you've encountered within services provided. Both qualitative and quantitative data will be utilised to evaluate whether the additional adjustments were successful in improving the journey of breast cancer as well as the service satisfaction levels among Aboriginal women in Armidale. The interviews and discussion groups will be held at a location convenient to you. All recordings will be transcribes and then destroyed after being evaluated.

Your involvement in the study is entirely voluntary and you may choose to withdraw at any time from the study. You may also choose to withdraw any data that was collected from you up until that point. Please note no penalties will be given if you choose to withdraw from the study.

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study.

While there is little risk involved in this research study, talking about specific health issues and experiences may make you feel uncomfortable at times. Please know that if you want to discontinue talking about these topics, let the interviewer or head of discussion group know that you would like a break and if need be can assist you in a referral for additional emotional support. There is also the possibility that results from a mammogram can contain diagnosis of Breast Cancer and therefore can be a traumatic event for the participant to endure. However, personal and emotional support will be given to ensure the greatest care of the patient.

Can I withdraw from the study?

Participation in this study is entirely up to you. You can choose to decline participation in the study or refuse to continue *at any time* as you are under no obligation to remain in it. Your decision will not result in any penalties or benefits in which you are otherwise entitled to. You also have the right to not answer any questions or experiences that make you feel uncomfortable talking about at any time during the process. You are also entitled to request information collected during the research period to not be included in the study. Please note that this will not affect your relationship or current treatment with Armajun AHS, the Poche Centre or any other party involved.

How can I withdraw?

The participant can verbally confirm with the researcher that they no longer wish to participate in the study. At that time no further questions will be asked.

Will anyone else know the results?

There will be a summary of completed study and its results at the conclusion of the study – you will be given the option to receive a copy of these outcomes. Results of interviews will be strictly confidential and only accessed by researchers. The publication of the results of the study will be available to the local Aboriginal community through a communal meetings and printed summaries which both participants and non-participants can attend. A report of the study will also be published in peer reviewed journals however, all individual participants will not be identified in the final publication.

Can I tell others about the study?

Yes, if you wish to tell others about the study you may. If others are interested in being a part of the study themselves they can express interest by contact researches in charge of conducting the study.

What if I need further information about the study or my involvement in it?

After you have read and understood this sheet, the head researcher can answer any questions you have and is able to discuss it with you in further depth.

If you would like to know more, please feel free to contact *Adjunct Assoc Prof Kylie Gwynne* (+61 448483348) or kylie.gwynne@mq.edu.au) or *Vita Christie* (0403 709 178 or vita.christie@sydney.edu.au) or *Debbie Green* (02 6772 5258 or dgreen@armajun.org.au)

What if I have a complaint or any concerns?

If you have any problems or concerns as a result of your participation in the study please feel free to contact Debbie Green at Armajun Aboriginal Health Service at dgreen@armajun.org.au or on 02 6772 5258.

This information sheet is for you to keep

Appendix 1

Questions for focus groups

1. Do you feel that you can discuss breast cancer openly in your community? If so, why? If not, why not?
2. In some Indigenous cultures there is a reported silence around breast cancer and cancer in general- do you think it is the same in your community?
3. What do you think this silence is about?
4. What is your attitude to screening and diagnosis of breast cancer?
5. What do you think gets in the way for a lot of women when it comes to screening and diagnosis?
6. Do you feel you understand how breast cancer affects Indigenous women in Australia? If not, why not?
7. How much trust do you have in the medical system when it comes to breast cancer? Why?
8. How does your community view breast cancer?
9. Do you think this is different from non-Indigenous culture? If so, why?
10. Who are the main supports for women suffering from breast cancer in your community?
11. How important is it for family and community to be involved in the journey? What difference do they make?
12. What did you think of the screening day events? If there was something you could change about them, what would it be?

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5 Questions for community members
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9 1. Do you now feel that you can discuss breast cancer openly in your community? If so, why? If
10 not, why not?
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15 2. How was your experience in the breast screen van today?
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20 3. Is there anything that could have improved it?
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26 4. What are your thoughts generally about the breast screening process?
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32 5. Do you feel you understand better now how breast cancer affects Indigenous women in
33 Australia?
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38 6. How does your community now view breast cancer?
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43 7. Who are the main supports for women suffering from breast cancer in your community?
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49 8. Do you have any other comments?
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56 9. Would you be interested in joining a focus group discussion or one on one interview in 2-3
57 weeks' time?
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Flow chart mapping the screening, diagnosis, treatment and post-treatment process

Blue boxes show the current process

Orange boxes show proposed additions to the process

Key to figures

420x594mm (200 x 200 DPI)

BMJ Open

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-048003.R3
Article Type:	Protocol
Date Submitted by the Author:	04-Oct-2021
Complete List of Authors:	Christie, Vita; Macquarie University; The University of Sydney Faculty of Medicine and Health, Poche Centre for Indigenous Health Rice, MacKenzie; The University of Sydney Dracakis, Jocelyn; The University of Sydney Faculty of Medicine and Health Green, Deb; Armajun Aboriginal Health Service Amin, Janaki; University of New South Wales, Department of Health Systems and Populations Littlejohn, Karen; Foundation for Breast Cancer Care Pyke, Christopher; Foundation for Breast Cancer Care McCowen, Debbie; Armajun Aboriginal Health Service Gwynne, Kylie; Macquarie University
Primary Subject Heading:	Public health
Secondary Subject Heading:	Health services research
Keywords:	PUBLIC HEALTH, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Breast tumours < ONCOLOGY, Adult oncology < ONCOLOGY

SCHOLARONE™
Manuscripts

Breast Cancer Protocol Outline

Title:

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study protocol

Authors:

Christie V (1,2)*, Rice M (3), Dracakis J (3), Green D (4), Amin J (1), Littlejohn K (5), Pyke C (5), McCowen D (4), and Gwynne K (1)

*Corresponding author: contact vita.christie@sydney.edu.au

Affiliations

1. Faculty of Medicine Health and Human Sciences, Macquarie University
2. Poche Centre for Indigenous Health, The University of Sydney
3. Faculty of Medicine and Health, The University of Sydney
4. Armajun Aboriginal Health Service
5. Foundation for Breast Cancer Care

Abstract:

Introduction

Breast cancer is the most commonly diagnosed cancer affecting Australian women, and the second highest cause of cancer death in Australian women. While the incidence of breast cancer is lower in Aboriginal women than non-Aboriginal women, the mortality rate for Aboriginal women is higher, with Aboriginal women 1.2 times more likely to die from the disease. In NSW, Aboriginal women are 69% more likely to die from their breast cancer than non-Aboriginal women.

Co-design is a research method recognized to enhance collaboration between those doing the research and those impacted by the research; which when used with Aboriginal communities, ensures research and services are relevant, culturally competent and empowers communities as co-researchers. We report the development of a new protocol using co-design methods to improve breast cancer outcomes for Aboriginal women.

Methods and analysis: Through a Community Mapping Project (CMP) in 2018, we co-designed an iterative quantitative and qualitative study consisting of 5 phases. In Phase 1, we will establish a governance framework. In Phase 2 we will provide information to community members regarding the modified parts of the screening, diagnosis, treatment and follow up processes and invite them to partake. In Phase 3, the research team will collect data on the outcomes of the modified processes and the outcomes for the women who have and have not participated. The data shall be analyzed quantitatively and thematically in Phase 4 with Aboriginal community representatives and reported back to community. Lastly, in Phase 5 we evaluate the co-design process and adapt our protocol for use in partnership with other communities.

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41 Ethics and dissemination: This study has ethics approval of the Aboriginal Health and
42 Medical Research Council ref:1525/19. The findings will be published in the literature,
43 presented at conferences and short summaries will be issued via social media.

44 **'Strengths and limitations of this study'**

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- This study will use mixed methods to identify milestones, enablers and barriers along the breast cancer prevention and treatment pathway for Aboriginal women.
 - The collective impact co-design methodology strengthens community engagement by sharing power, knowledge and skill with community members and health services.
 - Small study size limits the generalisability of the research findings.
 - This study will not report the sub-optimal completion rates for Aboriginal women.

54 55 **Introduction:**

56
57 Breast cancer is the most commonly diagnosed cancer in Australia, representing 28% of all
58 cancer incidence in women and the second highest number of deaths(1). Mortality due to
59 breast cancer has declined significantly over recent decades. This coincides with improved
60 rates of early detection following introduction of national population-based mammography
61 screening programs(2). Yet, Aboriginal and Torres Strait Islander women in Australia
62 continue to face high mortality rates, despite an incidence of breast cancer on par with or
63 less than non-Indigenous women(3). Between 1998 and 2013, there was no significant
64 decrease in the Indigenous mortality rates for breast cancer in comparison to a significant
65 decline for non-Indigenous women(3). When looking at the overall picture, tumour biology
66 is shown to be only part of the picture in the disparity of survival outcomes; preventable
67 causes relating to delayed diagnosis and treatment are also substantial contributors (4, 5).

68 Uptake of screening has increased over time among both non-Indigenous and Indigenous
69 populations in Australia, however a significant gap remains. Australia's national population-
70 based screening program BreastScreen offers free 2-yearly mammograms targeting women
71 aged 50-74 years. In 2019, 41% of Aboriginal and Torres Strait Islander women in this age
72 group participated compared with 54% of non-Indigenous women(6). As a consequence of
73 the gap, Aboriginal and Torres Strait Islander women are more likely to be diagnosed at an
74 advanced stage, experiencing worse disease outcomes and lower rates of survival(6-8).

75 While age is the greatest risk factor for breast cancer, Aboriginal women are more likely to
76 be younger than non-Aboriginal women at the time of diagnosis(9) and receive more
77 invasive surgical treatment compared with their non-Aboriginal counterparts(10). It is well

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3 78 established in the literature that this association likely contributes to difficulty in engaging
4 79 Aboriginal women in regular and timely follow-up monitoring and care(11)
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7 80 There is a demonstrable need for improved screening, diagnostic and care pathways for
8 81 Aboriginal women in Australia(12). The literature identifies numerous enabling factors and
9 82 barriers which contribute to ease, or not, of access, timeliness, and quality of care for
10 83 Aboriginal women with regard to breast cancer screening and services (13-23) .
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13 84 Overwhelmingly, barriers are related to the lack of cultural safety within health services.
14 85 Aboriginal women are apprehensive about utilising services due to recent or historical
15 86 experiences of racism, lack of culturally safe care and a deficit of resources featuring
16 87 culturally-appropriate educational and health promotion messages. Initiatives focused on
17 88 resourcing community-led initiatives to raise awareness have been found to facilitate
18 89 increased uptake and provide culturally safe care.(14, 15, 18, 19, 21, 24) This care involved
19 90 Aboriginal Health Workers and highlights the importance of primary health care following
20 91 diagnosis. Furthermore, individuals were less likely to engage in services as a consequence
21 92 of previous experiences or the experiences of women they knew with mammography and
22 93 breast cancer. Feelings of shame or stigma were also cited, as was the impact of financial
23 94 barriers and geographical remoteness. (25)
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30 95 There is a body of evidence surrounding initiatives aimed at increasing breast screening
31 96 among Aboriginal women which indicates that success is highest where there are
32 97 partnerships with Aboriginal community-controlled organisations(23). These initiatives
33 98 implemented culturally-appropriate engagement strategies to address a range of social,
34 99 cultural, personal and economic factors. An expanding evidence base supports the use of
35 100 'co-design' as a research methodology for the design, implementation, and evaluation of
36 101 successful, cost-effective and sustainable strengths-based solutions to health challenges
37 102 among Aboriginal communities(26).
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42 103 Application of rigorous co-design methods to enhance breast cancer screening amongst
43 104 Indigenous women internationally have been documented in the literature (27-31) but not
44 105 extensively. We also note in the literature that low participation in follow up services,
45 106 including anti-estrogen treatment (5) however, there is a need for more translational
46 107 research utilising co-design methodology that partners with Aboriginal women, their
47 108 communities and community-controlled health organisations to develop comprehensive
48 109 ecological framework for addressing barriers and improving women's engagement in
49 110 screening as well as follow-up diagnostic and breast cancer care services.
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54 111 The codesign approach of the research team follows the five stages of the collective impact
55 112 model. These include 1. Common agenda, 2. Shared measurement, 3. Mutually reinforcing
56 113 activities, 4. Continuous communication and 5. Backbone support. This process provides a
57 114 structured and shared process from conception, through to design, implementation and
58 115 evaluation and increases the likelihood that health services will be utilized by Aboriginal
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3 116 people and that, as a result, health outcomes will improve. This approach has been validated
4 117 with Aboriginal communities for translational health research. (26)

7 118 A preliminary mapping process co-designed with the communities in 2018 has informed this
8 119 research. The Community Mapping Project (CMP) consisted of interviews with Aboriginal
9 120 breast cancer survivors from local communities, staff from the local Aboriginal Health
10 121 Service (AHS), and other breast cancer care providers. The CMP explored experiences,
11 122 priorities and preferences, particularly from the survivors' perspectives. It was a
12 123 comprehensive mapping of existing screening, diagnosis, treatment and post treatment
13 124 service delivery, resulting in co-designed recommendations (see Table 1 below) to adjust
14 125 the existing services and improve the pathway for Aboriginal women in the area. An
15 126 important aspect of co-design is engaging with communities at the point the research is
16 127 being conceptualised. This is well prior to ethics approval. The AHMRC requires letters of
17 128 support from Aboriginal Community Controlled Health Services. The way we obtain these
18 129 letters of support is by engaging in a process, in this case the CMP, to literally co-design the
19 130 protocol. Once the protocol is approved by communities and then the AHMRC, we proceed
20 131 to implementation of the research. It is not possible therefore to report the detailed
21 132 discussions, interviews and process of the CMP beyond the output, shown in Figures 1-4,
22 133 because ethics approval was obtained after the co-design process of the CMP was
23 134 completed.

31
32 135 Table 1: Key recommendations of the Community Mapping Project

	Key recommendations
34	
35	1 Screening days for Aboriginal women, staffed by Aboriginal women
36	2 An Aboriginal health worker present at screening van for agreed periods of time (outside of screening days)
37	3 Provide transport to and from screening van
38	4 Community spokespeople promoting screening and extra support offered for diagnosis, treatment and follow up care
39	5 Directory booklets for women who are receiving treatment
40	6 Directory booklets for health services in order to ensure they are equipped with up to date information for women
41	7 Culturally appropriate area in local oncology department to increase comfort for Aboriginal patients
42	8 GP management plans prior to treatment
43	9 Follow up care plans post treatment
44	10 Follow up phone call/visit from an Aboriginal health Worker to check in and work through options
45	11 Local Aboriginal cancer support group formed
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48 137

50 138 This study will use the information garnered through the CMP to develop and evaluate a
51 139 culturally safe breast screening, diagnostic, treatment and follow up pathway for Aboriginal
52 140 women in selected regions. The findings of this work will inform policy and practice aimed at
53 141 reducing the rates of mortality of Aboriginal women from breast cancer.

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57 143 **Aims and Objectives:**

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59 145 Primary objective:

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3 146 In one region in NSW Australia we will evaluate a co-designed pathway for timely and
4 147 culturally safe screening diagnostic, treatment and post-treatment services for Aboriginal
5 148 women.
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8 149 **Aim:** improve communication and cultural safety of breast cancer prevention and treatment
9 150 services or Aboriginal women.
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12 151 **Methods and analysis**

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14 153 **Co-design**

15 154 Co-design is a process of developing something with or alongside stakeholders or intended
16 155 recipients or beneficiaries(26, 32).
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20 157 The design of the study has been based on recommendations provided by the CMP from
21 158 2018. The CMP was a collaboration between the Foundation for Breast Cancer Care, the
22 159 Poche Centre for Indigenous Health and Armajun Aboriginal Health Service. The CMP
23 160 included consultation with Aboriginal survivors of breast cancer, Aboriginal women in the
24 161 target age range for breast cancer prevention and early intervention, and Aboriginal Health
25 162 Workers as well as local service providers in a regional and rural location situated in the
26 163 Central North of New South Wales. The CMP informed this protocol. The development of
27 164 the research question and outcome measures were informed by patients' and healthcare
28 165 providers' priorities, experience, and preferences.
29

30 166 The CMP guided the development of this iterative mixed methods study consisting of five
31 167 main phases which makes adjustments to the present processes of screening, diagnosis,
32 168 treatment and post treatment follow up to enhance cultural safety and promote
33 169 engagement of Aboriginal women. The planned time period for data collection is one year:
34 170 2021-2022. The study commenced when ethics approval was granted in 2019 and will
35 171 conclude 2022.
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38 172 **Patient and Public Involvement**

39 173 Fundamental to the co-design model is patient and public involvement, with community
40 174 organisations and members involved in the conception, design, implementation and
41 175 evaluation of the study.
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44 176 **Co-designed assessment and treatment pathway**

45 177 The current screening, diagnosis, treatment and post-treatment services respectively and describe
46 178 the adjustments and additions created through the CMP are shown in Figures 1-4.
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49 179 Key to figures: (attached as an Image file)
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52 180 **Key:** Blue boxes show the current process Orange boxes show the proposed additions to the process.
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1
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5 182 (attached as Image file)

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7 183 Figure 2 Diagnostic services

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9 185 (attached as Image file)

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11 186 Figure 3 Treatment services

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13 188 (attached as Image file)

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15 189 Figure 4 Post treatment services

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17 18 19 191 **Governance**

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22 192 Through the CMP it was determined how the local community wanted to be involved in the
23 193 design, recruitment, implementation and evaluation of the study. Through the co-design
24 194 process the community was able to assess the burden of the research, including time and
25 195 resource commitments, in order to inform a sustainable approach.

26 196

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28
29 197 Local community members, breast cancer survivors and AHS staff will have continued input
30 198 throughout the study as part of the iterative co-design process. An Aboriginal Advisory
31 199 Group will inform the study and its progress and AHS staff who self-nominate will be
32 200 investigators on the study. The Aboriginal Advisory Group will meet every month and the
33 201 Investigators' Group every eight weeks. Data will be collected and owned and managed by
34 202 the AHS and will be shared with Investigator group. Any publication will need to be
35 203 approved by the Aboriginal Advisory Group and the AHMRC ethics committee. Members of
36 204 the Investigators Group will continue to participate in community meetings regarding the
37 205 progress and outcomes of the process, and community members will be given the option to
38 206 receive a copy of the completed study and its outcomes and be invited to attend community
39 207 meetings/workshops organised to disseminate the results of the study. The Aboriginal
40 208 Advisory Group and AHS staff will be involved in designing the dissemination process.

41 42 43 209 **Ethics**

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49 210 This project has ethics approval from the Aboriginal Health and Medical Research Council of
50 211 NSW, Ref: 1525/19.

51 52 53 212 **Design**

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55 213 The study will use a mixed-methods design. Qualitative methods will include semi-
56 214 structured, in-depth interviews and focus group discussions. Structured quantitative and
57 215 qualitative questionnaires will be used to assess participant satisfaction, as well as collect
58 216 information about demographics, patient journey and clinical data.

217 **Target population**

218

219 The target population for this study is Aboriginal women living in the study region. The
220 expected duration of this study is approximately three years, in which time the BreastScreen
221 van will have visited these areas at least twice.

222 The area we are working with is a regional and rural location situated in the Central North of
223 New South Wales. Seven percent of the local population in the region identify as Aboriginal
224 and/or Torres Strait Islander (ABS 2016 census data) which calculates as a possible sample
225 size of 631 Aboriginal women above the age of 30. Four specific study sites have been
226 selected by convenience sampling on the basis of a pre-existing relationship with the local
227 AHS which services the region. The communities expressed interest in working with the AHS
228 in this capacity. The study will rely on voluntary sampling of individuals who fit the criteria
229 of target population: Aboriginal women, >30 years and willing to receive care through the
230 AHS.

231

232 **Phases of implementation**

233 The process of implementation is shown in Figure 5.

234

235 **Phase 1: Preparation**

236

237 The Investigator team will work with Breast Screen NSW to gather the pre-intervention data
238 to use as a baseline to measure quantitative outcomes. Data collected will include:
239 retrospective data through the AHS related to participation as referral data is not available;
240 number of women who attended the Breast Screen van in the region in 2018 and 2019
241 (2020 data has been affected by Covid-19 and therefore is not representative), and how
242 many of these women identified as Aboriginal and/or Torres Strait Islander. The team will
243 also work closely with the AHS (one of the investigator team is a staff member and second is
244 the CEO of the AHS) in planning for a screening event, which is a fixed period of time where
245 the van is reserved for Aboriginal women only and, additionally, staffing the van with an
246 Aboriginal Health Worker for several extra days during its visit to the area. This work will be
247 done in consultation with Breast Screen NSW.

248

249 The team will also work on development of resources for patrons of the local health
250 services, including information on the different stages of the treatment journey and on the
251 local support services for these different stages. This will include working with the local
252 oncology unit to ensure that welcoming and culturally safe spaces are offered to Aboriginal
253 women in the area.

254

255

256 Figure 5. Process of implementation

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4 258 (attached as an Image file)
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7 260 **Phase 2: Community information**

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10 262 In our co-design process, 'community information' refers to both promoting the culturally
11 263 safe screening events and providing relevant information to potential participants regarding
12 264 the study. The local AHS staff and Investigator team member will reach out to communities
13 265 in the region to inform them of the screening day event and presence of an Aboriginal
14 266 Health Worker in the Breast Screen van in 2021, and the inclusion of additional support
15 267 services such as transport and child-minding. Outreach will include several forms of
16 268 communication such as phone calls, emails, flyers and community visits, and will include
17 269 written reminders 1 week out from the screening day date.
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23 270

24 271 Screening and follow up will be undertaken according to the procedures described in
25 272 Figures 1-4. The AHS will offer risk assessments for women between 30-39 years who will be
26 273 referred on for screening and MRI if they are found to meet high risk criteria. For women
27 274 who are 40-49 years old, letters will be sent out 6 weeks prior to screening dates and then
28 275 two follow up calls will be placed 4 weeks prior and 1 week prior to the screening dates. For
29 276 women who qualify for a reminder sent out by the government (50-74 years old), reminder
30 277 phone calls will be placed 4 weeks prior and 1 week prior to the screening dates. For the
31 278 women who are referred for further diagnosis, resources will be given to and support from
32 279 the local Aboriginal Health Workers on next steps.

33 280 Additionally, there will be Aboriginal Health Workers acting as support staff if treatment is
34 281 suggested, to inform affected women of the resources on offer and treatment pathways
35 282 suggested. Women who partake in any part of the modified screening, diagnosis, treatment
36 283 of follow up processes will be invited to join the study but there will be no consequences for
37 284 their treatment or support if they elect not to participate.
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45 286 **Phase 3: Data Collection and outcome measurement**

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47 288 All participants involved in the study will be recruited via the AHS. The AHS will contact each
48 289 prospective participant personally and explain the study to them. They will explain the
49 290 Participant Information Sheet and seek informed consent (PIS) (PIS- see Appendix 1). The
50 291 PIS outlines what the study is about; who is carrying out the study; what the study involves;
51 292 information about how they can withdraw from the study; information about the risks and
52 293 benefits of the study; and information on how to contact the researchers if needed.

53 294 All participants who complete the satisfaction questionnaire, participate in the in-depth
54 295 interviews, or participate in the focus group discussions will need to sign a consent form.
55 296 This consent form will allow the study to use the information provided and the participants
56 297 will be advised the information they provide will be de-identified. The consent process will

298 be managed by the AHS. Women participating in the in-depth interviews and focus group
299 discussions will be advised that these will be recorded. These recordings will be transcribed,
300 de-identified, and then destroyed.

301 All Aboriginal women in the community will be allowed to access any of the additional
302 services/modifications being implemented, regardless of participation in the study. This will
303 ensure equitable access to all services provided and will not negatively impact Aboriginal
304 women who do not feel comfortable participating in the study.

305

306 The Aboriginal Health Worker will manage the consent process and consents will be held by
307 the AHS. Consents will be gathered prior to participation in screening, in-depth interviews
308 and focus groups.

309

310 The quantitative data (numbers of attendees who identify as Aboriginal and Torres Strait
311 Islander) will be collected by the AHS at the culturally safe screening events and satisfaction
312 questionnaires will be supplied after the event via the AHS. The qualitative data will be
313 gathered during the in-depth interviews conducted by the AHS at a location acceptable to
314 the participants between two and four weeks after the event so as to capture the
315 experience when it is fresh in the minds of the participants. The focus groups will be
316 organised by and held at the local AHS and will include a shared meal over which a series of
317 questions will be asked (see Appendix 2_Questions for focus groups) and responses
318 collected. The discussions will be audio recorded and transcribed with the consent of the
319 participants.

320

321 Further qualitative data will be collected from women engaging in the diagnosis, treatment
322 and follow up processes via focus groups and interviews. This data aims to capture level of
323 satisfaction with the modifications outlined in the flow charts. The modifications include,
324 but are not limited to,: increased communication and support from AHS and specialists
325 around uptake of effective treatment options, access to information regarding treatment
326 options and comprehensive information regarding support available during treatment and
327 post treatment timeframe.

328 The AHS will also follow up with the participants to review their wellbeing after focus groups
329 and interviews.

330

331 The study will quantitatively measure:

332

- 333 • the participation rates of Aboriginal women in breast cancer screening (the van will
334 visit the region twice within the 12 month data collection phase of the study)
- 335 • the participation rates of Aboriginal women in timely and culturally safe diagnostic,
336 treatment and post-treatment services (over a one year period)

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3 336 • satisfaction levels among Aboriginal women in the local community who go through
4 337 the screening, diagnostic, treatment, and post-treatment process (over a one year
5 338 period)
6 339 • breast cancer health literacy among Aboriginal women in the local community (over
7 340 a one year period)

11 341 To determine the change in rates, study outcomes will be compared to the baseline
12 342 participation of Aboriginal women in breast screening service, defined as the number of
13 343 women who attended the BreastScreen van in the chosen area and the surrounding regions
14 344 in the 2-3 years preceding and how many of these identified as Aboriginal and/or Torres
15 345 Strait Islander.

16 346

17 347 To establish baseline satisfaction levels all women will be asked about satisfaction for each
18 348 of the 4 stages (screening, diagnosis, treatment and follow-up). For each stage, the sub set
19 349 of women who have previously accessed that stage will be asked if there is any change in
20 350 their level of satisfaction. Questionnaires will also be completed by Aboriginal women who
21 351 have not accessed the BreastScreen van previously, asking them why they have not.

22 352

23 353 Qualitative and quantitative data analysis will be used to establish whether the additional
24 354 adjustments implemented were successful in improving attendance and satisfaction levels
25 355 in breast cancer outcomes among Aboriginal women in the region.

26 356

27 357 Participation rates will be measured during the screening day event and at the clinics which
28 358 have an Aboriginal Health Worker present and will be compared to data ascertained from
29 359 Breast Screen Van during 2018-2019. Participation in diagnostic, treatment and post-
30 360 treatment services will be tracked in the six months post screening event via the AHS, which
31 361 will follow up with the local treatment services and with the women who have received
32 362 advice to go for further screening and treatment. This will entail a phone call and welfare
33 363 check and further referrals and advice as indicated.

34 364

35 365 To establish whether there was an improvement in satisfaction levels regarding screening,
36 366 services available to Aboriginal women questionnaires will be completed by those who
37 367 accessed the screening van in 2021, both during normal operation and the screening day
38 368 event (see Appendix 3). Questionnaires and in depth interviews will also be completed by
39 369 women who accessed diagnostic, treatment and/or post-treatment services for breast
40 370 cancer in 2021.

41 371

42 372 Semi-structured interviews will be conducted to gather more in-depth, qualitative data with
43 373 women who visited the Breast Screen van when it was running typically, those who visited
44 374 during the screening day event and also those who knew about the event but chose not to
45 375 attend. In addition, 2-hour focus groups will be conducted with 8-10 women who attended
46 376 while it was running typically and 8-10 women who attended the Screening day event.

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4 378 The Australian Commission on Safety and Quality in Health Care definition of Health literacy
5 379 is “about how people understand information about health and health care, and how they
6 380 apply that information to their lives, use it to make decisions and act on it. Health literacy is
7 381 important because it shapes people’s health and the safety and quality of health care.”(33)
8 382 The way this study will assess health literacy will be through increase in participation of
9 383 services (quantitative data collection) and also a self-reported increase in understanding
10 384 about breast cancer and the options for screening, diagnosis, treatment and follow up care
11 385 (via qualitative focus group discussion).
12
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17 387 Safety considerations

18 388 Safety of the participants and anyone involved in the research is a priority of the study. Any
19 389 adverse events during the study will be recorded and reported, and a follow-up of the event
20 390 will be completed. The AHS will be available to assist and refer.
21
22

23 391

24 392 **Phase 4: Data analysis and dissemination**

25 393

26 394 Data analysis plan

27 395 Quantitative data gathered through screening events and de-identified reports via the AHS
28 396 primary healthcare software system and will be analyzed through descriptive statistics. For
29 397 the qualitative data gathered through focus groups and in-depth interviews, we will perform
30 398 an inductive thematic analysis using NVivo11 to organize participant’s responses into key
31 399 themes. Coding and thematic analysis of qualitative data will be carried out by two
32 400 members of the study team and checked by an Aboriginal author who is also a member of
33 401 the community, following best practices for enhancing validity in qualitative methods(34,
34 402 35). The core research team will meet to review the findings and identify outstanding or
35 403 representative quotes for future presentation of the results. Preliminary findings will be
36 404 discussed with AHS and Aboriginal Advisory Group.
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44 406 Returning results to the community

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46 407 Results of the co-design study will be disseminated into the local Aboriginal community
47 408 through community meetings, social media and printed research summaries (including
48 409 Plain English summaries). We will work in collaboration with AHS to hold community
49 410 meetings and information evenings, which both participants and non-participants of the
50 411 study can attend. Community members will be encouraged to provide feedback and
51 412 comments on the process.
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56 413 Results will be published in peer reviewed journals and presented at professional
57 414 conferences. The AHS participating in the study will be invited to contribute to these
58 415 publications and presentations. We will acknowledge the sources of information and
59
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2
3 416 those who have contributed to the research through authorship and acknowledgement in
4 417 resulting publications, meetings with community members and conference presentations.
5
6 418 We will also acknowledge the cultural property rights of Aboriginal peoples in relation to
7 419 knowledge, ideas, cultural expressions and cultural materials by including AHS
8
9 420 representatives as research team members.

11 421 **Phase 5: Adaptation**

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13
14 422 In this phase we will evaluate the co-design process to evaluate whether it can be adapted
15 423 to similar health issues in Aboriginal communities elsewhere in Australia. We will do this
16 424 by sharing the findings of the study widely across AHSs and social media and inviting AHSs
17 425 to work with us to see if the protocol could be adapted with them for their community.
18
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25 429

26 430 **Corresponding author:**

27 431 Vita Christie

28 432 E: vita.christie@sydney.edu.au

29 433 T: 0403 709 178 F: 02 9351 3196

30 434 A: 225 Edward Ford Building A27, The University of Sydney NSW 2006

31 435

32 436 **Authors' contributions:**

33 437 Conception and design of the study - KG, DG, DM, MR, VC

34 438 Planning- VC, KG, JD, DG

35 439 Governance and scientific advice – KG, CP, JA DM, DG, VC

36 440 Conduct and reporting: VC, KG, DG

37 441 Drafting the Manuscript – VC, MR, KG, JD

38 442 Review and approval of the manuscript – VC, KG, JA, DG, KL, CP, DM, JD

39 443

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42 446 (Macquarie University)

43 447

44 448 **Competing interests statement.**

45 449 None

46 450

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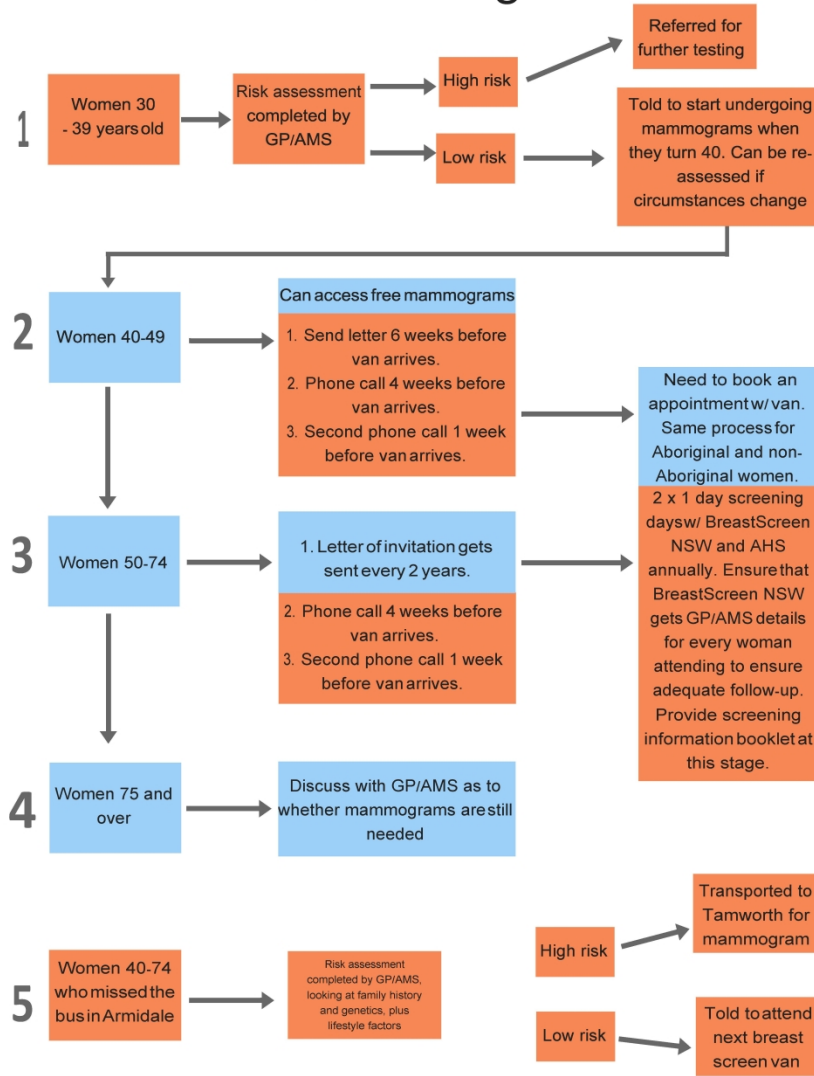
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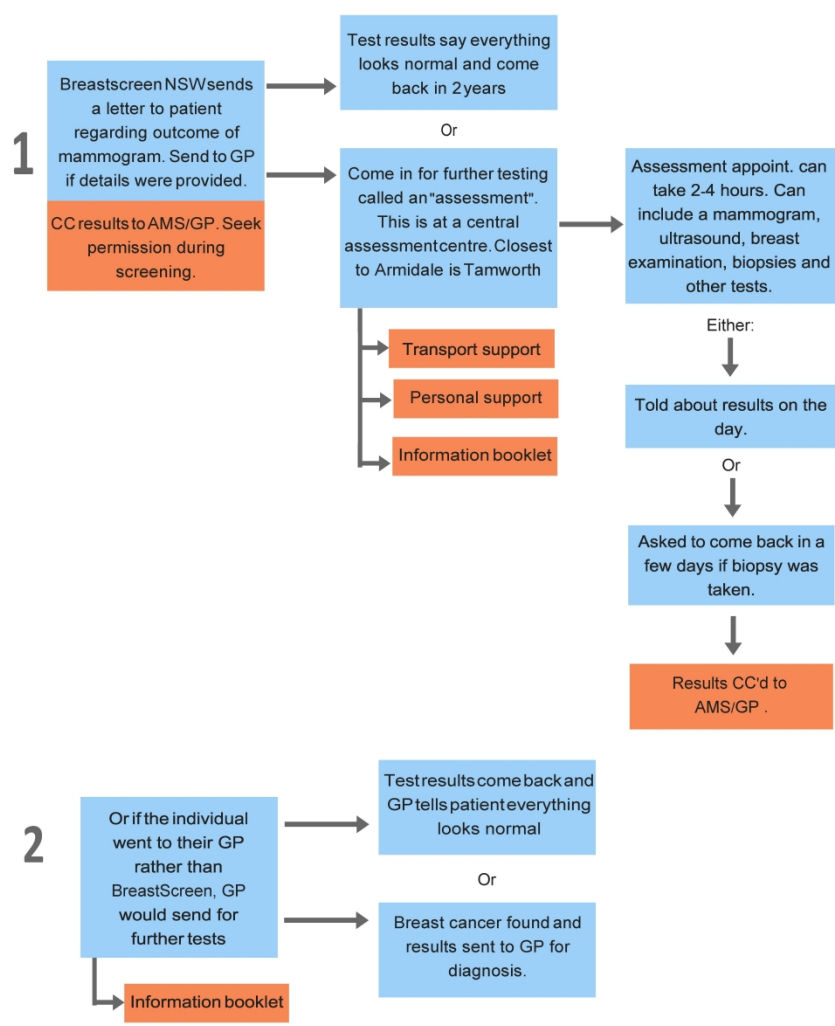
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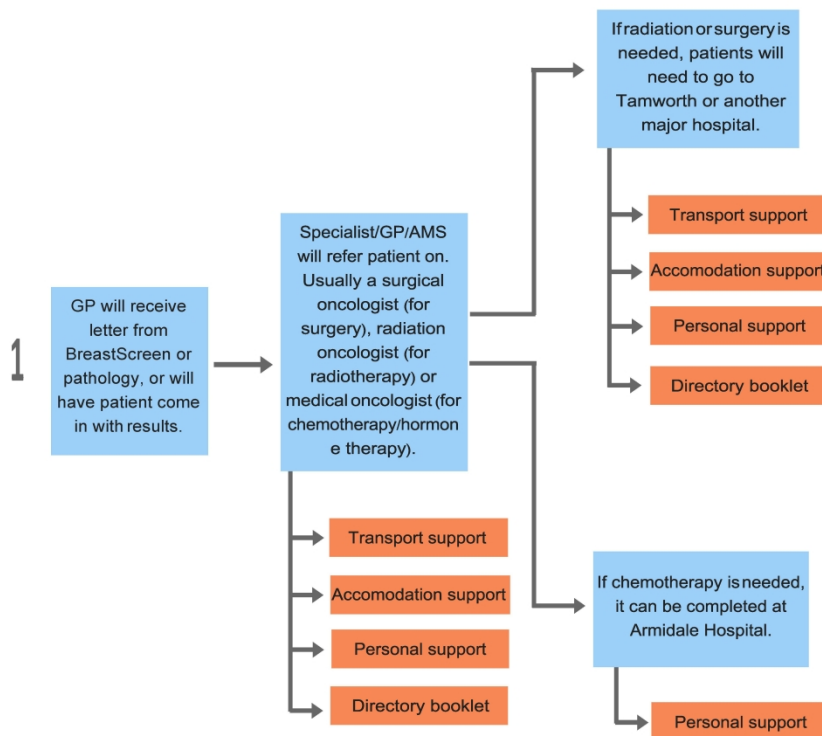
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Diagnosis



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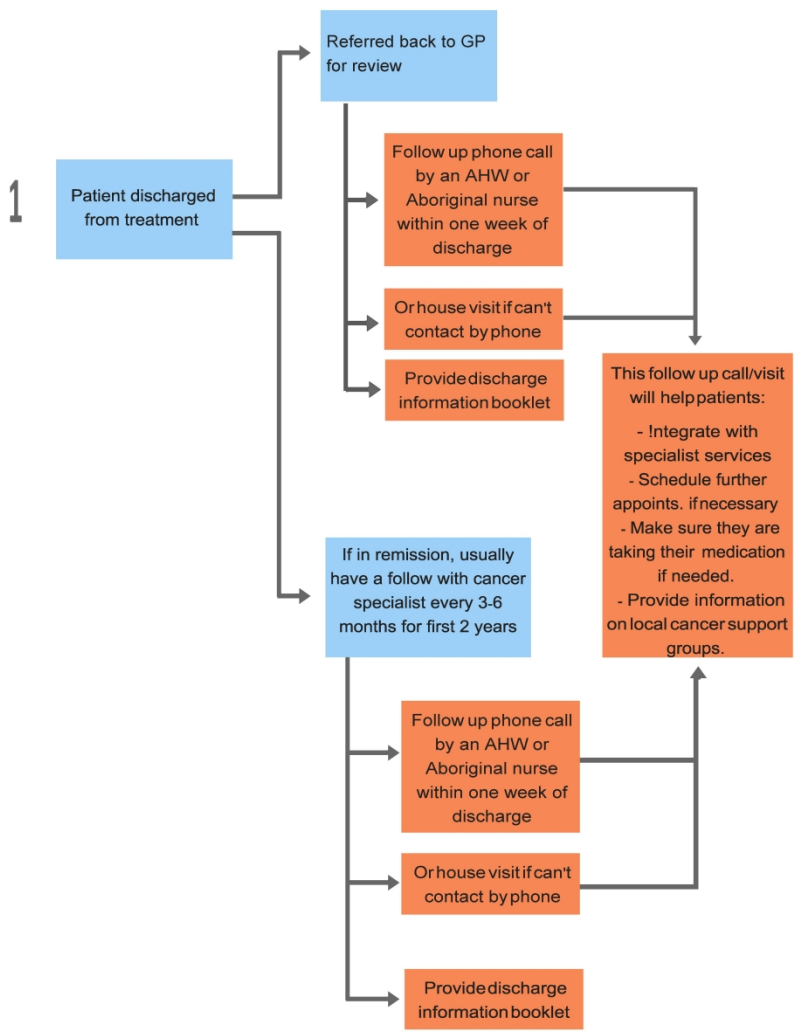
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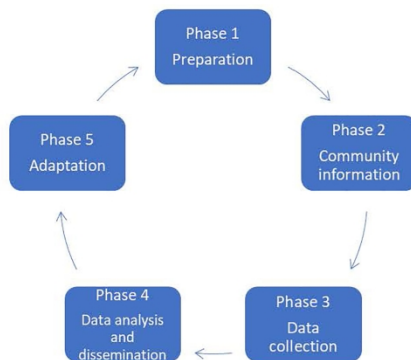
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Post Treatment



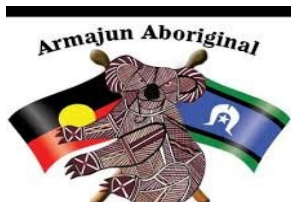
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Figure 5



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Adjunct Assoc Prof Kylie Gwynne

Macquarie University
Sydney, NSW
Telephone: +61 448 483 348
Email: kylie.gwynne@mq.edu.au

PARTICIPANT INFORMATION STATEMENT

Purpose of the study

This is an invitation to participate in a study by researchers at Macquarie University, Armajun Aboriginal Health Service and the Poche Centre for Indigenous Health, University of Sydney. The purpose of the research is to investigate whether the implementation of additional, culturally appropriate adjustments to the current breast cancer screening, diagnostic, treatment and post treatment services available to Aboriginal women in Armidale improves both the screening participation rates and the disease outcomes of Indigenous women living in the area. The study calls upon all Aboriginal women aged 30 years or older, living in Armidale or surrounding towns. Participants can be already be a breast cancer patient at Armajun Aboriginal Health Service (AHS) or choose to participate when they attend the screening day event.

This study acknowledges the factors influencing access to the current health care services in rural or remote communities in Australia. Preliminary research was undertaken with Armajun Aboriginal Health Service (AHS) to map the breast cancer screening, diagnostic and treatment services currently available to Aboriginal women in Armidale and identified numerous barriers that prevent access to these services effectively. The study will explore the impact of adjustments made to current stages of breast cancer services that aim to break down these barriers and allow for greater participate rates. Implementation and outcomes of the study are guided by Armajun and the local Aboriginal community of Armidale in which this study will take place, to ensure that the exact social and cultural needs of the local Aboriginal community are considered during the process.

The study is being conducted by Adjunct Assoc Prof Kylie Gwynne(Macquarie University). Other members of the research team members include Vita Christie, Debbie Green, Deb McCowen.

What does the study involve?

If you choose to take part in this study you will be asked to take part in in-depth interviews and focus group discussions with members of the research team to evaluate the quality of services provided to you. You may also be asked to complete questionnaires to assess your satisfaction of your experience with the screening and treatment services and may be recorded using Audio Recordings. The interview will assess the various types of adjustments being implemented and perceptions and experiences you've encountered within services provided. Both qualitative and quantitative data will be utilised to evaluate whether the additional adjustments were successful in improving the journey of breast cancer as well as the service satisfaction levels among Aboriginal women in Armidale. The interviews and discussion groups will be held at a location convenient to you. All recordings will be transcribes and then destroyed after being evaluated.

Your involvement in the study is entirely voluntary and you may choose to withdraw at any time from the study. You may also choose to withdraw any data that was collected from you up until that point. Please note no penalties will be given if you choose to withdraw from the study.

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study.

While there is little risk involved in this research study, talking about specific health issues and experiences may make you feel uncomfortable at times. Please know that if you want to discontinue talking about these topics, let the interviewer or head of discussion group know that you would like a break and if need be can assist you in a referral for additional emotional support. There is also the possibility that results from a mammogram can contain diagnosis of Breast Cancer and therefore can be a traumatic event for the participant to endure. However, personal and emotional support will be given to ensure the greatest care of the patient.

Can I withdraw from the study?

Participation in this study is entirely up to you. You can choose to decline participation in the study or refuse to continue *at any time* as you are under no obligation to remain in it. Your decision will not result in any penalties or benefits in which you are otherwise entitled to. You also have the right to not answer any questions or experiences that make you feel uncomfortable talking about at any time during the process. You are also entitled to request information collected during the research period to not be included in the study. Please note that this will not affect your relationship or current treatment with Armajun AHS, the Poche Centre or any other party involved.

How can I withdraw?

The participant can verbally confirm with the researcher that they no longer wish to participate in the study. At that time no further questions will be asked.

Will anyone else know the results?

There will be a summary of completed study and its results at the conclusion of the study – you will be given the option to receive a copy of these outcomes. Results of interviews will be strictly confidential and only accessed by researchers. The publication of the results of the study will be available to the local Aboriginal community through a communal meetings and printed summaries which both participants and non-participants can attend. A report of the study will also be published in peer reviewed journals however, all individual participants will not be identified in the final publication.

Can I tell others about the study?

Yes, if you wish to tell others about the study you may. If others are interested in being a part of the study themselves they can express interest by contact researches in charge of conducting the study.

What if I need further information about the study or my involvement in it?

After you have read and understood this sheet, the head researcher can answer any questions you have and is able to discuss it with you in further depth.

If you would like to know more, please feel free to contact *Adjunct Assoc Prof Kylie Gwynne* (+61 448483348) or kylie.gwynne@mq.edu.au) or *Vita Christie* (0403 709 178 or vita.christie@sydney.edu.au) or *Debbie Green* (02 6772 5258 or dgreen@armajun.org.au)

What if I have a complaint or any concerns?

If you have any problems or concerns as a result of your participation in the study please feel free to contact Debbie Green at Armajun Aboriginal Health Service at dgreen@armajun.org.au or on 02 6772 5258.

This information sheet is for you to keep

Appendix 2

Questions for focus groups

1. Do you feel that you can discuss breast cancer openly in your community? If so, why? If not, why not?
2. In some Indigenous cultures there is a reported silence around breast cancer and cancer in general- do you think it is the same in your community?
3. What do you think this silence is about?
4. What is your attitude to screening and diagnosis of breast cancer?
5. What do you think gets in the way for a lot of women when it comes to screening and diagnosis?
6. Do you feel you understand how breast cancer affects Indigenous women in Australia? If not, why not?
7. How much trust do you have in the medical system when it comes to breast cancer? Why?
8. How does your community view breast cancer?
9. Do you think this is different from non-Indigenous culture? If so, why?
10. Who are the main supports for women suffering from breast cancer in your community?
11. How important is it for family and community to be involved in the journey? What difference do they make?
12. What did you think of the screening day events? If there was something you could change about them, what would it be?

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5 Questions for community members
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- 8
- 9 1. Do you now feel that you can discuss breast cancer openly in your community? If so, why? If
10 not, why not?
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 - 15 2. How was your experience in the breast screen van today?
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 - 20 3. Is there anything that could have improved it?
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 - 26 4. What are your thoughts generally about the breast screening process?
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 - 32 5. Do you feel you understand better now how breast cancer affects Indigenous women in
33 Australia?
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 - 38 6. How does your community now view breast cancer?
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 - 43 7. Who are the main supports for women suffering from breast cancer in your community?
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 - 49 8. Do you have any other comments?
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 - 56 9. Would you be interested in joining a focus group discussion or one on one interview in 2-3
57 weeks' time?
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Flow chart mapping the screening, diagnosis, treatment and post-treatment process

Blue boxes show the current process

Orange boxes show proposed additions to the process

Key to figures

420x594mm (200 x 200 DPI)

BMJ Open

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-048003.R4
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SCHOLARONE™
Manuscripts

Breast Cancer Protocol Outline

Title:

Improving breast cancer outcomes for Aboriginal women: a mixed-methods study protocol

Authors:

Christie V (1,2)*, Rice M (3), Dracakis J (3), Green D (4), Amin J (1), Littlejohn K (5), Pyke C (5), McCowen D (4), and Gwynne K (1)

*Corresponding author: contact vita.christie@sydney.edu.au

Affiliations

1. Faculty of Medicine Health and Human Sciences, Macquarie University
2. Poche Centre for Indigenous Health, The University of Sydney
3. Faculty of Medicine and Health, The University of Sydney
4. Armajun Aboriginal Health Service
5. Foundation for Breast Cancer Care

Abstract:

Introduction

Breast cancer is the most commonly diagnosed cancer affecting Australian women, and the second highest cause of cancer death in Australian women. While the incidence of breast cancer is lower in Aboriginal women than non-Aboriginal women, the mortality rate for Aboriginal women is higher, with Aboriginal women 1.2 times more likely to die from the disease. In NSW, Aboriginal women are 69% more likely to die from their breast cancer than non-Aboriginal women.

Co-design is a research method recognized to enhance collaboration between those doing the research and those impacted by the research; which when used with Aboriginal communities, ensures research and services are relevant, culturally competent and empowers communities as co-researchers. We report the development of a new protocol using co-design methods to improve breast cancer outcomes for Aboriginal women.

Methods and analysis: Through a Community Mapping Project (CMP) in 2018, we co-designed an iterative quantitative and qualitative study consisting of 5 phases. In Phase 1, we will establish a governance framework. In Phase 2 we will provide information to community members regarding the modified parts of the screening, diagnosis, treatment and follow up processes and invite them to partake. In Phase 3, the research team will collect data on the outcomes of the modified processes and the outcomes for the women who have and have not participated. The data shall be analyzed quantitatively and thematically in Phase 4 with Aboriginal community representatives and reported back to community. Lastly, in Phase 5 we evaluate the co-design process and adapt our protocol for use in partnership with other communities.

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41 Ethics and dissemination: This study has ethics approval of the Aboriginal Health and
42 Medical Research Council ref:1525/19. The findings will be published in the literature,
43 presented at conferences and short summaries will be issued via social media.
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8 **'Strengths and limitations of this study'**

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- This study will use mixed methods to identify milestones, enablers and barriers along the breast cancer prevention and treatment pathway for Aboriginal women.
 - The collective impact co-design methodology strengthens community engagement by sharing power, knowledge and skill with community members and health services.
 - Small study size limits the generalisability of the research findings.
 - This study will not report the sub-optimal treatment rates for Aboriginal women.

54 **Introduction:**

55
56 Breast cancer is the most commonly diagnosed cancer in Australia, representing 28% of all
57 cancer incidence in women and the second highest number of deaths(1). Mortality due to
58 breast cancer has declined significantly over recent decades. This coincides with improved
59 rates of early detection following introduction of national population-based mammography
60 screening programs (2) and increasingly effective adjuvant therapies. Yet, Aboriginal and
61 Torres Strait Islander women in Australia continue to face high mortality rates, despite an
62 incidence of breast cancer on par with or less than non-Indigenous women(3). Between
63 1998 and 2013, there was no significant decrease in the Indigenous mortality rates for
64 breast cancer in comparison to a significant decline for non-Indigenous women(3). When
65 looking at the overall picture, tumour biology is shown to be only part of the picture in the
66 disparity of survival outcomes; preventable causes relating to delayed diagnosis and
67 treatment are also substantial contributors (4-6).

68 Uptake of screening has increased over time among both non-Indigenous and Indigenous
69 populations in Australia, however a significant gap remains. Australia's national population-
70 based screening program BreastScreen offers free 2-yearly mammograms targeting women
71 aged 50-74 years. In 2019, 41% of Aboriginal and Torres Strait Islander women in this age
72 group participated compared with 54% of non-Indigenous women(7). As a consequence of
73 the gap, Aboriginal and Torres Strait Islander women are more likely to be diagnosed at an
74 advanced stage, experiencing worse disease outcomes and lower rates of survival(7-9).

75 While age is the greatest risk factor for breast cancer, Aboriginal women are more likely to
76 be younger than non-Aboriginal women at the time of diagnosis(10) and receive more
77 invasive surgical treatment compared with their non-Aboriginal counterparts(11). It is well

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3 78 established in the literature that this association likely contributes to difficulty in engaging
4 79 Aboriginal women in regular and timely follow-up monitoring and care(12).

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7 80 There is a demonstrable need for improved screening, diagnostic and care pathways for
8 81 Aboriginal women in Australia(13). The literature identifies numerous enabling factors and
9 82 barriers which contribute to ease, or not, of access, timeliness, and quality of care for
10 83 Aboriginal women with regard to breast cancer screening and services (14-24) .

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12
13 84 Overwhelmingly, barriers are related to the lack of cultural safety within health services.
14 85 Aboriginal women are apprehensive about utilising services due to recent or historical
15 86 experiences of racism, lack of culturally safe care and a deficit of resources featuring
16 87 culturally-appropriate educational and health promotion messages. Initiatives focused on
17 88 resourcing community-led initiatives to raise awareness have been found to facilitate
18 89 increased uptake and provide culturally safe care.(15, 16, 19, 20, 22, 25) This care involved
19 90 Aboriginal Health Workers and highlights the importance of primary health care following
20 91 diagnosis. Furthermore, individuals were less likely to engage in services as a consequence
21 92 of previous experiences or the experiences of women they knew with mammography and
22 93 breast cancer. Feelings of shame or stigma were also cited, as was the impact of financial
23 94 barriers and geographical remoteness (26), leading to travel and time away from family.

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30 95 There is a body of evidence surrounding initiatives aimed at increasing breast screening
31 96 among Aboriginal women which indicates that success is highest where there are
32 97 partnerships with Aboriginal community-controlled organisations(24). These initiatives
33 98 implemented culturally-appropriate engagement strategies to address a range of social,
34 99 cultural, personal and economic factors. An expanding evidence base supports the use of
35 100 'co-design' as a research methodology for the design, implementation, and evaluation of
36 101 successful, cost-effective and sustainable strengths-based solutions to health challenges
37 102 among Aboriginal communities(27).

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42 103 Application of rigorous co-design methods to enhance breast cancer screening amongst
43 104 Indigenous women internationally have been documented in the literature (28-32) but not
44 105 extensively. We also note in the literature that low participation in follow up services,
45 106 including anti-estrogen treatment (33)however, there is a need for more translational
46 107 research utilising co-design methodology that partners with Aboriginal women, their
47 108 communities and community-controlled health organisations to develop comprehensive
48 109 ecological framework for addressing barriers and improving women's engagement in
49 110 screening as well as follow-up diagnostic and breast cancer care services.

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54 111 The codesign approach of the research team follows the five stages of the collective impact
55 112 model. These include 1. Common agenda, 2. Shared measurement, 3. Mutually reinforcing
56 113 activities, 4. Continuous communication and 5. Backbone support. This process provides a
57 114 structured and shared process from conception, through to design, implementation and
58 115 evaluation and increases the likelihood that health services will be utilized by Aboriginal

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3 116 people and that, as a result, health outcomes will improve. This approach has been validated
4 117 with Aboriginal communities for translational health research.(27)

7 118 A preliminary mapping process co-designed with the communities in 2018 has informed this
8 119 research. The Community Mapping Project (CMP) consisted of interviews with five
9 120 Aboriginal breast cancer survivors from local communities, plus staff, clients and families of
10 121 both from the local Aboriginal Health Service (AHS), the Advisory Committee of the AHS and
11 122 other breast cancer care providers, including staff at the local oncology unit. The CMP
12 123 explored experiences, priorities and preferences, particularly from the survivors’
13 124 perspectives. It was a comprehensive mapping of existing screening, diagnosis, treatment
14 125 and post treatment service delivery, resulting in co-designed recommendations to adjust
15 126 the existing services and improve the pathway for Aboriginal women in the area. A draft
16 127 patient journey and proposed modifications was drafted and checked with some members
17 128 of the local community including a local women’s group and one on one interactions.. It was
18 129 then presented to the clinicians from the Foundation for Breast Cancer Care, who provided
19 130 input to the clinical pathways.

26 131 An important aspect of co-design is engaging with communities at the point the research is
27 132 being conceptualised. This is well prior to ethics approval. The AHMRC requires letters of
28 133 support from Aboriginal Community Controlled Health Services. The way we obtain these
29 134 letters of support is by engaging in a process, in this case the CMP, to co-design the
30 135 protocol. Once the protocol is approved by communities and then the AHMRC, we proceed
31 136 to implementation of the research. It is not possible therefore to report the detailed
32 137 discussions, interviews and process of the CMP beyond the output, shown in Table 1 and
33 138 Figures 1-5(flowchart with key), because ethics approval was obtained after the co-design
34 139 process of the CMP was completed and interviewees were assured that identity would not
35 140 be recorded and findings would not be published.

41 141 Table 1: Key recommendations of the Community Mapping Project

	Key recommendations
44	1 Screening days for Aboriginal women, staffed by Aboriginal women
45	2 An Aboriginal health worker present at screening van for agreed periods of time (outside of screening days)
46	3 Provide transport to and from screening van
47	4 Community spokespeople promoting screening and extra support offered for diagnosis, treatment and follow up care
48	5 Directory booklets for women who are receiving treatment
49	6 Directory booklets for health services in order to ensure they are equipped with up to date information for women
50	7 Culturally appropriate area in local oncology department to increase comfort for Aboriginal patients
51	8 GP management plans prior to treatment
52	9 Follow up care plans post treatment
53	10 Follow up phone call/visit from an Aboriginal health Worker to check in and work through options
54	11 Local Aboriginal cancer support group formed

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3 144 This study will use the information garnered through the CMP to develop and evaluate a
4 145 culturally safe breast screening, diagnostic, treatment and follow up pathway for Aboriginal
5 146 women in selected regions. The findings of this work will inform policy and practice aimed at
6 147 reducing the rates of mortality of Aboriginal women from breast cancer.
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10 149 **Aims and Objectives:**

11 150
12 151 Primary objective:

13 152 In one region in NSW Australia we will evaluate a co-designed pathway for timely and
14 153 culturally safe screening diagnostic, treatment and post-treatment services for Aboriginal
15 154 women.

16 155 **Aim:** improve communication and cultural safety of breast cancer prevention and treatment
17 156 services or Aboriginal women.

18 157 **Methods and analysis**

19 158 20 159 **Co-design**

21 160 Co-design is a process of developing something with or alongside stakeholders or intended
22 161 recipients or beneficiaries(27, 34).

23 162
24 163 The design of the study has been based on recommendations provided by the CMP from
25 164 2018. The CMP was a collaboration between the Foundation for Breast Cancer Care, the
26 165 Poche Centre for Indigenous Health and Armajun Aboriginal Health Service. The CMP
27 166 included consultation with Aboriginal survivors of breast cancer, Aboriginal women in the
28 167 target age range for breast cancer prevention and early intervention, and Aboriginal Health
29 168 Workers as well as local service providers in a regional and rural location situated in the
30 169 Central North of New South Wales. The CMP informed this protocol. The development of
31 170 the research question and outcome measures were informed by patients' and healthcare
32 171 providers' priorities, experience, and preferences.

33 172 The CMP guided the development of this iterative mixed methods study consisting of five
34 173 main phases which makes adjustments to the present processes of screening, diagnosis,
35 174 treatment and post treatment follow up to enhance cultural safety and promote
36 175 engagement of Aboriginal women. The planned time period for data collection is one year:
37 176 2021-2022. The study commenced when ethics approval was granted in 2019 and will
38 177 conclude 2022.

39 178 **Patient and Public Involvement**

40 179 Fundamental to the co-design model is patient and public involvement, with community
41 180 organisations and members involved in the conception, design, implementation and
42 181 evaluation of the study.
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182 **Co-designed assessment and treatment pathway**

183 The current screening, diagnosis, treatment and post-treatment services respectively and describe
184 the adjustments and additions created through the CMP are shown in Figures 1-5.

185 Figure 1 Key to flow chart (attached as Image file)

186 Figure 2 Screening services (attached as Image file)

187
188 Figure 3 Diagnostic services (attached as Image file)

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190 Figure 4 Treatment services (attached as an Image file)

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192 Figure 5 Post treatment services (attached as an Image file)

193

194 **Governance**

195 Through the CMP it was determined how the local community wanted to be involved in the
196 design, recruitment, implementation and evaluation of the study. Through the co-design
197 process the community was able to assess the burden of the research, including time and
198 resource commitments, in order to inform a sustainable approach.

199

200 Local community members, breast cancer survivors and AHS staff will have continued input
201 throughout the study as part of the iterative co-design process. An Aboriginal Advisory
202 Group will inform the study and its progress and AHS staff who self-nominate will be
203 investigators on the study. The Aboriginal Advisory Group will meet every month and the
204 Investigators' Group every eight weeks. Data will be collected and owned and managed by
205 the AHS and will be shared with Investigator group. Any publication will need to be
206 approved by the Aboriginal Advisory Group and the AHMRC ethics committee. Members of
207 the Investigators Group will continue to participate in community meetings regarding the
208 progress and outcomes of the process, and community members will be given the option to
209 receive a copy of the completed study and its outcomes and be invited to attend community
210 meetings/workshops organised to disseminate the results of the study. The Aboriginal
211 Advisory Group and AHS staff will be involved in designing the dissemination process.

212 **Ethics**

213 This project has ethics approval from the Aboriginal Health and Medical Research Council of
214 NSW, Ref: 1525/19.

215 **Design**

216 The study will use a mixed-methods design. Qualitative methods will include semi-
217 structured, in-depth interviews and focus group discussions. Structured quantitative and

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3 218 qualitative questionnaires will be used to assess participant satisfaction, as well as collect
4 219 information about demographics, patient journey and clinical data.

7 220 **Target population**

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10 222 The target population for this study is Aboriginal women living in the study region. The
11 223 expected duration of this study is approximately three years, in which time the BreastScreen
12 224 van will have visited these areas at least twice.

15 225 The area we are working with is a regional and rural location situated in the Central North of
16 226 New South Wales. Seven percent of the local population in the region identify as Aboriginal
17 227 and/or Torres Strait Islander (ABS 2016 census data) which calculates as a possible sample
18 228 size of 631 Aboriginal women above the age of 30 (according to AIHW 2018: "*For Indigenous*
19 229 *Australians, five-year relative survival was lowest in life stage 25–44 and increased with life*
20 230 *stage. For non-Indigenous Australians, five-year relative survival was similar for life stage*
21 231 *15–24, 25–44 and 45–64 and decreased in life stage 65 or older*"(3)). Four specific study
22 232 sites have been selected by convenience sampling on the basis of a pre-existing relationship
23 233 with the local AHS which services the region. The communities expressed interest in
24 234 working with the AHS in this capacity. The study will rely on voluntary sampling of
25 235 individuals who fit the criteria of target population: Aboriginal women, >30 years and willing
26 236 to receive care through the AHS.

32 237

34 238 **Phases of implementation**

35 239 The process of implementation is shown in Figure 6.

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38 241 **Phase 1: Preparation**

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41 243 The Investigator team will work with Breast Screen NSW to gather the pre-intervention data
42 244 to use as a baseline to measure quantitative outcomes. Data collected will include:
43 245 retrospective data through the AHS related to participation as referral data is not available;
44 246 number of women who attended the Breast Screen van in the region in 2018 and 2019
45 247 (2020 data has been affected by Covid-19 and therefore is not representative), and how
46 248 many of these women identified as Aboriginal and/or Torres Strait Islander. The team will
47 249 also work closely with the AHS (one of the investigator team is a staff member and second is
48 250 the CEO of the AHS) in planning for a screening event, which is a fixed period of time where
49 251 the van is reserved for Aboriginal women only and, additionally, staffing the van with an
50 252 Aboriginal Health Worker for several extra days during its visit to the area. This work will be
51 253 done in consultation with Breast Screen NSW.

56 254

58 255 The team will also work on development of resources for patrons of the local health
59 256 services, including information on the different stages of the treatment journey and on the

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3 257 local support services for these different stages. This will include working with the local
4 258 oncology unit to ensure that welcoming and culturally safe spaces are offered to Aboriginal
5 259 women in the area.
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10 262 Figure 6. Process of implementation

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12 264 (attached as an Image file)

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14 266 **Phase 2: Community information**

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18 268 In our co-design process, 'community information' refers to both promoting the culturally
19 269 safe screening events and providing relevant information to potential participants regarding
20 270 the study. The local AHS staff and Investigator team member will reach out to communities
21 271 in the region to inform them of the screening day event and presence of an Aboriginal
22 272 Health Worker in the Breast Screen van in 2021, and the inclusion of additional support
23 273 services such as transport and child-minding. Outreach will include several forms of
24 274 communication such as phone calls, emails, flyers and community visits, and will include
25 275 written reminders 1 week out from the screening day date.
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31 277 Screening and follow up will be undertaken according to the procedures described in
32 278 Figures 1-5. The AHS will offer risk assessments for women between 30-39 years who will be
33 279 referred on for screening and MRI if they are found to meet high risk criteria. For women
34 280 who are 40-49 years old, letters will be sent out 6 weeks prior to screening dates and then
35 281 two follow up calls will be placed 4 weeks prior and 1 week prior to the screening dates. For
36 282 women who qualify for a reminder sent out by the government (50-74 years old), reminder
37 283 phone calls will be placed 4 weeks prior and 1 week prior to the screening dates. For the
38 284 women who are referred for further diagnosis, resources will be given to and support from
39 285 the local Aboriginal Health Workers on next steps.

40
41 286 Additionally, there will be Aboriginal Health Workers acting as support staff if treatment is
42 287 suggested, to inform affected women of the resources on offer and treatment pathways
43 288 options. Women who partake in any part of the modified screening, diagnosis, treatment or
44 289 follow up processes will be invited to join the study but there will be no consequences for
45 290 their treatment or support if they elect not to participate. The AHS will invite all women
46 291 who have survived breast cancer and registered with the health service to participate in
47 292 focus groups.
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54 294 **Phase 3: Data Collection and outcome measurement**

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57 296 All participants involved in the study will be recruited via the AHS. The AHS will contact each
58 297 prospective participant personally and explain the study to them. They will explain the
59 298 Participant Information Sheet and seek informed consent (PIS) (PIS- see Appendix 1). The
60

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3 299 PIS outlines what the study is about; who is carrying out the study; what the study involves;
4 300 information about how they can withdraw from the study; information about the risks and
5 301 benefits of the study; and information on how to contact the researchers if needed.

6 302 All participants who complete the satisfaction questionnaire, participate in the in-depth
7 303 interviews, or participate in the focus group discussions will need to sign a consent form.
8 304 This consent form will allow the study to use the information provided and the participants
9 305 will be advised the information they provide will be de-identified. The consent process will
10 306 be managed by the AHS. Women participating in the in-depth interviews and focus group
11 307 discussions will be advised that these will be recorded. These recordings will be transcribed,
12 308 de-identified, and then destroyed.

13 309 All Aboriginal women in the community will be allowed to access any of the additional
14 310 services/modifications being implemented, regardless of participation in the study. This will
15 311 ensure equitable access to all services provided and will not negatively impact Aboriginal
16 312 women who do not feel comfortable participating in the study.

17 313
18 314 The Aboriginal Health Worker will manage the consent process and consents will be held by
19 315 the AHS. Consents will be gathered prior to participation in screening, in-depth interviews
20 316 and focus groups.

21 317
22 318 The quantitative data (numbers of attendees who identify as Aboriginal and Torres Strait
23 319 Islander) will be collected by the AHS at the culturally safe screening events and satisfaction
24 320 questionnaires will be supplied after the event via the AHS. The qualitative data will be
25 321 gathered during the in-depth interviews conducted by the AHS at a location acceptable to
26 322 the participants between two and four weeks after the event so as to capture the
27 323 experience when it is fresh in the minds of the participants. The focus groups will be
28 324 organised by and held at the local AHS and will include a shared meal over which a series of
29 325 questions will be asked (see Appendix 2_ Questions for focus groups) and responses
30 326 collected. The discussions will be audio recorded and transcribed with the consent of the
31 327 participants.

32 328
33 329 Further qualitative data will be collected from women engaging in the diagnosis, treatment
34 330 and follow up processes via focus groups and interviews. This data aims to capture level of
35 331 satisfaction with the modifications outlined in the flow charts. The modifications include,
36 332 but are not limited to, increased communication and support from AHS and specialists
37 333 around uptake of effective treatment options, access to information regarding treatment
38 334 options and comprehensive information regarding support available during treatment and
39 335 post treatment timeframe.

40 336 The AHS will also follow up with the participants to review their wellbeing after focus groups
41 337 and interviews.

42 338
43 339 The study will quantitatively measure:
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- the participation rates of Aboriginal women in breast cancer screening (the van will visit the region twice within the 12 month data collection phase of the study)
- 4 341
5 342
- the participation rates of Aboriginal women in timely and culturally safe diagnostic, treatment and post-treatment services (over a one year period)
- 6 343
7 344
- satisfaction levels among Aboriginal women in the local community who go through the screening, diagnostic, treatment, and post-treatment process (over a one year period)
- 8 345
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- breast cancer health literacy among Aboriginal women in the local community (over a one year period)
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17 349 To determine the change in rates, study outcomes will be compared to the baseline
18 350 participation of Aboriginal women in breast screening service, defined as the number of
19 351 women who attended the BreastScreen van in the chosen area and the surrounding regions
20 352 in the 2-3 years preceding and how many of these identified as Aboriginal and/or Torres
21 353 Strait Islander.
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25 355 To establish baseline satisfaction levels all women will be asked about satisfaction for each
26 356 of the 4 stages (screening, diagnosis, treatment and follow-up). For each stage, the sub set
27 357 of women who have previously accessed that stage will be asked if there is any change in
28 358 their level of satisfaction. Questionnaires will also be completed by Aboriginal women who
29 359 have not accessed the BreastScreen van previously, asking them why they have not.
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33 361 Qualitative and quantitative data analysis will be used to establish whether the additional
34 362 adjustments implemented were successful in improving attendance and satisfaction levels
35 363 in breast cancer outcomes among Aboriginal women in the region.
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38 365 Participation rates will be measured during the screening day event and at the clinics which
39 366 have an Aboriginal Health Worker present and will be compared to data ascertained from
40 367 Breast Screen Van during 2018-2019. Participation in diagnostic, treatment and post-
41 368 treatment services will be tracked in the six months post screening event via the AHS, which
42 369 will follow up with the local treatment services and with the women who have received
43 370 advice to go for further screening and treatment. This will entail a phone call and welfare
44 371 check and further referrals and advice as indicated.
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49 372
50 373 To establish whether there was an improvement in satisfaction levels regarding screening,
51 374 services available to Aboriginal women questionnaires will be completed by those who
52 375 accessed the screening van in 2021, both during normal operation and the screening day
53 376 event (see Appendix 3). Questionnaires and in depth interviews will also be completed by
54 377 women who accessed diagnostic, treatment and/or post-treatment services for breast
55 378 cancer in 2021.
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3 380 Semi-structured interviews will be conducted to gather more in-depth, qualitative data with
4 381 women who visited the Breast Screen van when it was running typically, those who visited
5 382 during the screening day event and also those who knew about the event but chose not to
6 383 attend. In addition, 2-hour focus groups will be conducted with 8-10 women who attended
7 384 while it was running typically and 8-10 women who attended the Screening day event.
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11 386 The Australian Commission on Safety and Quality in Health Care definition of Health literacy
12 387 is “about how people understand information about health and health care, and how they
13 388 apply that information to their lives, use it to make decisions and act on it. Health literacy is
14 389 important because it shapes people’s health and the safety and quality of health care.”(35)
15
16 390 The way this study will assess health literacy will be through increase in participation of
17 391 services (quantitative data collection) and also a self-reported increase in understanding
18 392 about breast cancer and the options for screening, diagnosis, treatment and follow up care
19 393 (via qualitative focus group discussion).
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21 394

22 395 Safety considerations

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24 396 Safety of the participants and anyone involved in the research is a priority of the study. Any
25 397 adverse events during the study will be recorded and reported, and a follow-up of the event
26 398 will be completed. The AHS will be available to assist and refer.
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29 400 **Phase 4: Data analysis and dissemination**

30 401

31 402 Data analysis plan

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33 403 Quantitative data gathered through screening events and de-identified reports via the AHS
34 404 primary healthcare software system and will be analyzed through descriptive statistics. For
35 405 the qualitative data gathered through focus groups and in-depth interviews, we will perform
36 406 an inductive thematic analysis using NVivo11 to organize participant’s responses into key
37 407 themes. Coding and thematic analysis of qualitative data will be carried out by two
38 408 members of the study team and checked by an Aboriginal author who is also a member of
39 409 the community, following best practices for enhancing validity in qualitative methods(36,
40 410 37). The core research team will meet to review the findings and identify outstanding or
41 411 representative quotes for future presentation of the results. Preliminary findings will be
42 412 discussed with AHS and Aboriginal Advisory Group.
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44 413

45 414 Returning results to the community

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47 415 Results of the co-design study will be disseminated into the local Aboriginal community
48 416 through community meetings, social media and printed research summaries (including
49 417 Plain English summaries). We will work in collaboration with AHS to hold community
50 418 meetings and information evenings, which both participants and non-participants of the
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3 419 study can attend. Community members will be encouraged to provide feedback and
4 420 comments on the process.

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7 421 Results will be published in peer reviewed journals and presented at professional
8 422 conferences. The AHS participating in the study will be invited to contribute to these
9 423 publications and presentations. We will acknowledge the sources of information and
10 424 those who have contributed to the research through authorship and acknowledgement in
11 425 resulting publications, meetings with community members and conference presentations.
12 426 We will also acknowledge the cultural property rights of Aboriginal peoples in relation to
13 427 knowledge, ideas, cultural expressions and cultural materials by including AHS
14 428 representatives as research team members.

19 429 **Phase 5: Adaptation**

21
22 430 In this phase we will evaluate the co-design process to evaluate whether it can be adapted
23 431 to similar health issues in Aboriginal communities elsewhere in Australia. We will do this
24 432 by sharing the findings of the study widely across AHSs and social media and inviting AHSs
25 433 to work with us to see if the protocol could be adapted with them for their community.

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36 438 **Corresponding author:**

37 439 Vita Christie

38 440 E: vita.christie@sydney.edu.au

39 441 T: 0403 709 178 F: 02 9351 3196

40 442 A: 225 Edward Ford Building A27, The University of Sydney NSW 2006

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42 443

43 444 **Authors' contributions:**

44 445 Conception and design of the study - KG, DG, DM, MR, VC

45 446 Planning- VC, KG, JD, DG

46 447 Governance and scientific advice – KG, CP, JA DM, DG, VC

47 448 Conduct and reporting: VC, KG, DG

48 449 Drafting the Manuscript – VC, MR, KG, JD

49 450 Review and approval of the manuscript – VC, KG, JA, DG, KL, CP, DM, JD

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51 451

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30 482 **Full references:**

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Flow chart mapping the screening, diagnosis, treatment and post-treatment process



Figure 1 Key to flow chart (attached as Image file)

420x594mm (200 x 200 DPI)

Screening

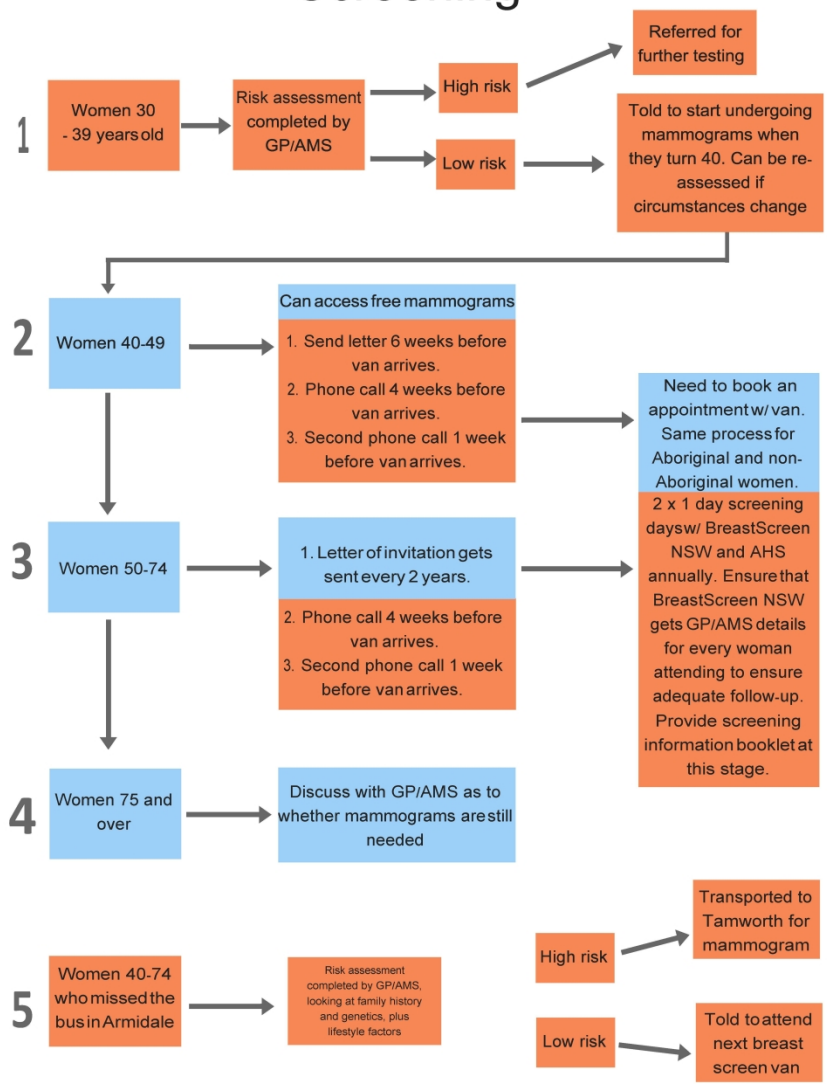


Figure 2 Screening services (attached as Image file)

393x558mm (300 x 300 DPI)

Diagnosis

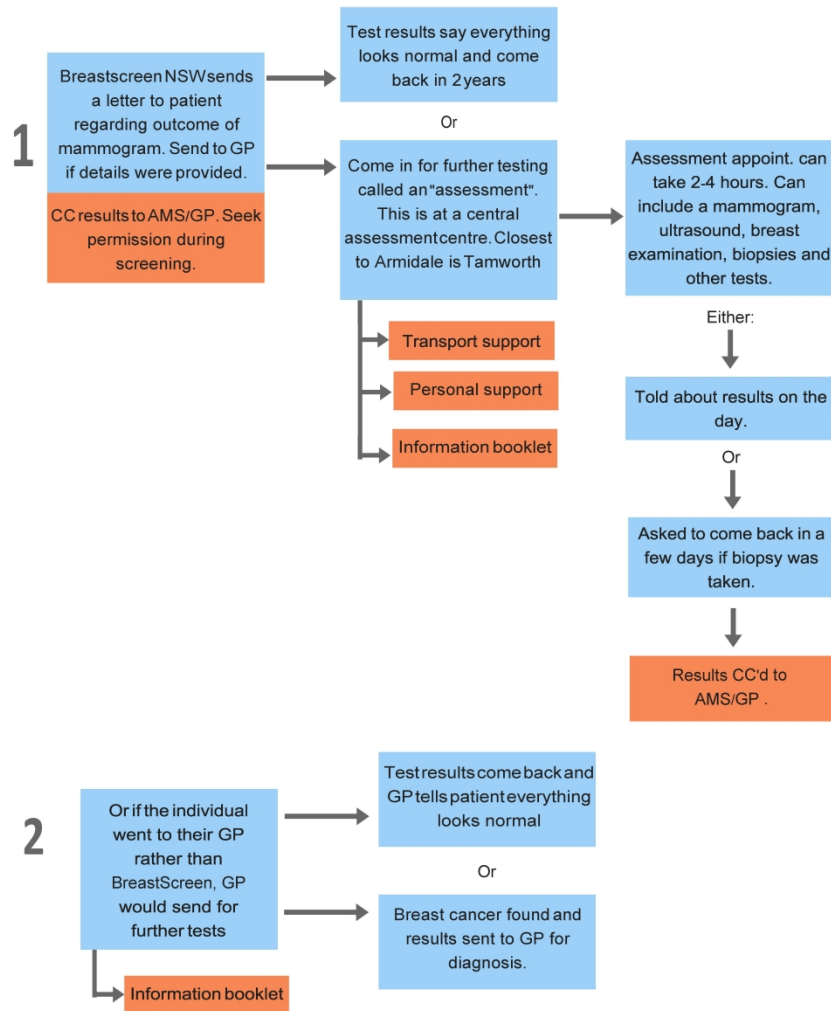


Figure 3 Diagnostic services (attached as Image file)

394x558mm (300 x 300 DPI)

Treatment

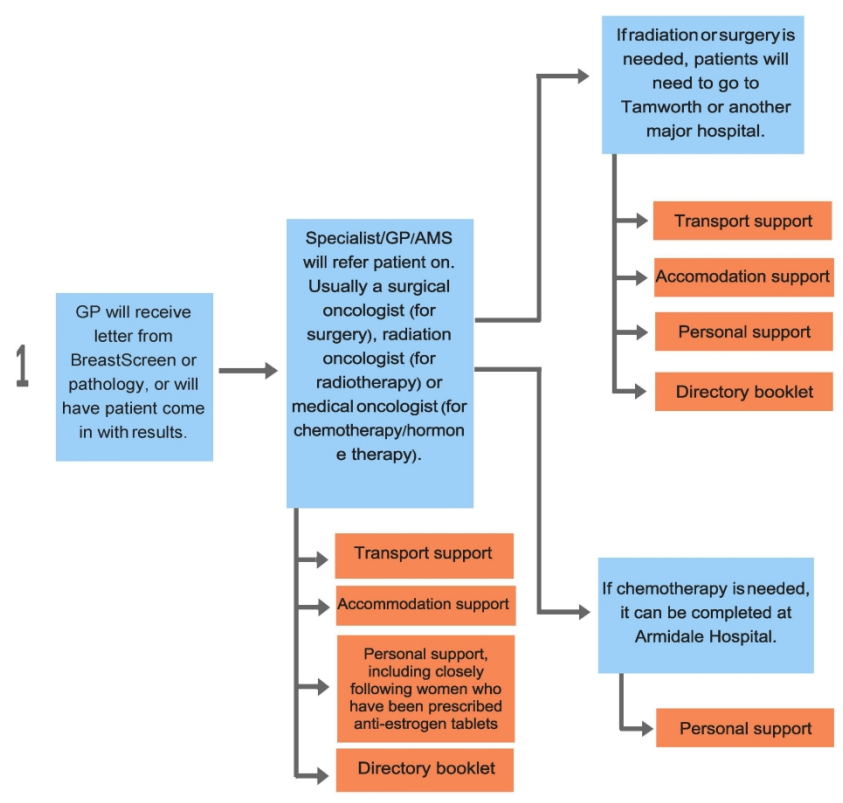


Figure 4 Treatment services (attached as an Image file)

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Post Treatment

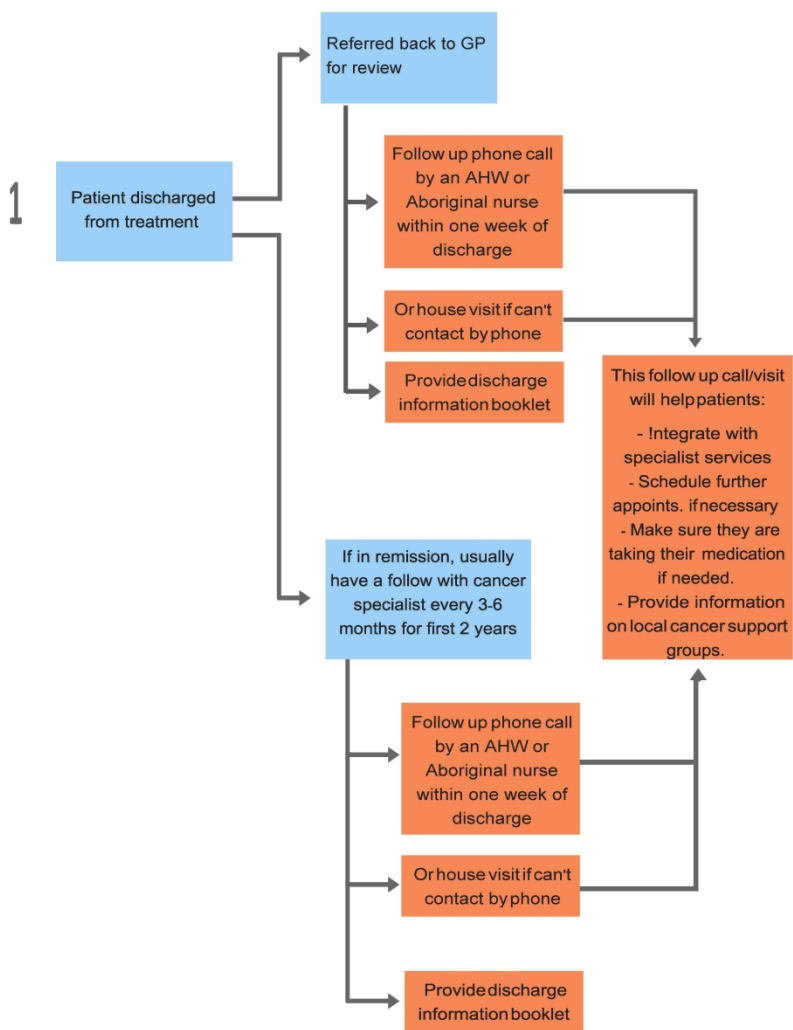


Figure 5 Post treatment services (attached as an Image file)

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Figure 5

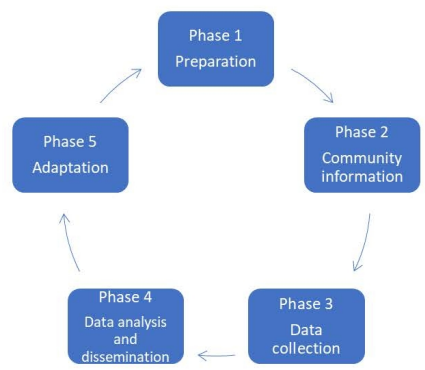
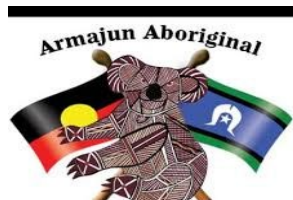


Figure 6. Process of implementation

210x297mm (150 x 150 DPI)



Adjunct Assoc Prof Kylie Gwynne

Macquarie University
Sydney, NSW
Telephone: +61 448 483 348
Email: kylie.gwynne@mq.edu.au

PARTICIPANT INFORMATION STATEMENT

Purpose of the study

This is an invitation to participate in a study by researchers at Macquarie University, Armajun Aboriginal Health Service and the Poche Centre for Indigenous Health, University of Sydney. The purpose of the research is to investigate whether the implementation of additional, culturally appropriate adjustments to the current breast cancer screening, diagnostic, treatment and post treatment services available to Aboriginal women in Armidale improves both the screening participation rates and the disease outcomes of Indigenous women living in the area. The study calls upon all Aboriginal women aged 30 years or older, living in Armidale or surrounding towns. Participants can be already be a breast cancer patient at Armajun Aboriginal Health Service (AHS) or choose to participate when they attend the screening day event.

This study acknowledges the factors influencing access to the current health care services in rural or remote communities in Australia. Preliminary research was undertaken with Armajun Aboriginal Health Service (AHS) to map the breast cancer screening, diagnostic and treatment services currently available to Aboriginal women in Armidale and identified numerous barriers that prevent access to these services effectively. The study will explore the impact of adjustments made to current stages of breast cancer services that aim to break down these barriers and allow for greater participate rates. Implementation and outcomes of the study are guided by Armajun and the local Aboriginal community of Armidale in which this study will take place, to ensure that the exact social and cultural needs of the local Aboriginal community are considered during the process.

The study is being conducted by Adjunct Assoc Prof Kylie Gwynne(Macquarie University). Other members of the research team members include Vita Christie, Debbie Green, Deb McCowen.

What does the study involve?

If you choose to take part in this study you will be asked to take part in in-depth interviews and focus group discussions with members of the research team to evaluate the quality of services provided to you. You may also be asked to complete questionnaires to assess your satisfaction of your experience with the screening and treatment services and may be recorded using Audio Recordings. The interview will assess the various types of adjustments being implemented and perceptions and experiences you've encountered within services provided. Both qualitative and quantitative data will be utilised to evaluate whether the additional adjustments were successful in improving the journey of breast cancer as well as the service satisfaction levels among Aboriginal women in Armidale. The interviews and discussion groups will be held at a location convenient to you. All recordings will be transcribes and then destroyed after being evaluated.

Your involvement in the study is entirely voluntary and you may choose to withdraw at any time from the study. You may also choose to withdraw any data that was collected from you up until that point. Please note no penalties will be given if you choose to withdraw from the study.



Improving breast cancer outcomes for Aboriginal women: a mixed-methods study.

While there is little risk involved in this research study, talking about specific health issues and experiences may make you feel uncomfortable at times. Please know that if you want to discontinue talking about these topics, let the interviewer or head of discussion group know that you would like a break and if need be can assist you in a referral for additional emotional support. There is also the possibility that results from a mammogram can contain diagnosis of Breast Cancer and therefore can be a traumatic event for the participant to endure. However, personal and emotional support will be given to ensure the greatest care of the patient.

Can I withdraw from the study?

Participation in this study is entirely up to you. You can choose to decline participation in the study or refuse to continue *at any time* as you are under no obligation to remain in it. Your decision will not result in any penalties or benefits in which you are otherwise entitled to. You also have the right to not answer any questions or experiences that make you feel uncomfortable talking about at any time during the process. You are also entitled to request information collected during the research period to not be included in the study. Please note that this will not affect your relationship or current treatment with Armajun AHS, the Poche Centre or any other party involved.

How can I withdraw?

The participant can verbally confirm with the researcher that they no longer wish to participate in the study. At that time no further questions will be asked.

Will anyone else know the results?

There will be a summary of completed study and its results at the conclusion of the study – you will be given the option to receive a copy of these outcomes. Results of interviews will be strictly confidential and only accessed by researchers. The publication of the results of the study will be available to the local Aboriginal community through a communal meetings and printed summaries which both participants and non-participants can attend. A report of the study will also be published in peer reviewed journals however, all individual participants will not be identified in the final publication.

Can I tell others about the study?

Yes, if you wish to tell others about the study you may. If others are interested in being a part of the study themselves they can express interest by contact researches in charge of conducting the study.

What if I need further information about the study or my involvement in it?

After you have read and understood this sheet, the head researcher can answer any questions you have and is able to discuss it with you in further depth.

If you would like to know more, please feel free to contact *Adjunct Assoc Prof Kylie Gwynne* (+61 448483348) or kylie.gwynne@mq.edu.au) or *Vita Christie* (0403 709 178 or vita.christie@sydney.edu.au) or *Debbie Green* (02 6772 5258 or dgreen@armajun.org.au)

What if I have a complaint or any concerns?

If you have any problems or concerns as a result of your participation in the study please feel free to contact Debbie Green at Armajun Aboriginal Health Service at dgreen@armajun.org.au or on 02 6772 5258.

This information sheet is for you to keep

Appendix 2

Questions for focus groups

1. Do you feel that you can discuss breast cancer openly in your community? If so, why? If not, why not?
2. In some Indigenous cultures there is a reported silence around breast cancer and cancer in general- do you think it is the same in your community?
3. What do you think this silence is about?
4. What is your attitude to screening and diagnosis of breast cancer?
5. What do you think gets in the way for a lot of women when it comes to screening and diagnosis?
6. Do you feel you understand how breast cancer affects Indigenous women in Australia? If not, why not?
7. How much trust do you have in the medical system when it comes to breast cancer? Why?
8. How does your community view breast cancer?
9. Do you think this is different from non-Indigenous culture? If so, why?
10. Who are the main supports for women suffering from breast cancer in your community?
11. How important is it for family and community to be involved in the journey? What difference do they make?
12. What did you think of the screening day events? If there was something you could change about them, what would it be?

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5 Questions for community members
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9 1. Do you now feel that you can discuss breast cancer openly in your community? If so, why? If
10 not, why not?
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15 2. How was your experience in the breast screen van today?
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20 3. Is there anything that could have improved it?
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26 4. What are your thoughts generally about the breast screening process?
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32 5. Do you feel you understand better now how breast cancer affects Indigenous women in
33 Australia?
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38 6. How does your community now view breast cancer?
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43 7. Who are the main supports for women suffering from breast cancer in your community?
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49 8. Do you have any other comments?
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56 9. Would you be interested in joining a focus group discussion or one on one interview in 2-3
57 weeks' time?
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