BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-048003
Article Type:	Protocol
Date Submitted by the Author:	16-Dec-2020
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
Keywords:	PUBLIC HEALTH, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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.

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

'Strengths and limitations of this study'

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

Introduction:

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

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

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

There is evidently a demonstrable need for improved screening, diagnostic and care pathways for Aboriginal women in Australia(10). The literature identifies numerous enabling factors and barriers which contribute to ease, or not, of access, timeliness, and quality of care for Aboriginal women with regard to breast cancer screening and services(11) (12-14) (15, 16) (17-19).

Overwhelmingly, barriers are related to the lack of cultural safety within health services. Aboriginal women are apprehensive about utilising services due to recent or historical experiences of racism, lack of culturally safe care and a deficit of resources featuring culturally-appropriate educational and health promotion messages. Initiatives which focused on resourcing community-led initiatives to raise awareness facilitated increased uptake and provided culturally safe care(13, 14, 17, 20-22). This care involved Aboriginal Health Workers and highlights the importance of primary health care following diagnosis (23). Furthermore, individuals were less likely to engage in services as a consequence of previous experiences or the experiences of women they knew with mammography and breast cancer. Feelings of shame or stigma were also cited, as was the impact of financial barriers and geographical remoteness.

There is a body of evidence surrounding initiatives aimed at increasing breast screening among Aboriginal women which indicates that success is highest where there are partnerships with Aboriginal community-controlled organisations(18). These initiatives implemented culturally-appropriate engagement strategies to address a range of social, cultural, personal and economic factors. An expanding evidence base supports the use of 'co-design' as a research methodology for the design, implementation, and evaluation of successful, cost-effective and sustainable strengths-based solutions to health challenges among Aboriginal communities(24).

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

This study will develop and evaluate, using codesign methods, a culturally safe breast screening, diagnostic, treatment and follow up pathway for Aboriginal women in selected regions. The findings of this work will inform policy and practice aimed at reducing the rates of mortality of Aboriginal women from breast cancer.

Aims and Objectives:

Primary objectives:
In one region in NSW Australia we will:

- Increase breast cancer health literacy among Aboriginal people.
- Co-design and evaluate a pathway for timely and culturally safe diagnostic, treatment and post-treatment services for Aboriginal women.

Methods and analysis

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

Patient and Public Involvement

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

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 qualitative research methods. Qualitative methods will include semi-structured, in-depth interviews and focus group discussions. Quantitative methods will include a structure questionnaire to assess participant satisfaction, as well as analysis of demographic and clinical cohort data from BreastScreen NSW. The target population for this study is Aboriginal women living in the study region. The expected duration of this study is approximately three years, in which time the BreastScreen van will have visited these areas at least twice.

Target population

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

Phases of implementation

The process of implementation is shown in Figure 5.

Phase 1: Preparation phase

The core research team will work with Breast Screen NSW to gather the pre-intervention data to use as a baseline to measure quantitative outcomes. Data collected will include: number of women who attended the Breast Screen van in Armidale and the surrounding regions in 2018 and 2019 (2020 data has been affected by Covid-19 and therefore is not representative), and how many of these women identified at Aboriginal and/or Torres Strait Islander. The team will also work closely with the AHS (one of the team is a staff member and second is the CEO of the AHS) in planning for the screening event and staffing the van with an Aboriginal Health Worker for several days during its visit to the area. This work will be done in consultation with Breast Screen NSW.

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

Figure 5. Process of implementation

(attached as an Image file)

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.

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

The quantitative data (numbers of attendees who identify as Aboriginal and Torres Strait Islander and satisfaction questionnaires) will be collected at the modified screening events. The qualitative data will be gathered during the in-depth interviews (held at the modified screening days where possible and after the event where not) and in-depth interviews held between two and four weeks after the event. The focus groups will be organised by and held at the local AHS and will include a shared meal over which a series of questions will be asked (see Appendix 1) and responses collected. The discussions will be audio recorded and transcribed with the consent of the participants.

Phase 4: Outcomes

The study will quantitatively measure:

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

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

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

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

Participation rates will be measured during the screening day event and at the clinics which have an Aboriginal Health Worker present and will be compared to data ascertained from

Breast Screen Van during 2018-2019. Participation in diagnostic, treatment and post-treatment services will be tracked in the six months post screening event via the AHS, which will follow up with the local treatment services and with the women who have received advice to go for further screening and treatment.

To establish whether there was an improvement in satisfaction levels regarding screening, diagnostic, treatment, and post-treatment services available to Aboriginal women questionnaires will be completed by those who accessed the screening van in 2021, both during normal operation and the screening day event. Questionnaires will also be completed by women who accessed diagnostic, treatment and/or post-treatment services for breast cancer following the attending a screening in 2021.

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

The Australian Commission on Safety and Quality in Health Care definition of Health literacy is "about how people understand information about health and health care, and how they apply that information to their lives, use it to make decisions and act on it. Health literacy is important because it shapes people's health and the safety and quality of health care."(30) The way this study will assess health literacy will be through increase in participation of services and also a self-reported increase in understanding about breast cancer and the options for screening, diagnosis, treatment and follow up care.

Safety considerations

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

Phase 5: Data analysis and dissemination

Data analysis plan

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

Returning results to the community

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

Results will be published in peer reviewed journals and presented at professional conferences. The AHS participating in the study will be invited to contribute to these publications and presentations. We will acknowledge the sources of information and those who have contributed to the research through authorship and acknowledgement in resulting publications, meetings with community members and conference presentations. We will also acknowledge the cultural property rights of Aboriginal peoples in relation to knowledge, ideas, cultural expressions and cultural materials by including AHS representatives as research team members.

Corresponding author:
Vita Christie
E: vita.christie@sydney.edu.au
T: 0403 709 178 F: 02 9351 3196
A: 225 Edward Ford Building A27, The University of Sydney NSW 2006

Authors' contributions:
Conception and design of the study - KG, DG, DM, MR, VC
Governance and scientific advice – KG, CP, JA DM, DG, VC
Drafting the Manuscript – VC, MR, KG, JD
Review and approval of the manuscript – all authors

Funding statement:
This work was supported by the Foundation for Breast Cancer Care grant no. 20202716 (Macquarie University)

Competing interests statement.
None

Acknowledgements:

Foundation for Breast Cancer Care, Armajun Aboriginal Health Service, Poche Centre for Indigenous Health (Dr John Skinner and Dr Jo Gwynne)

Key for Figures 1-4

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

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

Full references:

1. Health AIo, Welfare. Cancer in Australia 2019. Canberra: AIHW; 2019.

2. Health AIo, Welfare. BreastScreen Australia monitoring report 2018. Canberra: AIHW; 2018.

3. Health AIo, Welfare. Cancer in Aboriginal & Torres Strait Islander people of Australia. Canberra: AIHW; 2018.

4. Read DJ, Frentzas S, Ward L, De Ieso P, Chen S, Devi V. Do histopathological features of breast cancer in Australian Indigenous women explain the survival disparity? A two decade long study in the Northern Territory. Asia-Pacific journal of clinical oncology. 2020.

5. Moore SP, Soerjomataram I, Green AC, Garvey G, Martin J, Valery PC. Breast cancer diagnosis, patterns of care and burden of disease in Queensland, Australia (1998-2004): does being Indigenous make a difference? International journal of public health. 2016;61(4):435-42.

6. Tapia KA, Garvey G, Mc Entee M, Rickard M, Brennan P. Breast Cancer in Australian Indigenous Women: Incidence, Mortality, and Risk Factors. Asian Pacific journal of cancer prevention : APJCP. 2017;18(4):873-84.

7. Roder D, Webster F, Zorbas H, Sinclair S. Breast screening and breast cancer survival in Aboriginal and Torres Strait Islander women of Australia. Asian Pacific Journal of Cancer Prevention. 2012;13(1):147-55.

8. Dasgupta P, Baade PD, Youlden DR, Garvey G, Aitken JF, Wallington I, et al. Variations in outcomes for Indigenous women with breast cancer in Australia: A systematic review. European Journal of Cancer Care. 2017;26(6):e12662.

9. Banham D, Roder D, Keefe D, Farshid G, Eckert M, Howard N, et al. Disparities in breast screening, stage at diagnosis, cancer treatment and the subsequent risk of cancer death: a retrospective, matched cohort of aboriginal and non-aboriginal women with breast cancer. BMC Health Services Research. 2019;19(1):387.

10. Thompson SC. Indigenous women and breast cancer. Medical Journal of Australia. 2009;190(10):602-.

11. Byers L, Michell K, McCullough K. Awareness, acceptability and access to screening mammography for remote Aboriginal women. Health Promot J Austr. 2018;29(3):366-7.

12. Hedges S, Davidson M, Forrester S, Casey A, Pridmore V, Cooper A, et al. A Breast Screening Shawl to Help Aboriginal Women Feel More Comfortable and Culturally Safe. Journal of Global Oncology. 2018;4(Supplement 2):40s-s.

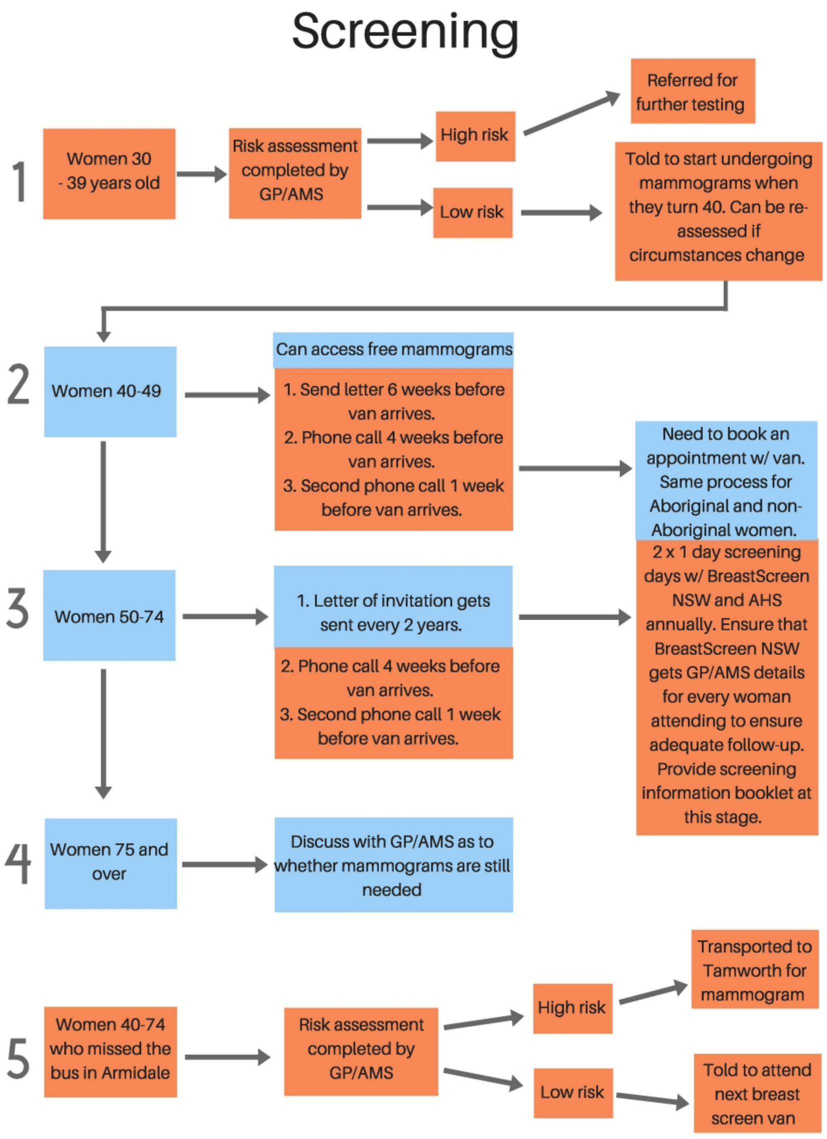
13. McMichael C, Kirk M, Manderson L, Hoban E, Potts H. Indigenous women's perceptions of breast cancer diagnosis and treatment in Queensland. Australian and New Zealand Journal of Public Health. 2000;24(5):515-9.

14. Fox W, Powell M, Hyland V, Honeyball F, editors. Supportive care for women with breast cancer living in rural Australia. Cancer Forum; 2017: The Cancer Council Australia.

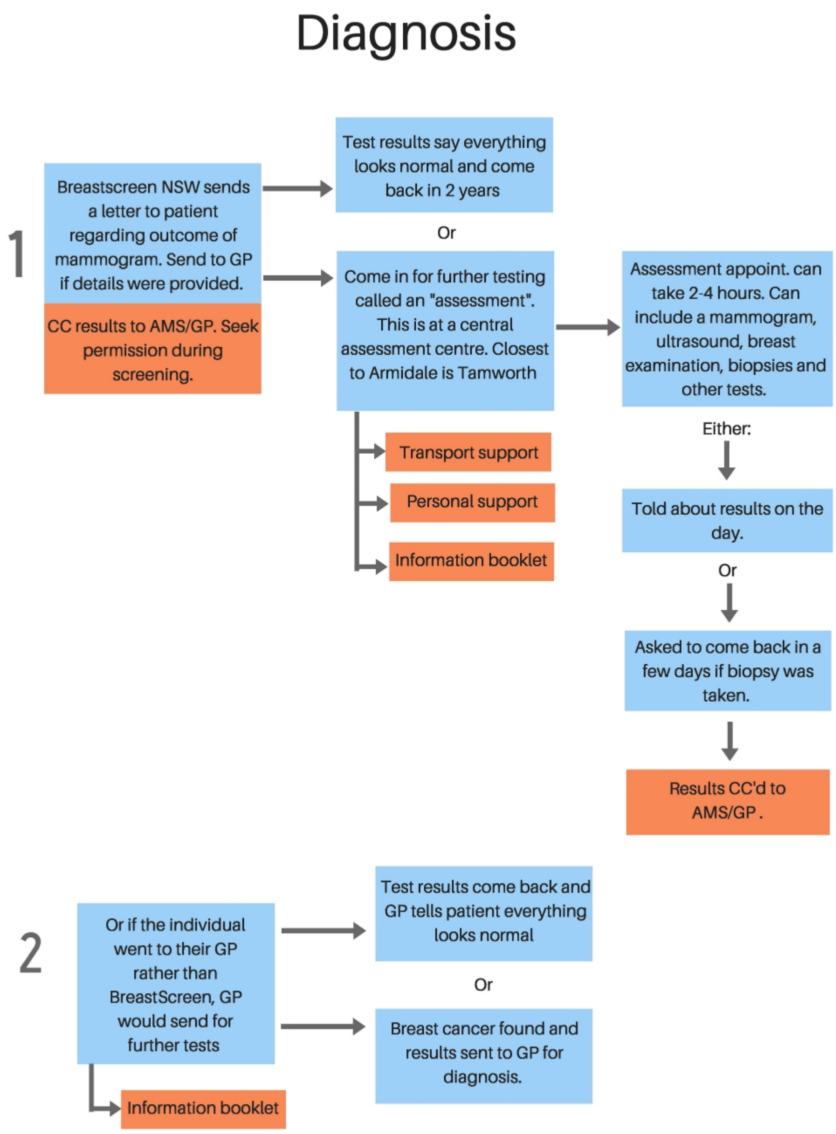
15. 'Orchid' Breastscreen Queensland's New 4WD Digital Mobile Service. 2010-08;34(5):39.

16. Campbell J, Kurnoth P. Well women making a diffence: evaluation report and program guide. Darwin: Women's Cancer Prevention Program, Department of Health and Community Services, Northern Territory Government; 2000.

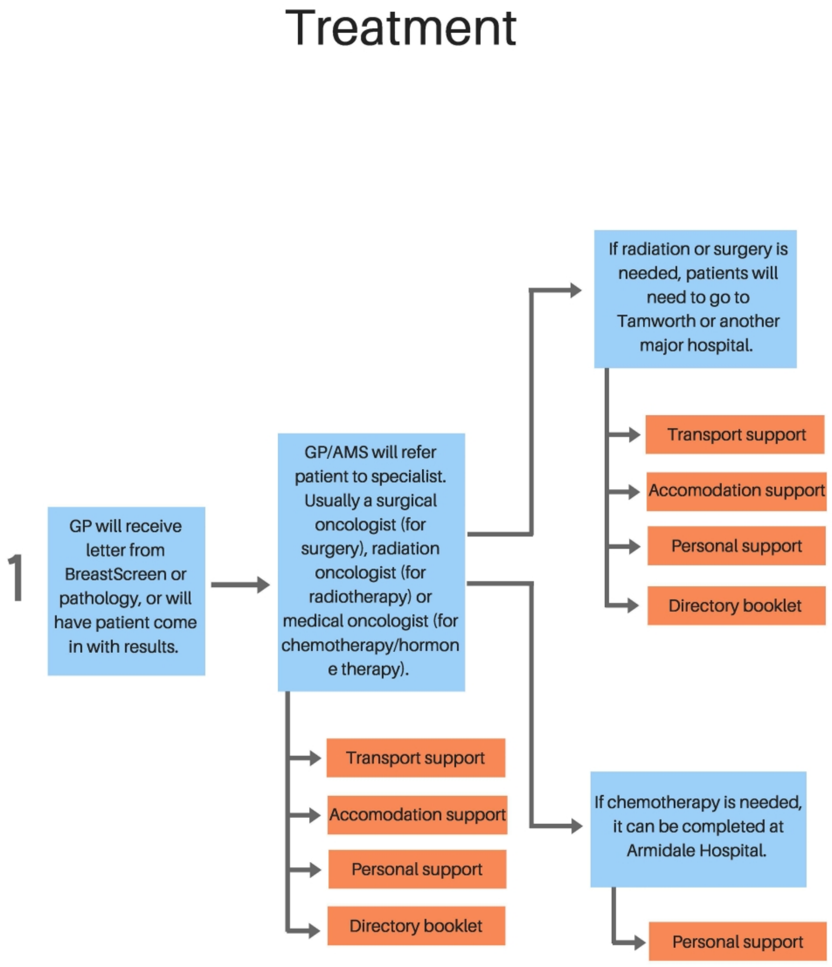
17. Pilkington L, Haigh MM, Durey A, Katzenellenbogen JM, Thompson SC. Perspectives of Aboriginal women on participation in mammographic screening: a step towards improving services. BMC public health. 2017;17(1):697.
18. Reath J, Carey M. Breast and cervical cancer in indigenous women-overcoming barriers to early detection. Aust Fam Physician. 2008;37(3):178-82.
19. Supramaniam R, Gibberd A, Dillon A, Goldsbury DE, O'Connell DL. Increasing rates of surgical treatment and preventing comorbidities may increase breast cancer survival for Aboriginal women. BMC Cancer. 2014;14(1):163.
20. Byers L, Michell K, McCullough K. Awareness, acceptability and access to screening mammography for remote Aboriginal women. Health Promotion Journal of Australia. 2018;29(3):366.
21. Hedges S, Davidson M, Forrester S, Casey A, Pridmore V, Cooper A, et al. A breast screening shawl to help Aboriginal women feel more comfortable and culturally safe. American Society of Clinical Oncology; 2018.
22. Reath J, Carey M. Breast and cervical cancer in Indigenous women: overcoming barriers to early detection. Australian Family Physician. 2008;37(3):178.
23. Valery PC, Bernardes CM, de Witt A, Martin J, Walpole E, Garvey G, et al. Patterns of primary health care service use of Indigenous Australians diagnosed with cancer. Support Care Cancer. 2020;28(1):317-27.
24. Gwynne K. Applying Collective Impact to Wicked Problems in Aboriginal Health. Metropolitan Universities. 2017;28:115.
25. Banner RO, DeCambra H, Enos R, Gotay C, Hammond OW, Hedlung N, et al. A breast and cervical cancer project in a native Hawaiian community: Wai'anae cancer research project. Preventive Medicine. 1995;24(5):447-53.
26. Brown SR, Nuno T, Joshweseoma L, Begay RC, Goodluck C, Harris RB, et al. Impact of a community-based breast cancer screening program on Hopi women. Preventive Medicine. 2011;52(5):390-3.
27. English KC, Fairbanks J, Finster CE, Rafelito A, Luna J, Kennedy M. A socioecological approach to improving mammography rates in a tribal community. Health Education & Behavior. 2008;35(3):396-409.
28. Ka'opua LS, Park SH, Ward ME, Braun KL. Testing the feasibility of a culturally tailored breast cancer screening intervention with Native Hawaiian women in rural churches. Health Soc Work. 2011;36(1):55-65.
29. Strickland CJ, Hillaire E. Conducting a Feasibility Study in Women's Health Screening Among Women in a Pacific Northwest American Indian Tribe. Journal of Transcultural Nursing. 2016;27(1):42-8.
30. Care ACoSaQiH. Health literacy: Taking action to improve safety and quality. 2014.
31. Saldaña J. The coding manual for qualitative researchers / Johnny Saldaña. London: SAGE; 2009.
32. Hyett N, Kenny A, Dickson-Swift V. Methodology or method? A critical review of qualitative case study reports. Int J Qual Stud Health Well-being. 2014;9:23606.



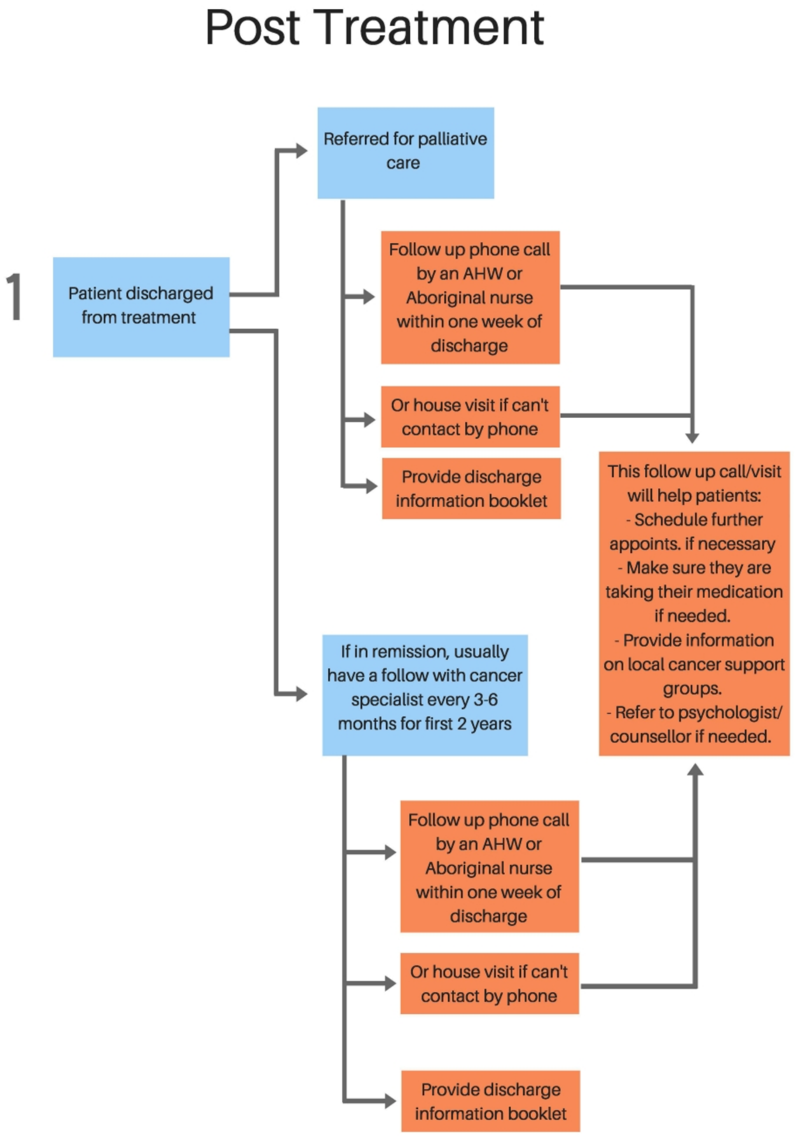
420x594mm (300 x 300 DPI)



420x594mm (300 x 300 DPI)

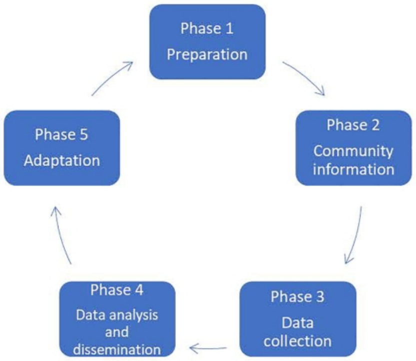


420x594mm (300 x 300 DPI)



420x594mm (300 x 300 DPI)

Figure 5



210x297mm (300 x 300 DPI)

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-048003.R1
Article Type:	Protocol
Date Submitted by the Author:	15-Jun-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

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.

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

'Strengths and limitations of this study'

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

Introduction:

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

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

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

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

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

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

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

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

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

Aims and Objectives:

Primary objective:
In one region in NSW Australia we will:

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

Methods and analysis

Co-design

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

The design of the study has been based on recommendations provided by the CMP from 2018. The CMP was a collaboration between the Foundation for Breast Cancer Care, the Poche Centre for Indigenous Health and Armajun Aboriginal Health Service. The CMP included consultation with Aboriginal survivors of breast cancer, Aboriginal women in the target age range for breast cancer prevention and early intervention, and Aboriginal Health Workers as well as local service providers in four towns of one central northern rural region of NSW. The CMP informed this protocol. The development of the research question and outcome measures were informed by patients' and healthcare providers' priorities, experience, and preferences
The CMP guided the development of this iterative mixed methods study consisting of five main phases which makes adjustments to the present processes of screening, diagnosis, treatment and post treatment follow up to enhance cultural safety and promote engagement of Aboriginal women. The planned start date for this study is May 2021 and end date is May 2022.

Patient and Public Involvement

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

Co-designed assessment and treatment pathway

The current screening, diagnosis, treatment and post-treatment services respectively and describethe adjustments and additions created through the CMP are shown in Figures 1-4.

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

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

Through the CMP it was 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 research, 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 study and its progress and AHS staff who self-nominate will be investigators on the study. The Aboriginal Advisory Group will meet every month and the Investigators Group every eight weeks. Data will be collected and owned and managed by the AHS and will be shared with Investigator group. Any publication will need to be approved by the Aboriginal Advisory Group and the AHMRC ethics committee. Members of the Investigators Group will continue to participate in 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. Qualitative methods will include semi-structured, in-depth interviews and focus group discussions. Structured quantitative and qualiitative questionnaires will be used to assess participant satisfaction, as well as collect information about demographics, patient journey and clinical data.

Target population

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

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

Phases of implementation

The process of implementation is shown in Figure 5.

Phase 1: Preparation

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

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

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

Figure 5. Process of implementation

(attached as an Image file)

Phase 2: Community information

In our co-design process, 'community information' refers to both promoting the culturally safe screening events and providing relevant information to potential participants regarding the study. The local AHS staff and Investigator 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 written 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 who will be referred on for screening and MRI if they are found to meet high risk criteria. 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, resources will be given to and support from the local Aboriginal Health Workers on next steps.
Additionally there will be Aboriginal Health Workers acting as support staff if treatment is suggested, to inform affected women of the resources on offer and treatment pathways suggested. Women who partake in any part of the modified screening, diagnosis, treatment

of follow up processes will be invited to join the study but will be no consequences for their treatment or support if they elect not to participate.

Phase 3: Data Collection and outcome measurement

All participants involved in the study will be given a participant information sheet (PIS- see Appendix 1) 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.

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. The consent process will be managed by the AHS. 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 additional services/modifications 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.

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

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

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

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

The study will quantitatively measure:

- the participation rates of Aboriginal women in breast cancer screening (over a 10 week period)
- the participation rates of Aboriginal women in timely and culturally safe diagnostic, treatment and post-treatment services (over a one year period)
- 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)
- breast cancer health literacy among Aboriginal women in the local community (over a one year period)

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

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

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

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

To establish whether there was an improvement in satisfaction levels regarding screening, diagnostic, treatment, and post-treatment services available to Aboriginal women questionnaires will be completed by those who accessed the screening van in 2021, both during normal operation and the screening day event(see Appendix 3). Questionnaires will also be completed by women who accessed diagnostic, treatment and/or post-treatment services for breast cancer in 2021.

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

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

Safety considerations

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

Phase 4: Data analysis and dissemination

Data analysis plan

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

Returning results to the community

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

Plain English summaries). We will work in collaboration with AHS to hold community meetings and information evenings, which both participants and non-participants of the study can attend. Community members will be encouraged to provide feedback and comments on the process.

Results will be published in peer reviewed journals and presented at professional conferences. The AHS participating in the study will be invited to contribute to these publications and presentations. We will acknowledge the sources of information and those who have contributed to the research through authorship and acknowledgement in resulting publications, meetings with community members and conference presentations. We will also acknowledge the cultural property rights of Aboriginal peoples in relation to knowledge, ideas, cultural expressions and cultural materials by including AHS representatives as research team members.

Phase 5: Adaptation

In this phase we will evaluate the co-design process to evaluate whether it can be adapted to other similar health issues in the Aboriginal community.

Corresponding author:
Vita Christie
E: vita.christie@sydney.edu.au
T: 0403 709 178 F: 02 9351 3196
A: 225 Edward Ford Building A27, The University of Sydney NSW 2006

Authors' contributions:

Conception and design of the study - KG, DG, DM, MR, VC
Planning- VC, KG, JD, DG
Governance and scientific advice – KG, CP, JA DM, DG, VC
Conduct and reporting: VC, KG, DG
Drafting the Manuscript – VC, MR, KG, JD
Review and approval of the manuscript – VC, KG, JA, DG, KL, CP, DM, JD

Funding statement:
This work was supported by the Foundation for Breast Cancer Care grant no. 20202716 (Macquarie University)

Competing interests statement.

None

Acknowledgements:

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

Full references:

1. Health AIo, Welfare. Cancer in Australia 2019. Canberra: AIHW; 2019.
2. Health AIo, Welfare. BreastScreen Australia monitoring report 2018. Canberra: AIHW; 2018.
3. Health AIo, Welfare. Cancer in Aboriginal & Torres Strait Islander people of Australia. Canberra: AIHW; 2018.
4. Read DJ, Frentzas S, Ward L, De Ieso P, Chen S, Devi V. Do histopathological features of breast cancer in Australian Indigenous women explain the survival disparity? A two decade long study in the Northern Territory. Asia-Pacific journal of clinical oncology. 2020.
5. Moore SP, Soerjomataram I, Green AC, Garvey G, Martin J, Valery PC. Breast cancer diagnosis, patterns of care and burden of disease in Queensland, Australia (1998-2004): does being Indigenous make a difference? International journal of public health. 2016;61(4):435-42.

6. Tapia KA, Garvey G, Mc Entee M, Rickard M, Brennan P. Breast Cancer in Australian Indigenous Women: Incidence, Mortality, and Risk Factors. Asian Pacific journal of cancer prevention : APJCP. 2017;18(4):873-84.

7. Roder D, Webster F, Zorbas H, Sinclair S. Breast screening and breast cancer survival in Aboriginal and Torres Strait Islander women of Australia. Asian Pacific Journal of Cancer Prevention. 2012;13(1):147-55.

8. Dasgupta P, Baade PD, Youlden DR, Garvey G, Aitken JF, Wallington I, et al. Variations in outcomes for Indigenous women with breast cancer in Australia: A systematic review. European Journal of Cancer Care. 2017;26(6):e12662.

9. Banham D, Roder D, Keefe D, Farshid G, Eckert M, Howard N, et al. Disparities in breast screening, stage at diagnosis, cancer treatment and the subsequent risk of cancer death: a retrospective, matched cohort of aboriginal and non-aboriginal women with breast cancer. BMC Health Services Research. 2019;19(1):387.

10. Thompson SC. Indigenous women and breast cancer. Medical Journal of Australia. 2009;190(10):602-.

11. Hedges S, Davidson M, Forrester S, Casey A, Pridmore V, Cooper A, et al. A Breast Screening Shawl to Help Aboriginal Women Feel More Comfortable and Culturally Safe. Journal of Global Oncology. 2018;4(Supplement 2):40s-s.

12. McMichael C, Kirk M, Manderson L, Hoban E, Potts H. Indigenous women's perceptions of breast cancer diagnosis and treatment in Queensland. Australian and New Zealand Journal of Public Health. 2000;24(5):515-9.

13. Fox W, Powell M, Hyland V, Honeyball F, editors. Supportive care for women with breast cancer living in rural Australia. Cancer Forum; 2017: The Cancer Council Australia.

14. 'Orchid' Breastscreen Queensland's New 4WD Digital Mobile Service. 2010-08;34(5):39.

15. Campbell J, Kurnoth P. Well women making a diffence: evaluation report and program guide. Darwin: Women's Cancer Prevention Program, Department of Health and Community Services, Northern Territory Government; 2000.

16. Pilkington L, Haigh MM, Durey A, Katzenellenbogen JM, Thompson SC. Perspectives of Aboriginal women on participation in mammographic screening: a step towards improving services. BMC public health. 2017;17(1):697.

17. Reath J, Carey M. Breast and cervical cancer in Indigenous women: overcoming barriers to early detection. Australian Family Physician. 2008;37(3):178.

18. Supramaniam R, Gibberd A, Dillon A, Goldsbury DE, O'Connell DL. Increasing rates of surgical treatment and preventing comorbidities may increase breast cancer survival for Aboriginal women. BMC Cancer. 2014;14(1):163.

19. Byers L, Michell K, McCullough K. Awareness, acceptability and access to screening mammography for remote Aboriginal women. Health Promotion Journal of Australia. 2018;29(3):366.

20. Byers L, Michell K, McCullough K. Awareness, acceptability and access to screening mammography for remote Aboriginal women. Health Promot J Austr. 2018;29(3):366-7.

21. Reath J, Carey M. Breast and cervical cancer in indigenous women-overcoming barriers to early detection. Aust Fam Physician. 2008;37(3):178-82.

22. Hedges S, Davidson M, Forrester S, Casey A, Pridmore V, Cooper A, et al. A breast screening shawl to help Aboriginal women feel more comfortable and culturally safe. American Society of Clinical Oncology; 2018.

23. Valery PC, Bernardes CM, de Witt A, Martin J, Walpole E, Garvey G, et al. Patterns of primary health care service use of Indigenous Australians diagnosed with cancer. Support Care Cancer. 2020;28(1):317-27.

24. Gwynne K. Applying Collective Impact to Wicked Problems in Aboriginal Health. Metropolitan Universities. 2017;28:115.

25. Banner RO, DeCambra H, Enos R, Gotay C, Hammond OW, Hedlung N, et al. A breast and cervical cancer project in a native Hawaiian community: Wai'anae cancer research project. Preventive Medicine. 1995;24(5):447-53.

26. Brown SR, Nuno T, Joshweseoma L, Begay RC, Goodluck C, Harris RB, et al. Impact of a community-based breast cancer screening program on Hopi women. Preventive Medicine. 2011;52(5):390-3.

27. English KC, Fairbanks J, Finster CE, Rafelito A, Luna J, Kennedy M. A socioecological approach to improving mammography rates in a tribal community. Health Education & Behavior. 2008;35(3):396-409.

28. Ka'opua LS, Park SH, Ward ME, Braun KL. Testing the feasibility of a culturally tailored breast cancer screening intervention with Native Hawaiian women in rural churches. Health Soc Work. 2011;36(1):55-65.

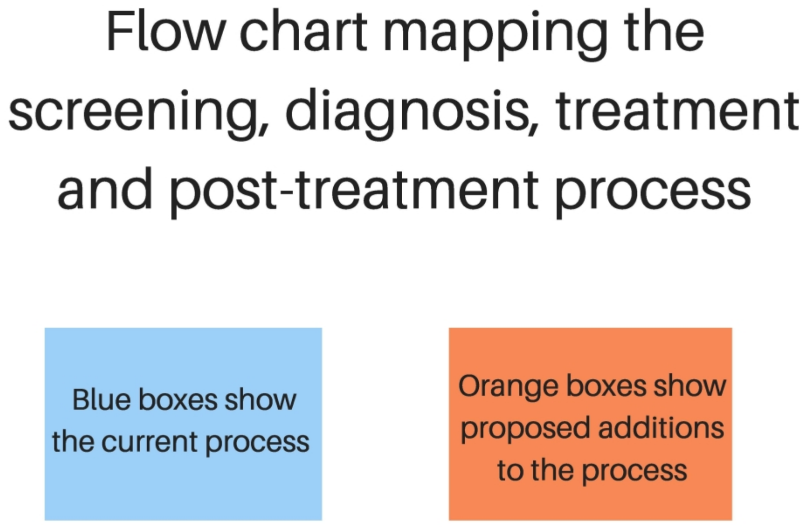
29. Strickland CJ, Hillaire E. Conducting a Feasibility Study in Women’s Health Screening Among Women in a Pacific Northwest American Indian Tribe. Journal of Transcultural Nursing. 2016;27(1):42-8.

30. Kania J HF, & Splansky Juster J. Essential Mindset Shifts for Collective Impact. Stanford Social Innovation Review. 2014.

31. Care ACoSaQiH. Health literacy: Taking action to improve safety and quality. 2014.

32. Saldaña J. The coding manual for qualitative researchers / Johnny Saldaña. London: SAGE; 2009.

33. Hyett N, Kenny A, Dickson-Swift V. Methodology or method? A critical review of qualitative case study reports. Int J Qual Stud Health Well-being. 2014;9:23606.



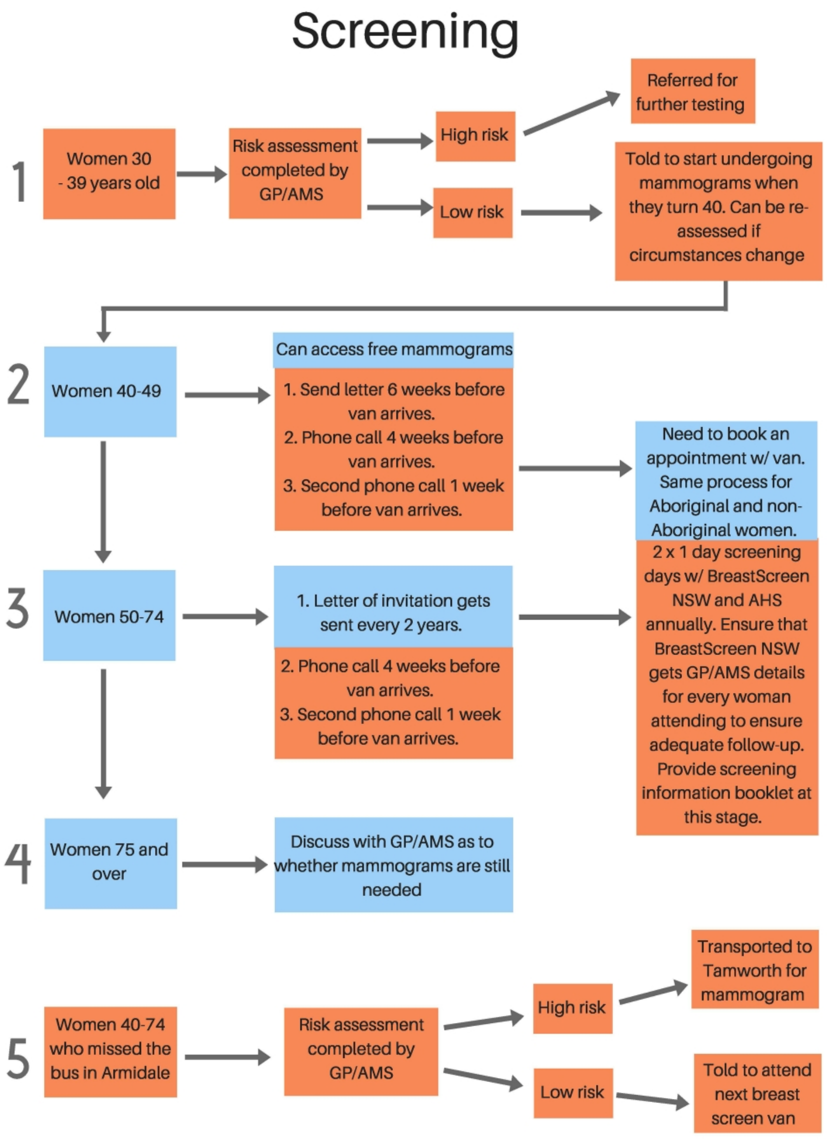
Flow chart mapping the screening, diagnosis, treatment and post-treatment process

🟦 Blue boxes show the current process

🟧 Orange boxes show proposed additions to the process

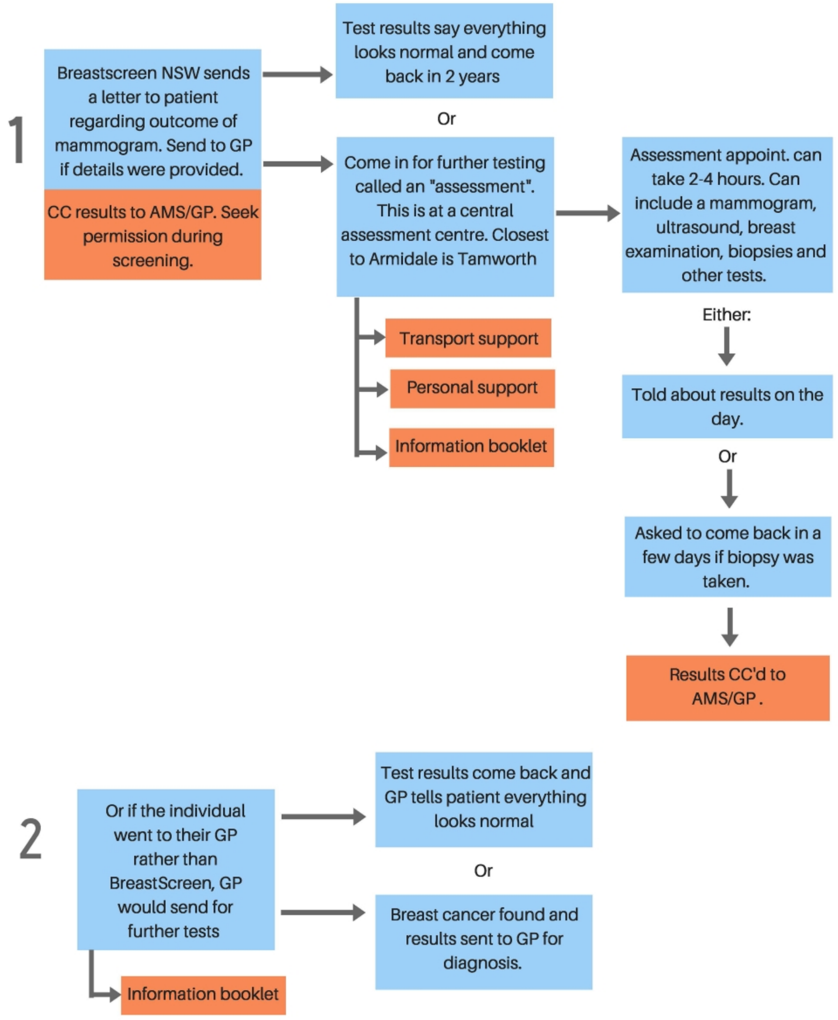
Key to figures

420x594mm (200 x 200 DPI)



420x594mm (300 x 300 DPI)

Diagnosis



Breastscreen NSW sends a letter to patient regarding outcome of mammogram. Send to GP if details were provided.

CC results to AMS/GP. Seek permission during screening.

Test results say everything looks normal and come back in 2 years

Or

Come in for further testing called an "assessment". This is at a central assessment centre. Closest to Armidale is Tamworth

- Transport support
- Personal support
- Information booklet

Assessment appoint. can take 2-4 hours. Can include a mammogram, ultrasound, breast examination, biopsies and other tests.

Either:

Told about results on the day.

Or

Asked to come back in a few days if biopsy was taken.

Results CC'd to AMS/GP .

Or if the individual went to their GP rather than BreastScreen, GP would send for further tests

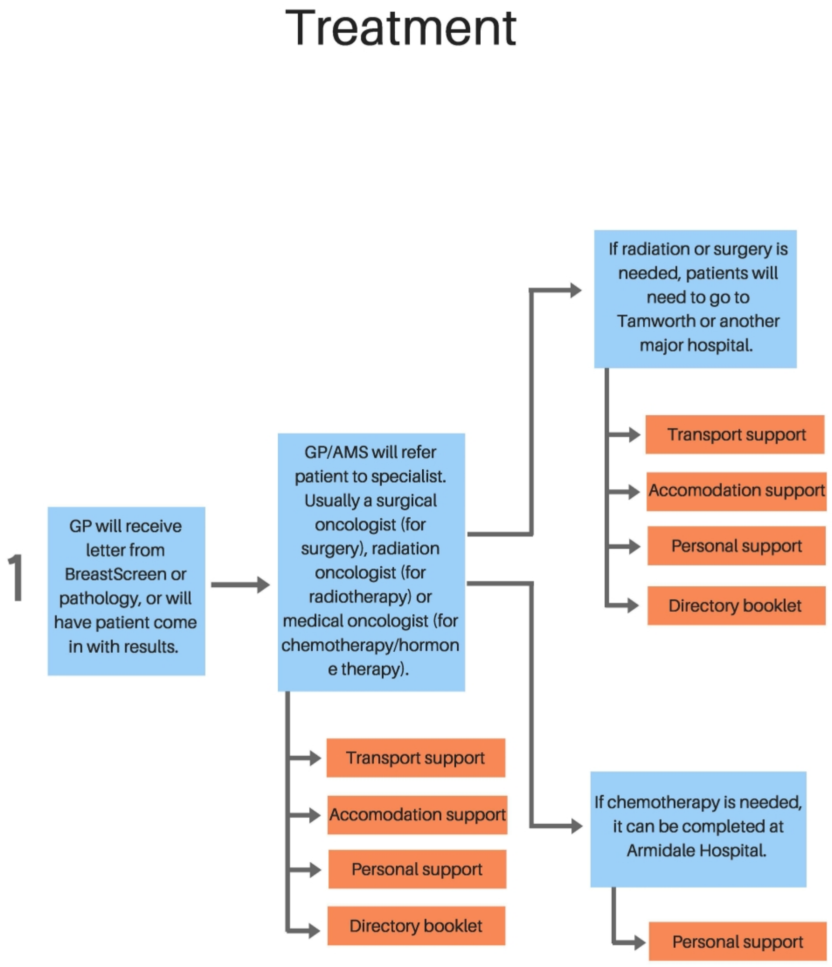
- Information booklet

Test results come back and GP tells patient everything looks normal

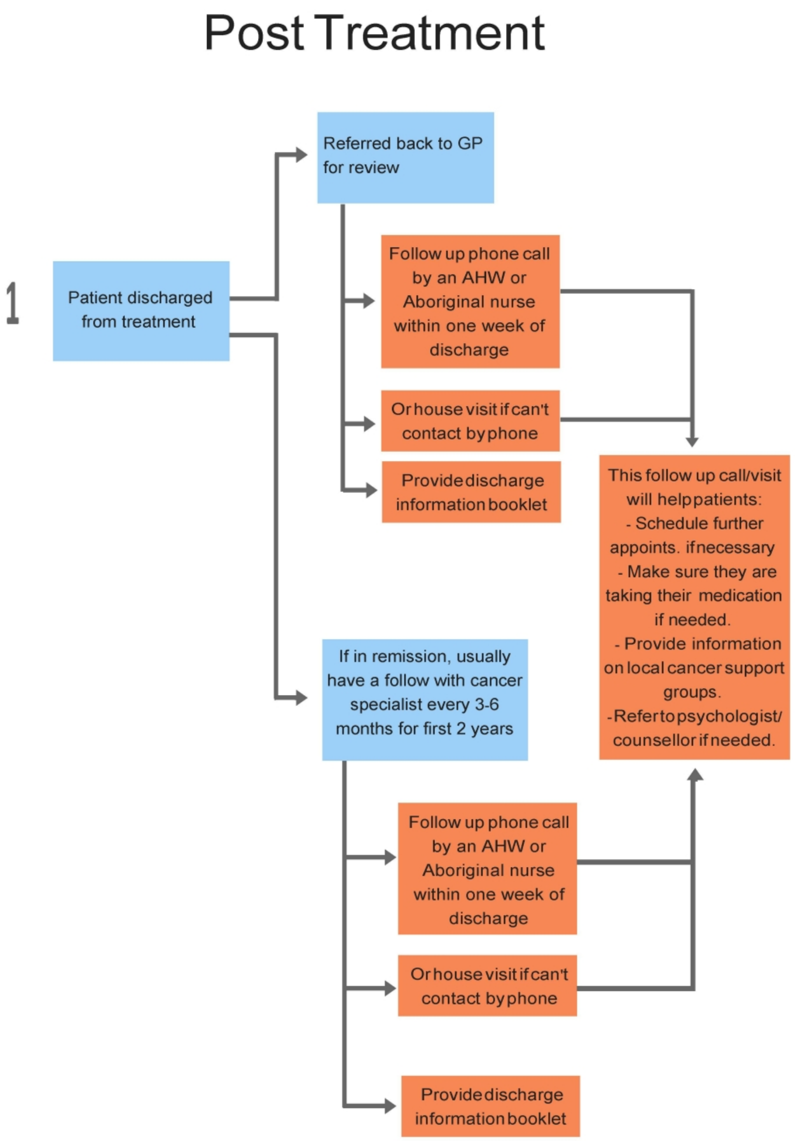
Or

Breast cancer found and results sent to GP for diagnosis.

420x594mm (300 x 300 DPI)



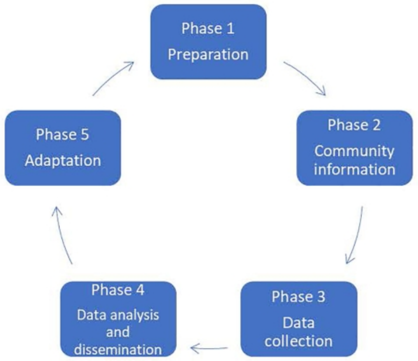
420x594mm (300 x 300 DPI)



revised Figure 4

394x558mm (200 x 200 DPI)

Figure 5



210x297mm (300 x 300 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.

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 your 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?

POST

Questions for community members

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

BMJ Open

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

Journal:	*BMJ Open*
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

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.

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

'Strengths and limitations of this study'

- This study aims to engage Aboriginal women to design and implement a framework for improving participation in breast cancer screening, diagnostic, treatment, and post-treatment services and will be designed and implemented with a local Aboriginal community-controlled health service and Aboriginal co-investigators
- The study employs a mixed-methods design with descriptive statistical analysis of quantitative data on service utilisation as well as qualitative analysis drawn from focus groups and in-depth interviews regarding user satisfaction
- Strengths: The collective action co-design methodology strengthens community engagement by sharing power, knowledge and skill with community members and health services
- Limitations: Small study size limits the generalisability of the research findings
- The author team appreciate completion by Aboriginal women often falls below optimum. Whereas others have documented that the completion rates for prescribed cancer treatment amongst Aboriginal cohorts is sub-optimal, this study is to identify milestones and barriers along the cancer treatment pathway.

Introduction:

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

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

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

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

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

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

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

A preliminary mapping process co-designed with the communities in 2018 has informed this research. The Community Mapping Project (CMP) consisted of interviews with Aboriginal breast cancer survivors from local communities, staff from the local Aboriginal Health Service (AHS), and other breast cancer care providers. The CMP explored experiences, priorities and preferences, particularly from the survivors' perspectives. It was a comprehensive mapping of existing screening, diagnosis, treatment and post treatment service delivery, resulting in co-designed recommendations to adjust the existing services and improve the pathway for Aboriginal women in the area. An important aspect of co-design is engaging with communities at the point the research is being conceptualised. This is well prior to ethics approval. The AHMRC requires letters of support from Aboriginal Community Controlled Health Services. The way we obtain these letters of support is by engaging in a process, in this case the CMP, to literally co-design the protocol. Once the protocol is approved by communities and then the AHMRC, we proceed to implementation of the research. It is not possible therefore to report the detailed discussions, interviews and process of the CMP beyond the output, shown in Figures 1-4, because ethics approval was obtained after the co-design process of the CMP was completed.

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

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

Aims and Objectives:

Primary objective:

In one region in NSW Australia we will:

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

Aim: improve communication and reduce anxiety and stress as screening transitions into treatment to improve initial treatment uptake.

Methods and analysis

Co-design

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

The design of the study has been based on recommendations provided by the CMP from 2018. The CMP was a collaboration between the Foundation for Breast Cancer Care, the Poche Centre for Indigenous Health and Armajun Aboriginal Health Service. The CMP included consultation with Aboriginal survivors of breast cancer, Aboriginal women in the target age range for breast cancer prevention and early intervention, and Aboriginal Health Workers as well as local service providers in a regional and rural location situated in the Central North of New South Wales.. The CMP informed this protocol. The development of the research question and outcome measures were informed by patients' and healthcare providers' priorities, experience, and preferences.
The CMP guided the development of this iterative mixed methods study consisting of five main phases which makes adjustments to the present processes of screening, diagnosis, treatment and post treatment follow up to enhance cultural safety and promote engagement of Aboriginal women. The planned time period for data collection is one year: 2021-2022.. The study commenced when ethics approval was granted in 2019 and will conclude 2022.

Patient and Public Involvement

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

Co-designed assessment and treatment pathway

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

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

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

Through the CMP it was 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 research, 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 study and its progress and AHS staff who self-nominate will be investigators on the study. The Aboriginal Advisory Group will meet every month and the Investigators' Group every eight weeks. Data will be collected and owned and managed by the AHS and will be shared with Investigator group. Any publication will need to be approved by the Aboriginal Advisory Group and the AHMRC ethics committee. Members of the Investigators Group will continue to participate in 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. Qualitative methods will include semi-structured, in-depth interviews and focus group discussions. Structured quantitative and qualitative questionnaires will be used to assess participant satisfaction, as well as collect information about demographics, patient journey and clinical data.

Target population

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

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

Phases of implementation

The process of implementation is shown in Figure 5.

Phase 1: Preparation

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

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

Figure 5. Process of implementation

(attached as an Image file)

Phase 2: Community information

In our co-design process, ‘community information’ refers to both promoting the culturally safe screening events and providing relevant information to potential participants regarding the study. The local AHS staff and Investigator 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 written reminders 1 week out from the screening day date.

Screening and follow up will be undertaken according to the procedures described in Figures 1-4. The AHS will be offer risk assessments for women between 30-39 years who will be referred on for screening and MRI if they are found to meet high risk criteria. 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, resources will be given to and support from the local Aboriginal Health Workers on next steps.
Additionally there will be Aboriginal Health Workers acting as support staff if treatment is suggested, to inform affected women of the resources on offer and treatment pathways suggested. Women who partake in any part of the modified screening, diagnosis, treatment of follow up processes will be invited to join the study but will be no consequences for their treatment or support if they elect not to participate.

Phase 3: Data Collection and outcome measurement

All participants involved in the study will be recruited via the AHS. The AHS will contact each prospective participant personally and explain the study to them. They will explain the Participant Information Sheet and seek informed consent (PIS) (PIS- see Appendix 1). The PIS 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.
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. The consent process will be managed by the AHS. 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 additional services/modifications 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.

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

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

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

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

The study will quantitatively measure:

- the participation rates of Aboriginal women in breast cancer screening (over a 10 week period)
- the participation rates of Aboriginal women in timely and culturally safe diagnostic, treatment and post-treatment services (over a one year period)
- 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)
- breast cancer health literacy among Aboriginal women in the local community (over a one year period)

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

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

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

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

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

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

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

Safety considerations

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

Phase 4: Data analysis and dissemination

Data analysis plan

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

Returning results to the community

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

Results will be published in peer reviewed journals and presented at professional conferences. The AHS participating in the study will be invited to contribute to these publications and presentations. We will acknowledge the sources of information and those who have contributed to the research through authorship and acknowledgement in resulting publications, meetings with community members and conference presentations. We will also acknowledge the cultural property rights of Aboriginal peoples in relation to knowledge, ideas, cultural expressions and cultural materials by including AHS representatives as research team members.

Phase 5: Adaptation

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

Corresponding author:
Vita Christie
E: vita.christie@sydney.edu.au
T: 0403 709 178 F: 02 9351 3196
A: 225 Edward Ford Building A27, The University of Sydney NSW 2006

Authors' contributions:
Conception and design of the study - KG, DG, DM, MR, VC
Planning- VC, KG, JD, DG
Governance and scientific advice – KG, CP, JA DM, DG, VC
Conduct and reporting: VC, KG, DG
Drafting the Manuscript – VC, MR, KG, JD
Review and approval of the manuscript – VC, KG, JA, DG, KL, CP, DM, JD

Funding statement:
This work was supported by the Foundation for Breast Cancer Care grant no. 20202716 (Macquarie University)

Competing interests statement.
None

Acknowledgements:
Foundation for Breast Cancer Care, Armajun Aboriginal Health Service, Poche Centre for Indigenous Health (Dr John Skinner and Associate Professor Lynette Riley)

Full references:

1. Health AIo, Welfare. Cancer in Australia 2019. Canberra: AIHW; 2019.
2. Health AIo, Welfare. BreastScreen Australia monitoring report 2018. Canberra: AIHW; 2018.
3. Health AIo, Welfare. Cancer in Aboriginal & Torres Strait Islander people of Australia. Canberra: AIHW; 2018.
4. Read DJ, Frentzas S, Ward L, De Ieso P, Chen S, Devi V. Do histopathological features of breast cancer in Australian Indigenous women explain the survival disparity? A two decade long study in the Northern Territory. Asia-Pacific journal of clinical oncology. 2020.
5. Moore SP, Soerjomataram I, Green AC, Garvey G, Martin J, Valery PC. Breast cancer diagnosis, patterns of care and burden of disease in Queensland, Australia (1998-2004): does being Indigenous make a difference? International journal of public health. 2016;61(4):435-42.
6. Tapia KA, Garvey G, Mc Entee M, Rickard M, Brennan P. Breast Cancer in Australian Indigenous Women: Incidence, Mortality, and Risk Factors. Asian Pacific journal of cancer prevention : APJCP. 2017;18(4):873-84.
7. Roder D, Webster F, Zorbas H, Sinclair S. Breast screening and breast cancer survival in Aboriginal and Torres Strait Islander women of Australia. Asian Pacific Journal of Cancer Prevention. 2012;13(1):147-55.
8. Dasgupta P, Baade PD, Youlden DR, Garvey G, Aitken JF, Wallington I, et al. Variations in outcomes for Indigenous women with breast cancer in Australia: A systematic review. European Journal of Cancer Care. 2017;26(6):e12662.
9. Banham D, Roder D, Keefe D, Farshid G, Eckert M, Howard N, et al. Disparities in breast screening, stage at diagnosis, cancer treatment and the subsequent risk of cancer death: a retrospective, matched cohort of aboriginal and non-aboriginal women with breast cancer. BMC Health Services Research. 2019;19(1):387.
10. Thompson SC. Indigenous women and breast cancer. Medical Journal of Australia. 2009;190(10):602-.
11. Hedges S, Davidson M, Forrester S, Casey A, Pridmore V, Cooper A, et al. A Breast Screening Shawl to Help Aboriginal Women Feel More Comfortable and Culturally Safe. Journal of Global Oncology. 2018;4(Supplement 2):40s-s.

12. McMichael C, Kirk M, Manderson L, Hoban E, Potts H. Indigenous women's perceptions of breast cancer diagnosis and treatment in Queensland. Australian and New Zealand Journal of Public Health. 2000;24(5):515-9.

13. Fox W, Powell M, Hyland V, Honeyball F, editors. Supportive care for women with breast cancer living in rural Australia. Cancer Forum; 2017: The Cancer Council Australia.

14. 'Orchid' Breastscreen Queensland's New 4WD Digital Mobile Service. 2010-08;34(5):39.

15. Campbell J, Kurnoth P. Well women making a diffence: evaluation report and program guide. Darwin: Women's Cancer Prevention Program, Department of Health and Community Services, Northern Territory Government; 2000.

16. Pilkington L, Haigh MM, Durey A, Katzenellenbogen JM, Thompson SC. Perspectives of Aboriginal women on participation in mammographic screening: a step towards improving services. BMC public health. 2017;17(1):697.

17. Reath J, Carey M. Breast and cervical cancer in Indigenous women: overcoming barriers to early detection. Australian Family Physician. 2008;37(3):178.

18. Supramaniam R, Gibberd A, Dillon A, Goldsbury DE, O'Connell DL. Increasing rates of surgical treatment and preventing comorbidities may increase breast cancer survival for Aboriginal women. BMC Cancer. 2014;14(1):163.

19. Byers L, Michell K, McCullough K. Awareness, acceptability and access to screening mammography for remote Aboriginal women. Health Promotion Journal of Australia. 2018;29(3):366.

20. Byers L, Michell K, McCullough K. Awareness, acceptability and access to screening mammography for remote Aboriginal women. Health Promot J Austr. 2018;29(3):366-7.

21. Reath J, Carey M. Breast and cervical cancer in indigenous women-overcoming barriers to early detection. Aust Fam Physician. 2008;37(3):178-82.

22. Hedges S, Davidson M, Forrester S, Casey A, Pridmore V, Cooper A, et al. A breast screening shawl to help Aboriginal women feel more comfortable and culturally safe. American Society of Clinical Oncology; 2018.

23. Valery PC, Bernardes CM, de Witt A, Martin J, Walpole E, Garvey G, et al. Patterns of primary health care service use of Indigenous Australians diagnosed with cancer. Support Care Cancer. 2020;28(1):317-27.

24. Gwynne K. Applying Collective Impact to Wicked Problems in Aboriginal Health. Metropolitan Universities. 2017;28:115.

25. Banner RO, DeCambra H, Enos R, Gotay C, Hammond OW, Hedlung N, et al. A breast and cervical cancer project in a native Hawaiian community: Wai'anae cancer research project. Preventive Medicine. 1995;24(5):447-53.

26. Brown SR, Nuno T, Joshweseoma L, Begay RC, Goodluck C, Harris RB, et al. Impact of a community-based breast cancer screening program on Hopi women. Preventive Medicine. 2011;52(5):390-3.

27. English KC, Fairbanks J, Finster CE, Rafelito A, Luna J, Kennedy M. A socioecological approach to improving mammography rates in a tribal community. Health Education & Behavior. 2008;35(3):396-409.

28. Ka'opua LS, Park SH, Ward ME, Braun KL. Testing the feasibility of a culturally tailored breast cancer screening intervention with Native Hawaiian women in rural churches. Health Soc Work. 2011;36(1):55-65.

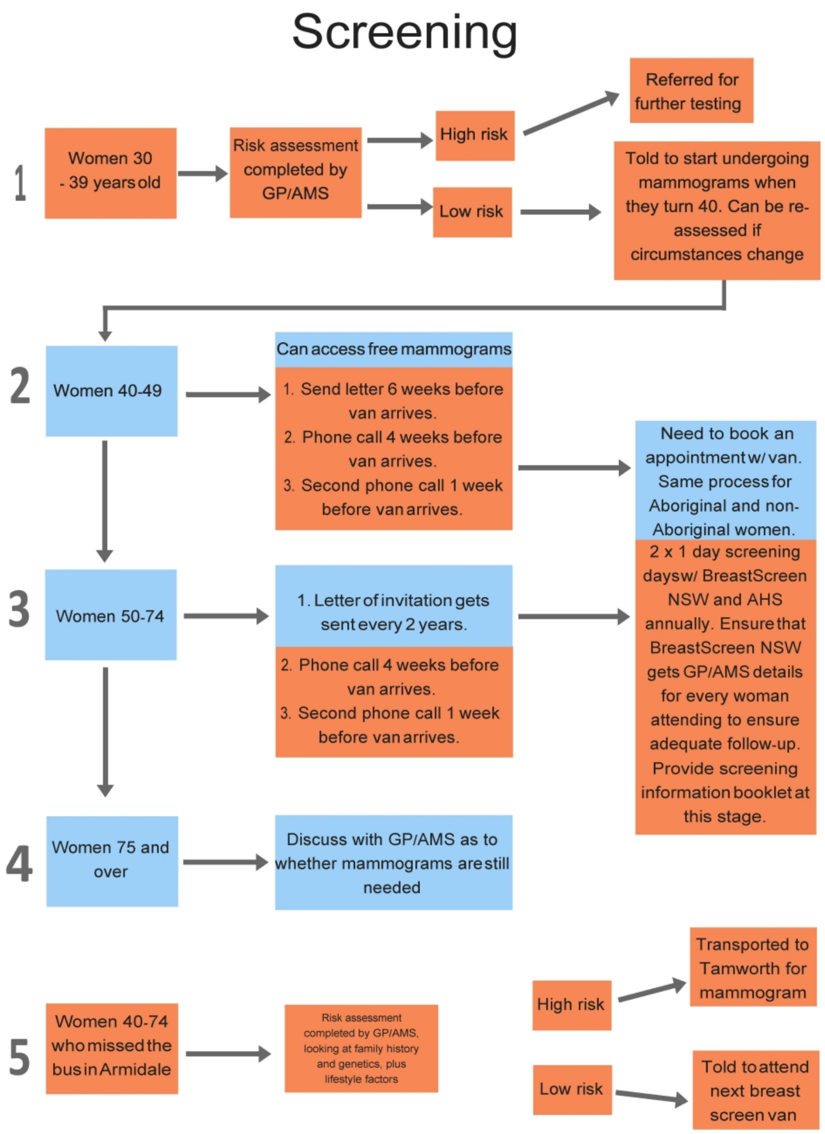
29. Strickland CJ, Hillaire E. Conducting a Feasibility Study in Women's Health Screening Among Women in a Pacific Northwest American Indian Tribe. Journal of Transcultural Nursing. 2016;27(1):42-8.

30. Kania J HF, & Splansky Juster J. Essential Mindset Shifts for Collective Impact. Stanford Social Innovation Review. 2014.

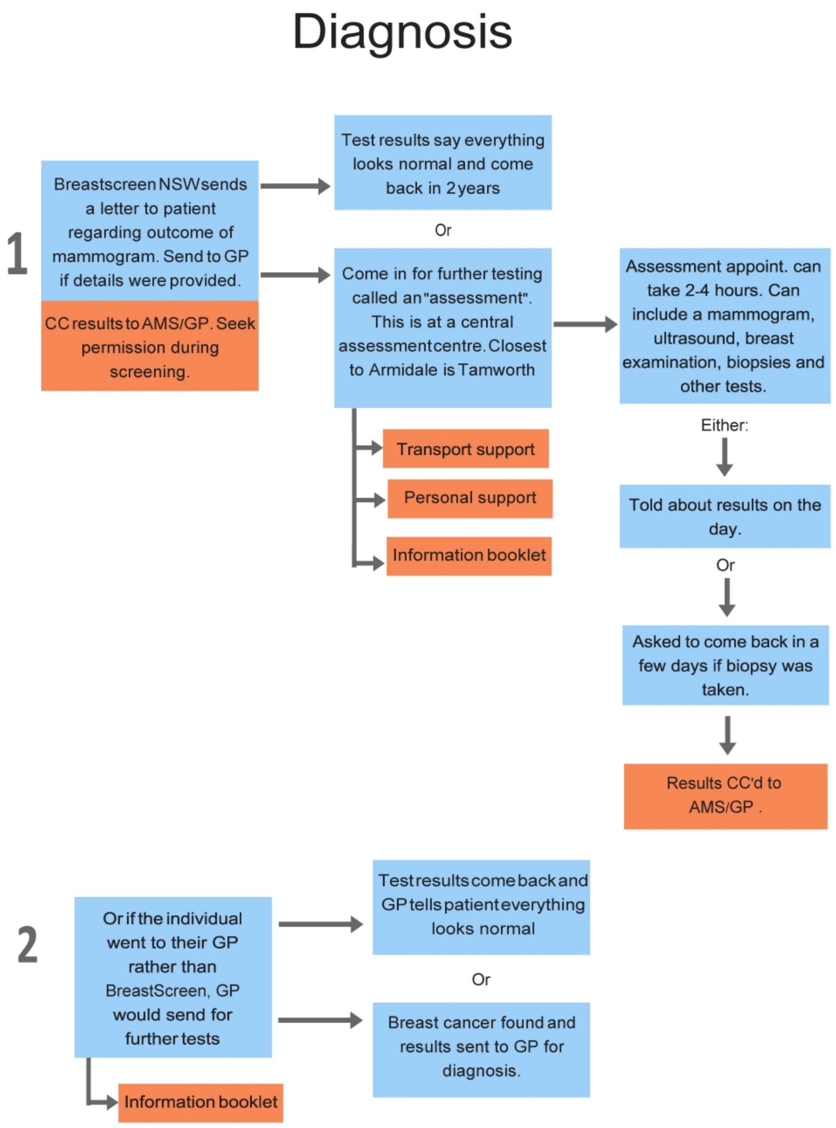
31. Care ACoSaQiH. Health literacy: Taking action to improve safety and quality. 2014.

32. Saldaña J. The coding manual for qualitative researchers / Johnny Saldaña. London: SAGE; 2009.

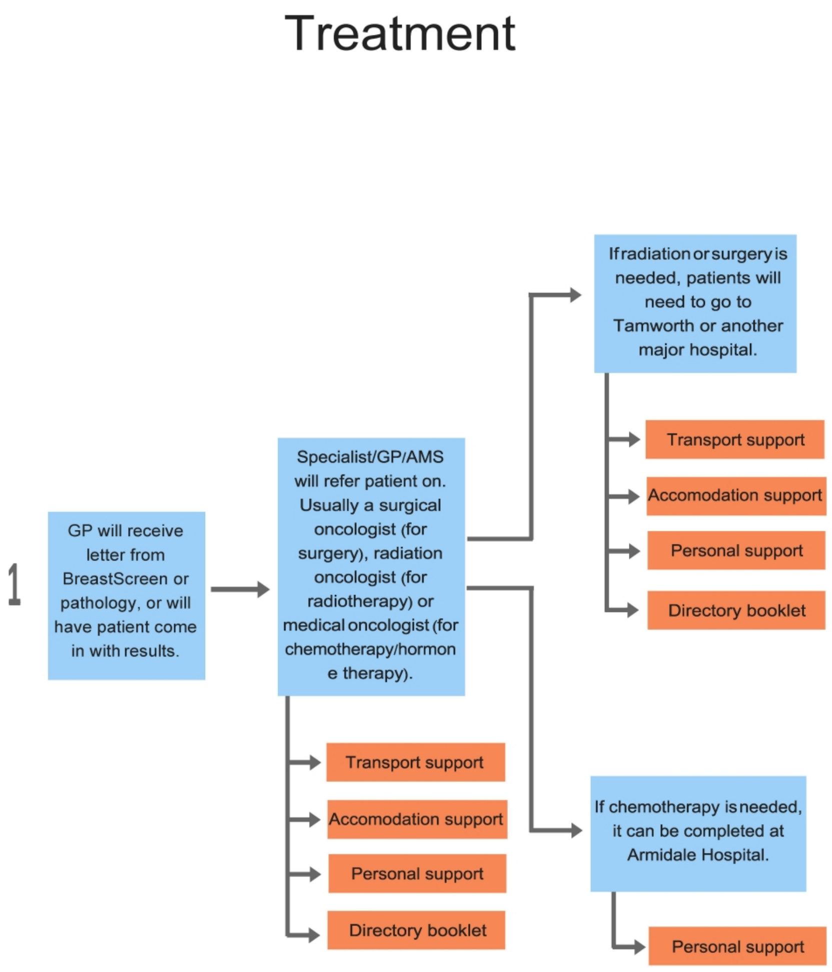
33. Hyett N, Kenny A, Dickson-Swift V. Methodology or method? A critical review of qualitative case study reports. Int J Qual Stud Health Well-being. 2014;9:23606.



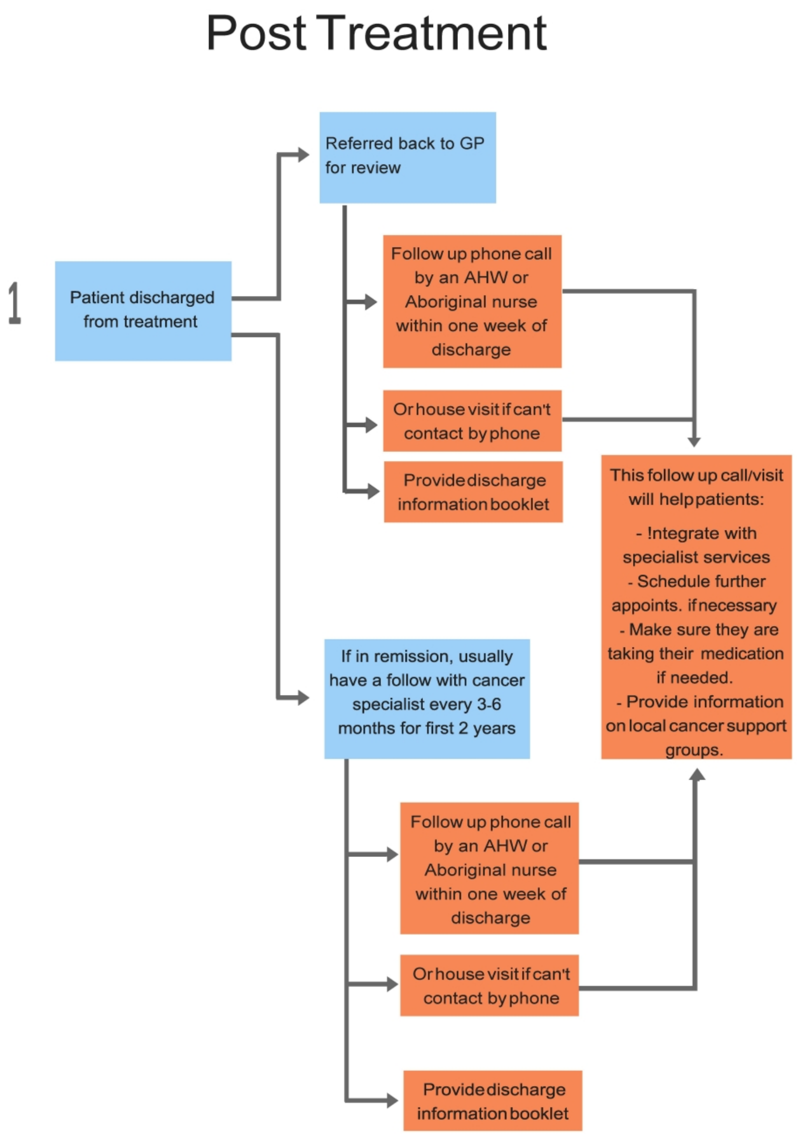
393x558mm (300 x 300 DPI)



394x558mm (300 x 300 DPI)

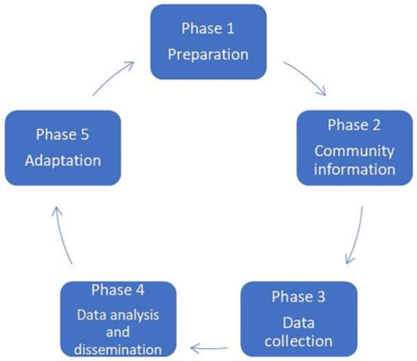


394x558mm (300 x 300 DPI)



394x558mm (300 x 300 DPI)

Figure 5



210x297mm (300 x 300 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 your 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

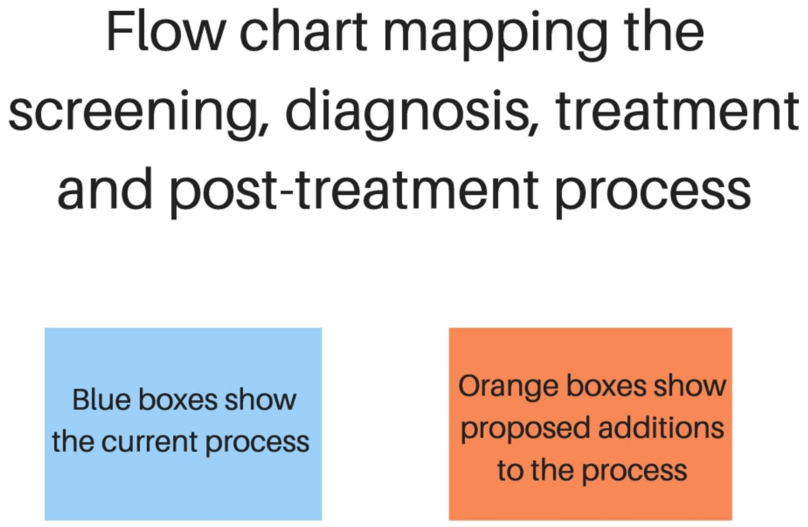
Questions for focus groups

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?

POST

Questions for community members

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



Key to figures

420x594mm (200 x 200 DPI)

BMJ Open

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

Journal:	*BMJ Open*
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

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.

<u>Methods and analysis:</u> 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.

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

'Strengths and limitations of this study'

- 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.

Introduction:

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

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

While age is the greatest risk factor for breast cancer, Aboriginal women are more likely to be younger than non-Aboriginal women at the time of diagnosis(9) and receive more invasive surgical treatment compared with their non-Aboriginal counterparts(10). It is well established in the literature that this association likely contributes to difficulty in engaging Aboriginal women in regular and timely follow-up monitoring and care(11)

There is a demonstrable need for improved screening, diagnostic and care pathways for Aboriginal women in Australia(12). The literature identifies numerous enabling factors and barriers which contribute to ease, or not, of access, timeliness, and quality of care for Aboriginal women with regard to breast cancer screening and services (13-23) .

Overwhelmingly, barriers are related to the lack of cultural safety within health services. Aboriginal women are apprehensive about utilising services due to recent or historical experiences of racism, lack of culturally safe care and a deficit of resources featuring culturally-appropriate educational and health promotion messages. Initiatives focused on resourcing community-led initiatives to raise awareness have been found to facilitate increased uptake and provide culturally safe care.(14, 15, 18, 19, 21, 24) This care involved Aboriginal Health Workers and highlights the importance of primary health care following diagnosis. Furthermore, individuals were less likely to engage in services as a consequence of previous experiences or the experiences of women they knew with mammography and breast cancer. Feelings of shame or stigma were also cited, as was the impact of financial barriers and geographical remoteness. (25)

There is a body of evidence surrounding initiatives aimed at increasing breast screening among Aboriginal women which indicates that success is highest where there are partnerships with Aboriginal community-controlled organisations(23). These initiatives implemented culturally-appropriate engagement strategies to address a range of social, cultural, personal and economic factors. An expanding evidence base supports the use of 'co-design' as a research methodology for the design, implementation, and evaluation of successful, cost-effective and sustainable strengths-based solutions to health challenges among Aboriginal communities(26).

Application of rigorous co-design methods to enhance breast cancer screening amongst Indigenous women internationally have been documented in the literature (27-31) but not extensively. We also note in the literature that low participation in follow up services, including anti-estrogen treatment (5) however, there is a need for more translational research utilising co-design methodology that partners with Aboriginal women, their communities and community-controlled health organisations to develop comprehensive ecological framework for addressing barriers and improving women's engagement in screening as well as follow-up diagnostic and breast cancer care services.

The codesign approach of the research team follows the five stages of the collective impact model. These include 1. Common agenda, 2. Shared measurement, 3. Mutually reinforcing activities, 4. Continuous communication and 5. Backbone support. This process provides a structured and shared process from conception, through to design, implementation and evaluation and increases the likelihood that health services will be utilized by Aboriginal people and that, as a result, health outcomes will improve.This approach has been validated with Aboriginal communities for translational health research.(26)

A preliminary mapping process co-designed with the communities in 2018 has informed this research. The Community Mapping Project (CMP) consisted of interviews with Aboriginal breast cancer survivors from local communities, staff from the local Aboriginal Health Service (AHS), and other breast cancer care providers. The CMP explored experiences, priorities and preferences, particularly from the survivors' perspectives. It was a comprehensive mapping of existing screening, diagnosis, treatment and post treatment service delivery, resulting in co-designed recommendations (see Table 1 below) to adjust the existing services and improve the pathway for Aboriginal women in the area. An important aspect of co-design is engaging with communities at the point the research is being conceptualised. This is well prior to ethics approval. The AHMRC requires letters of support from Aboriginal Community Controlled Health Services. The way we obtain these letters of support is by engaging in a process, in this case the CMP, to literally co-design the protocol. Once the protocol is approved by communities and then the AHMRC, we proceed to implementation of the research. It is not possible therefore to report the detailed discussions, interviews and process of the CMP beyond the output, shown in Figures 1-4, because ethics approval was obtained after the co-design process of the CMP was completed.

Table 1: Key recommendations 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

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

Aims and Objectives:

Primary objective:

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

Aim: improve communication and cultural safety of breast cancer prevention and treatment services or Aboriginal women.

Methods and analysis

Co-design

Co-design is a process of developing something with or alongside stakeholders or intended recipients or beneficiaries(26, 32).

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

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

Patient and Public Involvement

Fundamental to the co-design model is patient and public involvement, with community organisations and members involved in the conception, design, implementation and evaluation of the study.

Co-designed assessment and treatment pathway

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

Key to figures: (attached as an Image file)

Key: Blue boxes show the current process Orange boxes show the proposed additions to the process.

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

Through the CMP it was 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 was able to assess the burden of the research, 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 study and its progress and AHS staff who self-nominate will be investigators on the study. The Aboriginal Advisory Group will meet every month and the Investigators' Group every eight weeks. Data will be collected and owned and managed by the AHS and will be shared with Investigator group. Any publication will need to be approved by the Aboriginal Advisory Group and the AHMRC ethics committee. Members of the Investigators Group will continue to participate in 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. Qualitative methods will include semi-structured, in-depth interviews and focus group discussions. Structured quantitative and qualitative questionnaires will be used to assess participant satisfaction, as well as collect information about demographics, patient journey and clinical data.

Target population

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

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

Phases of implementation

The process of implementation is shown in Figure 5.

Phase 1: Preparation

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

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

Figure 5. Process of implementation

(attached as an Image file)

Phase 2: Community information

In our co-design process, ‘community information’ refers to both promoting the culturally safe screening events and providing relevant information to potential participants regarding the study. The local AHS staff and Investigator 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 written reminders 1 week out from the screening day date.

Screening and follow up will be undertaken according to the procedures described in Figures 1-4. The AHS will offer risk assessments for women between 30-39 years who will be referred on for screening and MRI if they are found to meet high risk criteria. 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, resources will be given to and support from the local Aboriginal Health Workers on next steps.
Additionally, there will be Aboriginal Health Workers acting as support staff if treatment is suggested, to inform affected women of the resources on offer and treatment pathways suggested. Women who partake in any part of the modified screening, diagnosis, treatment of follow up processes will be invited to join the study but there will be no consequences for their treatment or support if they elect not to participate.

Phase 3: Data Collection and outcome measurement

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

be managed by the AHS. 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 additional services/modifications 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.

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

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

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

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

The study will quantitatively measure:

- 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)
- the participation rates of Aboriginal women in timely and culturally safe diagnostic, treatment and post-treatment services (over a one year period)

- 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)
- breast cancer health literacy among Aboriginal women in the local community (over a one year period)

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

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

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

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

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

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

The Australian Commission on Safety and Quality in Health Care definition of Health literacy is "about how people understand information about health and health care, and how they apply that information to their lives, use it to make decisions and act on it. Health literacy is important because it shapes people's health and the safety and quality of health care."(33) The way this study will assess health literacy will be through increase in participation of services (quantitative data collection) and also a self-reported increase in understanding about breast cancer and the options for screening, diagnosis, treatment and follow up care (via qualitative focus group discussion).

Safety considerations

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

Phase 4: Data analysis and dissemination

Data analysis plan

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

Returning results to the community

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

Results will be published in peer reviewed journals and presented at professional conferences. The AHS participating in the study will be invited to contribute to these publications and presentations. We will acknowledge the sources of information and those who have contributed to the research through authorship and acknowledgement in resulting publications, meetings with community members and conference presentations. We will also acknowledge the cultural property rights of Aboriginal peoples in relation to knowledge, ideas, cultural expressions and cultural materials by including AHS representatives as research team members.

Phase 5: Adaptation

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

Corresponding author:
Vita Christie
E: vita.christie@sydney.edu.au
T: 0403 709 178 F: 02 9351 3196
A: 225 Edward Ford Building A27, The University of Sydney NSW 2006

Authors' contributions:
Conception and design of the study - KG, DG, DM, MR, VC
Planning- VC, KG, JD, DG
Governance and scientific advice – KG, CP, JA DM, DG, VC
Conduct and reporting: VC, KG, DG
Drafting the Manuscript – VC, MR, KG, JD
Review and approval of the manuscript – VC, KG, JA, DG, KL, CP, DM, JD

Funding statement:
This work was supported by the Foundation for Breast Cancer Care grant no. 20202716 (Macquarie University)

Competing interests statement.
None

Acknowledgements:

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

Full references:

1. Health AIo, Welfare. Cancer in Australia 2019. Canberra: AIHW; 2019.
2. Health AIo, Welfare. BreastScreen Australia monitoring report 2018. Canberra: AIHW; 2018.
3. Health AIo, Welfare. Cancer in Aboriginal & Torres Strait Islander people of Australia. Canberra: AIHW; 2018.
4. Read DJ, Frentzas S, Ward L, De Ieso P, Chen S, Devi V. Do histopathological features of breast cancer in Australian Indigenous women explain the survival disparity? A two decade long study in the Northern Territory. Asia-Pacific journal of clinical oncology. 2020.
5. Redfern AD, Fong JJ, Spalding LJ, Loi S, Dessauvagie B, Harvey J, et al. Abstract P5-04-18: Unfavourable tumour stromal immune cell infiltrates but not circulating immune cell profiles in Aboriginal women with breast cancer. Cancer Research. 2020;80(4 Supplement):P5-04-18.
6. Moore SP, Soerjomataram I, Green AC, Garvey G, Martin J, Valery PC. Breast cancer diagnosis, patterns of care and burden of disease in Queensland, Australia (1998-2004): does being Indigenous make a difference? Int J Public Health. 2016;61(4):435-42.
7. Tapia KA, Garvey G, Mc Entee M, Rickard M, Brennan P. Breast Cancer in Australian Indigenous Women: Incidence, Mortality, and Risk Factors. Asian Pacific journal of cancer prevention : APJCP. 2017;18(4):873-84.

8. Roder D, Webster F, Zorbas H, Sinclair S. Breast screening and breast cancer survival in Aboriginal and Torres Strait Islander women of Australia. Asian Pacific Journal of Cancer Prevention. 2012;13(1):147-55.

9. Dasgupta P, Baade PD, Youlden DR, Garvey G, Aitken JF, Wallington I, et al. Variations in outcomes for Indigenous women with breast cancer in Australia: A systematic review. European Journal of Cancer Care. 2017;26(6):e12662.

10. Banham D, Roder D, Keefe D, Farshid G, Eckert M, Howard N, et al. Disparities in breast screening, stage at diagnosis, cancer treatment and the subsequent risk of cancer death: a retrospective, matched cohort of aboriginal and non-aboriginal women with breast cancer. BMC Health Services Research. 2019;19(1):387.

11. Christie V, Green D, Amin J, Pyke C, Littlejohn K, Skinner J, et al. What Is the Evidence Globally for Culturally Safe Strategies to Improve Breast Cancer Outcomes for Indigenous Women in High Income Countries? A Systematic Review. International Journal of Environmental Research and Public Health. 2021;18(11).

12. Thompson SC. Indigenous women and breast cancer. Medical Journal of Australia. 2009;190(10):602-.

13. Hedges S, Davidson M, Forrester S, Casey A, Pridmore V, Cooper A, et al. A Breast Screening Shawl to Help Aboriginal Women Feel More Comfortable and Culturally Safe. Journal of Global Oncology. 2018;4(Supplement 2):40s-s.

14. McMichael C, Kirk M, Manderson L, Hoban E, Potts H. Indigenous women's perceptions of breast cancer diagnosis and treatment in Queensland. Australian and New Zealand Journal of Public Health. 2000;24(5):515-9.

15. Fox W, Powell M, Hyland V, Honeyball F, editors. Supportive care for women with breast cancer living in rural Australia. Cancer Forum; 2017: The Cancer Council Australia.

16. 'Orchid' Breastscreen Queensland's New 4WD Digital Mobile Service. 2010-08;34(5):39.

17. Campbell J, Kurnoth P. Well women making a diffence: evaluation report and program guide. Darwin: Women's Cancer Prevention Program, Department of Health and Community Services, Northern Territory Government; 2000.

18. Pilkington L, Haigh MM, Durey A, Katzenellenbogen JM, Thompson SC. Perspectives of Aboriginal women on participation in mammographic screening: a step towards improving services. BMC public health. 2017;17(1):697.

19. Reath J, Carey M. Breast and cervical cancer in Indigenous women: overcoming barriers to early detection. Australian Family Physician. 2008;37(3):178.

20. Supramaniam R, Gibberd A, Dillon A, Goldsbury DE, O'Connell DL. Increasing rates of surgical treatment and preventing comorbidities may increase breast cancer survival for Aboriginal women. BMC Cancer. 2014;14(1):163.

21. Byers L, Michell K, McCullough K. Awareness, acceptability and access to screening mammography for remote Aboriginal women. Health Promotion Journal of Australia. 2018;29(3):366.

22. Byers L, Michell K, McCullough K. Awareness, acceptability and access to screening mammography for remote Aboriginal women. Health Promot J Austr. 2018;29(3):366-7.

23. Reath J, Carey M. Breast and cervical cancer in indigenous women-overcoming barriers to early detection. Aust Fam Physician. 2008;37(3):178-82.

24. Hedges S, Davidson M, Forrester S, Casey A, Pridmore V, Cooper A, et al. A breast screening shawl to help Aboriginal women feel more comfortable and culturally safe. American Society of Clinical Oncology; 2018.

25. Valery PC, Bernardes CM, de Witt A, Martin J, Walpole E, Garvey G, et al. Patterns of primary health care service use of Indigenous Australians diagnosed with cancer. Support Care Cancer. 2020;28(1):317-27.

26. Gwynne K. Applying Collective Impact to Wicked Problems in Aboriginal Health. Metropolitan Universities. 2017;28:115.

27. Banner RO, DeCambra H, Enos R, Gotay C, Hammond OW, Hedlung N, et al. A breast and cervical cancer project in a native Hawaiian community: Wai'anae cancer research project. Prev Med. 1995;24(5):447-53.

28. Brown SR, Nuno T, Joshweseoma L, Begay RC, Goodluck C, Harris RB, et al. Impact of a community-based breast cancer screening program on Hopi women. Prev Med. 2011;52(5):390-3.

29. English KC, Fairbanks J, Finster CE, Rafelito A, Luna J, Kennedy M. A socioecological approach to improving mammography rates in a tribal community. Health Education & Behavior. 2008;35(3):396-409.

30. Ka'opua LS, Park SH, Ward ME, Braun KL. Testing the feasibility of a culturally tailored breast cancer screening intervention with Native Hawaiian women in rural churches. Health Soc Work. 2011;36(1):55-65.

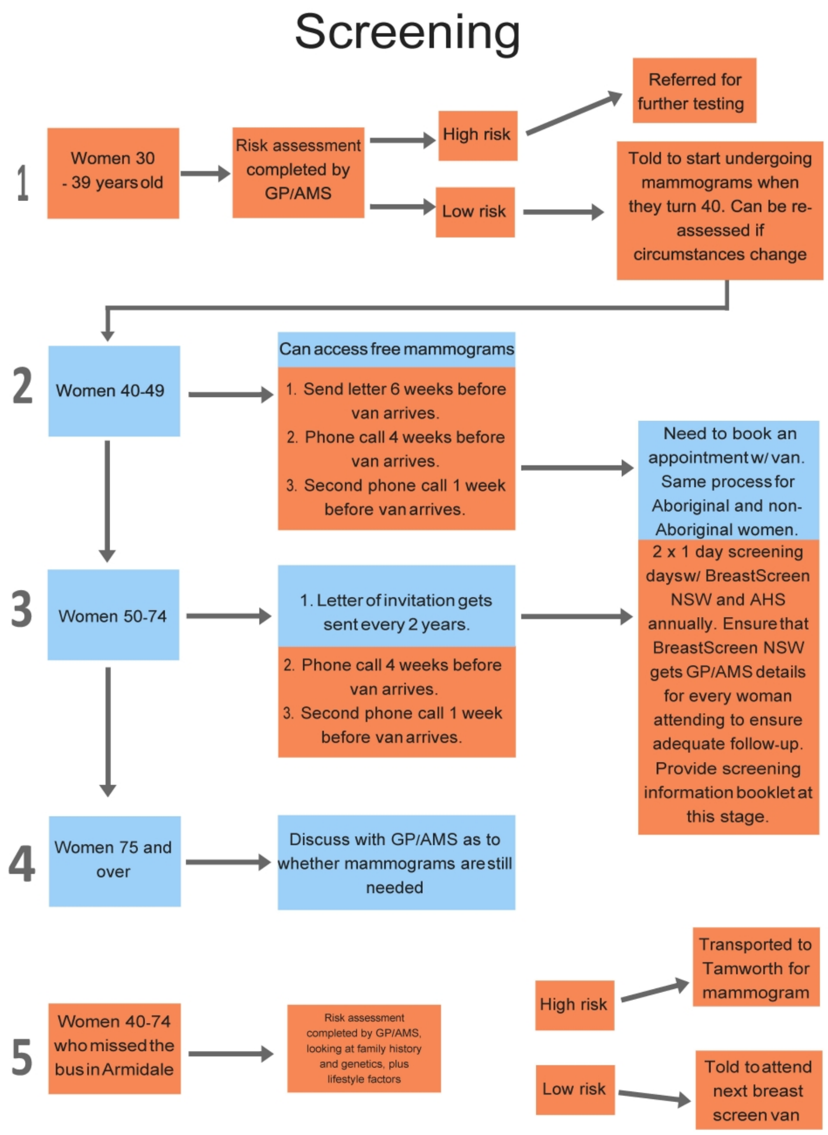
31. Strickland CJ, Hillaire E. Conducting a Feasibility Study in Women’s Health Screening Among Women in a Pacific Northwest American Indian Tribe. Journal of Transcultural Nursing. 2016;27(1):42-8.

32. Kania J HF, & Splansky Juster J. Essential Mindset Shifts for Collective Impact. Stanford Social Innovation Review. 2014.

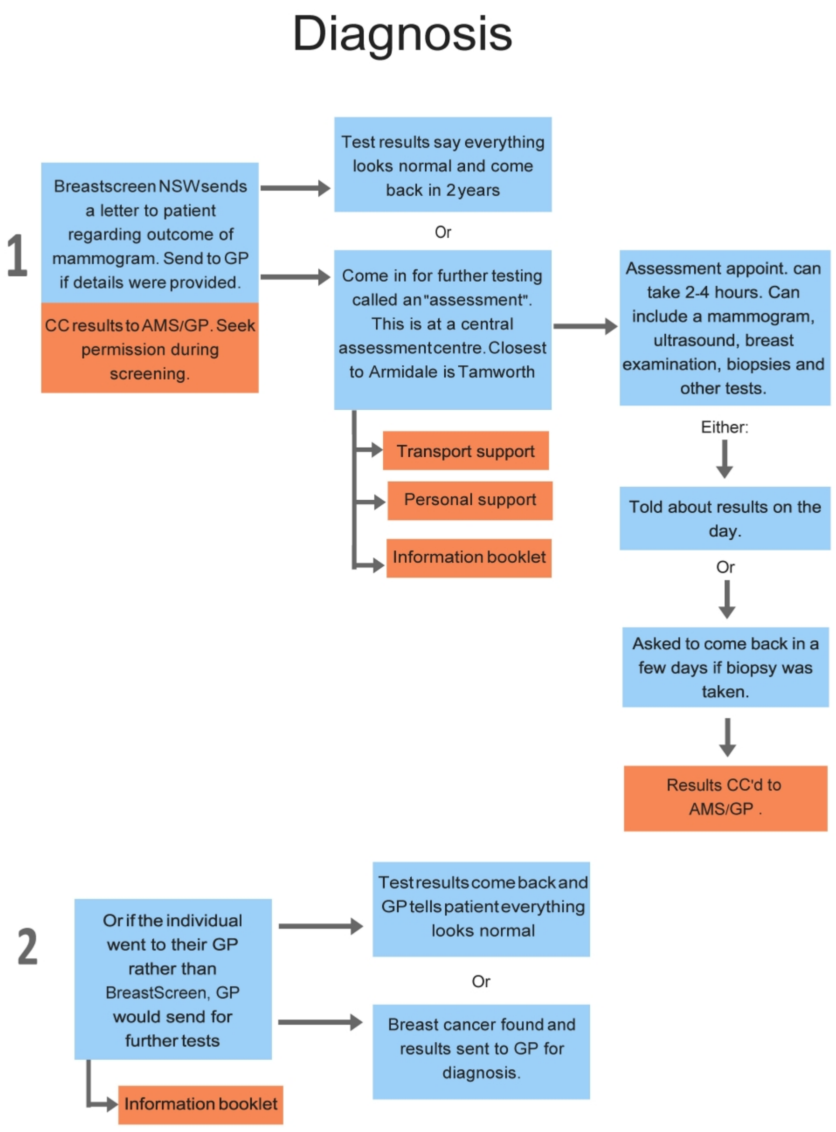
33. Care ACoSaQiH. Health literacy: Taking action to improve safety and quality. 2014.

34. Saldaña J. The coding manual for qualitative researchers / Johnny Saldaña. London: SAGE; 2009.

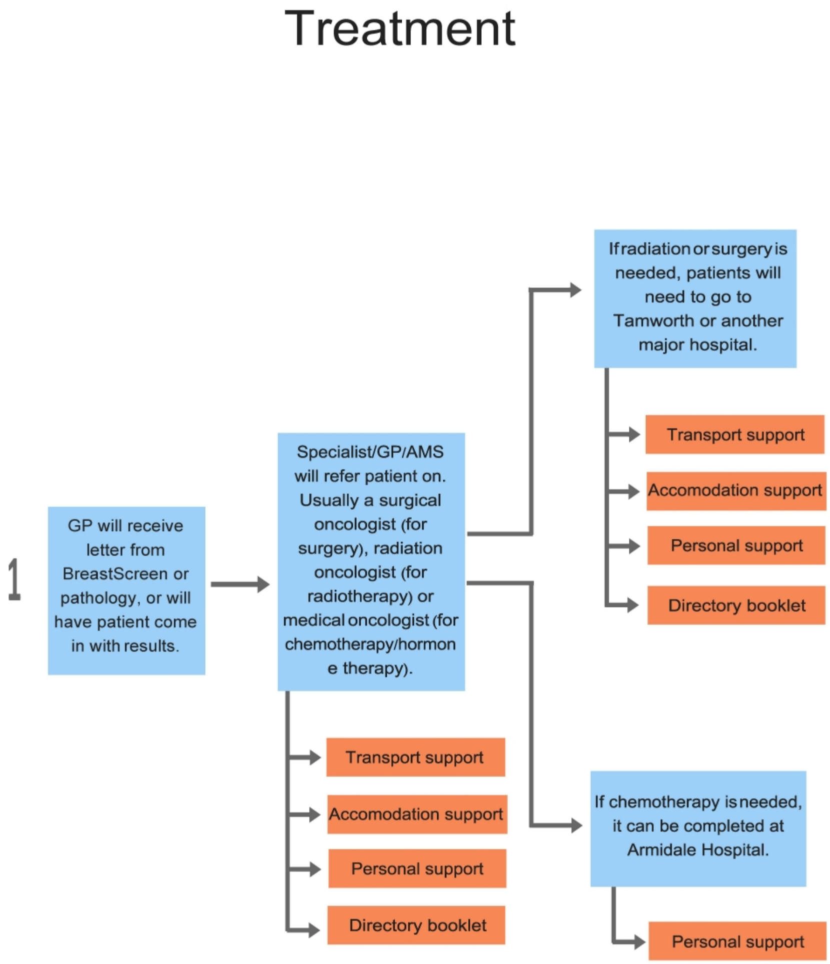
35. Hyett N, Kenny A, Dickson-Swift V. Methodology or method? A critical review of qualitative case study reports. Int J Qual Stud Health Well-being. 2014;9:23606.



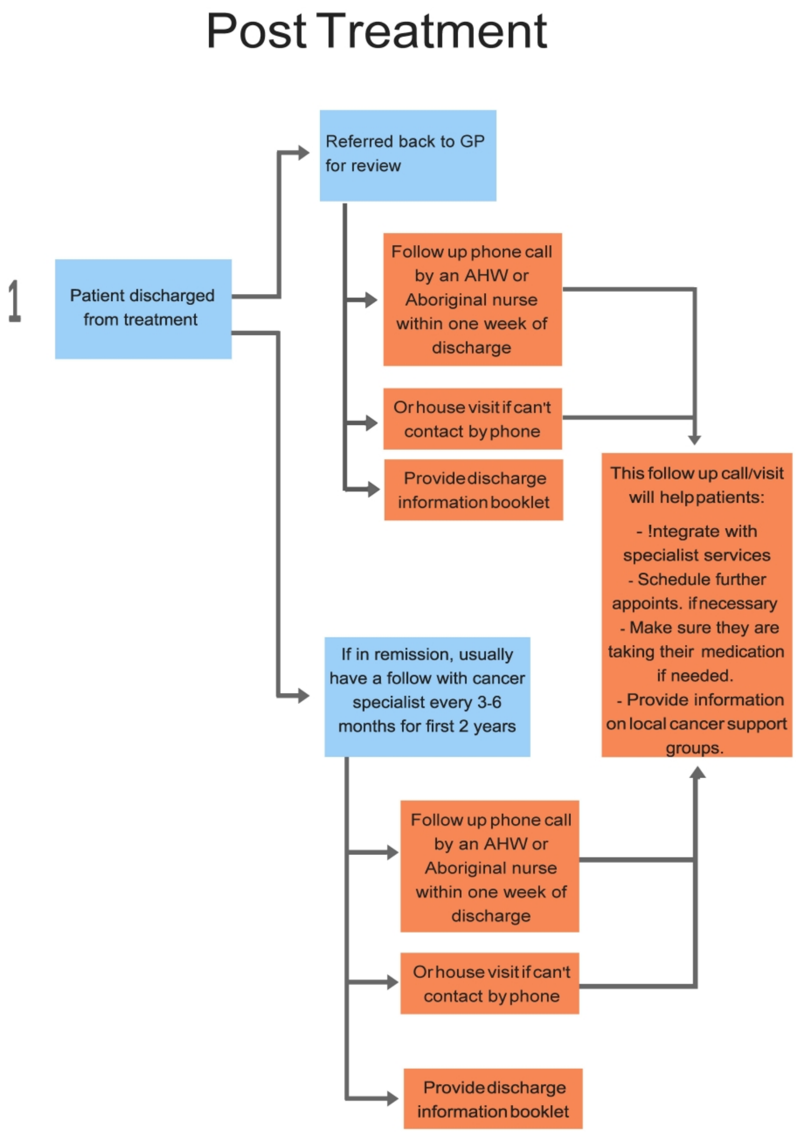
394x558mm (300 x 301 DPI)



394x558mm (300 x 300 DPI)

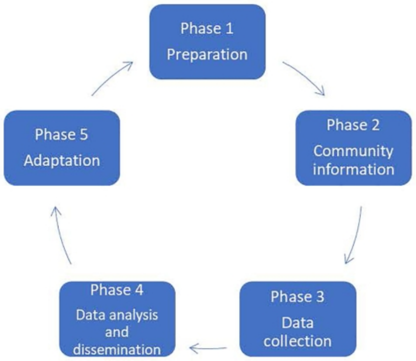


394x558mm (300 x 300 DPI)



394x558mm (300 x 300 DPI)

Figure 5



210x297mm (300 x 300 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 your 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

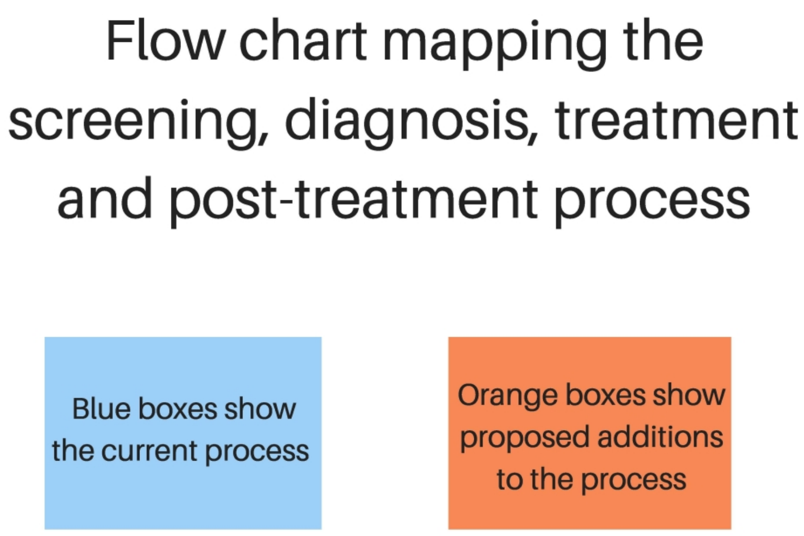
Questions for focus groups

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?

POST

Questions for community members

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



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:	*BMJ Open*
Manuscript ID	bmjopen-2020-048003.R4
Article Type:	Protocol
Date Submitted by the Author:	15-Dec-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

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.

<u>Methods and analysis:</u> 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.

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

'Strengths and limitations of this study'

- 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.

Introduction:

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

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

While age is the greatest risk factor for breast cancer, Aboriginal women are more likely to be younger than non-Aboriginal women at the time of diagnosis(10) and receive more invasive surgical treatment compared with their non-Aboriginal counterparts(11). It is well established in the literature that this association likely contributes to difficulty in engaging Aboriginal women in regular and timely follow-up monitoring and care(12).

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

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

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

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

The codesign approach of the research team follows the five stages of the collective impact model. These include 1. Common agenda, 2. Shared measurement, 3. Mutually reinforcing activities, 4. Continuous communication and 5. Backbone support. This process provides a structured and shared process from conception, through to design, implementation and evaluation and increases the likelihood that health services will be utilized by Aboriginal people and that, as a result, health outcomes will improve.This approach has been validated with Aboriginal communities for translational health research.(27)

A preliminary mapping process co-designed with the communities in 2018 has informed this research. The Community Mapping Project (CMP) consisted of interviews with five Aboriginal breast cancer survivors from local communities, plus staff, clients and families of both from the local Aboriginal Health Service (AHS), the Advisory Committee of the AHS and other breast cancer care providers, including staff at the local oncology unit. The CMP explored experiences, priorities and preferences, particularly from the survivors' perspectives. It was a comprehensive mapping of existing screening, diagnosis, treatment and post treatment service delivery, resulting in co-designed recommendations to adjust the existing services and improve the pathway for Aboriginal women in the area. A draft patient journey and proposed modifications was drafted and checked with some members of the local community including a local women's group and one on one interactions.. It was then presented to the clinicians from the Foundation for Breast Cancer Care, who provided input to the clinical pathways.

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

Table 1: Key recommendations 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

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

Aims and Objectives:

Primary objective:

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

Aim: improve communication and cultural safety of breast cancer prevention and treatment services or Aboriginal women.

Methods and analysis

Co-design

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

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

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

Patient and Public Involvement

Fundamental to the co-design model is patient and public involvement, with community organisations and members involved in the conception, design, implementation and evaluation of the study.

Co-designed assessment and treatment pathway

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

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

Figure 2 Screening services (attached as Image file)

Figure 3 Diagnostic services (attached as Image file)

Figure 4 Treatment services (attached as an Image file)

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

Governance

Through the CMP it was 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 was able to assess the burden of the research, 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 study and its progress and AHS staff who self-nominate will be investigators on the study. The Aboriginal Advisory Group will meet every month and the Investigators' Group every eight weeks. Data will be collected and owned and managed by the AHS and will be shared with Investigator group. Any publication will need to be approved by the Aboriginal Advisory Group and the AHMRC ethics committee. Members of the Investigators Group will continue to participate in 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. Qualitative methods will include semi-structured, in-depth interviews and focus group discussions. Structured quantitative and qualitative questionnaires will be used to assess participant satisfaction, as well as collect information about demographics, patient journey and clinical data.

Target population

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

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

Phases of implementation

The process of implementation is shown in Figure 6.

Phase 1: Preparation

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

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

Figure 6. Process of implementation

(attached as an Image file)

Phase 2: Community information

In our co-design process, 'community information' refers to both promoting the culturally safe screening events and providing relevant information to potential participants regarding the study. The local AHS staff and Investigator 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 written reminders 1 week out from the screening day date.

Screening and follow up will be undertaken according to the procedures described in Figures 1-5. The AHS will offer risk assessments for women between 30-39 years who will be referred on for screening and MRI if they are found to meet high risk criteria. 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, resources will be given to and support from the local Aboriginal Health Workers on next steps.
Additionally, there will be Aboriginal Health Workers acting as support staff if treatment is suggested, to inform affected women of the resources on offer and treatment pathways options. Women who partake in any part of the modified screening, diagnosis, treatment or follow up processes will be invited to join the study but there will be no consequences for their treatment or support if they elect not to participate. The AHS will invite all women who have survived breast cancer and registered with the health service to participate in focus groups.

Phase 3: Data Collection and outcome measurement

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

PIS 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.
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. The consent process will be managed by the AHS. 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 additional services/modifications 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.

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

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

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

The study will quantitatively measure:

- 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)
- the participation rates of Aboriginal women in timely and culturally safe diagnostic, treatment and post-treatment services (over a one year period)
- 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)
- breast cancer health literacy among Aboriginal women in the local community (over a one year period)

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

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

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

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

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

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

The Australian Commission on Safety and Quality in Health Care definition of Health literacy is "about how people understand information about health and health care, and how they apply that information to their lives, use it to make decisions and act on it. Health literacy is important because it shapes people's health and the safety and quality of health care."(35) The way this study will assess health literacy will be through increase in participation of services (quantitative data collection) and also a self-reported increase in understanding about breast cancer and the options for screening, diagnosis, treatment and follow up care (via qualitative focus group discussion).

Safety considerations

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

Phase 4: Data analysis and dissemination

Data analysis plan

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

Returning results to the community

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

Results will be published in peer reviewed journals and presented at professional conferences. The AHS participating in the study will be invited to contribute to these publications and presentations. We will acknowledge the sources of information and those who have contributed to the research through authorship and acknowledgement in resulting publications, meetings with community members and conference presentations. We will also acknowledge the cultural property rights of Aboriginal peoples in relation to knowledge, ideas, cultural expressions and cultural materials by including AHS representatives as research team members.

Phase 5: Adaptation

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

Corresponding author:
Vita Christie
E: vita.christie@sydney.edu.au
T: 0403 709 178 F: 02 9351 3196
A: 225 Edward Ford Building A27, The University of Sydney NSW 2006

Authors' contributions:
Conception and design of the study - KG, DG, DM, MR, VC
Planning- VC, KG, JD, DG
Governance and scientific advice – KG, CP, JA DM, DG, VC
Conduct and reporting: VC, KG, DG
Drafting the Manuscript – VC, MR, KG, JD
Review and approval of the manuscript – VC, KG, JA, DG, KL, CP, DM, JD

Funding statement:
This work was supported by the Foundation for Breast Cancer Care grant no. 20202716 (Macquarie University)

Competing interests statement.

None

Acknowledgements:

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

Full references:

1. Health AIo, Welfare. Cancer in Australia 2019. Canberra: AIHW; 2019.
2. Health AIo, Welfare. BreastScreen Australia monitoring report 2018. Canberra: AIHW; 2018.
3. Health AIo, Welfare. Cancer in Aboriginal & Torres Strait Islander people of Australia. Canberra: AIHW; 2018.
4. Read DJ, Frentzas S, Ward L, De Ieso P, Chen S, Devi V. Do histopathological features of breast cancer in Australian Indigenous women explain the survival disparity? A two decade long study in the Northern Territory. Asia-Pacific journal of clinical oncology. 2020.
5. Redfern AD, Fong JJ, Spalding LJ, Loi S, Dessauvagie B, Harvey J, et al. Abstract P5-04-18: Unfavourable tumour stromal immune cell infiltrates but not circulating immune cell profiles in Aboriginal women with breast cancer. Cancer Research. 2020;80(4 Supplement):P5-04-18.

6. Redfern AD, Spalding LJ, Lee EYC, Redfern CF, Pilkington L, Bulsara M, et al. Abstract P2-10-09: Aggressive tumour biology contributes to poor breast cancer outcomes for indigenous Australians. Cancer Research. 2020;80(4 Supplement):P2-10-09.

7. Moore SP, Soerjomataram I, Green AC, Garvey G, Martin J, Valery PC. Breast cancer diagnosis, patterns of care and burden of disease in Queensland, Australia (1998-2004): does being Indigenous make a difference? Int J Public Health. 2016;61(4):435-42.

8. Tapia KA, Garvey G, Mc Entee M, Rickard M, Brennan P. Breast Cancer in Australian Indigenous Women: Incidence, Mortality, and Risk Factors. Asian Pacific journal of cancer prevention : APJCP. 2017;18(4):873-84.

9. Roder D, Webster F, Zorbas H, Sinclair S. Breast screening and breast cancer survival in Aboriginal and Torres Strait Islander women of Australia. Asian Pacific Journal of Cancer Prevention. 2012;13(1):147-55.

10. Dasgupta P, Baade PD, Youlden DR, Garvey G, Aitken JF, Wallington I, et al. Variations in outcomes for Indigenous women with breast cancer in Australia: A systematic review. European Journal of Cancer Care. 2017;26(6):e12662.

11. Banham D, Roder D, Keefe D, Farshid G, Eckert M, Howard N, et al. Disparities in breast screening, stage at diagnosis, cancer treatment and the subsequent risk of cancer death: a retrospective, matched cohort of aboriginal and non-aboriginal women with breast cancer. BMC Health Services Research. 2019;19(1):387.

12. Christie V, Green D, Amin J, Pyke C, Littlejohn K, Skinner J, et al. What Is the Evidence Globally for Culturally Safe Strategies to Improve Breast Cancer Outcomes for Indigenous Women in High Income Countries? A Systematic Review. International Journal of Environmental Research and Public Health. 2021;18(11).

13. Thompson SC. Indigenous women and breast cancer. Medical Journal of Australia. 2009;190(10):602-.

14. Hedges S, Davidson M, Forrester S, Casey A, Pridmore V, Cooper A, et al. A Breast Screening Shawl to Help Aboriginal Women Feel More Comfortable and Culturally Safe. Journal of Global Oncology. 2018;4(Supplement 2):40s-s.

15. McMichael C, Kirk M, Manderson L, Hoban E, Potts H. Indigenous women's perceptions of breast cancer diagnosis and treatment in Queensland. Australian and New Zealand Journal of Public Health. 2000;24(5):515-9.

16. Fox W, Powell M, Hyland V, Honeyball F, editors. Supportive care for women with breast cancer living in rural Australia. Cancer Forum; 2017: The Cancer Council Australia.

17. 'Orchid' Breastscreen Queensland's New 4WD Digital Mobile Service. 2010-08;34(5):39.

18. Campbell J, Kurnoth P. Well women making a diffence: evaluation report and program guide. Darwin: Women's Cancer Prevention Program, Department of Health and Community Services, Northern Territory Government; 2000.

19. Pilkington L, Haigh MM, Durey A, Katzenellenbogen JM, Thompson SC. Perspectives of Aboriginal women on participation in mammographic screening: a step towards improving services. BMC public health. 2017;17(1):697.

20. Reath J, Carey M. Breast and cervical cancer in Indigenous women: overcoming barriers to early detection. Australian Family Physician. 2008;37(3):178.

21. Supramaniam R, Gibberd A, Dillon A, Goldsbury DE, O'Connell DL. Increasing rates of surgical treatment and preventing comorbidities may increase breast cancer survival for Aboriginal women. BMC Cancer. 2014;14(1):163.

22. Byers L, Michell K, McCullough K. Awareness, acceptability and access to screening mammography for remote Aboriginal women. Health Promotion Journal of Australia. 2018;29(3):366.

23. Byers L, Michell K, McCullough K. Awareness, acceptability and access to screening mammography for remote Aboriginal women. Health Promot J Austr. 2018;29(3):366-7.

24. Reath J, Carey M. Breast and cervical cancer in indigenous women-overcoming barriers to early detection. Aust Fam Physician. 2008;37(3):178-82.

25. Hedges S, Davidson M, Forrester S, Casey A, Pridmore V, Cooper A, et al. A breast screening shawl to help Aboriginal women feel more comfortable and culturally safe. American Society of Clinical Oncology; 2018.

26. Valery PC, Bernardes CM, de Witt A, Martin J, Walpole E, Garvey G, et al. Patterns of primary health care service use of Indigenous Australians diagnosed with cancer. Support Care Cancer. 2020;28(1):317-27.

27. Gwynne K. Applying Collective Impact to Wicked Problems in Aboriginal Health. Metropolitan Universities. 2017;28:115.

28. Banner RO, DeCambra H, Enos R, Gotay C, Hammond OW, Hedlung N, et al. A breast and cervical cancer project in a native Hawaiian community: Wai'anae cancer research project. Prev Med. 1995;24(5):447-53.

29. Brown SR, Nuno T, Joshweseoma L, Begay RC, Goodluck C, Harris RB, et al. Impact of a community-based breast cancer screening program on Hopi women. Prev Med. 2011;52(5):390-3.

30. English KC, Fairbanks J, Finster CE, Rafelito A, Luna J, Kennedy M. A socioecological approach to improving mammography rates in a tribal community. Health Education & Behavior. 2008;35(3):396-409.

31. Ka'opua LS, Park SH, Ward ME, Braun KL. Testing the feasibility of a culturally tailored breast cancer screening intervention with Native Hawaiian women in rural churches. Health Soc Work. 2011;36(1):55-65.

32. Strickland CJ, Hillaire E. Conducting a Feasibility Study in Women’s Health Screening Among Women in a Pacific Northwest American Indian Tribe. Journal of Transcultural Nursing. 2016;27(1):42-8.

33. Redfern AD, Khan A, Spalding LJ, Martin H. Abstract P2-10-16: Breast cancer treatment patterns and outcomes for Australian women by indigenous status and remoteness of residence. Cancer Research. 2020;80(4 Supplement):P2-10-6.

34. Kania J HF, & Splansky Juster J. Essential Mindset Shifts for Collective Impact. Stanford Social Innovation Review. 2014.

35. Care ACoSaQiH. Health literacy: Taking action to improve safety and quality. 2014.

36. Saldaña J. The coding manual for qualitative researchers / Johnny Saldaña. London: SAGE; 2009.

37. Hyett N, Kenny A, Dickson-Swift V. Methodology or method? A critical review of qualitative case study reports. Int J Qual Stud Health Well-being. 2014;9:23606.

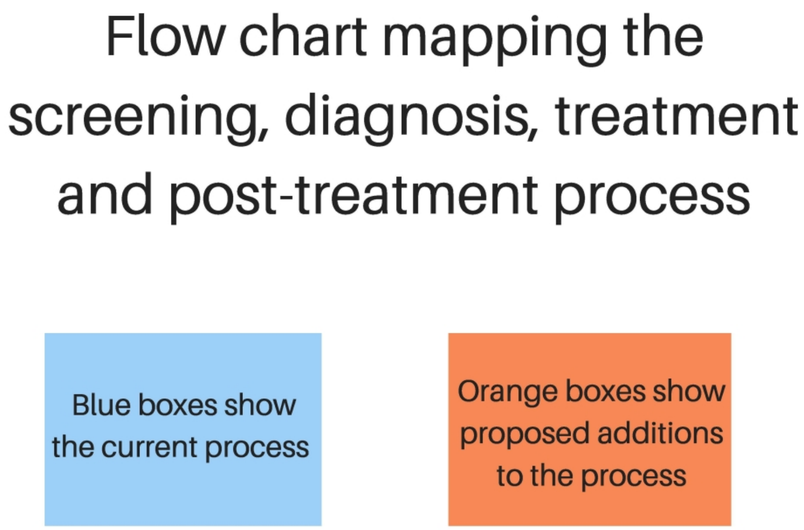


Figure 1 Key to flow chart (attached as Image file)

420x594mm (200 x 200 DPI)

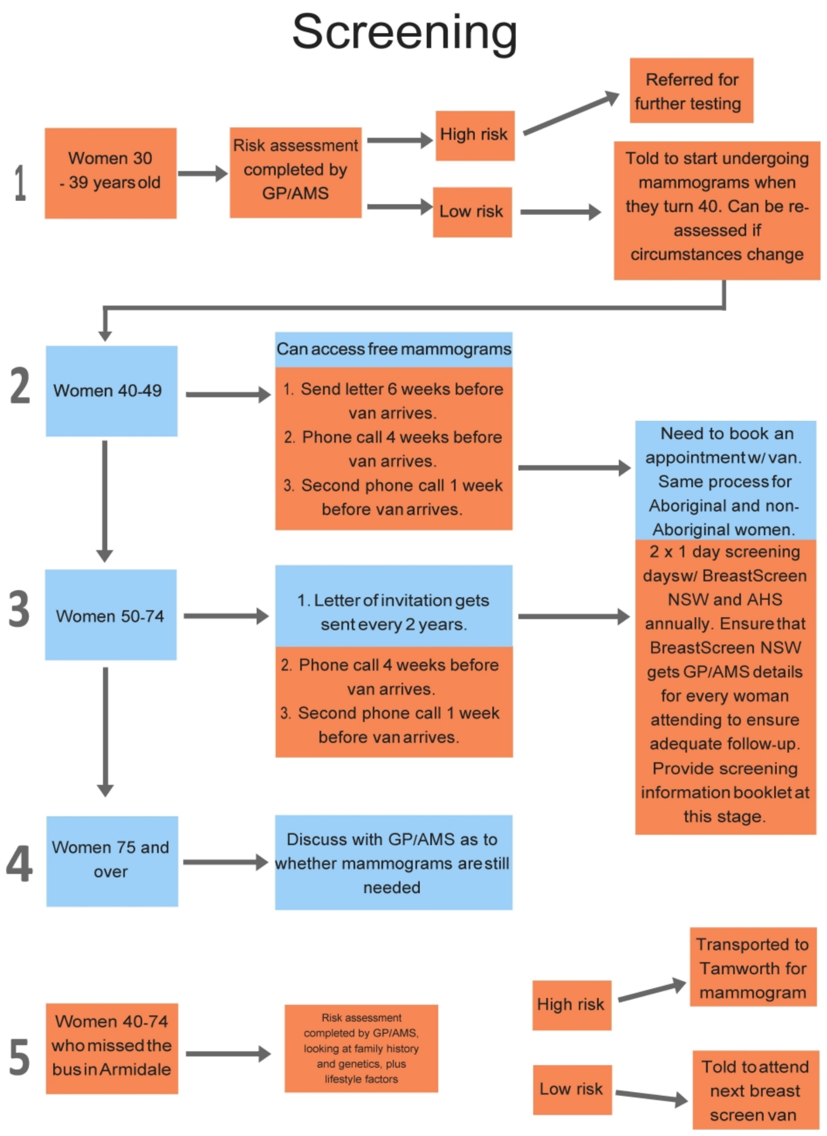


Figure 2 Screening services (attached as Image file)

393x558mm (300 x 300 DPI)

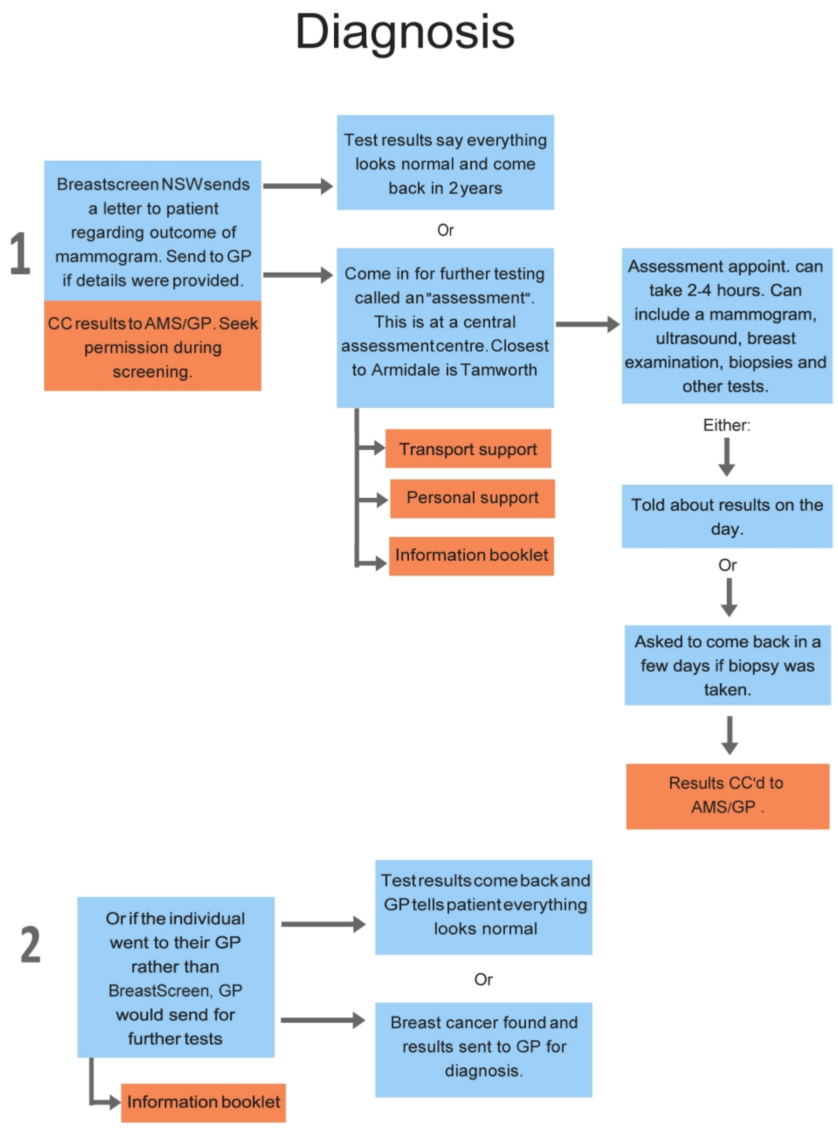
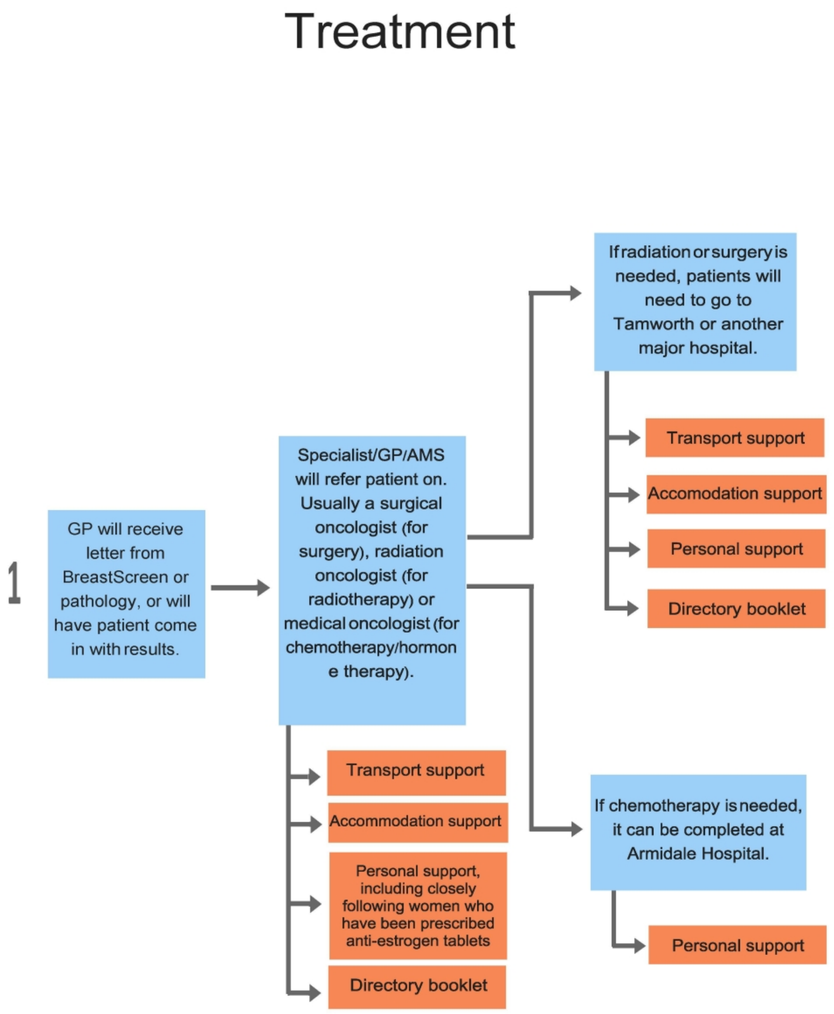


Figure 3 Diagnostic services (attached as Image file)

394x558mm (300 x 300 DPI)



GP will receive letter from BreastScreen or pathology, or will have patient come in with results.

Specialist/GP/AMS will refer patient on. Usually a surgical oncologist (for surgery), radiation oncologist (for radiotherapy) or medical oncologist (for chemotherapy/hormone therapy).

If radiation or surgery is needed, patients will need to go to Tamworth or another major hospital.

If chemotherapy is needed, it can be completed at Armidale Hospital.

Figure 4 Treatment services (attached as an Image file)

394x558mm (200 x 200 DPI)

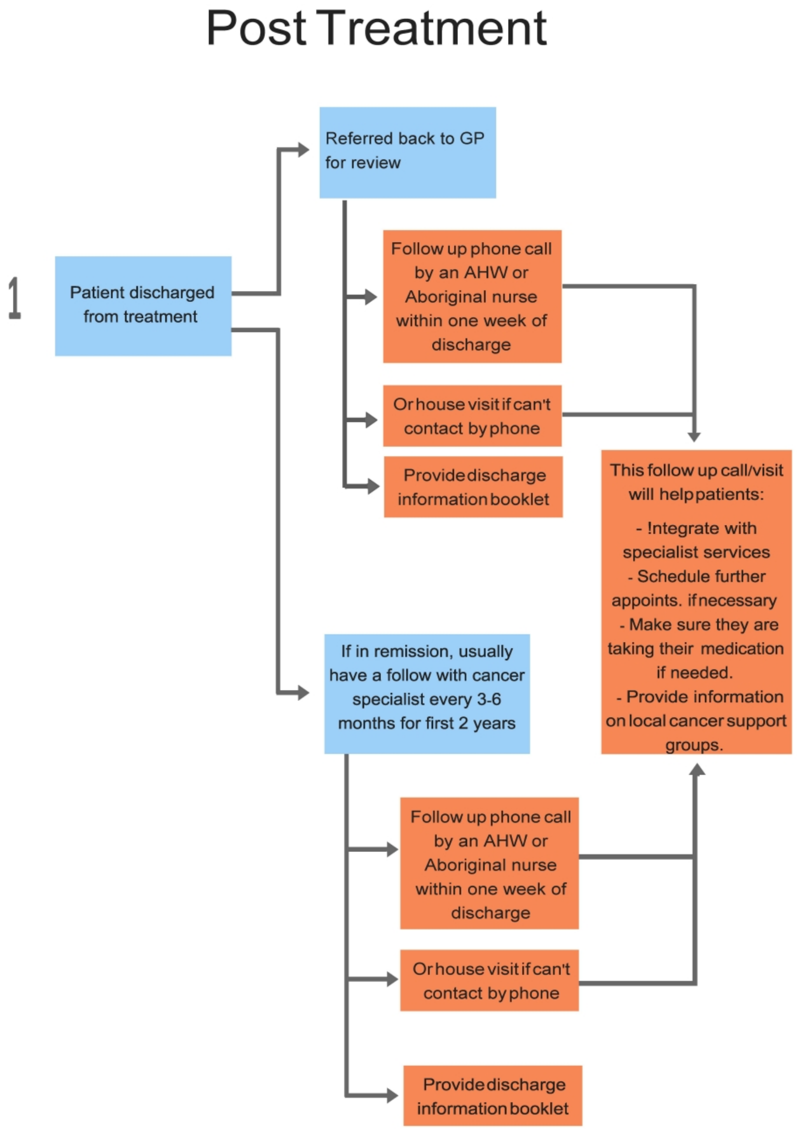


Figure 5 Post treatment services (attached as an Image file)

394x558mm (300 x 300 DPI)

Figure 5

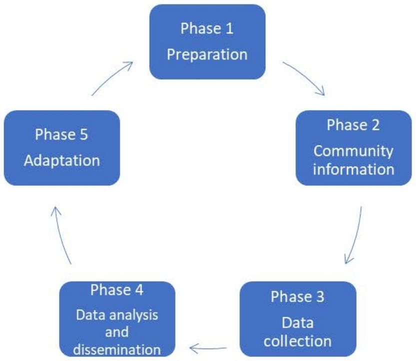


Figure 6. Process of implementation

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 your 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?

POST

Questions for community members

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