

Which way?

Gulibaa Project

STUDY PROTOCOL

Implementing and evaluating a state-wide, co-designed model of care to support Aboriginal and Torres Strait Islander women to be smoke and vape free

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Gulibaa Project: Study Information

Title: Gulibaa Project

Ethics: Ethical approval for the project will be obtained from the Aboriginal Health & Medical Research Council (AH&MRC) Human Research Ethics Committee (HREC) and registered with the University of Newcastle HREC (R-2024-0082).

Research Sites: This project will be conducted in participating Aboriginal Community Controlled Health Services (ACCHS) and non-Government health services across New South Wales (NSW).

Funding: The Gulibaa project has received \$2,085,549 in funding from the Medical Research Future Fund (MRFF) Maternal Health and Healthy Lifestyles Grant (MRF2022138).

Partners: This project will be conducted in partnership with AH&MRC and Aboriginal and Torres Strait Islander communities across NSW. Other key partners include: Lowitja Institute, NSW Health, Tobacco Endgame, and Tackling Indigenous Smoking (the National Best Practice Unit).

Governance: The project upholds Aboriginal community governance, including the governance of the data, through a Research Governance Committee. Project specific iterations of these have overseen the Which Way? project since inception. The Research Governance Committee is an inclusive Committee that will welcome representatives from all partnering sites as the project is implemented.



Artwork is the buraay (child) of Kennedy, nestled in a gulibaa on Wiradjuri country. Artwork created by Kennedy's mother Felicity, representing intergenerational connection to country and kin.

The Gulibaa Team: Roles and Responsibilities

Team member	Role
A/Prof Michelle Kennedy (Wiradjuri) ^{1,2}	Project lead. All aspects of the research, community governance, reporting and knowledge translation.
A/Prof Raglan Maddox (Bagumani/Modewa) ³	Co-lead data sovereignty and governance, data analysis and reporting. Investigator: Oversee and contribute to research implementation, data collection, analysis, and reporting.
Prof Alexandra Martiniuk (Inuit) ⁴	Investigator: Oversee and contribute to implementation, data collection, analysis, and reporting.
Prof Cath Chamberlain (Palawa) ⁵	Investigator: Oversee and contribute to implementation, data collection, analysis, and reporting.
Dr Jamie Bryant ^{1,2}	Investigator: Oversee and contribute to implementation, data collection, analysis, and reporting.
Prof Sandra Eades (Noongar) ⁵	Investigator: Oversee and contribute to implementation, data collection, analysis, and reporting.
A/Prof Luke Burchill (Yorta Yorta) ⁵	Investigator: Oversee and contribute to implementation, data collection, analysis, and reporting.
Dr Mary Belfrage ⁶	Investigator: Oversee and contribute to implementation, data collection, analysis, and reporting.
Mrs Jessica Bennett (Gamilaroi) ^{1,2,7}	Neonatal nurse/ PhD candidate. Investigator: Oversee and contribute to implementation, data collection, analysis, and reporting.
Dr Tameka McFadyen (Wonnaruah) ¹	Investigator: Oversee and contribute to implementation, data collection, analysis, and reporting.
Dr Kade Booth ^{1,2}	Research Fellow. Support research implementation, data collection, analysis, and reporting.
Dr Amanual Mersha ^{1,2}	Research Fellow: Support data collection, management and reporting
Professor Chris Doran ⁸	Lead Economic Evaluation
Mrs Joley Foster ^{1,2} (Worimi)	Tobacco Treatment Specialist. Which Way team member supporting implementation, governance, data collection, reporting, and translational activities.
Ms Zabowie Mills (Kaurag Clan) ^{1,2}	Psychology student. Which Way team member supporting implementation, governance, data collection, reporting, and translational activities.
Mr Raymond Kelly Jnr (Worimi/Dunghutti) ^{1,2}	Knowledge Translation lead Which Way team member supporting implementation, governance, data collection, reporting, and translational activities.
Mr Kayden Roberts-Barker (Wiradjuri) ^{1,2}	Social Science Graduate. Which Way team member supporting implementation, governance, data collection, reporting, and translational activities.
Ms Felicity Collis (Gomeri) ^{1,2}	Social Worker/PhD candidate. Which Way team member supporting implementation, governance, data collection, reporting, and translational activities.
Ms Sian Maidment (Noongar) ^{1,2}	Which Way team member supporting implementation, governance, data collection, reporting, and translational activities.
Dr Christopher Oldmeadow ^{1,2}	Investigator: Oversee and contribute to implementation, data collection, analysis, and reporting.
Nathan Taylor	AH&MRC representative

Affiliations: 1. University of Newcastle 2. Hunter Medical Research Institute 3. Australian National University 4. University of Sydney 5. University of Melbourne 6. Royal Australian College of General Practitioners 7. Hunter New England Health 8. Central Queensland University

Preface: The Which Way? research programme

The Gulibaa project is part of the broader Which Way? research programme, leading the development of Indigenous-led evidence for smoking and vaping cessation care. The Which Way? programme, led by A/Prof Michelle Kennedy, has been driving community-led research since 2019. The Which Way? programme currently includes:

1. Which Way? Quit Pack: mailout smoking and vaping cessation support package to Aboriginal and Torres Strait Islander people in NSW, VIC and ACT
2. Which Way? ELEVATE: Engaging Lessons Empowering Vape and Tobacco Endgame (*non-research*): Tackling Indigenous Smoking funded project developing and implementing youth programs to empower smoke and vape free generations, in partnership with Riverina Medical & Dental and Waminda South Coast Women's Health and Wellbeing Aboriginal Corporation.
3. Which Way? Women's Kits National Roll Out (*non-research*): Tackling Indigenous Smoking funded project developing and implementing women's smoking and vaping health promotion educational kits, in partnership with Waminda South Coast Women's Health and Wellbeing Aboriginal Corporation.
4. Which Way? Gulibaa Project (*this application*).

The Gulibaa project has been informed by long-standing relationships and work with and by Aboriginal and Torres Strait Islander women and community partners as evidenced through the continuing Which Way? research.

Publications from the Which Way? programme

The publications from past work by A/Prof Kennedy and partners which have informed this project can be found below. These findings have led the process to embed a co-designed model of care for and by Aboriginal and Torres Strait Islander women to empower them to make informed decisions around quitting smoking and vaping.

Publication details	Reference
Study protocol	(Kennedy) Bovill M, et al. Building an Indigenous-Led Evidence Base for Smoking Cessation Care among Aboriginal and Torres Strait Islander Women during Pregnancy and Beyond: Research Protocol for the Which Way? Project. <i>Int. J. Environ. Res. Public Health</i> 2021.
MJA Supplement and findings from national survey of Aboriginal and Torres Strait Islander women	Michelle Kennedy and Raglan Maddox, coordinating editors, Indigenous-led evidence to inform smoking cessation care for Aboriginal and Torres Strait Islander women. <i>Med J Aust.</i> 2022.
	Rahman, T... Kennedy, M. Factors Associated with Smoke-Free Pregnancy among Aboriginal and Torres Strait Women and Their Experience of Quitting Smoking in Pregnancy: A Mixed Method Cross-Sectional Study. <i>Int. J. Environ. Res. Public Health</i> 2021.
Yarning with Aboriginal women about smoking during pregnancy	(Kennedy) Bovill M. 'What ngidhi yinaaru nhal yayi (this woman told me) about smoking during pregnancy', <i>Med J Aust</i> , 2020.
National survey on web-based healthcare for Aboriginal and Torres Strait Islander women	Perkes SJ, ..., Kennedy M. 'Aboriginal and Torres Strait Islander Women s Access to and Interest in mHealth: National Web-based Cross-sectional Survey', <i>JMIR</i> , 2023.

Editorial with community partner on our research practice	Kennedy M & Longbottom H. Doing “deadly” community-based research during COVID-19: the Which Way? study <i>Med J Aust</i> 2022.
Results from survey of Aboriginal and Torres Strait Islander Health Workers and Practitioners	Kennedy M et al. Which Way? Indigenous-led Smoking Cessation Care: Knowledge, Attitudes and Practices of Aboriginal and Torres Strait Islander Health Workers and Practitioners – A National Cross-sectional Survey, <i>Nicotine Tob Res</i> , 2023.
	Mersha, A ... Kennedy, M. “It Needs a Full-Time Dedicated Person to Do This Job in Our Local Communities with Our Aboriginal Health Services”—Aboriginal and Torres Strait Islander Health Workers and Practitioners Perspectives on Supporting Smoking Cessation during Pregnancy. <i>Int. J. Environ. Res. Public Health</i> 2023.
Systematic review of group-based smoking cessation programs	Mersha AG ... Kennedy M. What are the effective components of group-based treatment programmes for smoking cessation? A systematic review and meta-analysis. <i>Nicotine Tob Res</i> . 2023.
Co-design publication (<i>under review</i>)	Kennedy M et al. Beyond co-design: Upholding sovereign knowing and community rights to develop a smoking and vaping cessation program for and by Aboriginal and Torres Strait Islander women. <i>Global Public Health</i> . 2024

Gulibaa Project Overview

The project is led by Wiradjuri woman, Michelle Kennedy. *Gulibaa* means Coolamon in Wiradjuri language, a vessel used for many things, but particularly for caring for our babies, keeping them safe and warm. The Gulibaa project is an Indigenous-led and community embedded project to co-design, implement and evaluate a model of care to support Aboriginal and Torres Strait Islander women to be smoke and vape-free. Embedding culturally safe support to quit smoking and vaping will result in improved outcomes for women, their children, and families, immediately improving intergenerational health and wellbeing.

The aim of the project is to reduce the prevalence of smoking among Aboriginal and Torres Strait Islander women by developing and implementing group-based smoking cessation care within services across NSW. Each phase of the project utilises Indigenist methodologies, centred on the lead researcher's standpoint as a Wiradjuri woman and mother, and draws on evidence of predictors for effective tobacco control with Indigenous people and an exemplar model of care. These methodologies have been central to the co-design process, developed with recognition of appropriate community timeframes and governance structures built on reciprocal lines of accountability.

This project has been informed by over 5 years of research undertaken within two previous AH&MRC approved projects:

1. [2170/23: Which Way? Smoking Cessation](#)
2. [1603/19: Which Way?: Exploring non-pharmacological approaches to smoking cessation during pregnancy with Aboriginal communities in New South Wales.](#)

The project's research design is informed by and adapted from the RISE framework, originally developed for the Birthing on Country model of care¹. It incorporates four strategic aims that are achieved in parallel across three phases (Table 1).

	Aim 1: (Re)design health service delivery	Aim 2: Embed community governance and control	Aim 3: Invest in health workforce	Aim 4: Strengthen women's capacity to quit smoking
Phase 1 Evidence-building (complete) AH&MRC: 1603/19	Environmental scan of Service delivery to support smoking cessation during pregnancy.	Conduct multi-stakeholder consultation.	Understand AHW/P resources, capacity, and interest in supporting expecting mothers to quit smoking.	Understand Aboriginal women's interest and needs for smoking cessation support.
Phase 2 Co-design (complete) AH&MRC: 2170/23	Co-design model of care with Aboriginal women, ACCHS and key stakeholders.	Co-design formal systems of governance using Culturally Adaptive Governance Framework.	Co-design training and support package for AHW/Ps.	Co-design culturally responsive group-based smoking cessation program.
Phase 3: Implementation and evaluation	Stage 1: Recruit sites to implement model of care	Stage 2: Facilitate Indigenous leadership and oversight	Stage 3: Implement and evaluate training	Stage 4: Implement and evaluate the program

Table 1: Aims of Gulibaa across the three phases of the program.

The three phases are:

1. **Evidence-building** (*complete*): This phase was completed in 2021. This phase was approved by AH&MRC (1603/19). Findings from this work are presented in the publication table below (see Table 2).
2. **Co-design** (*complete*): This phase was completed in 2023-2024. This phase was approved by AH&MRC (2170/23). The findings are presented in the publication table below (see table 2) with more currently in-press.
3. **Implementation and evaluation**: Implementation development and evaluation will be conducted in urban, regional, and remote ACCHS' and non-government health services in NSW. **This phase is the scope of work covered in this ethics application.**

Each component of Phase 3 has been developed based on the co-design process and integrates cultural protocols with implementation science theories of experience-based co-design which will be comprehensively evaluated.

Background and Rationale

Smoking is responsible for over one-third of ALL Aboriginal deaths and is the single biggest modifiable lifestyle risk factor. The mechanics of colonisation, including payment in tobacco to Aboriginal workers until 1968, have embedded tobacco use within the Aboriginal population². 43% of Aboriginal people are daily smokers – three times the rate of non-Indigenous Australians³. Aboriginal experts and clinicians have called for comprehensive approaches to support Aboriginal people to be smoke-free⁴. Reducing tobacco prevalence among Aboriginal people is central to Australia’s long term national health plan, the National Preventive Health Strategy, and the recently updated Implementation Plan for the National Aboriginal Health Plan 2013-2023.

Smoking during pregnancy is an important modifiable risk factor for short and long-term health outcomes for babies and expecting mothers. Smoking during pregnancy is associated with pre-term birth, placental complications, and low birth weight⁵. Aboriginal and Torres Strait Islander experts and clinicians have called for comprehensive approaches to support Aboriginal and Torres Strait Islander people to be smoke-free^{4,6}. Reducing rates of smoking during pregnancy has been identified as a key target to close the gap in life expectancy between Indigenous and non-Indigenous people, to reduce the child mortality rate for Aboriginal and Torres Strait Islander children, and to increase the proportion of Aboriginal and Torres Strait Islander babies with a healthy birthweight⁷. Despite investment in programs such as the Tackling Indigenous Smoking Program⁸ that explicitly target pregnant women as a priority group, smoking rates amongst Aboriginal and Torres Strait Islander women remain high. In 2021, 42% of Aboriginal and Torres Strait Islander women reported smoking at any time during pregnancy, compared to 8.7% of all mothers. Only 1 in 8 Aboriginal and Torres Strait Islander women report stopping smoking during pregnancy⁵.

Aboriginal and Torres Strait Islander women care deeply about the health risks to their babies from smoking. Our recent research found that 93% (n=103) of women who smoke change their smoking behaviour during pregnancy, including reducing cigarette consumption or being smoke-free for weeks or months. However cessation is frequently attempted without support⁹ which may influence relapse. Aboriginal and Torres Strait Islander women face significant, complex and multi-layered barriers to smoking cessation. Qualitative and quantitative studies have identified environmental and social factors, conflicting health advice and messaging, and a lack of culturally relevant cessation care¹⁰⁻¹².

Development and co-design of the Which Way? Women's program

Over the past five years, the Which Way? team has been conducting Indigenous-led and community-owned research to understand what smoking cessation supports are relevant and meaningful to Aboriginal and Torres Strait Islander women during pregnancy and beyond. Key findings from our work include:

- Aboriginal women report unfavourable attitudes to nicotine replacement therapy and the use of Quitline¹³ and prefer incorporation of non-pharmacological approaches to empower them to be smoke-free¹¹.
- Aboriginal and Torres Strait Islander women want group based smoking cessation support delivered by Aboriginal Health Workers/Practitioners at their Aboriginal Health Service (AHS) to help them quit smoking¹⁴⁻¹⁶. While group-based smoking cessation programs have been shown to be effective in the general population, increasing quitting by 50-130%¹⁷, they have never been designed, implemented, or evaluated in Aboriginal communities.
- Aboriginal Health Workers/Practitioners (AHW/P) felt smoking cessation care was part of their role, and those based in an AHS were significantly more likely to offer best practice smoking cessation care. However, AHW/P were not consistently offered comprehensive smoking cessation training and called for a targeted workforce to support and empower their community to be smoke-free¹⁸.
- AHW/P felt group-based supports that incorporate cultural practices were the best strategies to support Aboriginal and Torres Strait Islander pregnant women to quit smoking, but a targeted workforce was required to embed support¹⁹.

Building on the voices, experiences and recommendations of Aboriginal and Torres Strait Islander people and this research evidence, the Which Way? team have co-designed a group-based smoking and vaping cessation program that will be implemented state-wide as part of the Gulibaa project. The group-based program was developed using theoretical underpinnings of group-based models¹⁷, theory of behaviour change²⁰ and an extensive co-design process including community led piloting. The group-based program offers Aboriginal and Torres Strait Islander women and their health service with key information, resources, activities, and strategies to support smoking and vaping cessation in a group-based setting. The co-design process has been conducted over a two-year period funded by the National Heart Foundation Aboriginal and Torres Strait Islander Award. The co-design process was led by Aboriginal and Torres Strait Islander project team members and included a Yarning circle, systematic review of effective components to group-based smoking cessation programs²¹ and series of workshops with Health Providers over 18 months to develop and refine the group-based program and supporting health provider and women's resources. These resources have been pilot tested over the past 12 months both face-to-face and online (#2170/23) and refined ahead of this application and state-wide roll out.

Which Way?: Upholding community rights to govern research their way

The lead researcher, alongside a team of Aboriginal and Torres Strait Islander researchers and subject matter experts in Aboriginal and Torres Strait Islander health and medical research, have undertaken a national examination of the implementation of ethical guidelines privileging Aboriginal and Torres Strait Islander community voices ²².

The *Murru Minya* study undertook national examination of Aboriginal and Torres Strait Islander communities' experiences of research, and recommendations of how to improve research processes and practices into the future. These in process findings are being applied to the Gulibaa project to uphold community requested ethical research practices and continue evidence building for best practice ethical research. We acknowledge there is a lack of appropriate frameworks to inform responsive and meaningful research governance processes and practices that ensure communities have decision-making and leadership in the research that impacts them ²³.

The Murru Minya cross-sectional survey of 51 communities nationally reported that whilst most communities reported feeling slightly or very positive about research (72%), almost half reported that research had only sometimes or never had any benefit (49%) for their communities. Ethical principles reported to be the most essential included research agreements (69%), Indigenous data sovereignty and governance (72%), sharing results back with community (88%) and translating research into policy and practice (73%). These results, combined with reflective research approaches by the research team have been used to examine current research practices.

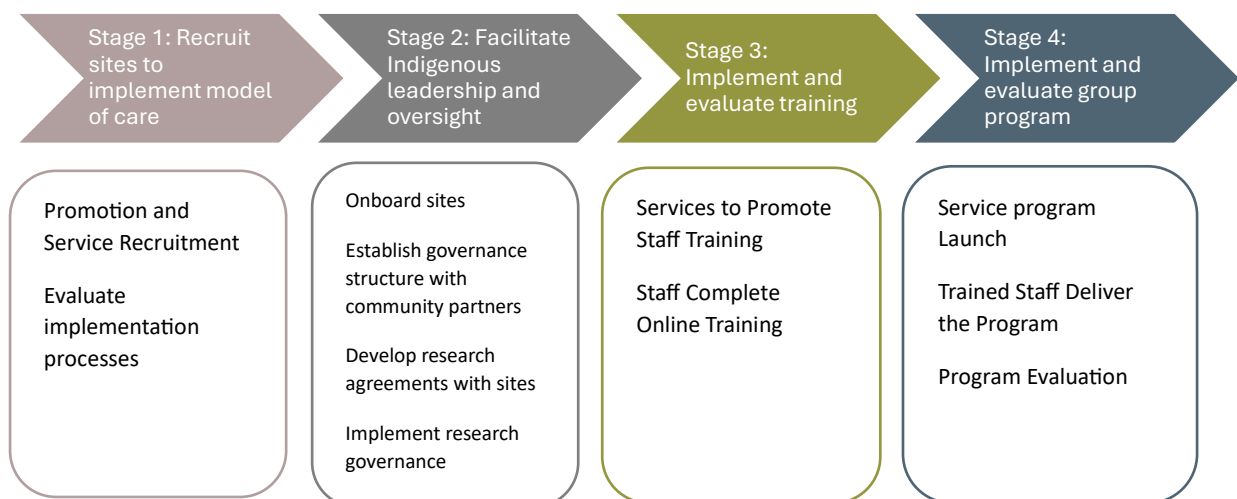
It is timely and critical for these governance processes to be examined, to contribute to critical national dialogue regarding the rights for Aboriginal and Torres Strait Islander communities to lead and implement research that is responsive to their needs and leads to improve health and wellbeing outcomes on a local and national scale. The collective experiences and knowledges of the research team have ensured that there is Aboriginal and Torres Strait Islander leadership in the chief investigative team as well as the Which Way? team members implementing the project on a day-to-day basis. Further, multi-faceted levels of governance have been embedded throughout the design, development, implementation and evaluation of the program including a Policy Governance Committee and Aboriginal and Torres Strait Islander Research Governance Committee, made up of all members of partnering services throughout the life of the project.

Methods and Approach

Aims: The Gulibaa Project aims to reduce the prevalence of smoking and vaping among Aboriginal and Torres Strait Islander women by implementing and evaluating a co-designed group-based smoking and vaping cessation program and relevant training within NSW.

Study Design and Setting: A single arm multicentre, hybrid type 1, implementation trial will be conducted to determine the effectiveness of a group-based smoking and vaping cessation support program for Aboriginal and Torres Strait Islander women and training for health staff across NSW. The intervention can be delivered flexibly, including across 6-weeks or through a compressed model.

The purpose of this study is to determine the reach, effectiveness, adoption, implementation, and maintenance of the group-based program. Program evaluation will be guided by the RE-AIM framework which is recommended to evaluate public health impact and is used in implementation studies in Aboriginal and Torres Strait Islander health, including pregnancy²⁴. The implementation and evaluation of the program involves 4 key stages:



To support the evaluation, data will be collected from Health Service Staff, Program Participants and Service Representatives. Process data capturing program implementation will also be collected.

Interventions for implementation and evaluation

The Group-based program: The Which Way? women's program covers key content including the harms of smoking and vaping, benefits of quitting, overcoming challenges to quitting, education on nicotine dependence, cessation supports available, how to make a quit plan, motivations, and social supports. Group-based sessions embed cultural practices and cover topics of the health effects of smoking and vaping, setting a quit date, identifying triggers, behavioural tools to resist cravings, importance of healthy lifestyle, relapse, and celebrating successes (see figure 2). The program has been designed to be flexible so that services can deliver the six sessions in a way that is responsive and appropriate to their community and service (i.e., across 6 weeks, condensed across two days, half-day event etc.).

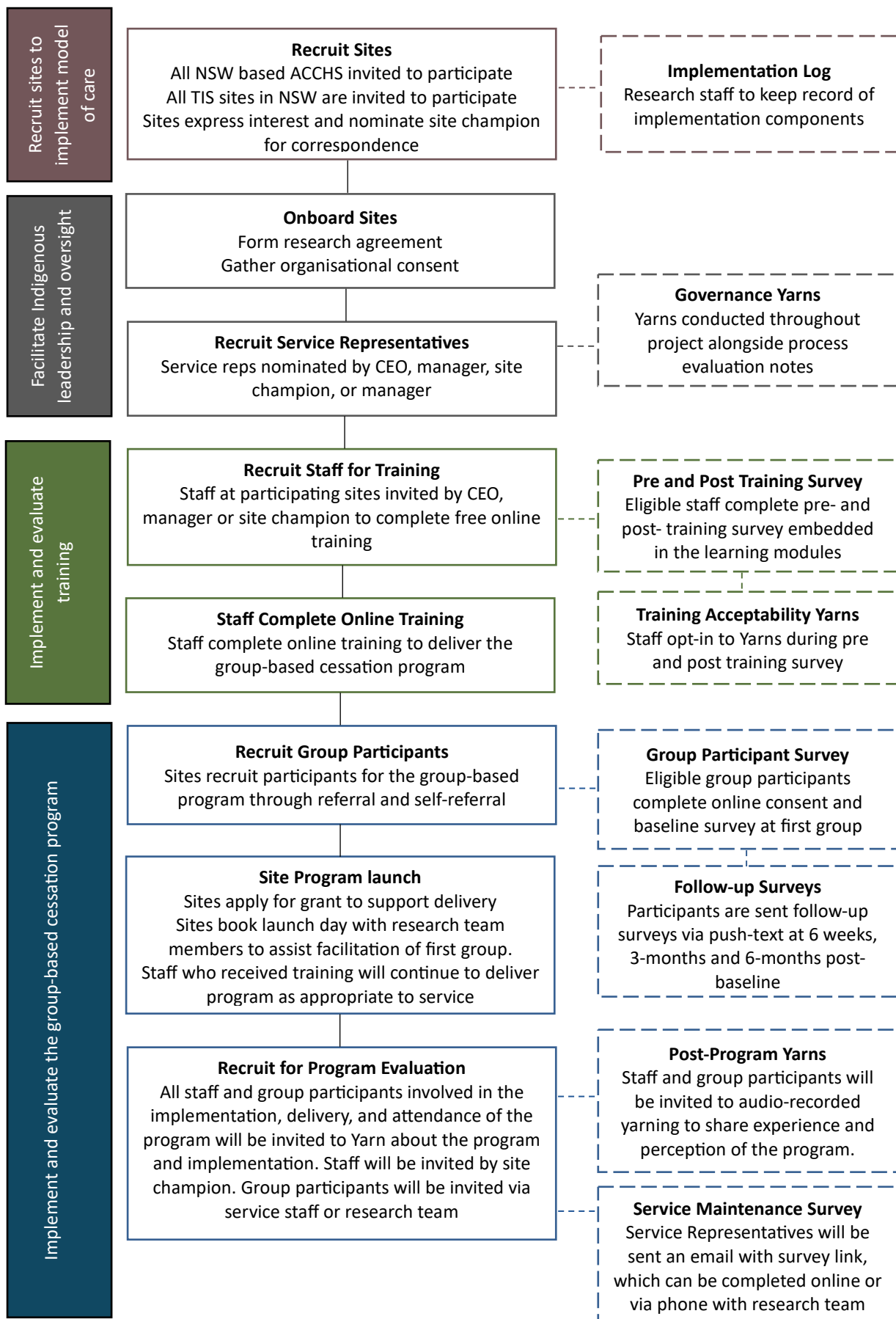
Session 1: Benefits of Quitting the Smokes and Vapes	<ol style="list-style-type: none"> 1) Welcome 2) The impacts of smoking and vaping on your health 3) The benefits of quitting the smokes and vapes
Session 2: Overcoming Challenges to Quitting	<ol style="list-style-type: none"> 1) Why do people smoke and vape? 2) Overcoming challenges to quitting
Session 3: Support to Quit	<ol style="list-style-type: none"> 1) Why do I need support to quit? 2) What is NRT and how can it support you to quit? 3) What are some other supports to help? 4) Goal setting
Session 4: Changing Behaviours and Developing a Quit Plan	<ol style="list-style-type: none"> 1) Making a quit plan 2) Changing smoking and vaping behaviours 3) Self-care
Session 5: Celebrating success and staying on track	<ol style="list-style-type: none"> 1) Celebrating success 2) Staying on track and reviewing goals 3) Positive feedback and support
Session 6: Graduation	<ol style="list-style-type: none"> 1) Review past content 2) Re-enforce group specific learning 3) Celebrate

Figure 2. Which Way? program session content overview

The program uses activities, worksheets, facilitator manuals, and women’s journals to deliver the content and information in each session.

Training for health service staff to deliver the program: Prior to community-led group-based smoking and vaping cessation sessions being implemented in services, all health service staff will be offered free online training to develop skills to support Aboriginal and Torres Strait Islander women to be smoke and vape free. At least one health service staff member from each participating site will complete the training before administering the program. The online modules will include smoking and vaping education, including the history of tobacco, facts on smoking and vaping, and the benefits of quitting, and modules on how to effectively implement group-based programs, education on behaviour change techniques, and other resources to help build confidence of health professionals to provide best-practice cessation care to Aboriginal and Torres Strait Islander women. Training will be offered on a rolling basis over a 12-month period to allow services to opt in at a time that meets their availabilities. The training is self-paced and has been co-developed with community partners, cessation experts and training company Access IQ. Access IQ have expertise in delivering effective and successful online training for Aboriginal and Torres Strait Islander people, and relevant health education.

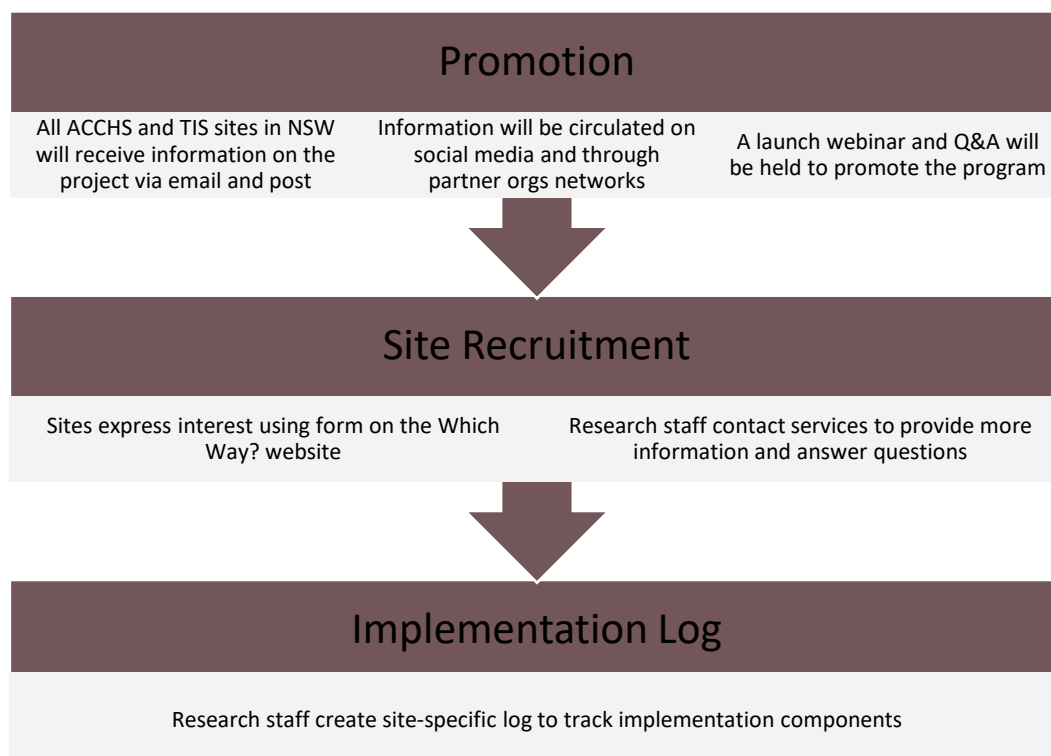
Study flow



1. Recruit sites to implement model of care

Overview: This component of the Gulibaa project involves the recruitment of sites to integrate the group-based program and record the implementation process.

Study population: Aboriginal Community Controlled Health Services (ACCHS') and Tackling Indigenous Smoking (TIS) sites across NSW will be recruited to implement of the model of care.



Study Sites

Site Eligibility: All ACCHS' in NSW (n=38) and non-government Health Services who implement the Tackling Indigenous Smoking (TIS) programme will be eligible to participate.

Site Recruitment: All ACCHS' and non-government Health Services who implement the Tackling Indigenous Smoking programme will be sent an information sheet (Appendix 1. A) and brochure (Appendix 1. B) that outlines key details on the program via. email and post (Appendix 1. C). This will direct the service to the Which Way? website and include the study team contact details to sign-up as a participating site. Information regarding the program will be disseminated by the research team and AH&MRC to member organisations. Further advertisement of the program will be conducted by AH&MRC through newsletters, advertisement at AH&MRC events and face to face updates with member organisations. Current partnering sites will also support

the development of short videos and information on the program to be uploaded to the Which Way? website for accurate information of the program. This content will not focus on recruitment, but rather provide detailed information on the project and communities experiences delivering the pilot version of the group-based program. Lead researcher A/Prof Michelle Kennedy will continue to present the program as invited at key events across NSW such as the TIS workshops and AH&MRC Health Summit, providing the context of the project and answering any questions services might have. The project will also be promoted through social media on the established Which Way? Facebook page, AH&MRC, and partnering services/organisations. Services will be directed to the Which Way? website to express their interest in participating, relevant photographs of the research team and phone and email information will also be provided to ensure services can engage in a way that is meaningful to them. Services will nominate a 'site champion' to facilitate communication between the service staff and research team. All participating services will be offered face to face or zoom discussions regarding the project and will provide organisational consent prior to any engagement of staff or community members for individual consent (see stage 2).

Data collection

Implementation Evaluation: The researchers will keep a log to measure the adoption, reach, and cost effectiveness of intervention implementation (Appendix 1.D). This will include the number of services involved, the number and proportion of services who implement the program, the number of times services run programs, how many people participate in the program, and the cost effectiveness of running the program and training. This data will be collected throughout the duration of the project, however, will not commence until organisational consent is obtained (see Stage 2).

Service Implementation log			
Method	Timepoints	Measure	Analysis
Researchers will keep a log of factors regarding the implementation as aligned with the Re-aim framework.	Throughout duration of implementation period.	<p>Adoption: The number, proportion, and representativeness of services who implement the program.</p> <p>Reach: Number, proportion and representativeness of group participants (number of referrals, uptake, and follow-up by the number of women who smoke at each service)</p>	Descriptive analysis.
Economic Evaluation			
Method	Timepoints	Measure	Analysis
Economic evaluation	Post-intervention	<p>Cost effectiveness Cost and economic effectiveness of the program and training.</p>	Economic evaluation will adopt a societal perspective to capture costs and outcomes from stakeholders. Budget impact analysis will be used to assess

			health service affordability.
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Table 2. Overview of data collection for Stage 1

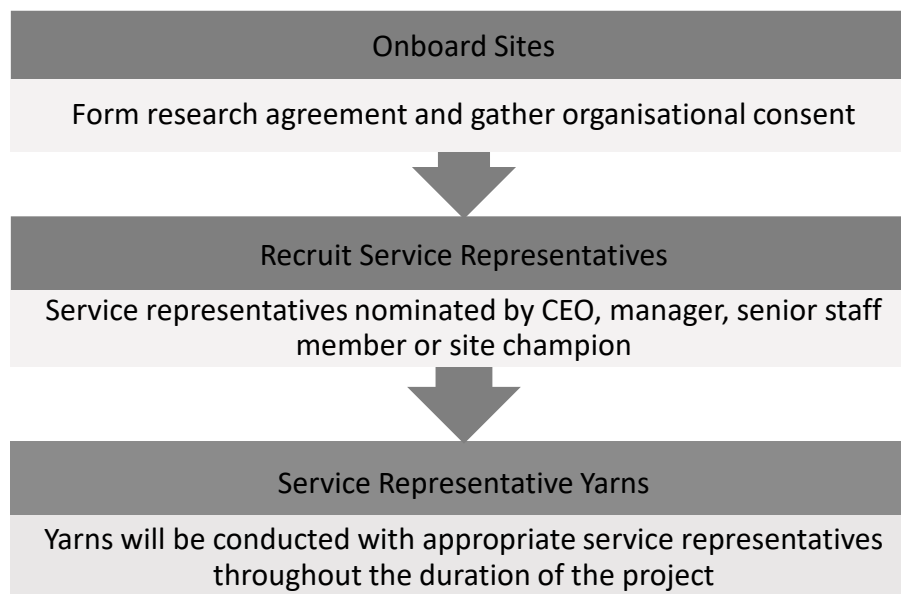
Analysis and Sample Size

Implementation Evaluation: Analysis: The data from the service implementation and program participant logs will adopt be analysed descriptively. Categorical data will be presented as counts and percentages with continuous data presented as means and standard deviations. The economic evaluation will adopt a societal perspective to capture costs and outcomes from stakeholders. Budget impact analysis will be used to assess health service affordability. **Sample Size:** No sample size is necessary for this phase of the research; however, we anticipate recruiting a minimum of 10 services.

2. Facilitate Indigenous leadership and oversight

Overview: This component of the *Gulibaa* project embeds and evaluates Aboriginal and Torres Strait Islander governance structures to oversee the implementation of the model of care.

Design: Qualitative interviews using Yarning method and process evaluation.



Onboarding process: A consultation process to develop the research agreement will be completed with each partnering service upon sign-up to ensure the agreement is responsive and applicable for their local community and service needs. A research agreement template will be used (Appendix 2. A), which will be adapted to suit individual community context. This process will also include providing partnering services with relevant suite of Lowitja Institute factsheets and tools including ‘Aboriginal and Torres Strait Islander Leadership and Participation in Research’, ‘Indigenous Data Governance and Sovereignty’ and the ‘Indigenous Data Sovereignty: Readiness Assessment and Evaluation Toolkit’ to ensure participating services have received independent information to guide their decision-making throughout this process and have control over the research, in line with AH&MRCs ‘Key Principle 2: Aboriginal Community Control of Research’.

Study Participants

Study population: Representatives from the partnering services involved in the *Gulibaa* study.

Eligibility: Any service representative involved in the implementation, facilitation or delivery of the group-based program.

Recruitment: Service representatives will be recruited on an ongoing basis throughout the duration of the project. This will be at the discretion of the service based on their role and involvement in the implementation of the program and training. Service representatives will be nominated by the CEO, site champion, manager, or senior staff member of the participating site at relevant time intervals. Contact details will be provided by the site champion. When services undertake the organisational consent (Appendix 2. B) and research agreement making process, they will be able to opt-in to participate into the Governance Yarns where they will be provided with a detailed information sheet (Appendix 2. C). Before Yarning interviews are conducted, the researcher will ask if the representative consents to a recording or note taking of the discussion (Appendix 2. D). If consent to recording is granted, verbal consent will be collected at the beginning of the interview. Those who do not opt-in to the Yarns will still be able to be involved in the governance of the project but will not have data collected for this component.

Data Collection

Governance Yarns

Yarning interviews will be recorded either using an audio recorder or if participant prefers, the researcher will take notes. Process evaluation data will include data collected by the research team including fields notes, research agreements, observations, and meeting minutes. Yarns will be held face-to-face throughout the delivery of the project and where the opportunity arises, otherwise yarns will be completed over the telephone or videoconferencing as preferred by the participant. All Yarning interview participants will have the opportunity to review their transcript or interview notes taken by the researcher, prior to data analysis and be able to make any edits or changes.

Governance Yarns				
Participants	Method	Timepoints	Measure	Analysis
Partnering service Representatives	Yarning and Process Evaluation	Throughout duration of the project	Evaluation Experiences, perspectives and recommendations	Descriptive and thematic analysis

Table 3: Overview of data collection for Stage 2.

Analysis and Sample Size

Governance Yarns

Analysis: Qualitative data will be analysed by Aboriginal and Torres Strait Islander members of the research team using thematic analysis techniques that combine inductive and deductive coding as responsive to the data, such as template analysis²⁵ or reflexive thematic analysis²⁶.

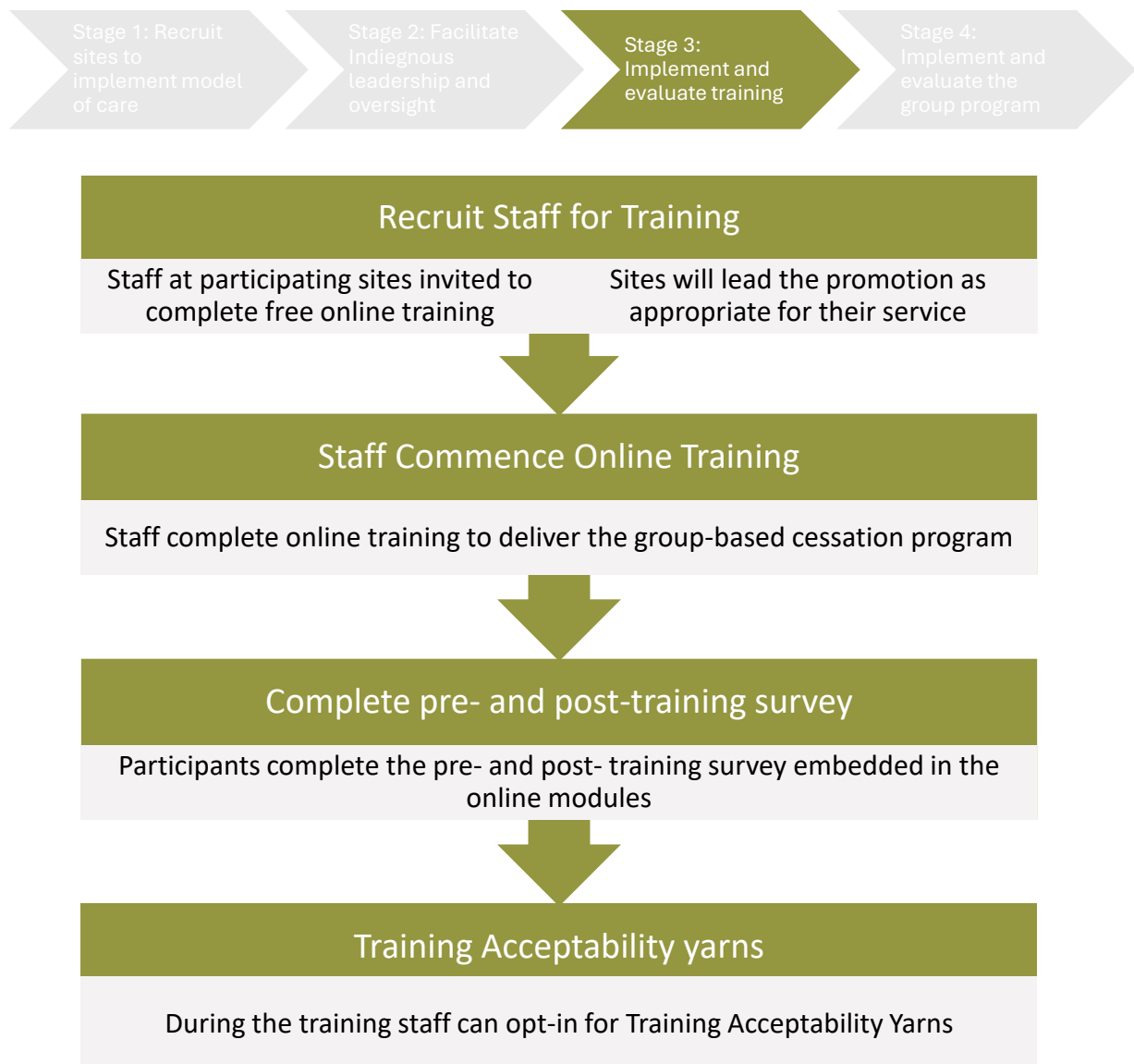
Sample Size: All partnering service representatives from participating sites and who have been involved in the governance process of the project will be able to opt-in for a Yarn. Yarns will be conducted at the discretion of the research team, who have extensive experience in qualitative methods. Data saturation or pre-determined sample size is not deemed appropriate for this study²⁷.

Integrated knowledge translation: The researcher will report in process learnings to the Aboriginal and Torres Strait Islander Research Governance Committee throughout the course of the project. This will uphold community rights to inform and own the governance process for this study. Further information on the governance can be found in the Terms of Reference (Appendix 2. E).

3. Implement and evaluate training

Overview: This component of the Gulibaa project will implement and evaluate the relevant training for health service staff at participating services to support the implementation and delivery of the group-based program.

Design: A mixed-methods approach using an online survey and qualitative yarns with health service staff to evaluate the feasibility and acceptability of the training.



Study Participants

Health Service Staff

Eligibility: All health professionals will be eligible to participate in the pre- and post-training surveys. All health service staff from participating sites who complete the training will be eligible to participate in a qualitative yarn.

Recruitment: Health Service Staff will be invited to participate after the organisation has consented to participating in the Gulibaa project. Services will invite staff in a way that is suitable to their service and community. It is anticipated that the CEO or manager will share the relevant training opportunity. The research team will provide an email for services to use if they wish (Appendix 3. A). The research team will also offer to connect in person or via zoom and attend staff meetings to explain the study and training content on offer. At the training registration process, staff will be able to access the detailed information statement (Appendix 3. B) and asked to provide informed online consent for participation in the pre and post training surveys which are embedded in training modules (Appendix 3. C). During the survey, the participant will be able to select to opt-in to an additional yarn to share their perception of the training after completion.

Data collection

Pre- and Post- Training Surveys

Health Service Staff will complete their eligibility screening and consent during the training registration process. Once they have provided informed consent, Health Service Staff will be able to access the training and online survey at their preferred time and pace. A pre- and post-training survey will be embedded in the modules to measure knowledge, attitudes, and behaviours. All survey data will be collected using the Access IQ platform. The Access IQ platform includes a secure data storage system and integrates user feedback for other Aboriginal and Torres Strait Islander companies and peak bodies such as CATSINaM and ABSTARR Consulting.

Training Acceptability Yarns

To evaluate the feasibility and acceptability of training resources, health service staff from participating sites will have the opportunity to opt-in to an audio-recorded Yarn with an Aboriginal or Torres Strait Islander research team member to provide feedback about the training program and areas for enhancement or improvement (Appendix 3.D). Yarns will be held face-to-face or over a phone or web-based call after the completion of training to discuss perceptions of training content, interface, recruitment, resources, and future recommendations for delivery. Participants will provide verbal consent prior to data collection. All qualitative data will be transcribed by a professional service. Participants will have the opportunity to review their transcripts prior to data analysis and make any edits or changes.

Pre- and post- training surveys				
Participants	Method	Timepoint	Measure	Analysis
Health Service Staff who participate in training	Online Survey	Pre- and post-training	Evaluation Knowledge, attitudes, and behaviours.	Descriptive statistics using frequencies and percentages.
Training Acceptability Yarns				
Participants	Method	Timepoint	Measure	Analysis
Health Service Staff who participate in training	Audio recorded Yarns over phone, web-based call, or face-to-face	After training completion	Feasibility and acceptability Perceptions of training content, interface, recruitment, resources. Recommendations.	Thematic analysis

Table 4. Overview of data collection for Stage 3.

Analysis and Sample Size

Pre and Post Training Surveys

Analysis: Descriptive statistics using frequencies and percentages will be used to evaluate the pre-post knowledge, attitudes, and behaviours of Health Service Staff. This approach aims to provide a comprehensive overview of the changes in knowledge, attitudes, and behaviours before and after the training intervention.

Sample Size: At least one Health Service Staff member from each participating organisation will complete the training and associated surveys.

Training Acceptability Yarns

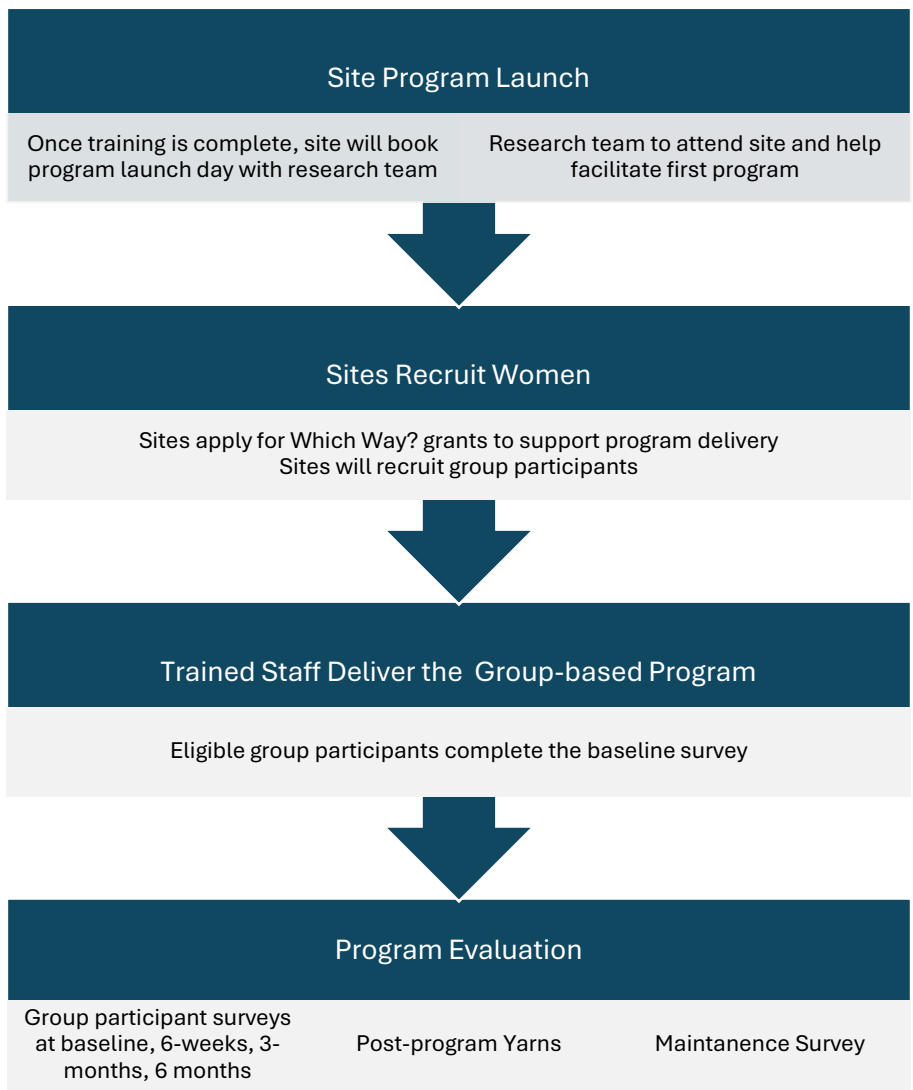
Analysis: Qualitative data will be analysed by Aboriginal and Torres Strait Islander members of the research team using thematic analysis techniques that combine inductive and deductive coding as responsive to the data, such as template analysis²⁵ or reflexive thematic analysis²⁶.

Sample Size: All Health Service Staff from participating sites who complete the training will be able to opt-in for a Yarn. Yarns will be conducted at the discretion of the research team, who have extensive experience in qualitative methods. Data saturation or pre-determined sample size is not deemed appropriate for this study²⁷. Instead, the research team will determine if further data collection is warranted to capture additional perceptions, experiences, and recommendations.

4. Implement and evaluate the group-based cessation program

Overview: This component of the Gulibaa project will privilege Aboriginal and Torres Strait Islander women’s voices and experiences in the group-based program to understand its effectiveness. Health Service Staff from participating sites who are involved in delivering the program will also have opportunity to deliver feedback on facilitating the program.

Design: A mixed-methods approach using online surveys and qualitative yarns with group participants and service representatives to evaluate the program.



Study Population

Group Program Participants

Eligibility: The group-based program will be delivered to Aboriginal and Torres Strait Islander women as determined by the participating health services. To be eligible for the research component of the program, participants must identify as an Aboriginal and/or Torres Strait Islander woman; be pregnant or of reproductive age (16 years to 49 years); currently smoke or vape at least once per day; and be willing to attend the group program. If women are seeking cessation support but do not wish to enrol in the research component of the program they will not be excluded from groups. Instead, they will not provide consent or any contact details and can continue to attend the groups run by the health service.

Recruitment: Aboriginal and Torres Strait Islander women will be recruited to join the smoking and vaping cessation groups by self-referral or referral by health service staff at participating services. Recruitment approaches will be led by the health service and may include face-to-face engagement, posters, social media advertisements or brochures. Examples of the promotional materials that will be offered from the research team for communities to adapt can be found in Appendix 4. A & 4. B. Participants can access further relevant information on the Gulibaa project and the broader Which Way? programme via the live website www.whichway.info.

Health service staff will provide a detailed participant information statement (Appendix 4. C) to all group participants who can take all the time required to consider involvement which is able to be accessed again at the beginning of the survey. Consent will be gathered either prior to the first session or at the first session before the group commences via QR link to survey. During the first session, group participants will be given the opportunity to ask any questions about the program prior to consenting. Services will be advised that if a group program participant does not want to consent to the research component, they are still welcome to participate in the groups, and no information will be collected. At the 6-week follow-up survey, participants will have the opportunity to opt-in via a tick box in the survey to participating in an audio-recorded yarn or yarning circle to share their perceptions and experiences with the program. Group Program Participants will also be invited to Yarns or Yarning Circles by the Health Service Staff, or the research team if they opted in during the survey.

Service Representatives

Eligibility: Post-program Yarns: Health service staff at participating sites who were involved in the delivery and implementation of the program are eligible to participate Maintenance Survey: A service representative from each participating site, such as the CEO, service manager, or senior staff member, will be eligible to participate.

Recruitment: Post-program Yarns: Appropriate representatives will be nominated by the CEO, manager, senior staff members, and site champions to share their perceptions of the program, resources and facilitation. Maintenance Survey: An appropriate representative will be nominated by the CEO, manager, senior staff members, or site champion to complete a short survey 6-months post-implementation. The survey will be sent team to the appropriate contact provided (i.e., email or phone; Appendix 4. D).

Group Participant Surveys

To determine the effectiveness of the program in supporting women to quit smoking/vaping, group program participants will be asked to complete an eligibility and baseline survey at enrolment to the program, and sent follow-up surveys at 6-weeks, 3 months, and 6 months (Appendix 4.E; 4.F; 4.G; 4.H). Survey items will include self-reported 7-day prevalence abstinence, smoke/vape frequencies, and intention to quit. Measures of wellbeing will be captured using the Growth and Empowerment Measure (GEM).

Follow up surveys: Participants phone numbers will be gathered at the end of the baseline survey to support the dissemination of follow-up surveys. All follow-up surveys will be sent via a scheduling program in the RedCap platform via push text. The research team will collect a log of participants who completed their baseline survey, which will be shared in with the partnering service (Appendix 4. I). Three follow up texts will be sent to participants who do not complete follow-up surveys and will be left at the discretion of the service if they would like to remind the participant to complete the survey. All survey data will be collected and stored using REDCap platform.

Post-program Yarns

Health Service Staff who were involved in the delivery and facilitation of the program and implementation as well as group program participants will be invited to participate in one-on-one Yarns or Yarning circles after completion of the program. The way that these Yarns will be conducted will be responsive to each community and their needs. Sites will be able to determine if they would prefer one-on-one Yarns or host a Yarning Circle to examine the acceptability and feasibility of the program and its delivery and the sustainability of running the groups. Topics will include the effectiveness, adoption, implementation, and maintenance of the program. Potential participants will receive a detailed information sheet and have opportunity to have any questions answered about the research before verbal consent is obtained (Appendix 4. J; 4. K). The audio-recorded Yarns and Yarning Circles will be conducted by experienced Aboriginal and Torres Strait Islander team members over the phone, web-based call, or face-to-face as determined by the participant and participating sites. These are anticipated to take between 30-60 minutes.

Maintenance Survey

Maintenance and sustainability of the program will be evaluated after the implementation of the program via a short online survey (<5 minutes) by the service representative at participating sites. During the onboarding process, the sites will have provided organisational consent for the appropriate service representative to complete the survey on behalf of the site. The service representative will have the option to complete the online survey which will be emailed to them or over the phone with an Aboriginal research team member. The survey data will be collected using REDCap platform. Survey items will include questions on the maintenance of the intervention, such as frequency of program facilitation, number of participants, and any barriers to the process (Appendix 4. L). No personal individual data of the service representative will be collected.

Group Participant Survey				
Participants	Method	Timepoints	Measure	Analysis
Group program participants	Online Survey	Baseline, 6-weeks, 3 months, and 6-months post intervention	<p>Effectiveness Self-report 7-day prevalence abstinence. Those who have not quit will be asked their smoke/vape frequency per day and intention to quit.</p> <p>Maintenance Sustained abstinence and quit attempts</p>	Will be responsive to the data source(s) and the co-design questions, but will include controlled interrupted time series, regression, and descriptive analyses
Service Yarns				
Participants	Method	Timepoints	Measure	Analysis
Service Representatives and group program participants.	Audio-recorded Yarns or Yarning Circles either face-to-face or over phone or web-based call.	Post-program implementation	<p>Implementation Program fidelity, consistency of delivery in line with established protocols, community adaptations tailored for the local context and acceptability.</p> <p>Adoption: Acceptability and feasibility of running the program related questions.</p>	Thematic analysis.
Maintenance Survey				
Participants	Method	Timepoints	Measure	Analysis
Service Representatives	Online survey or over the phone	12-months post intervention	<p>Maintenance: Frequency of groups, duration of groups, trained staff, barriers to implementation</p>	Categorical data will be presented as counts and percentages with 95% confidence levels. Continuous data will be presented as means and standard deviations.

Table 5: Overview of data collection for Stage 4.

Analysis and Sample Size

Group Participant Surveys

Analysis: To evaluate smoking cessation outcomes, an intention-to-treat analysis will be used. This means that individuals lost to follow-up will be included in the analysis, assuming that they continue to smoke or vape. A further analysis using logistic regression will be conducted to evaluate the factors associated with smoking cessation.

Sample Size: We aim to engage a minimum of 500 women in the program.

Post-implementation Yarns

Analysis: Qualitative data will be analysed by Aboriginal and Torres Strait Islander members of the research team using analysis techniques as responsive to the data collected, such as Template Analysis²⁵ or Reflexive Thematic Analysis²⁶.

Sample Size: All Health Service Staff involved in the implementation and delivery of the program and intervention will be able to express interest. Yarns and Yarning Circles will be conducted at the discretion of the research team, who have extensive experience in qualitative methods. Data saturation is not deemed appropriate for this study nor is a pre-determined sample size, as it is not intended to be representative²⁷.

Project Management

Timeline

2024												
	J	F	M	A	M	J	J	A	S	O	N	D
Develop research materials												
Refine program resources												
Develop training content												
Submit ethics approvals												
Recruit ACCHSs												

2025												
	J	F	M	A	M	J	J	A	S	O	N	D
Recruit ACCHSs												
Onboarding of ACCHSs and roll out of training												
Evaluation of training												
Program implementation in ACCHSs												
Data collection (women and health service staff)												

2026												
	J	F	M	A	M	J	J	A	S	O	N	D
Onboarding of ACCHSs and roll out of training												
Evaluation of training												
Program implementation in ACCHSs												
Data collection (women and health service staff)												
Data collection (health services)												
Statistical analysis												
Economic analysis												

2027						
	J	F	M	A	M	J
Dissemination						

Potential Risks

This research has been co-designed with Aboriginal and Torres Strait Islander women and communities, and their preferences and priorities. All aspects of the research have Aboriginal governance and oversight, including the program content, training, and research components. This research is led by Aboriginal and Torres Strait Islander and Indigenous academics with extensive experience in research with community, health services, and Aboriginal and Torres Strait Islander participants. As such, there are minimal anticipated risks associated with the research or to participants. The following table details the research team's mitigation strategy in the event of risk:

Risk	Description	Mitigation strategy
People	Difficulty recruiting qualified staff to fulfil project roles	A suitably qualified research fellow and research assistant have been identified to take on roles if

		funding is granted. The CIs have extensive networks of other suitably qualified professionals, as well as existing staff, highly suitable to fulfil the required roles.
People	Poor partner organisation engagement, impacting the co-design process and resulting in an ineffective model.	Project partners have provided agreement about their level of involvement. The timeline allows flexibility in the co-design and implementation stages to account for commitments.
Delivery	Poor engagement in project by ACCHSs (lack of engagement, difficulty training sufficient AHW/P, problems with program implementation, or services withdrawing from the research). These risks could result in an inadequate sample to measure effectiveness on cessation outcomes.	Partnerships have already been established with services to ensure feasibility of the project. Funding has been requested to support equitable access to the project through provision of funding to support services experiencing capacity issues. Support for integration of the model will be provided by the research team to limit the burden on services.
Delivery	Difficulty recruiting women to participate in group-based smoking cessation programs, leading to small sample sizes, low power, and lack of generalisability.	CI team have extensive experience working with the target population and pre-established relationships with services to ensure successful recruitment. Pilot work confirms that a group-based cessation program is desired by ~70% of pregnant Aboriginal women who smoke.
Delivery	Impact of COVID-19 on project activities	Our methods include both face-to-face and web-based platforms as contingencies for COVID. The co-design process can be completed either face-to-face or online. Flexible learning options will be available for training. Group cessation programs will be implemented in open outdoor areas, or online as virtual groups, if COVID impacts face-to-face meeting. Our project partners will ensure the project is conducted in line with Aboriginal community responses, restrictions, and adaptations due to COVID or similar global/health events. Appropriate data handling practices are in place at the university to allow the research to proceed in a work from home environment.
Information	Model of care developed is not feasible and/or acceptable to implement	Our governance structure, expert investigators and the co-design process will ensure the project gathers quality data and develops a relevant and feasible model of care. The project is led by a mostly Indigenous research team and in close partnership with relevant stakeholders, which supports project feasibility, impact, and knowledge translation.
Information	Difficulty collecting outcome data	CIs have used the proposed strategy for obtaining smoking data from the target population in previous trials. It is feasible and acceptable method of data collection.
Regulatory	Delays in obtaining ethics approval	The research team has extensive experience obtaining ethics approvals for similar projects. The senior research fellow assigned to the project will follow-up with the Human Research Ethics Committee if a response is not received within the expected timeframe.

Governance	Budget shortfall	This project has been carefully costed. The team has a demonstrable track record of delivery, and capability of delivering on time and to budget.
Governance	Not completing project in required timeframe	The project timeline has been carefully planned to allow an appropriate amount of time for various components of the project. The timeline allows for flexibility in study processes to ensure each component of the project is completed despite potential disruptions due to COVID, or other impacts.

Benefits

The Which Way? programme has been designed for and by Aboriginal and Torres Strait Islander people to uphold individual and community level benefit of involvement. This is evidenced in our continued partnership with a growing body of work. The Gulibaa project has been co-designed to ensure there is reduced burden of communities participating in the study and an appropriate short, middle and long-term benefit for participating.

Benefit to Service: Services will have a range of benefits for participating in the Gulibaa project. Firstly, the study will embed a range of training and capacity building processes that will be offered for free including: smoking and vaping cessation training and data sovereignty training (not included in any research element of the program). Services will receive resources for staff and women to deliver the core smoking and vaping cessation group content and will have access to downloadable versions of all content for use both in the Gulibaa project or for other programs.

All data collected will be owned by the service and shared with the research team (as outlined in the draft Research Agreement). Services will be offered ongoing opportunities for the research team to report back findings and data in a way that is meaningful to the service for use beyond research. Research staff will establish ongoing relationships with the services, community and staff which can extend to other work that is of interest to the community. For example, this relationship the Which Way? programme has with Waminda has resulted in Waminda requested partnership to develop and deliver Tackling Indigenous Smoking projects.

To recognise the time and resources required to participate in this project services will have access to small grants to implement the groups. Grants will be provided based on the mode of group-based program delivery and include a \$5,000 project launch grant (all sites offered once the launch event is confirmed to support purchasing any resources). Further, ongoing small grants will be offered as follows with base payments paid up front and participant payments at the conclusion of their chosen program delivery method:

Half day event: applicable for services who deliver the program in one day. Total amount available: \$1,000 for 1-5 eligible group participants. \$100 per additional eligible group participant.

Compressed program: applicable for services who conduct the compressed version of the program over 2-4 days. Total amount available: \$2,000 for 1-5 eligible group participants. \$200 per additional eligible group participant.

6 Week program: applicable for services who deliver the program across 6 weeks. Total amount available: \$3,000 for 1-5 eligible group participants. \$500 per additional eligible group participant.

All payments will be made via invoice payment system to the service in a way that is appropriate for them. If a service requires payments before programs commence, the research team will work with the service to ensure this can occur. The payments are not intended to be an incentive, they will support any catering, travel support, resource purchasing and staff time to deliver the program. A budget of \$250,000 has been allocated for small grants, which will allow recruitment of 500 Aboriginal and Torres Strait Islander women.

The project has been designed with a plan for sustainability in community settings. Once services have access to the training and resources, we hope they will benefit from continuing to implement this evidence-based program in their community in a way that suits them and their community's needs.

Benefit to Service Staff: Staff at participating services will have access to smoking and vaping cessation training that has been developed based on their reported requests and needs. The training has been developed by Indigenous people and community partners to meet the needs of the community-controlled sector. This training is unlike any other available training and meets a current gap in what staff have access to. Staff will receive a certificate upon completion of the training which is currently in the process to receive CPD points and endorsement across the AHW/P and Tobacco Control sector.

Staff will also have support and guidance to implement the group-based program by a Tobacco Treatment Specialist and Worimi woman, Mrs Joley Foster. Staff will be able to join an online group facilitated by Joley to support ongoing learning and support. The Which Way? team also build reciprocal relationships, staff will have a responsive and empowering support provided by the team.

The staff will be offered a range of different merchandise to acknowledge their work and commitment to delivering the group-based program throughout the study. This does not form part of the research component but rather our celebration of tobacco resistance.

Benefit to Aboriginal and Torres Strait Islander women: The Gulibaa project was established because Aboriginal and Torres Strait Islander women nationally told us they want access to group based programs to support and empower them to be smoke and vape free. Women will be accessed a world first, group-based smoking and vaping cessation care has never been developed or implemented for and by Indigenous people.

Women will have the immediate benefit for participating in this study as they will receive Indigenous-led, community driven and evidence based smoking and vaping cessation support and access to a range of resources to support their quitting journey. With minimal data being collected from women and all data collected remote to their service, we have developed the study to have minimal impact and burden on women. Women will have access to a range of resources developed by the Which Way? team including our women's journal and resources available on our website through involvement in the program. Women will be able to go in the draw for a monthly Clothing the Gaps merchandise pack upon registration and go in the draw for one of 3 Airpod Max headphones for completing the 6-week, 12-week and 6-month survey.

The Which Way? team believe women will benefit from receiving culturally responsive smoking and vaping cessation care. Our Quit Pack study found 34% of participants were smoke and vape-free at 6 months, we anticipate our women's program being as, if not more successful based on the face to face and comprehensive content offered to women.

Data Management

Survey data: The survey will be hosted on REDCap, and the data will be stored in password-protected files and only accessed by the researchers on the team.

Pre- and post-training survey data: Survey responses will be collected through accessIQ Learning Management System (LMS), situated on a password protected web-based platform of which only authorised staff have access. The accessIQ platform uses secure development practices to ensure that the application level does not have vulnerabilities, including automated monitoring of security vulnerabilities at the package and operating system level accessIQ to the platform by administrators is controlled with multi-factor authentication. The database is encrypted at rest, and the application transacts with the database using forced HTTPS.

Interview data: All electronic data will be stored on the University of Newcastle secure network and can only be accessed through passwords. Hard copies containing data will be stored in locked filing cabinets at the University of Newcastle. Only the named research team will have access to this data. Data will be managed in line with the NHMRCs National Statement and University of Newcastle policies.

Data Storage: All hard copies of study documentation will be stored in a locked filing cabinet at the University of Newcastle. All electronic data will be stored password protected files on the University of Newcastle secure network. Identifying data (i.e. names and contact details) will be stored separately. Only the key research personnel will have access to this data. Study-specific information will be stored for a minimum of 7 years in line with University of Newcastle policy.

Indigenous Data Sovereignty

The research team acknowledges the rights of Aboriginal and Torres Strait Islander peoples to govern the creation, collection, ownership, and application of their data and will uphold Indigenous Data Sovereignty and Governance throughout the project through the Aboriginal Governance Committee. The Aboriginal Governance Committee will include Indigenous research team members and at least one community representative from each partnering service, chaired by lead researcher A/Prof Michelle Kennedy (Wiradjuri). No data will be used without full consultation, plan, review, and approval by Aboriginal Governance Committee members who will also be offered ongoing opportunities to be named authors on the work. The project will uphold community rights to their data collected through offering free Indigenous Data Governance training as developed by Prof Raymond Lovett (ability to offer this is through our long term partnership with Prof Lovett and his team), offering data enhancement support for service level CQI (this is not a research component of the study) and through the ability for the research team to extract and report both raw data and analysed data back to community if and when requested.

Data will be kept confidential by the research team. No third party will ever have access to the data at any time during the data collection, data analysis and after the completion of the study. At the completion of the study the community partners will have the opportunity to have their

data either returned to them or offered safe storage and ongoing reporting support from the Which Way? team.

Outcomes and Significance

To date there is no trial or developed program to offer the group-based smoking and vaping cessation support requested by Aboriginal and Torres Strait Islander women.

This study will result in sustainable re-design of health service delivery by embedding a culturally responsive group-based smoking cessation program and training into services. Currently, support to quit smoking for Aboriginal pregnant women is absorbed into usual maternity care with no additional resources. Maternal health staff report low confidence to support Aboriginal women to quit smoking and have concerns that this will impact their relationship with the mother and their ability to provide antenatal and post-natal care²⁸. An Australian-wide population health initiative, Tackling Indigenous Smoking, has been in place since 2010, shifting community norms to foster smoke free environments. However, it does not include face-to-face support which is fundamental to increasing quit success. Services have identified challenges in training workers to provide cessation support, lack of funding and resources to support smoking cessation activities, and a lack evidence to inform their practice²⁹ that will be addressed throughout the implementation and evaluation of this study.

This study will also increase the number of Aboriginal and Torres Strait Islander women who make quit attempts and stay smoke free. To date, no interventions implemented in Australia have identified effective strategies to increase smoking cessation amongst pregnant Aboriginal and Torres Strait Islander women. It is critical that Aboriginal women have access to culturally responsive care to empower them to be smoke and vape-free during pregnancy and beyond. Group based therapy offers individuals the opportunity to learn behavioural techniques for smoking and vaping cessation, and to provide each other with mutual support. A 2017 Cochrane systematic review found that a group-based approach to smoking cessation increased chances of quitting by 50% to 130%.

To support sustainability of the program this study will generate rigorous evidence of effectiveness and cost-effectiveness by facilitating interdisciplinary research with an Indigenist approach. The proposed research includes co-design, implementation, and evaluation phases to determine the effectiveness and cost-effectiveness of a group-based smoking and vaping cessation program and critical community leadership in supporting Aboriginal women to quit smoking. It will include a full-scale economic evaluation to provide robust evidence of the cost-effectiveness of the intervention.

Returning Results and research findings

Findings from the project will be disseminated via partner organisations, such as AH&MRC as well as through social media. Participants will be asked if they wish to receive results from the study during the recruitment process. We will work with the Aboriginal Governance Committee to develop meaningful knowledge translation activities. Our broader Which Way? team will continue to engage regularly at community events, develop social media updates and content as well as host webinars to share results during the study process, not just at the end.

Dissemination Plan

The result of the study will be presented in relevant local, national and international conferences inviting and funding Which Way? project team, including community researchers

and community partners to do this (not just CIA Kennedy). This approach is evidenced in both the World Indigenous Cancer Conference with community researcher/undergraduate student Kayden Roberts-Barker presenting Quit Pack findings, and the Which Way? project supporting two staff at Waminda to travel to the upcoming Oceania Tobacco Control Conference to share findings from the pilot study. A comprehensive dissemination plan will be developed with the Aboriginal Governance Committee and the Policy Committee to ensure community level and policy level translation and impact. We anticipate several manuscripts will be co-authored with the Aboriginal Governance Committee and research team and submitted to relevant journals. A range of community-led dissemination strategies will be informed by partnering communities and conducted by the research team, these may include but will not be limited to; face to face presentations to community, infographics, webinars, short videos and brief reports.

Ethical Approach and Oversight

Aboriginal Governance: The research team acknowledges that Aboriginal and Torres Strait Islander people have the right to oversee research conducted and uphold Aboriginal Research Governance across all current Which Way? projects in a way that is informed by the partnering communities and scope of work. The Gulibaa project has been developed following findings from the Which Way? Women's project. The Aboriginal Governance Committee (AGC) will be an extension of the current AGC and offer all partnering services an opportunity to participate. The lead researcher and broader Which Way? team would report progress on the project to the AGC at least quarterly. The AGC will oversee the data collection, analysis and reporting, ensuring it is appropriate for the communities involved. Further details on the Aboriginal Governance can be found in the Terms of Reference (Appendix 2.E).

Contributions and Acknowledgment: As described in above sections, all community partners will be acknowledged in all communication and publication in a way that is appropriate to them. All services will be invited to participate as authors on peer reviewed publications. Further details of contributions and acknowledgement will be negotiated on a case-by-case basis with each community as part of the Research Agreement process.

Principles of Ethical Research:

Net Benefits for Aboriginal people and communities: The Which Way? Gulibaa Project has been co-designed with Aboriginal and Torres Strait Islander women and communities to uphold multiple levels of direct net benefit for Aboriginal and Torres Strait Islander women and children, service staff and participating organisations. Additionally, the Gulibaa Project has been a culmination of over 5 years of community engagement and co-design, ensuring the project has been developed by communities in line with their priorities and needs for short, middle and long-term benefit, as well as ensuring there is minimal burden placed on communities for their participation and involvement in the project.

The Gulibaa project has been developed as a result of national engagement and deep listening to Aboriginal and Torres Strait Islander women who have identified the need for access to culturally responsive and empowering group-based smoke and vaping cessation programs that has been developed by and for Aboriginal and Torres Strait Islander women. There will be immediate benefits experienced by participating in the project as they will receive Indigenous-led, community-driven and evidence-based smoking and vaping cessation support. Participation in the group program provides women with access to a range of resources and support on their quitting journey including a Women's Journal and additional resources available on the Which Way? website and in addition to the group-based program.

The Gulibaa Project will provide additional benefit to partner services as well as their staff who elect to participate in the smoking and vaping cessation training that has been developed specifically for the community-controlled sector by Indigenous people and community partners. The study embeds a range of training and capacity building opportunities that are offered throughout the project including smoking and vaping cessation training, group facilitation training, and data sovereignty training (not included in the research component). Resources will be provided to services to ensure staff are equipped to facilitate and deliver group-based smoking and vaping cessation programs to women in their local communities in a way that is responsive to their needs. The training that service staff will receive has not

previously been developed and meets a current gap in available resources that staff in the community-controlled sector have access to. Staff will receive a certificate of completion after completing the training and the research team are seeking opportunities to have this certificate accredited towards Continuing Professional Development (CPD) points and endorsement across the AHW/P and Tobacco Control sector.

Aboriginal Community Control of Research: Aboriginal and Torres Strait Islander communities are full partners in the development, design, implementation, evaluation and dissemination of the Which Way? Gulibaa Project. Engagement with communities has been an ongoing process over a 5-year period lead by CIA Kennedy to ensure Aboriginal Community Control of the research is transparently upheld throughout all stages of the project including development, design, implementation and evaluation. The project has been developed by Indigenous people and community partners. Upon sign up, each partnering service will have the opportunity to develop a research agreement to ensure their rights and requests for the research and data are upheld. Each partnering service will have at least one staff representative on the Research Governance Committee to oversee the project. Aboriginal community partners have been involved in the design of the Gulibaa project and will continue through all aspects of data collection, analysis and publication of project outcomes. The process for Aboriginal community control of research is managed through the Research Governance Committee with embedded in-process opportunities to ensure governance is being upheld transparently and appropriately.

The Gulibaa project acknowledges the rights of Aboriginal communities to have decision-making and meaningful partnerships in research to ensure project outcomes are tangible and beneficial for each respective partnering service and community. The research team also recognises the diversity of each community as the knowledge holders and experts in their community. Data analysis and interpretation throughout this project will be a transparent process that will allow in-process analysis to occur at multiple stages with oversight provided by the Research Governance Committee. If there are any stages that partnering services disagree with the analysis or reporting plans, these changes will be made in line with community requests. Partnering services will have the opportunity to nominate a representative/s from the service to be co-authors on any peer-reviewed publications, as well as opportunities to present at research conferences, workshops or symposiums.

A data sovereignty plan is outlined in the 'data governance' section of this protocol, in recognition of Aboriginal communities being the knowledge holders and owners of all data collection.

Cultural Sensitivity: The Gulibaa project and research team recognises that colonisation has been the first social determinant of health for Aboriginal and Torres Strait Islander people and this continues to have profound impacts on access to supportive, culturally safe and responsive health care. The Gulibaa project is the culmination of over five years of engagement, consultation and development of culturally safe, sensitive and support smoking and vaping cessation care by and for Aboriginal and Torres Strait Islander women, recognising there has previously been no examination or critical evaluation of the supports provided to Aboriginal women wanting to make a quit attempt. Building on the knowledge, expertise and wisdom of Aboriginal and Torres Strait Islander women in the Which Way? project, the Gulibaa project has been developed and designed by community partners to inform the implementation of a program that offers new and innovative approaches to service delivery and care for Aboriginal and Torres Strait Islander women. This research engages in Indigenous research methodologies to build safe research spaces that privilege the voices and experiences of Aboriginal and Torres

Strait Islander women to develop meaningful smoking and vaping cessation support strategies that are effective and sustainable into the future.

Reimbursement of costs: The Gulibaa Project has been designed to ensure there is minimal impact on partner services and staff internal resourcing and will provide each partnering service with a box of resources and equipment required to deliver their group-based program. Additionally, partner services will have access to small grants to deliver and facilitate the groups. Grant will be provided based on the mode of the group-based program delivery chosen by the partnering service, including a \$5,000 project launch grant offered once the launch event is confirmed to support in purchasing any resources such as weaving supplies and printing additional resources. Sites will be able to apply for ongoing small grants with base payments paid up front and participant payments at the conclusion of their chosen program delivery method:

Half day event: applicable for services who deliver the program in one day. Total amount available: \$1,000 for 1-5 eligible group participants. \$100 per additional eligible group participant.

Compressed program: applicable for service who conduct the compressed version of the program over 2-4 days. Total amount available: \$2,000 for 1-5 eligible group participants. \$200 per additional eligible group participant.

6 Week program: applicable for services who deliver the program across 6 weeks. Total amount available: \$3,000 for 1-5 eligible group participants. \$500 per additional eligible group participant.

All payments will be made via invoice payment system to the partnering service in a way that is suitable for them. If a service require payment before their group-based program commences, the research team will work with the service to ensure this can occur. The payments are intended to support resourcing including catering, travel support for participating, resource purchasing and staff time to deliver and facilitate the program. Women will have access to a range of resources developed by the Which Way? team including our women's journal and resources available on our website through involvement in the program. Women will be able to go in the draw for a monthly Clothing the Gaps merchandise pack upon registration and follow up and go in the draw for one of 3 Airpod Max headphones for completing and 6-month survey. Appropriate funding has also been allocated for travel in the project, including any travel required for meetings or attendance at conferences which will be reimbursed to partnering services as required.

Enhancing Aboriginal skills and knowledge: The Gulibaa Project provides training and employment opportunities for Aboriginal and Torres Strait Islander research assistants to enhance Aboriginal skills and knowledge ensuring the project implemented has continual benefit to Aboriginal communities. There are currently five Aboriginal and Torres Strait Islander Community Researchers working on the project including an Aboriginal Tobacco Treatment Specialist supporting across all areas of the project including development, implementation, data collection and analysis, evaluation and dissemination. These research team members have worked with CIA Kennedy for the past 1 – 3 years and this project will see the continual development and enhancement of their skills and knowledge in smoking and vaping cessation care and research training. This project includes two Aboriginal PhD students as investigators,

in their final year of their PhD, who have embedded their own lead work within this application, supporting their career development as early career researchers.

Additionally, staff at each partnering service will receive a suite of training and support in smoking and vaping cessation care from the training program which will include skills in group facilitation and supporting women on their quitting journey. There will be additional access to the Aboriginal Tobacco Treatment Specialist throughout their own knowledge development and training, as well as throughout the facilitation of group-based programs with women to ensure each partnering service and their staff have strong knowledge, skills and resources to implement smoking and vaping cessation care in a range of ways and sustainably into the future. Each partnering service will have the opportunity to nominate staff and representatives to undertake the training available within their service. CIA Kennedy will work with each nominated service representative throughout the implementation of the research, data collection, data sovereignty training, dissemination and knowledge translation components of the project to provide mentoring, training and support both formally and informally to increase skills and knowledge in health research that are transferrable and sustainable across settings.

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