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# Which way? Group-based smoking and vaping cessation support for Aboriginal and Torres Strait Islander women: protocol for a non-randomised type 1 hybrid implementation study

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## ABSTRACT

**Introduction** Tobacco use is the most significant modifiable risk factor for adverse health outcomes, and early research indicates there are also significant harms associated with vaping. National targets aim to reduce smoking and vaping during pregnancy for Aboriginal and Torres Strait Islander people. While most Aboriginal and Torres Strait Islander people want to quit, cessation is frequently attempted without support, increasing the chance of relapse. Group-based smoking cessation programmes increase quit success by 50%–130% in the general population; however, they have never been evaluated in Aboriginal and/or Torres Strait Islander communities.

**Methods and analysis** *The Gulibaa study* is an Indigenous-led and community-embedded project that will co-design, implement and evaluate a group-based model of care to support Aboriginal and Torres Strait Islander women to be smoke- and vape-free. Staff of Health Services in New South Wales, Australia, will receive training to deliver a face-to-face group-based smoking and vaping cessation intervention. Aboriginal and/or Torres Strait Islander people who identify as a woman or non-binary, are pregnant or of reproductive age (16 to 49 years), currently smoke or vape at least once per day and are willing to attend the programme are eligible to participate. Up to 500 participants will be recruited. A mixed method evaluation approach will be implemented guided by the RE-AIM framework. Outcomes will include intervention reach, intervention effectiveness (determined primarily by self-reported 7-day point prevalence abstinence at 6 months follow-up), acceptability and feasibility of the intervention, programme fidelity and maintenance and cost effectiveness.

**Ethics and dissemination** Embedding culturally safe support to quit during pregnancy can result in improved outcomes for both mother and child and immediately improve intergenerational health and well-being. Ethics approval has been provided by the Aboriginal Health and Medical Research Council and the University of Newcastle. Study findings will be disseminated to Aboriginal and Torres Strait Islander communities in ways that are meaningful to them, as well as through Aboriginal health services, key national bodies, relevant state and federal government departments.

**Trial registration number** ACTRN12625001050448.

### STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is an Indigenous-led project that will evaluate a group-based cessation programme developed for and by Aboriginal and Torres Strait Islander women.
- ⇒ This large single arm, non-randomised type one hybrid implementation study will provide evidence about the effectiveness and implementation of a group-based smoking and vaping cessation for Aboriginal and Torres Strait Islander women.
- ⇒ The research design and methods have been selected to address implementation challenges identified in prior research on smoking and vaping during pregnancy within Aboriginal and Torres Strait Islander communities,[47 48 49] and best-practice principles for evaluating health service and programme evaluations in Indigenous contexts.[50]
- ⇒ Key limitations of the study include the restriction of recruitment to Aboriginal and Torres Strait Islander people living in one jurisdiction of Australia, which may limit the external validity of the findings.

## INTRODUCTION

Aboriginal and Torres Strait Islander women are caretakers of expert birthing and ceremonial practices to nurture future generations. Colonisation disrupted cultural practices and caused harm to Aboriginal and Torres

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Strait Islander people through the introduction of diseases, dispossession from land, family and communities, forcibly removing children and exclusion from society through missions, reserves and slavery. Tobacco was introduced to Aboriginal and Torres Strait Islander people through colonisation in lieu of monetary payment which has resulted in significant harms to Aboriginal and Torres Strait Islander people.[1] Today, commercial tobacco is responsible for over one-third of all Aboriginal and Torres Strait Islander deaths and is the single greatest modifiable behavioural health risk factor.[2] In Australia, there have been additional concerns with the growth in use of non-regulated vapes (e-cigarettes) which have been found to contain harmful, and sometimes prohibited, chemicals.[3] While research on the long-term effects of using non-regulated vapes is limited due to its relatively recent emergence, early reports indicate the potential of significant harms, including in pregnancy with potential implications for a baby's development.[4 5]

Aboriginal and Torres Strait Islander and non-Indigenous experts and clinicians have called for comprehensive approaches to support Aboriginal and Torres Strait Islander people to be smoke- and vape-free.[6–9] Reducing rates of smoking during pregnancy has been identified as a key target to improve life expectancy for Aboriginal and Torres Strait Islander people, to reduce the child mortality rate for Aboriginal and Torres Strait Islander children[10] and to increase the proportion of Aboriginal and Torres Strait Islander babies with a healthy birthweight.[11 12]

Aboriginal and Torres Strait Islander women care deeply about the health risks to their babies. More than 93% of Aboriginal and Torres Strait Islander women who smoke report changing their smoking behaviour during pregnancy, including reducing cigarette consumption or being smoke-free for weeks or months.[13] However, Aboriginal and Torres Strait Islander women face significant, complex and multilayered barriers to smoking and vaping cessation[14–16] including environmental and social factors, conflicting health advice and messaging, and a lack of culturally responsive cessation care.[17]

The *Gulibaa* study aims to implement and evaluate a culturally responsive group-based smoking and vaping cessation support programme for Aboriginal and Torres Strait Islander women in New South Wales (NSW). The *Gulibaa* study is Aboriginal-led and co-owned with community partners to deliver a programme for, and by, Aboriginal and Torres Strait Islander women. The programme is situated within the broader *Which Way?* body of work with the goal to empower Aboriginal and Torres Strait Islander people with knowledge, tools and support to be smoke- and vape-free.

### *Which Way?* Building Indigenous-led evidence-based cessation support

*Which Way?* is an Indigenous-led body of research which has been conducted over the past 5 years to address the lack of responsive care and Indigenous-led evidence for smoking and vaping cessation.[18–23] Conceptualised and led by Wiradjuri woman, Michelle Kennedy, *Which Way?* has engaged community partners, Aboriginal and Torres Strait Islander women, researchers, and people, Aboriginal Health Workers/Practitioners (AHW/Ps), Aboriginal health services (AHS) and peak bodies to inform evidence-based cessation care strategies. Early research from *Which Way?* informed the *Gulibaa study*. This included a national survey of 428 Aboriginal and Torres Strait Islander women, which identified that group-based support delivered by AHW/Ps at AHS was their preferred quitting support strategies.[22–24] Building on this, a national survey of over 250 AHW/Ps was conducted to understand knowledge, attitudes and practices towards cessation care. Higher rates of provision of smoking cessation care were found than have been previously reported.[25] AHW/Ps who had received smoking cessation training felt cessation care was part of their role, and those based in an AHS were significantly more likely to offer best practice cessation care.[21] AHW/Ps also reported that group-based supports that incorporate cultural practices were the best strategies to support Aboriginal and Torres Strait Islander pregnant women to quit; however, standardised training for the workforce is required.[26]

In response to these findings, the research team and community partners designed the *Which Way? Women's Group-based programme* to empower Aboriginal and Torres Strait Islander women with access to culturally enriched evidence-based smoking and vaping cessation care, delivered as determined by them.

### The 'Which Way? Women's Group-based programme

The *Which Way? Women's Group-based programme* underwent an extensive development process, which moves beyond usual reports of co-design.[27] In brief, the development of the programme and resources occurred over a 2-year period led by Aboriginal and Torres Strait Islander women, funded by *the National Heart Foundation Aboriginal and Torres Strait Islander Award*. Development led by Aboriginal and Torres Strait Islander *Which Way?* team members included a Yarning circle, systematic review of effective components to group-based smoking cessation programmes,[28] a series of workshops with health providers and an iterative design process. Yarning is a culturally appropriate method used by Aboriginal and Torres Strait Islander people to collect qualitative data through relationality and sharing information.[29] Workshops continued over 18 months to develop and refine the programme and resources and associated health provider training and concluded with a pilot testing of the programme both face-to-face and online. Given the comprehensive nature of this 'beyond co-design' process, the details have been reported in a stand-alone manuscript which was authored by Aboriginal and Torres Strait Islander team members and community partners.[27]

Alongside the development process, and drawing on findings from the broader *Which Way?* research, the *Which Way? Women's Group-based programme* was developed using



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theoretical underpinnings of group-based models,[30] and theory of behaviour change.[31] This work has privileged Indigenous methodologies and incorporated western-theoretical approaches to form a comprehensive programme which facilitates cultural flexibility and appropriate community adaptation. The integration of Indigenous knowledges and behaviour change techniques has been detailed elsewhere.[32] The programme was piloted with Aboriginal and Torres Strait Islander women in both face-to-face (n=12) and online (n=32) group-based modes. Group-based programme delivery included one face-to-face intensive programme offered as a half-day event, one 6-week programme offered as 1-hour sessions over 6weeks and three online group programmes offered as 1-hour sessions over 6weeks. The programme, resources and activities were altered as responsive to community feedback during this pilot phase. Vaping content was also included as well as additional delivery resources including games and worksheets based on community requests. Although evidence is in its infancy, the behaviour change underpinning of the programme supports the inclusion of vaping cessation.[33] The programme 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.

## Objectives

The overall objective of the *Gulibaa* study is to reduce the prevalence of smoking and vaping among Aboriginal and Torres Strait Islander women by implementing and evaluating the effectiveness of the Indigenous led *Which Way? Women's Group-based programme* in NSW.

This will be achieved through the following aims: (1) evaluate a co-designed group-based smoking and vaping cessation programme in health services across NSW using the RE-AIM framework, (2) improve health service staff confidence and knowledge to facilitate cessation care for Aboriginal and Torres Strait Islander women, (3) reduce the prevalence of smoking and vaping among Aboriginal and Torres Strait Islander women of reproductive age and (4) embed and uphold Indigenous governance in the implementation and evaluation process.

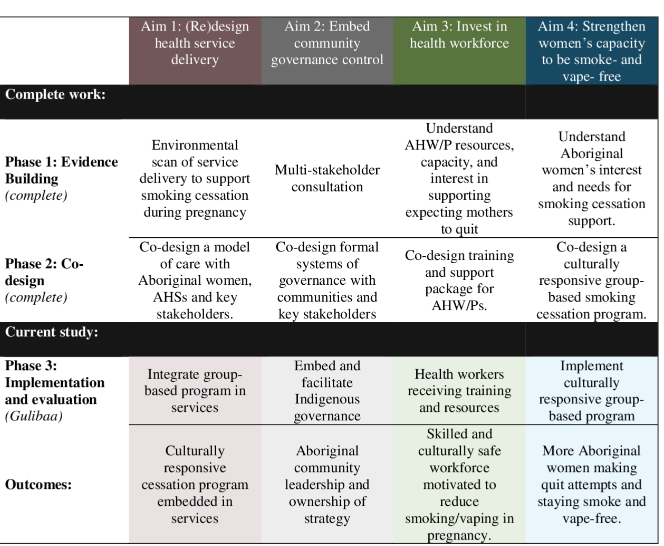
# METHODS AND ANALYSIS

## Research team

This research has been built on community priorities for Indigenous-led evidence and programmes to empower smoke and vape-free generations. This work has been conceptualised and led by MK who is a Wiradjuri woman, mother and ex-smoker. The relationships between the researcher and communities in this study have been nurtured and cared for since MK began working in partnership with Aboriginal and Torres Strait Islander women and communities in the field of health research. The research is grounded in, and builds on, the knowledges and wisdom of Aboriginal and Torres Strait Islander women who have gifted such with MK since her doctoral studies.[17] The centrality of this relationality and reciprocity ensures the research and communities in which it has partnered with remain acknowledged, respected and safeguarded throughout. This work has been informed by key project partners Waminda South Coast Women's Health and Wellbeing Aboriginal Corporation, Birra Li Aboriginal Infant Maternal Health Service and the Aboriginal Health and Medical Research Council (AH&MRC). Our team brings together Aboriginal and Torres Strait Islander researchers (TR, SM, CC, SE, LJB, JBe, FC, ZM, JF, KRB, HL, KW, NT, MK), Indigenous researchers (RM, AM) and expertise in clinical practice (SM, CC, JBe, LJB, AGM, HL, KW, NT, MK), health service research (JBr, AM, SE, CD, LJB, MK), policy (JBr, RM, CC, CD), evaluations (CD, AM), tobacco research (KB, JBr, RM, SM, AM, CC, SE, MB, FC, ZM, JF, AGM, KRB, MK), knowledge translation (RM, CC, MB, MK) and qualitative (KB, TR, CC, JBe, FC, ZM, JF, KRB, MK) and quantitative (JBr, RM, MK, AM, CO) research methods and analysis. Leadership and capacity building for Aboriginal (TR, SM, JF, KRB) and Torres Strait Islander (ZM) community researchers is embedded in this project.

## Study design

*Gulibaa* is a non-randomised, single arm, multicentre, hybrid type one implementation study designed to assess both the effectiveness and implementation of a group-based smoking and vaping cessation support delivered to Aboriginal and Torres Strait Islander women. Indigenist and Indigenous methodologies[29 34 35] will be used alongside the RE-AIM framework to guide evaluation. The framework includes strategies to redesign the health service, invest in the workforce, strengthen families and embed Aboriginal and/or Torres Strait Islander community governance and control (figure 1). *Gulibaa* is designed to align with the four components of the RISE Framework and builds on extensive formative work conducted



| | Aim 1: (Re)design health service delivery | Aim 2: Embed community governance control | Aim 3: Invest in health workforce | Aim 4: Strengthen women's capacity to be smoke- and vape- free |
|---|---|---|---|---|
| **Complete work:** | | | | |
| **Phase 1: Evidence Building** *(complete)* | Environmental scan of service delivery to support smoking cessation during pregnancy | Multi-stakeholder consultation | Understand AHW/P resources, capacity, and interest in supporting expecting mothers to quit | Understand Aboriginal women's interest and needs for smoking cessation support. |
| **Phase 2: Co-design** *(complete)* | Co-design a model of care with Aboriginal women, AHSs and key stakeholders. | Co-design formal systems of governance with communities and key stakeholders | Co-design training and support package for AHW/Ps. | Co-design a culturally responsive group-based smoking cessation program. |
| **Current study:** | | | | |
| **Phase 3: Implementation and evaluation** *(Gulibaa)* | Integrate group-based program in services | Embed and facilitate Indigenous governance | Health workers receiving training and resources | Implement culturally responsive group-based program |
| **Outcomes:** | Culturally responsive cessation program embedded in services | Aboriginal community leadership and ownership of strategy | Skilled and culturally safe workforce motivated to reduce smoking/vaping in pregnancy. | More Aboriginal women making quit attempts and staying smoke and vape-free. |

**Figure 1** The four pillars of the RISE framework and implementation phases. AHW/Ps, Aboriginal Health Workers/Practitioners.



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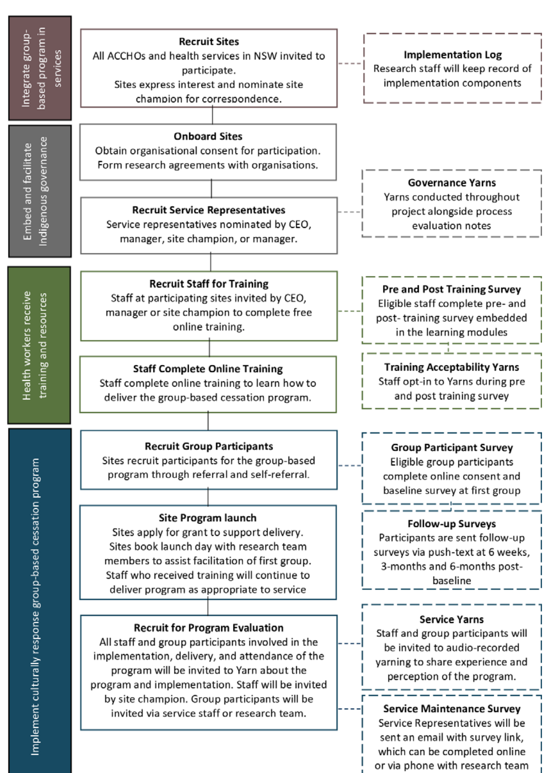


**Figure 2** Study flow in line with the RISE framework pillars. AACHOs, Aboriginal community-controlled organisations; NSW, New South Wales.

in the earlier phases of the broader *Which Way?* project (depicted as phases 1 and 2 below).[18–24] The study flow of *Gulibaa* can be seen in figure 2. Data collection will be conducted from March 2025 to December 2026.

## Patient and public involvement statement

*Governance*. The governance processes in this research have been developed to ensure multiple levels of accountability to Aboriginal and Torres Strait Islander people and communities. Recently, communities engaged in the *Murru Minya* study led by MK have called for community governance, leadership and control over research.[36] Evolving governance processes in this study are embedded to ensure the research is implemented to safeguard and give voice to communities by upholding their rights to responsive and meaningful impact and benefit. Thus, this research is governed by Aboriginal and Torres Strait Islander communities through our partnership with the AH&MRC. The research aims, research design and methods have been developed in collaboration with Indigenous researchers, Aboriginal community-controlled organisations (ACCHOs), Aboriginal community members and peak organisations and will be conducted with direct lines of community and policy accountability via three separate Governance Committees. An *Aboriginal Community Governance Committee* will uphold Aboriginal community leadership, decision-making and voices over all aspects of the project, ensuring accountability and transparency. This committee will oversee all aspects of the research design, implementation, analysis and interpretation and will comprise representatives of ACCHOs, interested Aboriginal and Torres Strait Islander community members (smokers and non-smokers), elders and young women, from urban, regional and remote areas of NSW. A *Policy Governance Committee* will provide oversight of project implementation and evaluation, work collectively to address implementation barriers experienced by services as they arise and plan for sustainability of the model post research stages. It will comprise representatives from peak policy and health service organisations. Finally, a *Tobacco Advisory Committee* will ensure smoking cessation programme content reflects best practice scientific evidence. The committee will be very active in the early stages of the project implementation, ensuring the model of care upholds scientific rigour and up-to-date evidence on smoking and vaping cessation care. The committee will support requests for information made by the *Aboriginal Community Governance Committee* if these arise.

## Eligibility and recruitment

*Health Services*. All ACCHO (n=38) and health services in NSW, Australia, will be eligible to participate. Eligible services will be sent an information sheet and brochure that outlines key details of the programme via email and post. Recruitment materials will direct services to the *Which Way?* website to obtain additional information about the programme and sign up as a participating site. Information about the programme will also be disseminated by the research team to AH&MRC member organisations, and through newsletters, face-to-face events and social media. All sites that express interest will be offered a face-to-face or Zoom meeting with the research team to answer any questions. Services will nominate a 'site champion' to facilitate communication between the service staff and research team. All participating services will provide organisational consent prior to any engagement of staff or community members for individual consent and will enter into a research agreement with the research team to ensure clarity of their communities' rights and involvement in the project and ensure the research is safe, responsible and ethical for the participating service.

*Health service representatives*. Staff who are involved in the implementation, facilitation or delivery of the intervention from participating health services will be eligible. Service representatives will be recruited on an ongoing basis throughout the project as nominated by the CEO, site champion, manager or senior staff member of the participating site at relevant time intervals. Contact details will be provided to the research team by the site champion for invitation.

*Health service staff*. All health professionals at participating services will be eligible to complete training to learn how to deliver the smoking and vaping cessation group programme and participate in the pre- and post-training surveys. Following organisational consent, participating services will invite staff in a way that is suitable to their service and community. It is anticipated that the



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CEO or manager will share information about the training with staff via email. The research team will present information about the training to staff at a relevant meeting (either face-to-face or via Zoom) if requested. Staff who wish to participate in training will be directed to the online training platform to register. Staff will be able to access a detailed information statement and will provide informed online consent for participation. During the survey, participants will be able to opt in to an additional Yarn to share their perception of the training after completion. All health service staff from participating sites who complete the training will be eligible to participate in the Yarn.

*Group-based programme participants.* Eligible participants will identify as Aboriginal and/or Torres Strait Islander; 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 *Which Way? Women's Group-based programme.* This programme was designed for, and by, Aboriginal and Torres Strait Islander women. People who identify as 'male' or 'man' will therefore be excluded from participating in the research. People who identify as 'non-binary' or describe their gender in another way using open text will remain eligible to participate if they wish. Recruitment approaches will be led by each participating site and may include face-to-face engagement, posters, social media advertisements or brochures. Programme participants can self-refer to participate in the programme or be recruited via referral from a health professional at a participating site. All promotion material will include the time, date and location of the group-based programme(s) being delivered by the participating site. Health service staff will provide a detailed participant information statement to all participants which is able to be accessed again at the beginning of the survey. Informed consent will be obtained prior to commencing the survey. Participants will have the opportunity to opt in via a tick box in the 6-week follow-up survey to participate in an audio-recorded Yarn or Yarning circle to share their perceptions and experiences with the programme.

## Intervention

*Training for service staff to deliver the programme.* Online training will be offered to all health service staff to deliver the programme. At least one staff member at each participating site will complete training. Training has been co-designed with key partners including Cancer Council NSW, National Aboriginal Community Controlled Health Organisation, Awabakal Aboriginal Medical Service and the Indigenous and Aboriginal and Torres Strait Islander research team. 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 programmes, education on behaviour change techniques and other resources to help build the confidence of health professionals to provide best-practice cessation care to Aboriginal and Torres Strait Islander women. Training has been developed based on an audit of available smoking and vaping cessation and health education and aims to increase confidence to educate and support clients during their quitting journey. Training will be offered on a rolling basis over the life of the research to allow services to opt in at a time that meets their needs and availabilities. Downloadable resources and refresher training will also be available for staff. All staff who participate in training will complete a short survey assessing knowledge, attitudes and behaviours before and after completion of each module. Data will be captured via an online survey embedded into the training programme.

*Which Way? Women's Group-based programme.* The programme covers key content based on relevant behaviour change techniques,[28 31 37] including the harms of smoking and vaping, benefits of quitting, overcoming challenges to quitting, education on nicotine dependence, available cessation supports, how to make a quit plan, motivations and social supports. The research team will deliver a face-to-face group-based programme of 1-day duration at each participating site to demonstrate delivery of the programme to staff. This will serve as a foundational step in ensuring the smooth implementation of the programme across all participating sites. Subsequent group programmes will be implemented by trained service staff. Recognising the diversity of Aboriginal and Torres Strait Islander communities, programme implementation is flexible, and participating sites can deliver programme content and activities in a way that meets the needs and preferences of their community. Participating sites will be able to deliver the programme face-to-face via 1.5-hour group sessions delivered once per week over a 6-week period or in a condensed format of their choosing. The different formats and implementation processes used by services will be documented.

Group-based sessions will embed cultural practices and cover the topics outlined in Box 1. Aboriginal and Torres Strait Islander women will receive a journal at the start of the programme that supports and extends on the behaviour change techniques covered in the sessions. Participating sites will be provided with a health provider manual which details the content and planning required for each session, access to video overviews and additional supporting materials for each session, printed health education activities and access to an Aboriginal Tobacco Treatment Specialist through monthly community of practice meetings and on-call support.

**Box 1 Overview of the *Which Way? Women's Group-based programme* content**

Benefits of quitting the smokes and vapes.
Overcoming challenges to quitting.
Changing behaviours and support to quit.
Setting goals and developing a quit plan.
Celebrating success and staying on track.
Reflections and graduation.



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### Outcomes

Programme evaluation will be guided by the RE-AIM framework (see table 1 for details) which is recommended to evaluate public health impact.[38]

#### Health economic evaluation

A prospective trial-based cost-effectiveness analysis will be conducted, adopting the CHEERS (Consolidated Health Economic Evaluation Reporting Standards) reporting guidance for health economic evaluations. Analysis will consider a healthcare perspective; transparent and scientific methods to identify, measure and value both costs and outcomes; modelling and uncertainty testing of epidemiological and costing input parameters; and interpretation of results within a broader decision-making framework. Adopting a health-system perspective, the system costs required to deliver the intervention will be included (ie, medical consultations, staff time, tests, training, etc), while patient non-medical costs (eg, travel, productivity losses) will be excluded. Epidemiological modelling will be used to estimate the potential impact of smoking cessation in terms of both hard endpoints (deaths, incident cases) and summary measures such as health adjusted life expectancy (HALE) for both the cohort and the wider Aboriginal and Torres Strait Islander population of smokers. Modelling would rely on the latest burden of disease data for Aboriginal and Torres Strait Islander people (eg, Australian Institute of Health and Wellbeing (AIHW) Australian Burden of Disease Study[39]) and rates of smoking prevalence (eg, AIHW, NDSHS 2022–2023). Estimates of risk reversibility would come from established studies (eg, CPS II) for key outcomes (lung cancer, COPD, cardiovascular disease) and extrapolated to other causes as appropriate. The model will estimate potential hospitalisations prevented due to smoking cessation. We will model outcomes up to 10 years. The analysis will determine an incremental cost-effectiveness ratio (ICER) in dollars per HALE gained. Non-parametric bootstrapping will be used to derive 95% uncertainty intervals for outcomes and costs and determine the probability of intervention cost-effectiveness against an accepted cost-effectiveness threshold (ie., $50,000 per HALE gained). ICER results will be displayed on a cost-effectiveness plane with affordability issues addressed in an acceptability curve. The comparison of net costs with incremental benefits is expected to present a cost-effectiveness ratio as a dominant strategy (positive benefits and economic savings). The results of the CEA will be considered in the context of affordability by conducting a budget impact analysis to estimate the likely change in expenditure for health service providers.

### Service data collection

#### Researchers' implementation log

The research team will keep detailed logs to capture key data to measure the adoption, reach and cost effectiveness of intervention implementation. This will include the number of services involved, the number and proportion of services who implement the programme, the number of times services run programmes and how many people participate in each programme. *Service Implementation log*. Programme facilitators will keep a log of participants who attend the programme, trained staff who deliver the programme and type of programme delivered (compressed vs multisession).

### Survey data collection

Quantitative data collection will include pre- and post-training surveys; group participant surveys collected at baseline, 6 weeks, 3 months and 6 months; and a service maintenance survey (see online supplemental file 1 for survey domains and themes). Data for the pre- and post-training surveys will be collected through the Access IQ platform, which includes a secure data storage system. All remaining survey data will be collected using the REDCap platform.[40]

#### 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, they 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.

#### Group participant surveys

To determine the effectiveness of the programme in cessation support, group programme participants will complete an eligibility and baseline survey at enrolment to the programme and be sent follow-up surveys at 6 weeks, 3 months and 6 months. Survey items will include self-reported 7-day prevalence abstinence, both smoking and vaping frequencies and intention to quit. Measures of well-being will be captured using the GEM.[41]

#### Maintenance survey

Maintenance and sustainability of the programme will be evaluated after the implementation of the programme via a short survey (<5 min) by a service representative at participating sites. During the onboarding process, sites will provide 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. Survey items will include questions on the maintenance of the intervention, such as frequency of programme facilitation, number of participants and any barriers to the process.

### Yarning data collection

Qualitative data collection will include Governance Yarns, Training Acceptability Yarns and Service Yarns. All potential participants will receive an information sheet and have the opportunity to have any questions answered about the research, before verbal consent is obtained.

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**Table 1** Outcome measures by RE-AIM dimension

| Dimension | Outcome measures | Data collection mode |
|---|---|---|
| **Reach**<br>*The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention or programme, and reasons why or why not.* | ▶ Total number of group programme participants who consent to participate<br>▶ Representativeness of group programme participants who consent to participate (age, geographical location, use of ACCHOs, smoking vs vaping vs both, children under 18 caring for, pregnant, HSI)<br>▶ Number and proportion of group programme participants who attend all sessions of multi-session programmes<br>▶ Number and type (ACCHOs vs mainstream health services; geographical location) of eligible services who run at least one group<br>▶ Number of services who participate in governance and reasons | Researcher implementation log<br>Group participant surveys (Baseline; 6 weeks)<br>Health staff pre- and post-training surveys<br>Governance Yarns |
| **Effectiveness**<br>*The impact of an intervention on important Individual outcomes, including potential negative effects, and broader impact including quality of life and economic outcomes; and variability across subgroups (generalisability or heterogeneity of effects).* | Intervention effectiveness:<br>▶ Self-reported 7-day prevalence abstinence rates at 6 weeks, 3 months and 6 months (primary outcome) follow-up<br>▶ Increase in number of quit attempts lasting more than 24 hours at 6 weeks, 3 months and 6 months follow-up<br>▶ Reduction in amount smoked/vaped each day at 6 weeks, 3 months and 6 months follow-up<br>▶ Increase in empowerment measured on the growth and empowerment measure<br>▶ Cost effectiveness | Group participant surveys (6 weeks; 6 months) |
| | Training effectiveness:<br>▶ Changes in staff knowledge, attitude, and confidence | Health staff pre-training and post-training surveys |
| **Adoption**<br>*The absolute number, proportion and representativeness of settings and intervention agents (people who deliver the programme) who are willing to initiate a programme and why* | Service adoption:<br>▶ Number and type (ACCHO vs mainstream health services; geographical location) of eligible services who express interest in participating<br>▶ Number and type (ACCHO vs mainstream health services; geographical location) of eligible services who sign organisational consent to participate<br>▶ Number, proportion and representativeness (geographical location, service type) of services who implement the programme<br>▶ Total number of programmes delivered<br>▶ Service perceptions of the acceptability and feasibility of running the programme | Research implementation log<br>Service implementation log<br>Service Yarns |
| | Training adoption:<br>▶ Number of staff who sign up for training<br>▶ Representativeness of health staff who sign up for training (age, service type (ACCHOs vs mainstream health services), geographical location, role, smoking/vaping status, previous training)<br>▶ Number, proportion and representativeness of health staff who complete all training modules<br>▶ Number, proportion and representativeness of health staff who complete refresher training modules<br>▶ Number, proportion and representativeness of health workers who have completed training and delivered a group programme | Service implementation log |
| **Implementation**<br>*The intervention agents' fidelity to the various elements of an intervention's key functions or components, including consistency of delivery as intended and the time and cost of the intervention. Importantly, it also includes adaptations made to interventions and implementation strategies.* | Programme:<br>▶ Type (compressed vs multi-session) of programmes delivered<br>▶ Types of adaptations made to the programme<br>▶ Barriers and enablers to implementation | Service implementation log<br>Service Yarns |
| | Training:<br>▶ Barriers and facilitators<br>▶ and acceptability (content, interface, recruitment, resources) of training<br>▶ Programme fidelity, consistency of delivery in line with established protocols, adaptability for local context and acceptability | Training acceptability Yarns |

Continued



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Table 1 Continued

| Dimension | Outcome measures | Data collection mode |
|---|---|---|
| **Maintenance**<br>*At the setting level, the extent to which a programme or policy becomes institutionalised or part of the routine organisational practices and policies. Maintenance also applies at the individual level. At the individual level, maintenance has been defined as the long-term effects of a programme on outcomes after a programme is completed.* | 6–12 months following the cessation of the research component:<br>▶ Number of staff who complete training<br>▶ Number of group programmes run by the service<br>▶ Types of adaptations made to the programme<br>▶ Barriers and enablers to continuing implementation | Maintenance survey |

ACCHOs, aboriginal community-controlled organisations; HSI, Heaviness of Smoking Index.

Yarns will be audio-recorded and be conducted either face-to-face or over telephone or web-based call. Participants of the Governance Yarns will have the option to have the researcher take notes instead of recording if preferred. Participants will have the opportunity to review their transcripts prior to data analysis and make any edits or changes. All qualitative data will be transcribed by a professional service. Domains of enquiry will be used to guide the Yarns (see online supplemental file).

### Governance arns

When services undertake the organisational consent and research agreement making process, they will be able to opt in to participate in the Governance Yarns where they will be provided with a detailed information sheet. Before Yarning interviews are conducted, the researcher will ask if the representative consents to a recording or note taking of the discussion. 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. Yarns with service representatives will be held throughout the delivery of the project and where the opportunity arises.

### Training Acceptability arns

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 programme and areas for enhancement or improvement. Yarns will be held after the completion of training to discuss perceptions of training content, interface, recruitment, resources and future recommendations for delivery.

### Service arns

Health service staff and representatives who were involved in the delivery, facilitation and implementation of the programme, as well as group programme participants, will be invited to participate in one-on-one Yarns after completion of the programme. 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 programme and its delivery and the sustainability of running the groups. Topics will include the effectiveness, adoption, implementation and maintenance of the programme. These are anticipated to take between 30 and 60 min.

## Sample size

### Services

All ACCHOs (n=38) and health services located in NSW will be invited. We anticipate that at least 10 services will be recruited.

### Surveys

*Pre- and post-training surveys:* At least one staff member from each participating organisation will complete the training surveys. *Group participant surveys:* We aim to recruit at least 300 women of reproductive age (16–49 years) across 10 participating sites. According to the AIHW data tables for the Online Services Collection and Key Performance Indicators data collections, approximately 27 000 women aged 15–49 attend an ACCHO each year in NSW/ACT, averaging about 700 eligible participants per service. This study aims to enrol at least 30 women from each service. Our primary outcome is to evaluate the programme's effectiveness in increasing the proportion of participants who report abstaining from smoking and/or vaping at 6 months post-baseline. Assuming a null hypothesis of 10% for the self-reported 7-day abstinence rate, the study will have 85% power to detect a 15% alternative hypothesis, with a type 1 error rate of 5%, using a single-sample test of a proportion (normal approximation to the binomial distribution). *Maintenance survey:* At least one service representative from each participating organisation will complete the maintenance survey.

### Yarns

All service representatives from participating sites who have been involved in the governance process of the project will be able to opt in for a Governance Yarn. All Health Service Staff involved in the implementation and delivery of the programme and intervention, and group programme participants will be able to express interest in a Yarn. All Health Service Staff from participating sites who complete the training will be able to express interest for a Yarn. Yarns will be conducted at the discretion of the



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research team, who have extensive experience in qualitative methods. Data saturation or predetermined sample size is not deemed appropriate for this study,[42] as it is not intended to be representative. Instead, the research team will work responsively to communities and determine if further data collection is warranted to capture additional perceptions, experiences and recommendations.

## Analysis

### Surveys

*Pre- and post-training surveys:* 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. *Group participant surveys:* To evaluate smoking and vaping cessation outcomes, the proportion of eligible women who report abstaining from smoking and vaping at each follow-up time point will be reported with 95% CIs (6 months being the primary time point of interest). A single sample test of a binomial proportion (normal approximation) will be used to test the hypothesis that the proportion abstaining at 6 months is>10%. A further analysis using logistic regression (GEE with compound symmetric covariance structure) will be conducted to evaluate the trend over time in abstinence rates, as well as the factors which are cross-sectionally associated with abstaining as detailed in table 1. *Maintenance survey:* Categorical data will be presented as counts and percentages with 95% confidence levels. Continuous data will be presented as means and SD.

### Yarns

Qualitative data will be analysed by Aboriginal and Torres Strait Islander members of the research team using thematic analysis techniques which are responsive to the data, such as Reflexive TA[43] or template analysis.[44]

# ETHICS AND DISSEMINATION

## Ethics approvals

This project was approved by the local Aboriginal community research panel at the University of Newcastle *Wukul Yabang* and has received ethical approval from the Aboriginal Health & Medical Research Council Ethics Committee of NSW (2328/24) and registered with the University of Newcastle (R-2024–0082). The National Health and Medical Research Council[45] data management policy will be used to collect, store and use data. This project has been registered with ANZCTR (ACTRN12625001050448).

## 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 MK (Wiradjuri) and FC (Gomeroi). No data will be used without full consultation, 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, offering data enhancement support for service level CQI 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.

## Consent

Each site will be offered a formal research agreement and give organisational consent to participate. Participation is voluntary, and participants can withdraw from the study at any time. Health service staff and group participants will be provided with a detailed information sheet that includes details of the research team and the complaints process, and informed written consent will be obtained prior to participation.

## Confidentiality

All data collected will be de-identified and remain confidential, and no identifiable data will be published or shared. All use of the data will adhere to processes of Indigenous data governance[46] and uphold data privacy and confidentiality. Contact details of participants will not be linked to survey answers.

## Dissemination

The findings of the study will be presented to and shared with relevant stakeholders including back to individual communities in a way that is useful to them. Dissemination strategies will be developed through ongoing relational approaches with community partners upholding their rights to research that is of benefit. A website has been created and will be managed by the project team to update community partners on the project and in-process findings. Further translational activities will be shared with the AH&MRC, NSW Ministry of Health, National Aboriginal Community Controlled Health Organisation and Tackling Indigenous Smoking Programme. The research team will also present findings in conferences and make the findings available through scientific publications.

## Discussion and implications

This project addresses a key national priority area to improve the health and well-being of Aboriginal and Torres Strait Islander people.[12] Re-designing health service delivery for Aboriginal women who want to quit has potential to increase the number of Aboriginal women who successfully become smoke and vape free. To date, no interventions implemented in Australia have identified effective strategies to specifically increase smoking



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and vaping cessation among Aboriginal and Torres Strait Islander people who are pregnant, or of reproductive age. This study will deliver smoking and vaping cessation support as determined by Aboriginal and Torres Strait Islander women and upholding their right to self-determination and access to evidence-based cessation care. Further, it will develop the skills, knowledge and confidence for health workers to ensure continuation of evidence-based care in health services across NSW. The culturally responsive approach to this project will offer learnings for implementation and evaluation research in Aboriginal and Torres Strait Islander health by upholding Aboriginal and Torres Strait Islander expertise and expertise through all stages of the process, including ownership of the programme.

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**Competing interests** None declared.

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