



BMJ Open Koori Quit Pack mailout smoking cessation support for Aboriginal and Torres Strait Islander people who smoke: a feasibility study protocol

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ABSTRACT

Introduction Smoking remains the leading preventable cause of death for Aboriginal and Torres Strait Islander people in Australia. Aboriginal and Torres Strait Islander people who smoke are more likely to make a quit attempt than their non-Aboriginal counterparts but less likely to sustain the quit attempt. There is little available evidence specifically for and by Indigenous peoples to inform best practice smoking cessation care.

The provision of a free Koori Quit Pack with optional nicotine replacement therapy sent by mail may be a feasible, acceptable and effective way to access stop smoking support for Aboriginal and Torres Strait Islander peoples.

Methods and analysis An Aboriginal-led, multisite non-randomised single-group, pre–post feasibility study across three states in Australia will be conducted. Participants will be recruited via service-targeted social media advertising and during usual care at their Aboriginal Community Controlled Health Services. Through a process of self-referral, Aboriginal and Torres Strait Islander people who smoke daily will complete a survey and receive mailout smoking cessation support. Data will be collected over the phone by an Aboriginal Research Assistant. This pilot study will inform the development of a larger, powered trial.

Ethics and dissemination Ethics approval has been obtained from the Aboriginal Health & Medical Research Council Ethics Committee of New South Wales (NSW) (#1894/21) and the University of Newcastle (#H-2022-0174). Findings will be reported through peer-reviewed journals and presentations at relevant local, national and international conferences. The findings will be shared with the NSW and Victoria Quitline, Aboriginal Health and Medical Research Council and Victorian Aboriginal Community Controlled Organisation and the National Heart Foundation.

Trial registration number ACTRN12622000654752.

INTRODUCTION

Commercial tobacco is killing Aboriginal and Torres Strait Islander people. Tobacco use among Aboriginal and Torres Strait Islander people is intrinsically linked with colonisation, dispossession and racism.^{1–3} It

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This will be the first study to explore mailout smoking cessation support in an Indigenous setting in Australia and internationally.
- ⇒ This study will address a national priority area for Aboriginal and Torres Strait Islander people by providing an insight on a new and innovative way of improving uptake of smoking cessation support and smoking cessation.
- ⇒ This pilot is aimed to assess mailout smoking cessation support feasibility, acceptability, abstinence and adherence, and is not powered to assess the effectiveness of the intervention.

was introduced into Australia by European colonisers who used tobacco to establish relationships and gain assistance from Aboriginal and Torres Strait Islander people.⁴ Tobacco became a staple of employers and government issued rations, in lieu of wages, which continued until the 1940s and on some cattle stations until 1968.⁵ Today, tobacco use is the largest single-risk behaviour for the adverse health conditions of Aboriginal and Torres Strait Islander people, contributing 17% of total burden.⁶ Despite a reduction in the prevalence of smoking among Aboriginal and Torres Strait Islander people,^{7,8} smoking remains the leading preventable cause of death for Aboriginal and Torres Strait Islander people.⁴

Aboriginal and Torres Strait Islander people want to quit smoking. They are more likely to make a quit attempt than their non-Aboriginal counterparts but less likely to sustain a quit attempt.⁹ This suggests that public health measures addressing tobacco use are successfully motivating people who smoke to attempt quitting. However, Aboriginal and Torres Strait Islander people who smoke may require support to sustain that

quit attempt and achieve long-term abstinence.¹⁰ There is a comprehensive evidence base from the general population indicating a combination of behavioural counselling and pharmacotherapy gives people who smoke the best chance at quitting. However, there has been no measure of effectiveness with Indigenous peoples. Additionally, Aboriginal and Torres Strait Islander people who smoke may not be receiving best practice smoking cessation support. For example, studies have found that although most (93%) Aboriginal and Torres Strait Islander people were asked if they smoked, only 49% of those who had been advised to quit were offered smoking cessation information and only 28% were referred to Quitline.¹¹

Social media and community marketing is effective in changing attitudes, beliefs and intentions surrounding tobacco use and motivation to quit smoking.¹² However, evidence suggests only a small proportion of people who smoke have used evidence-based smoking cessation treatments¹³ that can increase the likelihood of longer-term smoking cessation. Best practice treatment includes multi-session behavioural counselling¹⁴ combined with pharmacotherapies, such as nicotine replacement therapies (NRTs).¹⁵ While pharmacotherapies and counselling are effective on their own, quit rates increase when they are used together.¹⁶ Quitline call-back services are effective in increasing smoking cessation in the general population¹⁴ but have not been effectively measured among Aboriginal and Torres Strait Islander people. A recent New South Wales (NSW) Aboriginal Quitline evaluation reported positive insights in relation to Quitline outcome, benefits, cultural appropriateness, (safety) access and awareness.¹⁷ The evaluation reported that Aboriginal and Torres Strait Islander people are receiving Quitline support from trained Aboriginal and Torres Strait Islander counsellors, and recommended the inclusion of NRT provision for consideration.¹⁷

The Royal Australian College of General Practitioners (RACGP) guidelines recommend the use of pharmacotherapies in addition to behavioural counselling for all Aboriginal and Torres Strait Islander people who want to quit smoking.¹⁸ NRT increases the success in quitting by 50%–60%.¹⁹ Despite this, the use of NRT among Aboriginal and Torres Strait Islander adults is low compared with other Australians (23% vs 42%), with barriers such as knowledge, access and cost of NRT potentially impacting use. Further, 74% of Aboriginal and Torres Strait Islander peoples who used NRT reported receiving NRT at 'no cost', suggesting removal of the cost barrier could significantly increase use.²⁰ Among Aboriginal and Torres Strait Islander people who smoke that reported using NRT, those with higher nicotine dependence were more likely to believe that NRT helped quitting.²⁰ Increasing awareness and knowledge about the effectiveness and safety of NRT may be important to address acceptance and adherence, which can potentially influence cessation rates. Further, no innovative approaches to simultaneously address cost, access and adherence among Aboriginal and Torres Strait Islander people has been conducted.

Aboriginal Community Controlled Health Services (ACCHS) are the leading health provider for Aboriginal and Torres Strait Islander people in Australia,²¹ and are owned and operated under the leadership of the local Aboriginal community. Aboriginal communities have reported that the use of NRT to support smoking cessation could be increased with readily available NRT through ACCHS, and avoiding having to access a pharmacy to collect cessation aids.²² While short-term funding solutions to purchase NRT are regularly sought by ACCHS to address and mitigate barriers to NRT use, no long-term initiatives have been provided. There has been limited research conducted exploring the uptake and use of NRT, follow-up/review or (re)issue of NRT, or adherence among Aboriginal and Torres Strait Islander people. The Pharmaceutical Benefits Scheme offers prescription two times annually to Aboriginal and Torres Strait Islander people; however, it is unclear if doctors are prescribing 10 weeks of NRT as recommended by the RACGP, or offering follow-up and review.

Evidence of the effectiveness of smoking cessation interventions is strong among the general population; however, intervention studies are urgently needed to address smoking rates for Aboriginal and Torres Strait Islander people.²³ This is consistent with the WHO Framework Convention on Tobacco Control, which calls for Indigenous peoples to be involved in the development, implementation and evaluation of Indigenous tobacco control. There is a critical need for more Indigenous-led intervention research and evaluation on ways to assist Aboriginal and Torres Strait Islander people to achieve and sustain long-term smoke-free norms.

This study will explore a scalable method of improved, flexible and potentially low-cost access to evidence-based smoking cessation supports for Aboriginal and Torres Strait Islander people. Additionally, this study will test the feasibility and acceptability of Koori Quit Pack, a mailed out smoking cessation package, including optional NRT, smoking cessation pamphlets information on the MyQuit-Buddy app, iCanQuit app, Koori Quitline Facebook page and Aboriginal Quitline webpage, and offer proactive Quitline referrals for Aboriginal and Torres Strait Islander people in NSW, Australian Capital Territory (ACT) and Victoria.

Research has demonstrated the receptivity of people who smoke to the proactive offer of Quitline, and its effectiveness at increasing cessation rates.²⁴ The Quitline in Queensland offers a Yarn to Quit programme, combining telephone counselling and postal NRT delivery to support Aboriginal and Torres Strait Islander people. However, no evaluations to date have reported its effectiveness. This research combines two evidence-based smoking cessation outreach interventions (NRT and Quitline) with a range of readily available resources and assesses the level of interest, acceptability and feasibility among Aboriginal and Torres Strait Islander people in NSW, ACT and Victoria.

This project is Aboriginal-led and has been designed in partnership and co-owned with the Aboriginal Health and

Medical Research Council (AH&MRC), Victorian Aboriginal Community Controlled Organisation (VACCHO), NSW/ACT and Victorian Quitlines, and Cancer Institute NSW to implement the first study exploring mailout smoking cessation support, including NRT in an Indigenous setting internationally.

METHODS AND ANALYSIS

Research team

This is an Aboriginal-led, community owned, research study aimed at increasing Indigenous-led tobacco control evidence. The study was conceptualised and led by the first author (MK, Wiradjuri woman), in partnership with Aboriginal communities in NSW and Victoria. Our team brings Aboriginal lived experience (MK, CC, SM, PO, KC), Indigenous lived experience (RM), expertise in Aboriginal health services (MH, BD), and tobacco research (MK, RM, CC, AGM, CS, BB). The project also employs two Aboriginal research assistants to support the culturally safe research implementation.

Study overview

There have been no studies exploring mailout smoking cessation support in an Indigenous setting in Australia or internationally. Successful smoking cessation programmes among Indigenous people locally and internationally are reported to include; Indigenous leadership, community ownership and long-term implementation and sustainability.⁴

This Indigenous-led study will report crucial knowledge on the interest, uptake and adherence of Aboriginal and Torres Strait Islander people to a range of scalable smoking cessation strategies in partnership with key stakeholders. This study will also address a national priority area for Aboriginal and Torres Strait Islander people by providing insights on a new and innovative way of improving smoking cessation care.

The findings of the study will provide vital intelligence for the scale-up and conduct of larger trials. It will also help inform clinical service and health promotion practice in NSW, ACT and Victoria.

The aims of the pilot in NSW, ACT and Victoria are to:

1. Examine the feasibility and acceptability of a mailout smoking cessation package among Aboriginal and Torres Strait Islander people.
2. Examine what support strategies included in the Quit Pack are taken up by Aboriginal and Torres Strait Islander people. Specifically, to examine uptake of:
 - a. Mailed NRT.
 - b. Other smoking cessation pharmacotherapies.
 - c. Proactive Quitline.
 - d. Mobile phone smoking cessation applications.
 - e. Other forms of smoking cessation behavioural support.
3. Examine impact of a mailout smoking cessation package on self-reported quit attempts and abstinence.

4. Examine adherence to smoking cessation support, including Quitline, NRT and mobile phone apps.
5. Evaluate the factors associated with uptake of mailout NRT among Aboriginal and Torres Strait Islander people.
6. Compare recruitment and retention of participants between NSW, ACT and Victoria.

Design

This is a non-randomised single-group, pre–post feasibility study of a mailout smoking cessation intervention with Aboriginal and Torres Strait Islander people in NSW, ACT and Victoria. The findings will help inform the development of a larger, powered trial. Participants will self-refer to receive mailout smoking cessation support.

Timeline of the study

Data collection commenced in May 2022 and will continue to December 2023.

Setting

Participant recruitment will be over a 12-month period using self-referral. Two forms of recruitment will be used. First, service-targeted online social media recruitment using Facebook advertising, posts shared by ACCHS and Quitline. Social media advertisements will promote the study with links to self-refer. Second, face to face through partnering ACCHS (in line with annual health checks, visits to the doctor and at community events), potential participants will be provided with a recruitment card including a QR code for the programme by their doctor or Aboriginal health worker/practitioner.

Participants

Participants will provide informed consent before survey commencement and eligibility screening questions. Eligible participants will be asked to provide their phone number for follow-up. The baseline survey will be administered by the Aboriginal research assistant over the phone and entered manually into the secure Research Electronic Data Capture (REDCap) system. Measures will include demographic characteristics (identifying their ACCHS and adding their postal address), health status, smoking behaviours and previous experience with NRT. All participants will then be offered best practice smoking cessation treatment, that is, combination NRT (patch plus a faster-acting formulation) plus behavioural counselling via Aboriginal Quitline, together with supporting written and promotional materials (see figure 1 for a summary of the participant flow).

Eligibility criteria

Participants will be eligible if they self-identify as Aboriginal and/or Torres Strait Islander people, currently smoke daily, are aged 16 years and above, and reside in NSW, ACT or Victoria. Participants will only be eligible if they have a plan to quit smoking in the next 30 days following enrolment to the programme. If the participant is pregnant or becomes pregnant while in the trial, we

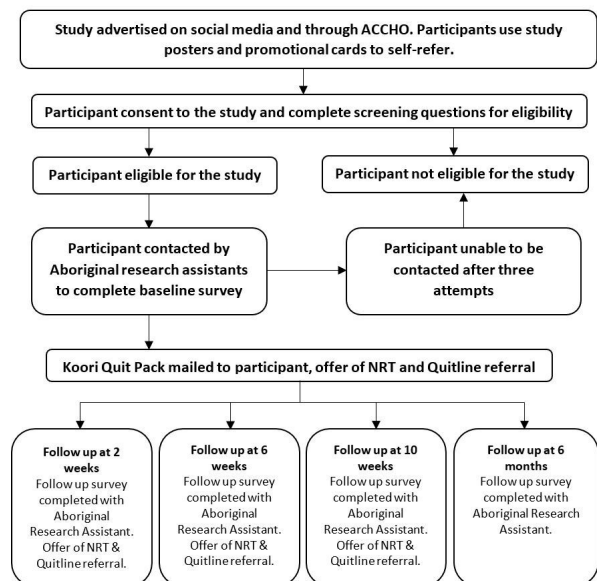


Figure 1 Flow of participants through the study. ACCHO, Aboriginal Community Controlled Organisation; NRT, nicotine replacement therapy.

will recommend speaking with their general practitioner (GP) before using the optional NRT component.

Participants who have a history of contraindications to NRT, such as having recent myocardial infarction, stroke, or a serious heart or circulation problem will be provided with smoking cessation support without NRT. People with health contraindication(s) wishing to use NRT will be encouraged to consult their regular GP for advice. These participants will not be excluded and can still access other supports available in their Quit Pack. Participants who do not intend to quit smoking in the next 30 days will not be eligible; however, they will be provided with online resources regarding the benefits of smoking cessation. They will then have the option to reconsider and if motivated to quit can return to the study anytime during the study recruitment period.

Intervention: Koori Quit Pack Quit Pack

The Quit Pack will include readily available universal quitting resources such as; pamphlets and resources on quitting, an information card on existing government-provided support options such as MyQuitBuddy App, and iCanQuit App. In addition, there will be Aboriginal and Torres Strait Islander specific supports such as a link to Aboriginal Quitline webpage, as well as health promotion and Aboriginal merchandise.

An offer of NRT

An Aboriginal research assistant will telephone participants and conduct a brief assessment of smoking behaviours. All participants will be offered the option of NRT at recruitment, and each follow-up time point. If participants agree to the offer of NRT they will be asked if they intend to use the NRT in the first week. NRT will include 21 mg nicotine patches and a number of

faster-acting oral NRT formulations (lozenge, gum, inhalator) as combination NRT, consistent with the recommended best practice according to the 2019 RACGP smoking cessation guidelines. The RACGP recommends a 10-week course of NRT treatment for effective smoking cessation.²⁵ The first Quit Pack will include 2 weeks of NRT based on participant preference. Participants who do not tolerate the type of NRT they are provided with will be offered with a different type of NRT. For example, if the participant does not tolerate nicotine gum, inhalers will be provided. At 2 weeks, we will assess adherence, NRT preference changes, utilisations and provide a further 4 weeks of NRT supply for two courses (total of 10 weeks).

Behavioural counselling

Participants will be offered a referral to Aboriginal Quitline. An Aboriginal research assistant will explain that the most effective way to quit smoking is to have something to help with the cravings (the NRT) plus help to manage triggers to smoke (eg, stress or others smoking around you) like that provided by an Aboriginal Quitline. After describing what Aboriginal Quitline offers (i.e., a dedicated Aboriginal counsellor, yarning approach, as many or as few calls from Quitline as they would like, help with using the NRT products), the research assistant will only refer the participant to Aboriginal Quitline if they are interested and consent. One of the benefits of Aboriginal Quitline is that it is able to provide highly flexible and timely support, for example, more frequent calls in the first week immediately following a quit attempt when the risk of smoking relapse, even when using NRT, is highest.²⁶

Follow-up

Follow-up will be conducted for all participants including those that do not wish to use NRT and/or Aboriginal Quitline. At each follow-up time point, an Aboriginal research assistant will offer NRT and Quitline referral to the participant. Participants who agree to have NRT mailed to their home will receive a 10-week programme that will be sent after each follow-up time point. This was chosen due to the cost of NRT and to reassess use and participant preference regarding oral forms of NRT. Follow-up schedule is found in [table 1](#).

All follow-ups will be conducted by an Aboriginal research assistant with all follow-up attempts made upholding culturally safety and Indigenous ways of knowing, being and doing through building of reciprocal relationships. If follow-up phone calls are not answered, a text message will be sent and if no response, two further text reminders will be sent, the final text including a link to the follow-up survey and offer of supports. Follow-up will be conducted at 2 weeks, 6 weeks, 10 weeks and 6 months. Participants who complete follow-up will be provided with a AUD\$30 gift card at 2, 6 and 10 weeks to reimburse their time. At 6-month time point participants will be sent a survey via text message and/or email to report smoking behaviours, self-reported quit attempt lasting 24 hours,

Table 1 Summary of measures and follow-ups

Measures	Baseline	2 weeks follow-up	6 weeks follow-up	10 weeks follow-up	6 months follow-up
Baseline data	✓				
Quit Pack: health education resources	✓	✓	✓		
Quit Pack: proactive Quitline referral	✓	✓	✓		
Quit Pack: offer of free NRT	✓	✓	✓		
Adherence and acceptability of NRT		✓	✓	✓	
Feasibility and acceptability of study		✓	✓	✓	
Quit attempt lasting 24 hours		✓	✓	✓	✓
Self-reported 7-day abstinence rates				✓	✓
Postintervention follow-up survey				✓	✓

NRT, nicotine replacement therapy.

self-reported 7-day smoking abstinence, NRT and Quitline use and acceptability of the programme.

Outcome measures

Feasibility and acceptability outcomes measures are summarised in [table 2](#).

Primary outcome measure

The primary outcomes include feasibility of the programme, acceptability of the programme and rate of smoking abstinence. Feasibility and acceptability of the intervention will be measured by recruitment rates,

Table 2 Feasibility and acceptability of outcomes

Outcome	Data collection method	Analysis	Timepoints
Feasibility (primary)	Audit of study records	Recruitment by channel type (Facebook ad vs QR code) Recruitment by channel intensity (amount of Facebook advertising, number of ACCHS actively recruiting) Evaluating the update of resources.	Recruitment period
Acceptability (primary)	Participant survey Participant interview	Self-reported questionnaire reporting usefulness, engagement and improvement questions. Statistical analysis of survey. Thematic analysis of open-ended questions. Feasibility and acceptability of the programme and suggestions for improvements.	2 weeks, 6 weeks (primary endpoint), 10 weeks and 6 months after pack is delivered 10 weeks after pack is delivered
Abstinence (primary)	Participant survey	Study-specific questionnaire including self-reported 7-day point prevalence abstinence rates. Statistical analysis.	2 weeks, 6 weeks (primary endpoint), 10 weeks and 6 months after pack is delivered
Adherence (secondary)	Participant survey	Self-reported, study-specific questionnaire asking the frequency of use of individual intervention components. Adherence will be assessed with the following two survey questions adapted from previous studies ¹ how often did you use the (NRT type) and ² how long did you use the (NRT type). Statistical analysis.	2 weeks, 6 weeks and 10 weeks after pack is delivered
Recruitment rate (secondary)	Audit of study records	Assessed by audit of study database (number and % of people eligible and consenting into study).	Baseline,
Retention rate (secondary)	Audit of study records	Assessed by the number (and %) of participants completing each follow-up.	2 weeks, 6 weeks (primary endpoint), 10 weeks and 6 months after pack is delivered

ACCHS, Aboriginal Community Controlled Health Services; NRT, nicotine replacement therapy.

uptake of Quitpack and uptake/adherence to both NRT and Quitline (best practice treatment) and uptake of a cessation app, retention rates and other measures collected by the research assistant during follow-up. The rates of self-referral and referral through the ACCHS will be measured. Smoking cessation outcomes: participants will be asked whether they have smoked, even a puff, in the last 7 days to assess 7-day point prevalence abstinence, an item recommended by the Society for Research in Nicotine and Tobacco. Participants who have not quit will be asked how many cigarettes per day they currently smoke and their intentions to quit smoking; how soon after waking they smoke their first cigarette; and if, since their baseline interview, they have stopped smoking for even 1 day because they were trying to quit.

Secondary outcomes

The secondary outcomes include adherence to the intervention components, participant recruitment rates and participant retention rates at each follow-up time points. Adherence will be measured by participants' self-reported usage of the individual intervention components at each follow-up time point. Participant recruitment rate will be assessed by auditing the study databases at baseline and follow-up. Participant retention rates will be evaluated using the number of participants in each follow-up using study database.

Data collection

Participants will complete a telephone survey at baseline, 2 weeks, 6 weeks and 10 weeks of follow-up. A final survey link will be sent by text message at 6 months. The survey instruments were prepared in the English language and will be filled in the electronic survey using REDCap by the Aboriginal research assistant.

Measures

Baseline survey

The baseline survey includes the following five sections.

Sociodemographic characteristics

The first section will assess gender (man, women, transgender, non-binary or others); postal code; level of education (primary school, or up to year 9, year 10–11, year 12, current student at university/TAFE/apprentice, trade certificate, university degree); number of people living in the household; number of children living in the household; and frequency of anyone smoking inside their home (daily, weekly, monthly, less than monthly, never). For women, we will assess pregnancy status and plans to conceive in the next 3 months.

Smoking and cigarette behaviours

The second section will elicit smoking characteristics of participants including: (1) the type of tobacco products the participant usually smokes (cigarettes, roll your own cigarettes from commercial tobacco, roll your own cigarettes or other sources of tobacco and nicotine, cigars, shisha or pipe or hookah or others); (2) use of e-cigarette/

vape with nicotine and e-cigarette/vape without nicotine will be assessed and (3) the level of nicotine dependence using the Heaviness of Smoking Index.²⁷ The frequency of urge to smoke in 24-hour period will be assessed (not at all, a little of the time, some of the time, a lot of the time, almost all the time, all the time). We will also assess the strength of urge to smoke (no urges, slight, moderate, strong, very strong, extremely strong).²⁸ This method of assessing the strength and frequency of urges to smoke has been used successfully in previous studies conducted among Aboriginal and Torres Strait Islander People.²⁹

Motivation and confidence in quitting smoking

We will explore participants level of motivation and confidence to quit. Participants will be asked to rate their level of motivation to quit smoking out of 10 (1 being 'very low motivation' and 10 being 'very high motivation'). Participants' confidence to quit smoking will be assessed as 'not at all confident', 'slightly confident', 'moderately confident', 'very confident' or 'extremely confident'.^{29 30}

Quitting history and future intention

The fourth section will explore quitting history and future intentions. Participants will be asked question about their quit attempts and the methods they have used to assist their quit attempts. The following smoking cessation medication related issues will be evaluated: previous use, safety and efficacy beliefs, reasons for not using medications, duration and frequency of medication use, their intention to use the medications, preferred smoking cessation medication. Additionally, previous use of other smoking cessation supports such as Quitline, websites, Mobile phone apps will be elicited. Previous studies have used the duration and frequency of NRT use to measure adherence to NRT.^{31 32}

Mental health and well-being

Section five will explore mental health and well-being using the adapted version of the 9-item Patient Health Questionnaire (PHQ-9) for use in Aboriginal and Torres Strait Islander peoples. A cut-point score of 10 points from a maximum score of 27 will be used to consider further support and referral.³³ Participants with a PHQ-9 Score of 10 and above will be encouraged to contact their local GPs and provided with the phone numbers for an immediate online support (Lifeline or Mental Health Line).

Follow-up survey

At each follow-up, we will examine current smoking status; quit attempts; and among abstainers, nicotine withdrawal symptoms. Continuous and 7-day point prevalence abstinence from smoking will be explored. Similarly, the usage patterns of smoking cessation supports, such as MyQuitBuddy App, Quitline, Aboriginal Quitline webpages, Pamphlets or booklets, iCanQuit App, Koori Quitline Facebook page use will also be elicited. Change in safety and efficacy beliefs about NRT will be evaluated in each follow-up survey. Adherence to the NRT will be evaluated based on the duration and frequency of use.

If participants are not using the medications as per the recommendation, the reasons will be elicited. Participants' treatment preference, motivation and confidence to quit smoking will be assessed at each follow-up. The frequency and intensity of urge to smoke will be evaluated in each follow-up visit. Participants mental health status will be evaluated using the adapted version of the 9-item PHQ-9 in each follow-up survey.

Sample size calculation

The number of participants required for a feasibility study varies with a minimum of 100 participants.³⁴ We will recruit up to 500 people and cease recruitment after 12 months, with a target sample of 200.

Data analysis plan

In accordance with the Consolidated Standards of Reporting Trials statement guideline for feasibility and pilot studies,³⁵ no formal hypothesis testing for effectiveness will be undertaken. Descriptive statistics will be presented to characterise participants enrolled in the feasibility study at each follow-up time points. The acceptability and adherence to smoking cessation supports will be described using frequency and percentages. Rate of smoking cessation, participant recruitment and retention rate will be evaluated and presented using tables and figures. The rate of smoking cessation will be reported using an intention-to-treat approach. Participants who are lost from follow-up will be considered still smoking and will be included in the analysis in such a way. Thematic analysis of open-ended questions will be undertaken to evaluate acceptability of the programme and to provide directions for a powered trial.

Patient and public involvement

The research team acknowledge that Aboriginal and Torres Strait Islander people have the right to oversee research conducted. Following consultation with Aboriginal Health Services across the states and territories included in this study and other stakeholders, we were advised that an appropriate Aboriginal Community Governance for this project is the AH&MRC's Tobacco Advisory Committee (TAC). The lead researcher and Aboriginal research assistant will report progress on the project to the TAC approximately quarterly. The TAC will oversee the data collection, analysis and reporting ensuring it is appropriate community involvement. TAC members will also be invited to join the authorship team on publications resulting from this study. We acknowledge this is not reflective of ACT or Victoria communities and will continue to consult on appropriate oversight, respecting local protocols. Acknowledging the impact on Aboriginal Health Services during COVID-19, this approach was deemed appropriate and assists to minimise the burden to the Aboriginal and Torres Strait Islander communities.

Registration

The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12622000654752).

Ethics and dissemination

Ethics approval has been obtained from the Aboriginal Health & Medical Research Council Ethics Committee of NSW with approval number 1894/21 and the University of Newcastle with approval number of H-2022-0174.

Informed consent will be obtained from all participants. Participant information will be always kept confidential. No data will be published that identifies individual participants. Data will be collected, stored and used in accordance with the National Health and Medical Research Council data management policy.

A range of community-led knowledge translation activities and resources will be developed and shared based on the needs and interest of participants and community partners to disseminate results. These will include but will not be limited to; infographics, webinars, short videos and brief reports. The results will also be presented in relevant local, national and international conferences, and with the NSW and Victoria Quitline, AH&MRC and VACCHO and the National Heart Foundation. Academic publications are also expected.

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Contributors MK conceived the study and obtained funding for the project. MK and AGM drafted the manuscript. MK, AM, RM, CC, SM, PO, CS, MH, KC, BD and BB contributed to developing the study design and content. All authors provided comments and revisions on the manuscript and approved the final version.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods and analysis section for further details.

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REFERENCES

- Brady M. Historical and cultural roots of tobacco use among Aboriginal and Torres Strait Islander people. *Aust N Z J Public Health* 2002;26:120–4.
- van der Sterren A, Greenhalgh EM, Knoche D, et al. *History of tobacco use among Aboriginal peoples and Torres Strait Islanders. tobacco in Australia: facts and issues*. Melbourne: Cancer Council Victoria, 2016.
- Ratsch A, Mason A, Rive L, et al. The Pituri learning circle: central Australian Aboriginal women's knowledge and practices around the use of Nicotiana spp. as a chewing tobacco. *Rural Remote Health* 2017;17:17.
- Colonna E, Maddox R, Cohen R. Review of tobacco use among Aboriginal and Torres Strait Islander peoples. *Australian Indigenous Health Bulletin* 2020;20. <https://aodkknowledgecentre.ecu.edu.au/learn/specific-drugs/tobacco/>
- Ivers RG. Tobacco addiction and the process of colonisation. *Aust N Z J Public Health* 2002;26:280–1.
- Vos T, Barker B, Begg S, et al. Burden of disease and injury in Aboriginal and Torres Strait Islander peoples: the Indigenous health gap. *Int J Epidemiol* 2009;38:470–7.
- Maddox R, Thurber KA, Calma T, et al. Deadly news: the downward trend continues in Aboriginal and Torres Strait Islander smoking 2004–2019. *Aust N Z J Public Health* 2020;44:449–50.
- Statistics. ABo. National Aboriginal and Torres Strait Islander health survey, 2018–19; 2019.
- AIHW. Tobacco indicators: measuring midpoint progress- reporting under the National tobacco strategy 2012–2018 Drug statistics series; 2016, CAT. no. PHE 210: 30.
- Kotz D, West R. Explaining the social gradient in smoking cessation: it's not in the trying, but in the succeeding. *Tob Control* 2009;18:43–6.
- Thomas DP, Bennet PT, Briggs VL, et al. Smoking cessation advice and non-pharmacological support in a national sample of Aboriginal and Torres Strait Islander smokers and ex-smokers. *Med J Aust* 2015;202.
- Cohen R, Maddox R, Sedgwick M, et al. Tobacco related attitudes and behaviours in relation to exposure to the tackling Indigenous smoking program: evidence from the Mayi Kuwayu study. *Int J Environ Res Public Health* 2021;18:10962.
- White S, McCaffrey, N, Scollo M. Tobacco dependence treatment in Australia – an untapped opportunity for reducing the smoking burden. *Public Health Res Pract* 2020;30.
- Matkin W, Ordóñez-Mena JM, Hartmann-Boyce J. Telephone counselling for smoking cessation. *Cochrane Database Syst Rev* 2019;5:CD002850.
- Cahill K, Stevens S, Perera R, et al. Pharmacological interventions for smoking cessation: an overview and network meta-analysis. *Cochrane Database Syst Rev* 2013;2015.
- SERVICES USDOHAH. Smoking cessation; a report of the surgeon general, executive summary Office of the Surgeon General; 2020.
- Cancer Institute NSW. NSW aboriginal quitline evaluation report; 2022 [Accessed 20 Dec 2021].
- RACGP. Supporting smoking cessation: a guide for health professionals, pharmacotherapy for smoking cessation. Available: <https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/pharmacotherapy-for-smoking-cessation> [Accessed 01 Sep 2021].
- Hartmann-Boyce J, Chepkin SC, Ye W, et al. Nicotine replacement therapy versus control for smoking cessation. *Cochrane Database Syst Rev* 2018;5:CD000146–CD.
- Thomas DP, Briggs VL, Couzos S, et al. Use of nicotine replacement therapy and stop-smoking medicines in a national sample of Aboriginal and Torres Strait Islander smokers and ex-smokers. *Med J Aust* 2015;202:92.
- Pearson O, Schwartzkopff K, Dawson A, et al. Aboriginal community controlled health organisations address health equity through action on the social determinants of health of Aboriginal and Torres Strait Islander peoples in Australia. *BMC Public Health* 2020;20:1859.
- Maddox RC R, Kennedy M, Barrett E, et al. *Aboriginal tobacco scoping project*. Cancer Institute NSW (commissioned), 2021.
- Minichiello A, Lefkowitz ARF, Firestone M, et al. Effective strategies to reduce commercial tobacco use in Indigenous communities globally: a systematic review. *BMC Public Health* 2016;16:1–25.
- Tzelepis F, Paul CL, Wiggers J, et al. A randomised controlled trial of proactive telephone counselling on cold-called smokers' cessation rates. *Tob Control* 2011;20:40.
- Health AGDo. My QuitBuddy APP, 2020. Available: <https://www.health.gov.au/resources/apps-and-tools/my-quitbuddy-app>
- Jackson SE, McGowan JA, Ubhi HK, et al. Modelling continuous abstinence rates over time from clinical trials of pharmacological interventions for smoking cessation. *Addiction* 2019;114:787–97.
- Heatherton TF, Kozlowski LT, Frecker RC, et al. Measuring the heaviness of smoking: using self-reported time to the first cigarette of the day and number of cigarettes smoked per day. *Br J Addict* 1989;84:791–9.
- Fidler JA, Shahab L, West R. Strength of urges to smoke as a measure of severity of cigarette dependence: comparison with the Fagerström test for nicotine dependence and its components. *Addiction* 2011;106:631–8.
- Kennedy M, Barrett E, Heris C, et al. Smoking and quitting characteristics of Aboriginal and Torres Strait Islander women of reproductive age: findings from the which way? study. *Med J Aust* 2022;217 Suppl 2:S6–18.
- Kahler CW, Leventhal AM, Brown RA. Behavioral interventions in smoking cessation. In: Ries RK, Fiellin DA, Miller SC, et al, eds. *Principles of addiction medicine*. 4th ed. Philadelphia, PA: Wolters Kluwer, 2009: 803–17.
- Mersha AG, Eftekhari P, Bovill M, et al. Evaluating level of adherence to nicotine replacement therapy and its impact on smoking cessation: a systematic review and meta-analysis. *Arch Public Health* 2021;79:26.
- Mersha AG, Kennedy M, Eftekhari P, et al. Predictors of adherence to smoking cessation medications among current and ex-smokers in Australia: findings from a national cross-sectional survey. *Int J Environ Res Public Health* 2021;18. doi:10.3390/ijerph182212225. [Epub ahead of print: 21 11 2021].
- Getting it Right Collaborative Group. Getting it right: validating a culturally specific screening tool for depression (aPHQ-9) in Aboriginal and Torres Strait Islander Australians. *Med J Aust* 2019;211:24.
- Billingham SAM, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom clinical research network database. *BMC Med Res Methodol* 2013;13:104.
- Eldridge SM, Chan CL, Campbell MJ, et al. Consort 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i52 39–i.