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Mailed smoking cessation support for Aboriginal and Torres Strait Islander people who smoke: protocol for a hybrid type 1 effectiveness – implementation trial

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ABSTRACT

Introduction Smoking is the leading preventable cause of death and the single most significant risk behaviour contributing to adverse health conditions among Aboriginal and Torres Strait Islander people. There is an urgent need for innovative approaches to support reductions in smoking prevalence. This study will assess the implementation and effectiveness of a mailed smoking cessation support programme that includes nicotine replacement therapy (NRT) (*Which Way Quit Pack*) for Aboriginal and Torres Strait Islander people.

Methods and analysis A hybrid type 1 effectiveness—implementation trial will be conducted in Australia from 2023 to 2025. A sample of 500 Aboriginal and Torres Strait Islander people aged over 16 who smoke will be recruited using social media. All participants will: (a) receive a mailed *Which Way Quit Pack* that includes pamphlets and resources on quitting, information about quit smoking support options (MyQuitBuddy App) and a selection of merchandise; (b) be offered a referral to Aboriginal Quitline; and (c) be offered a free 12-week mail out course of combination NRT. Outcome data will be obtained using quantitative surveys and qualitative Yarning. Effectiveness outcomes will include assessment of 7-day point prevalence, continuous abstinence and quit attempts at 3- and 6-month follow-up. Implementation outcomes will include assessment of recruitment and retention rates, intervention uptake and adherence, and intervention acceptability.

Cessation data will be analysed using an intention-to-treat principle with all individuals lost to follow-up considered as smoking. Yarns will be analysed by Aboriginal and Torres Strait Islander members of the research team privileging Collaborative Yarning, with the support of a reflexive thematic analysis approach that will identify themes while also reflecting potential biases and perspectives of the researcher throughout the analysis process.

Ethics and dissemination Ethics approvals were obtained from Aboriginal Health and Medical Research Council Ethics Committee of NSW (1894/21) and the University of Newcastle (H-2022-0174). Findings will be disseminated through publications, conference presentations and sharing with relevant government bodies.

Trial registration number Australian New Zealand Clinical Trials Registry (ACTRN12623001021662).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will be conducted as a hybrid effectiveness—implementation trial to test both the effectiveness and implementation of an innovative mailed smoking cessation programme with Aboriginal and Torres Strait Islander people.
⇒ A sample of 500 Aboriginal and Torres Strait Islander smokers will be recruited via social media using previously established protocols.
⇒ The intervention will be implemented flexibly to accommodate participant preferences for the use of nicotine replacement therapy.
⇒ Evaluation of implementation outcomes will be guided by the RE-AIM framework.
⇒ Key limitations of the study include reliance on self-reporting of smoking status, and restriction of recruitment to Aboriginal and Torres Strait Islander people living in specific regions of Australia, which may limit the external validity of the findings.

BACKGROUND

In 2018–2019, 37% of Aboriginal and Torres Strait Islander people aged 15 years and over reported daily smoking.[1] Colonisation systematically embedded commercial tobacco use across the country, including payment of Aboriginal and Torres Strait Islander peoples in tobacco, flour, tea and sugar in lieu of wages. Further, the commercial tobacco industry continues to actively promote and market commercial tobacco products, actively targeting Aboriginal and

Torres Strait Islander people.[2] Despite this, Aboriginal and Torres Strait Islander community leadership has driven significant reductions in smoking prevalence over the past decade[3] with smoking remaining the leading preventable cause of death and the single most significant risk behaviour contributing to adverse health conditions. Reducing rates of smoking is a primary target for prevention of multi-morbidity and a key national priority reflected in the National Aboriginal and Torres Strait Islander Health Plan 2013–2023,[4] the National Closing the Gap Health Campaign,[5] the National Preventative Health Strategy 2021–2030[6] and the National Tobacco Strategy 2023–2030.[7]

Existing evidence of ways to support smoking cessation underscores the efficacy of combining multi-session behavioural counselling and clinically appropriate pharmacotherapies to maximise quit success.[8 9] The Royal Australian College of General Practitioners (RACGP) guidelines recommend the use of pharmacotherapies in addition to behavioural support for people who want to quit smoking.[10] While data clearly shows that Aboriginal and Torres Strait Islander people want to quit smoking,[11] only a small proportion are offered evidence-based smoking cessation treatments.[12] Data from a national survey found that only 49% of Aboriginal and Torres Strait Islanders who smoke were offered information on how to quit, 28% were given a brochure or pamphlet, 27% were referred to Quitline and 23% had used nicotine replacement therapy (NRT) despite over half indicating interest in using NRT in the future.[13] A recent study has shown that Aboriginal and Torres Strait Islander people want to, and do use NRT, but barriers such as knowledge, access and cost of NRT and the cultural appropriateness of behavioural support is impacting uptake.[14] There is an urgent need for innovative approaches to support Aboriginal and Torres Strait Islander people to achieve long-term smoking cessation and accelerate reductions in smoking rates.

In Canada, the provision of free NRT by mail following brief telephone intervention has been shown to be effective in promoting quit attempts among general population adults who smoke.[15] Mailing NRT alone was also effective in reducing smoking rates[16] and has been verified in a 5-year follow-up to promote long-term cessation.[17] Until recently, no studies had explored the feasibility or acceptability of mail out smoking cessation support combined with best practice behavioural counselling with Aboriginal and Torres Strait Islander people in Australia. In 2022, a non-randomised single-group, pre–post feasibility study termed 'Koori Quit Pack' was conducted to evaluate the feasibility, acceptability and effectiveness for smoking cessation of a mailout smoking cessation intervention for Aboriginal and Torres Strait Islander people in New South Wales (NSW), the Australian Capital Territory (ACT) and Victoria, Australia,[18] which included pamphlets and resources on quitting, an information card on existing government-provided support options, and optional NRT. Of 165 participants recruited, at a 6-week follow-up, 87.3% reported a quit attempt and 46.8% sustained quitting. The complete case analysis and the intention-to-treat analysis at 6 months showed 7-day self-reported point prevalence abstinence of 34% and 19.4%, respectively. Given the success of this pilot, a full-scale implementation trial is warranted to determine the effectiveness of the mailed intervention on cessation outcomes at 3- and 6-month follow-up.[19]

This study aims to assess the effectiveness of a mailed smoking cessation support programme (*Which Way Quit Pack*) for Aboriginal and Torres Strait Islander people and explore the implementation factors and processes that may influence use and adherence to the intervention.

1. Primary aim: to determine the effectiveness of *Which Way Quit Pack* on self-reported 7-day point-prevalence abstinence at 3- and 6-month follow-up.
2. Secondary aim: to examine the impact of implementation of *Which Way Quit Pack* on (a) continuous abstinence at 3- and 6-month follow-up; (b) self-reported quit attempts lasting ≥24 hours at 3- and 6-month follow-up; (c) participant recruitment and retention rates; (d) participants uptake of, and adherence to, each of the smoking cessation support strategies; and (e) participants perceptions of the acceptability of the *Which Way Quit Pack* intervention, including barriers and enablers to use of intervention components.

METHODS

Research team

This is an Aboriginal-led and community-owned research study aimed at increasing Indigenous-led tobacco control evidence. The study was conceptualised and led by the last author (MK, Wiradjuri woman), in partnership with Aboriginal communities in NSW and Victoria. Our team brings Aboriginal and Torres Strait Islander lived experience (MK, CC, KB, JF, KR-B, ZM), Indigenous lived experience (RM), expertise in Aboriginal health services (NT) and tobacco control research (MK, JB, RM, CC, AGM, CS, BB). The project will employ Aboriginal and Torres Strait Islander community researchers (JF, KR-B, ZM) to support culturally safe research implementation.

Study design

A hybrid type 1 effectiveness—implementation trial will be conducted. This study design integrates the evaluation of both the effectiveness of the *Which Way Quit Pack* intervention on smoking cessation outcomes, while also understanding the context for intervention implementation and scale-up in real-world settings. This protocol followed the statement 'Standard Protocol Items: Recommendations for Interventional Trials' reporting guideline (online supplemental material 1).

Timeline of the study

The study will be conducted between June 2023 and May 2025. Participants will be recruited over a 10-month period from 2 October 2023 to August 2024.

Setting

Participants will be recruited from NSW, ACT and Victoria, Australia.

Sample

To be eligible to participate, individuals will need to (a) identify as Aboriginal and/or Torres Strait Islander; (b) self-report current daily smoking; (c) be aged 16 years and above; (d) live in NSW, ACT or Victoria and (e) willing to consider quitting smoking in the next 30 days (assessed using a 'yes' or 'no' question at enrolment to the study). Participants who do not have an intention to quit smoking will be excluded but will be provided with online materials regarding the benefits of smoking cessation and will have the option to enrol in the study at a later date. Women who are pregnant or become pregnant while in the trial are eligible to participate, however will be required to speak with their general practitioner and self-report back to the research team before using the optional NRT component on the intervention.

Procedure

Participants were recruited using self-referral. Information about the trial will be disseminated using targeted online social media recruitment methods, including Facebook advertising, and posts shared by Aboriginal Community Controlled Health Services (ACCHS') and Quitline. Participant recruitment will also be conducted at community events and via banners and flyers distributed to ACCHS' that include QR codes with a link to detailed information about the study including eligibility criteria and how to participate. Potential participants will provide informed written consent before completing eligibility screening questions (online supplemental material 2). This will assist in excluding any bots. Eligible participants will then complete the baseline survey, including answering questions about their preferred type of NRT and any NRT contraindications either via online survey or telephone dependent on individual preferences. Survey data will be collected online via REDCap (Research Electronic Data CAPture). All participants will be offered best practice smoking cessation treatment, that is, combination NRT (cNRT; nicotine patch plus a faster-acting formulation such as gum or spray) alongside behavioural counselling (via Aboriginal and Torres Strait Islander community researcher or referral to Quitline), together with supporting written and promotional materials reported as acceptable in the feasibility pilot[18 19] (figure 1).

Intervention: *Which Way Quit Pack*

The intervention remains the same as previously piloted.[18] In summary, at completion of baseline data collection, all participants will receive the following intervention components.

Which Way Quit Pack

Each participant will be sent a mailed *Which Way Quit Pack* within 1 week of completing baseline data collection. The *Which Way Quit Pack* will include pamphlets and resources on quitting, an information card on existing government sponsored quit smoking support options (MyQuitBuddy App https://www.health.gov.au/resources/apps-and-tools/my-quitbuddy-app) and a link to the Aboriginal Quitline webpage (https://www.quit.org.au/articles/aboriginal-quitline). Multiple options for support are provided to allow participants to choose the supports that best suit their needs and preferences. The *Which Way Quit Pack* will also include a selection of merchandise (eg, clothing the gaps socks, mints, hand sanitiser, stress ball) to celebrate culture and inclusion in the programme. The *Which Way Quit Pack* will include 1 month of cNRT if requested by the participants (see next step of intervention).

An offer of NRT

As part of the baseline survey, participants will be offered the opportunity to receive NRT. Those who indicate they would like to use NRT will complete an additional survey to provide their preference for type of NRT, either online or via a telephone call with a trained Aboriginal and Torres Strait Islander community researcher. Before NRT is provided, participants will answer questions about possible contraindications with NRT including the presence of recent (within the last 6 weeks) myocardial infarction, unstable angina, arrhythmias, recent cerebrovascular events (within the last 6 weeks) including stroke, other serious heart or circulatory conditions (not including high blood pressure) and known hypersensitivity to NRT. Those with any contraindication to NRT will be asked to consult with their general practitioner if they would like to use NRT. If a participant is pregnant, a doctor's consultation will also be required if they would like to use NRT. Available NRT will include nicotine patches as well as oral NRT options (lozenge, gum, inhalator, mouth spray) as cNRT, consistent with the recommended best practice according to the 2019 RACGP smoking cessation guidelines. Dosage will be determined using the RACGP guideline which considers time to first cigarette and number of cigarettes smoked per day.[20] Participants will initially receive a 4-week supply of NRT based on their preferences. Four and 8 weeks after the first supply of NRT, all participants who have received NRT will receive a text message with a link to a short online survey to assess adherence to the previously supplied NRT, and preferences for NRT re-supply. NRT will be sent via express post to ensure participants have continuous access to NRT throughout the intervention. Participants can receive a maximum of 12-week course of NRT. This staged approach to provision will allow for modification of NRT type based on participant preferences, and adjustment of doses based on changes to smoking behaviours. Any participants who stop using NRT before completing the recommended 12 weeks of therapy will complete an exit survey to document the reasons for discontinuation. Any participant who discontinues NRT will have the option to restart during the 3-month intervention period. Participants who elect not to commence NRT at baseline can opt in for NRT use at any

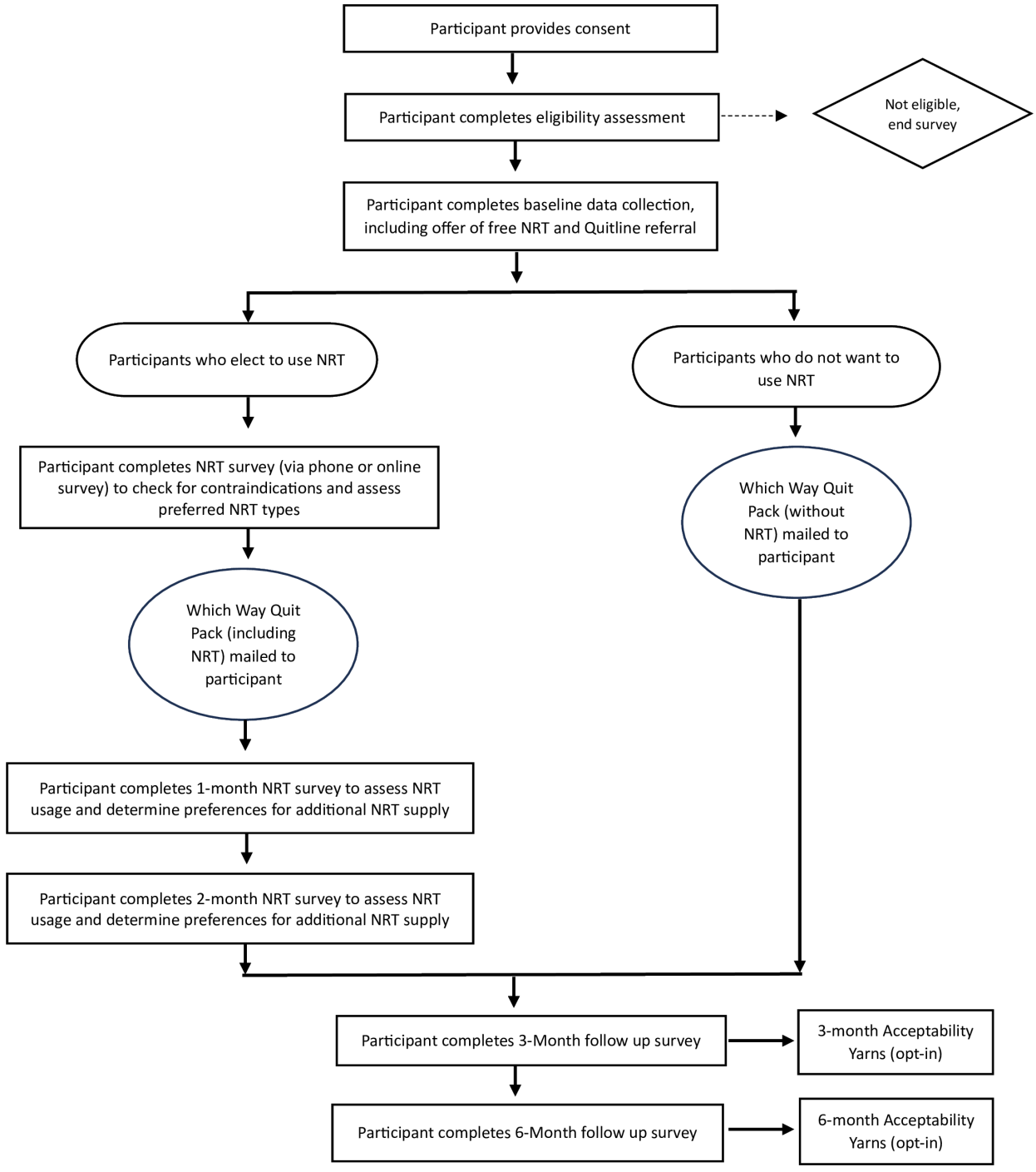

Figure 1 Flow of participants through the study. NRT, nicotine replacement therapy.

time by contacting the research team using information provided in their Quit Pack.

Behavioural counselling

Participants will be offered a referral to Aboriginal Quitline. Aboriginal Quitline offers a dedicated Aboriginal smoking and vaping cessation counsellor (profiles available on Aboriginal Quitline webpage), a Yarning approach, as many or as few calls from Quitline as they would like, and help with using the NRT products. One of the benefits of Aboriginal Quitline is the provision of 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.[21] Initial findings of the feasibility pilot found that participants often preferred behavioural support from the community researchers.[14] Community researchers will have training from a tobacco treatment specialist to provide incidental behavioural support during interactions with participants.

Data collection

Participants will complete online surveys sent via push text with the option of over the phone completion

with an Aboriginal or Torres Strait Islander community researcher at baseline, 3- and 6-month follow-up time points. Data collection measures are the same as the feasibility study,[18] a summary is offered below, further details can be found in our previous protocol paper.[19]

Baseline measures

The baseline survey will include collection of the following information, which will also confirm eligibility:

1. Demographic characteristics including age, gender, Aboriginal and/or Torres Strait Islander identity, state of current residence, highest level of education, household size, whether currently pregnant.
2. Smoking characteristics including current smoking status, number of cigarettes smoked per day, type of tobacco used, nicotine dependence using the Heaviness of Smoking Index,[22] number of years smoking, intention to quit smoking in the next 30 days and strength of urge to smoke. Strength of urges to smoke will be assessed using a 6-point Likert scale (no urges, slight, moderate, strong, very strong, extremely strong).[23 24] Frequency of urges to smoke will be assessed using a Likert scale (not at all, a little of the time, some of the time, a lot of the time, almost all the time, all the time).
3. Vaping status including whether the participant uses an e-cigarette/vape, and whether it contains nicotine or is nicotine-free.
4. Previous quit attempts lasting at least 24 hours including number and duration of past quit attempts, longest ever been smoke free, past use of NRT and other anti-smoking medications including type and length of use, perceptions of the safety and effectiveness of NRT, and previous use of stop smoking services.

Follow-up measures

Follow-up will be conducted for all enrolled participants via a self-administered survey at 3- and 6-month postbaseline. These time frames are in line with recommendations from the Society for Research in Nicotine and Tobacco and the Russell standard of assessing smoking cessation outcomes.[25 26] All follow-up will be conducted via a push text to the participants' mobile phone that includes a survey link. Participants will also be given the option of a community researcher calling to complete the survey over the phone. Participants will be provided with a $50 electronic gift card for 3 months as a thank you for their time completing the survey. Participants who complete the 6-month follow-up will be entered into a prize draw to win one of three Beats headphones.

Effectiveness outcomes

An overview of outcome measures is provided in table 1. The primary endpoint will be self-reported 7-day point-prevalence abstinence at 6-month follow-up. Reported 7-day point prevalence abstinence at 3-month follow-up will also be assessed. Self-reported 7-day point-prevalence was chosen as the primary outcome as it is subject to less recall bias as it assesses quitting over a shorter timeframe, and because while participants are encouraged to set a target quit date, the timing of the selected date is likely to be significantly varied across participants. Self-reported 7-day abstinence rates were defined as answering 'yes' to the question 'In the last 7 days, have you stayed smoke free (not even a puff)?' in line with recommendations from the Society for Research in Nicotine and Tobacco, but modified for the patient population.[25] Secondary outcomes will include continuous abstinence at 3- and 6-month follow-up and self-reported quit attempts lasting ≥24 hours at 3- and 6-month follow-up. Continuous abstinence will be defined as continuously abstinent (not smoking, even a puff) from the end of the intervention to the 6-month follow-up time point and will be defined as answering 'yes' to the question 'In the last 3 months, have you stayed smoke free (not even a puff)?'. A quit attempt will be defined as a period of intentional abstinence from smoking lasting at least >24 hours. Participants will be asked 'In the last 3 months, how many times have you made a quit attempt lasting more than 24 hours?' and will be asked to select the number of times they have made a quit attempt using a sliding scale. 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. Change in motivation and perceived confidence to quit smoking will be assessed at each follow-up visit. Presence of withdrawal

Table 1 Summary of outcome measures and follow-ups

Outcomes	Baseline	3 months	6 months
Effectiveness outcomes			
7-day point prevalence abstinence		x	x (Primary outcome)
Quit attempts >24 hours		x	x
Continuous abstinence		x	x
Implementation outcomes			
Reach—Recruitment and retention	x	x	x
Adoption—Uptake and adherence	x	x	x
Implementation—Acceptability (survey+Yarning)		x	x

symptoms will be assessed for participants who made a quit attempt. Change in the frequency and strength of urge to smoke will be evaluated. Additionally, at the 3- and 6-month follow-ups participants will be asked if they used an e-cigarette (vape) in the last 3-month period.

Implementation outcomes

Evaluation of implementation outcomes will be guided by the RE-AIM framework, which is recommended to evaluate public health impact.[27]

1. *Reach*. Participant recruitment and retention will be assessed using the number of self-referrals from advertisements, the number of self-referring individuals who meet eligibility criteria, and retention rates at each follow-up time point. This data will help assess the effectiveness of the recruitment strategies, the reach of the intervention, participant retention and overall intervention feasibility.
2. *Adoption*. Participant uptake of each of the offered smoking cessation support strategies included in the *Which Way Quit Pack* and adherence to NRT will be recorded at each follow-up timepoint. Participants will be asked to self-report at each follow-up point if they accessed the MyQuitBuddy app and for those that accessed, the frequency and duration of use. Participants acceptance of Quitline referrals will be captured by the research team, and participants will self-report whether they used Quitline at each follow-up point.
3. *Implementation*. Participant perceptions of intervention acceptability, barriers and enablers to intervention use will be determined through surveys and optional Yarning interviews at 3- and 6-month follow-up. Survey questions explore:
   - Whether each intervention component was used (yes/no), and for those used, perceptions of helpfulness (yes/no).
   - Participant perceptions of the effectiveness of NRT in reducing cravings, and ease of use (assessed using a 4-point Likert scale from not at all to very effective).
   - Overall satisfaction with the *Which Way Quit Pack* programme (assessed using a 4-point Likert scale from extremely dissatisfied to extremely satisfied), and whether participants would recommend *Which Way Quit Pack* to family and friends (4-point Likert scale from strongly agree to strongly disagree).
   - Participant perceptions of the importance of key components of intervention delivery including talking to Aboriginal and Torres Strait Islander staff, receiving support to understand how to use NRT, having NRT mailed to home, receiving NRT for free and being able to text message the research team for additional support (assessed using a 4-point Likert scale from very important to not important).
   - Participant perceptions of the acceptability of research follow-up methods used in the study including receiving information via text message, being sent reminders to complete surveys via text, completing surveys online, receiving merchandise in the *Which Way Quit Pack*, receiving a gift voucher for completing 3-month survey, having option to complete surveys on the telephone (assessed using a 4-point Likert scale 'I didn't like this, this was okay, this was great, this doesn't apply to me').

Participants who consent to be contacted for further research will be offered the opportunity to partake in a qualitative interview with the community researcher. Interviews will follow Yarning method,[28] in which the research team have extensive experience and expertise.[14 29] Yarning is the most frequently used qualitative data collection method in Aboriginal and Torres Strait Islander health, and can be described as a culturally responsive conversational exchange between the researcher and participants, which privileges participants stories, relationality, expertise and Indigenous knowledges.[29] Purposive sampling will be used to ensure participants that did and did not accept Quitline referral and NRT at baseline, and those who did and did not experience quit success (defined as at least one reported period of 7-day point prevalence abstinence) are invited to participate in Yarning. The message will be sent from the generic study team via text message with a follow-up email containing a link to a participant information statement, and consent for the interview. Yarns will take place over telephone or Zoom at a time convenient to the participant, be audio recorded and transcribed. Participant information and data will only be known by the research team. Yarning will be conducted with a subsample of participants at 3-month follow-up (n=20) and a second subsample at 6-month follow-up (n=20) to understand participant perceptions of the acceptability of the smoking cessation supports included in the *Which Way Quit Pack,* acceptability of the trial procedures, and any barriers or enablers to using each of the intervention components.

Sample size

The sample size for this single-group intervention study was determined using a significance level of 0.05 and a power of 80%. The anticipated effect size was based on the pilot trial, which found a 7-day point prevalence abstinence rate of 34% at a 6-month follow-up.[19] A sample of 345 participants will provide sufficient power to detect a statistically significant difference in abstinence rates between baseline and 6-month follow-up, assuming similar effect sizes as observed in the pilot trial. Considering a 43% attrition from baseline to 6-month follow-up, in line with the dropout rate in the pilot study,[19] we set a target sample size of 494 participants. It is expected that the required sample will be able to be recruited in 12 months.

Data management

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 has developed an Aboriginal Data Governance Committee

to uphold Indigenous data sovereignty throughout the project. The Aboriginal Data Governance Committee will include Indigenous research team members and at least one community representative from each state and chaired by lead researcher. No data will be used without full consultation, plan, review and approval by all Aboriginal Data Governance Committee members. Data will be kept confidential by the research team. No third party will have access to the data at any time during the data collection, data analysis and after the completion of the study.

Data analysis

Analyses for all effectiveness outcomes will be computed by including all enrolled participants assuming that, on the basis of the intention-to-treat principle, all individuals lost to follow-up continue to smoke. The proportion of people who quit and people who make quit attempts will be reported descriptively. Acceptability and adherence to smoking cessation supports, and participant recruitment and retention rates, will be described using frequencies and percentages. Sociodemographic characteristics collected as part of the baseline comprehensive assessment will allow examination of the factors that may moderate both quit success and intervention adherence. Yarns will be analysed by Aboriginal and Torres Strait Islander members of the research team through Collaborative Yarning[28] as used in past research.[14] Researcher reflexivity and positioning, and Aboriginal and Torres Strait Islander ownership, stewardship and custodianship of data collected from yarns will be reported.

Expected outcomes

To date, no smoking cessation trials that have explored the effectiveness of mailed smoking cessation support for Indigenous people in Australia or internationally. This study will report crucial knowledge on the effectiveness of mailed smoking cessation support, and comprehensive information about how to scale the model of care if successful. This trial will address a national priority area for Aboriginal and Torres Strait Islander people and inform clinical service and health promotion practice at the ACCHS in NSW, ACT and Victoria.

Patient and public involvement

This research project has been co-designed with, and will be conducted with full control of, Aboriginal and Torres Strait Islander communities. The Aboriginal Health and Medical Research Council (AH&MRC), the Victorian ACCHS and NSW/ACT and Victorian state Quitlines are key project partners who co-own and inform the research. The project will be governed by the AH&MRC Tobacco Advisory Committee (TAC), who will oversee data collection, analysis and reporting ensuring it is appropriate for communities involved. The lead researcher and Aboriginal community researcher will report progress on the project to the TAC approximately quarterly. TAC members will also be invited to join the authorship team on publications resulting from this study.

Ethics approval and dissemination

Ethics approval was obtained from the AH&MRC Ethics Committee of NSW (1894/21) and the University of Newcastle (H-20220174).

Informed written consent will be obtained from all participants included in this study. Participant information will be kept confidential, and 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.[30] Study findings will be presented in relevant local, national and international conferences. The findings will be shared with the NSW and Victoria Quitline, AH&MRC and VACCHO and the funders and disseminated via peer-reviewed publications in relevant journals. 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. These will include but will not be limited to infographics, webinars, short videos and brief reports.

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Contributors MK conceptualised the study. JB and MK wrote the original draft of the manuscript. JB, BB, MK, CC, RM and CS developed the protocol and determined measurement of study outcomes. KR-B, ZM, JF, JB, MK, KB and AGM assisted in refining the study questionnaires and study design. KR-B, ZM, JF will implement the intervention and undertake data collection. NT is providing expertise in Aboriginal health services and study governance. AGM will analyse data. All authors reviewed manuscript drafts and read and approved the final manuscript. MK is responsible for the overall content as guarantor.

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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 section for further details.

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