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The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy Pilot Study protocol: a feasibility step-wedge cluster randomised trial to improve health providers' management of smoking during pregnancy

Yael Bar-Zeev,[1] Billie Bonevski,[1] Michelle Bovill,[1] Maree Gruppetta,[1] Chris Oldmeadow,[2] Kerrin Palazzi,[2] Lou Atkins,[3] Jennifer Reath,[4] Gillian S Gould,[1] ICAN QUIT in Pregnancy Pilot Group

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[1]The University of Newcastle, Newcastle, New South Wales, Australia
[2]Hunter Medical Research Institute, Newcastle, New South Wales, Australia
[3]Centre for Behaviour Change, University College London, London, UK
[4]Western Sydney University, Penrith, New South Wales, Australia

Correspondence to
Dr Yael Bar-Zeev;
yael.barzeev@uon.edu.au

ABSTRACT

Introduction Indigenous women have the highest smoking prevalence during pregnancy (47%) in Australia. Health professionals report lack of knowledge, skills and confidence to effectively manage smoking among pregnant women in general. We developed a behaviour change intervention aimed to improve health professionals' management of smoking in Indigenous pregnant women—the Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy. This intervention includes webinar training for health professionals, an educational resources package for health professionals and pregnant women, free oral nicotine replacement therapy (NRT) for pregnant women, and audit and feedback on health professionals' performance. The aim of this study is to test the feasibility and acceptability of the ICAN QUIT in Pregnancy intervention to improve health professionals' provision of evidence-based culturally responsive smoking cessation care to Australian Indigenous pregnant smokers.

Methods and analysis This protocol describes the design of a step-wedge cluster randomised pilot study. Six Aboriginal Medical Services (AMSs) are randomised into three clusters. Clusters receive the intervention staggered by 1 month. Health professionals report on their knowledge and skills pretraining and post-training and at the end of the study. Pregnant women are recruited and followed up for 3 months. The primary outcome is the recruitment rate of pregnant women. Secondary outcomes include feasibility of recruitment and follow-up of participating women, and webinar training of health professionals, measured using a designated log; and measures of effectiveness outcomes, including quit rates and NRT prescription rates.

Ethics and dissemination In accordance with the Aboriginal Health and Medical Research Council guidelines, this study has been developed in collaboration with a Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP). The SCAAP provides cultural consultation, advice and direction to ensure that implementation is acceptable and respectful to the Aboriginal communities involved. Results will be disseminated to AMSs, Aboriginal communities and national Aboriginal bodies.

Registration details This protocol (version 4, 14 October 2016) is registered with the Australian and New Zealand Clinical Trials Registry (Ref #: ACTRN12616001603404).

Strengths and limitations of this study

- This is the first study in Australia to target specifically Indigenous smoking during pregnancy that covers three different states and different settings.
- This study is designed to overcome specific implementation issues identified in previous research, including ensuring community representation in governance of the research; participant recruitment by known health staff from the service; and adequate reimbursement for time and effort of services and women.
- The intervention tested in this study was informed by theory and based on extensive formative research beforehand.
- This study is a pilot study aimed to assess feasibility and acceptability, and is not powered to assess the effectiveness of the intervention.
- This study covers health professionals treating Indigenous pregnant women who work at Aboriginal Medical Services only, and does not cover other general antenatal care settings that Indigenous women may attend.

INTRODUCTION

Tobacco smoking in pregnancy is the most important preventable risk factor for poor maternal and infant health outcomes.

In 2013, 12% of women who gave birth in Australia smoked during pregnancy.[1] Indigenous Australian women have the highest

smoking prevalence during pregnancy (47%).[1] Indigenous women also quit smoking during pregnancy at a lower rate compared with the general population (11% compared with 25%).[1] Smoking has been identified as an important contributor to the health and life expectancy gaps between the Indigenous and non-Indigenous people in Australia.[2]

Barriers to quitting

Australian Indigenous pregnant women face multiple barriers to quitting smoking.[3–6] These include social norms of smoking in some Indigenous communities, multiple life stressors, lack of prioritisation of smoking cessation, lack of support for cessation, lack of salience of antitobacco messages and inadequate access to targeted programmes.[4 5 7] Health professionals report they are ill-equipped to tackle the complexities of smoking cessation care for pregnant women, and lack resources and optimism.[8 9] First-line medications (oral nicotine replacement therapy (NRT)) are currently not subsidised in Australia,[3] disproportionally impacting lower socioeconomic populations and Indigenous women.[10]

Evidence for smoking cessation care in pregnancy

The combination of behavioural counselling and pharmacotherapy has been shown to be the most effective treatment for smokers generally.[11] Studies specific to pregnant women have also shown that psychosocial interventions such as counselling are effective.[12] Recently a taxonomy was developed and validated to detail the specific 'active ingredients' of behavioural counselling termed behaviour change techniques.[13–15] These include, for example, goal setting and identifying smoking triggers.[16]

Pharmacotherapy

In a Cochrane review on pharmacotherapy for smoking cessation in pregnancy, the use of NRT increased cessation rates by 40% (RR 1.41, 95% CI 1.03 to 1.93); the exclusion of non-placebo controlled trials resulted in a lower, non-significant increase in the cessation rate (RR 1.28, 95% CI 0.99 to 1.66).[17] The discrepancy between these findings, and the apparent effectiveness of NRT for the general population,[18] may be explained by the faster nicotine metabolism in pregnancy, requiring higher doses than those used in the included studies.[17 19 20] Importantly, the use of NRT was not associated with any significant differences in pregnancy or birth outcomes.[17] Experts agree that NRT is always safer than smoking in pregnancy, and guidelines from several countries, including Australia, recommend the use of NRT, if a woman has been unsuccessful in quitting.[21–24] These guidelines recommend first using oral forms of NRT, and if the woman is still unsuccessful quitting smoking, adding an NRT patch. This is done to ensure that the lowest effective dose is used.[22 25]

Need for health professionals' training

Health professionals report that they lack the knowledge, skills and confidence to assist pregnant women to quit smoking. A recent national Australian cross-sectional survey[9] found that few general practitioners (GPs) and obstetricians routinely perform all of the required components of the clinical guidelines.[11 26] Furthermore, only 11% reported always prescribing NRT, 7% arranging follow-up, 22% discussing the psychosocial context of smoking and 26% referring to a specialised cessation programme (such as the national Quitline). Surveys with other antenatal health professionals in Australia (Aboriginal health workers, midwives, nurses) report similar findings.[8]

These findings mirror surveys internationally,[25 27–39] portraying an evidence-practice gap in the way health professionals currently manage smoking in pregnant women.

Addressing this gap is crucial, as it has been shown that advice from health professionals increases the chances of a quit attempt in the general population (RR 1.66, 95% CI 1.42 to 1.92),[40] and is positively associated with intention to quit in Australian Indigenous smokers of reproductive age (OR 3.82, 95% CI 1.43 to 10.2).[41] Training health professionals has been proven to increase rates of smoking cessation (OR=1.60, 95% CI 1.26 to 2.03),[42] although this has not been studied specifically for Indigenous pregnant women.

Interventions for pregnant Indigenous smokers

Interventions developed to address smoking in Indigenous people have often lacked either rigorous evaluation or deep cultural understanding.[43 44] Two randomised controlled trials (RCTs) among Indigenous pregnant smokers have been conducted: one in Indigenous Australians, and the other in Alaska native women.[45 46] Neither demonstrated any statistically significant differences between intervention and control groups, although the underpowered Eades' study found an assisted quit rate of 11% compared with a control rate of 5%.[45 46] Several implementation factors marred the outcomes of these studies, including low enrolment, high attrition and possible contamination between study arms.[45 46] Patten's study included NRT only through referral to a separate programme;[46] Eades' study included an option for NRT at the third visit, after 7–10 days of unsuccessful quit attempts.[45]

The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy intervention

In 2015, a pragmatic guide to the management of smoking cessation in Indigenous pregnant women was published.[47] These guidelines are structured on the ABC pathway (Ask about tobacco use; Brief advice to quit; Cessation support),[23] with the addition of a D component (Discuss the psychosocial context of smoking)[47] the ABCD approach. A proactive approach is recommended—offering assistance to all pregnant smokers (regardless of readiness to quit and smoking level) and an expedited offer of NRT after 1–2 days of an unsuccessful quit attempt.[47] These guidelines follow other Australian clinical guidelines, recommending the use of oral NRT as first line, higher doses of NRT due to the

higher metabolism in pregnancy and combination NRT if needed.[21,48,49]

On the basis of these ABCD guidelines,[47] we used the Theoretical Domains Framework,[49] the Behaviour Change Wheel[50] and Behaviour Change Techniques recommended in pregnancy,[16] to develop a theory-based behaviour change intervention aimed to improve health professionals management of smoking in Indigenous pregnant women—ICAN QUIT in Pregnancy. The Theoretical Domains Framework and Behaviour Change Wheel are used to identify barriers and facilitators to achieving evidence-based care to inform intervention design.[50]

The intervention was developed in collaboration and negotiation with two Aboriginal Medical Services (AMSs) in New South Wales (NSW). The chief executive officers of those AMSs are associate investigators on the study and partnered with the research team to establish a Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP), to advise on the design of the study. They also contributed to a working party including AMSs staff and community members that developed educational resources for the intervention. This collaborative process of intervention development has been described elsewhere.[51]

The aim of this study is to test the feasibility and acceptability of the ICAN QUIT in Pregnancy intervention to increase health professionals' provision of evidence-based, culturally responsive smoking cessation care to Australian Indigenous pregnant smokers, positioning Aboriginal women and communities at the centre of the research with engagement and ownership upheld through the study.[51] This study will inform the final design and implementation of a clustered RCT (cRCT) aimed to study the effectiveness of health professionals' training on smoking cessation rates in pregnant Australian Indigenous smokers.

METHODS AND ANALYSIS

Study overview

The overall objective is to reduce smoking in Aboriginal and/or Torres Strait Islander pregnant women.

Specific aims of this pilot are:

Primary aims

Assess feasibility and acceptability of a multicomponent targeted intervention to train health professionals at AMSs in the culturally responsive management of smoking in Australian Indigenous pregnant women.

Secondary aims

1. Assess the effectiveness on NRT prescribing practices.
2. Evaluate the effectiveness on health professionals' knowledge, attitudes and practices in managing smoking in pregnant Indigenous women.
3. Estimate the trends for quit attempts and biochemically verified smoking cessation rates in pregnant patients managed by trained health professionals.
4. Assess patients' perceived receipt and quality of smoking cessation care by the trained health professionals.
5. Evaluate changes in the perceived well-being of pregnant patients.
6. Evaluate behaviour change techniques use by the trained health professionals.

Study design

This is a step-wedge cluster randomised pilot study with six participating sites randomised to three clusters (each of two AMSs). Allocation of the sites to the clusters is based on geographical convenience. For each cluster, the period of treatment crossover was randomised using simple randomisation. Allocation concealment was not possible. All of the sites will receive the same intervention which will be sequentially delivered 2 months following commencement of the study, staggered by 1 month between clusters (the intervention is described below). Two cohorts, one of health professionals and one of pregnant women, will provide data with repeated measures: from 2 months prior to receiving the intervention until 6 months following the intervention. See figure 1 for a schematic illustration.

A step-wedge design was chosen since it allows the intervention to be delivered sequentially and therefore reduces the cost and burden of simultaneous implementation, while also providing some control of confounding factors through randomisation.[52] Furthermore, this

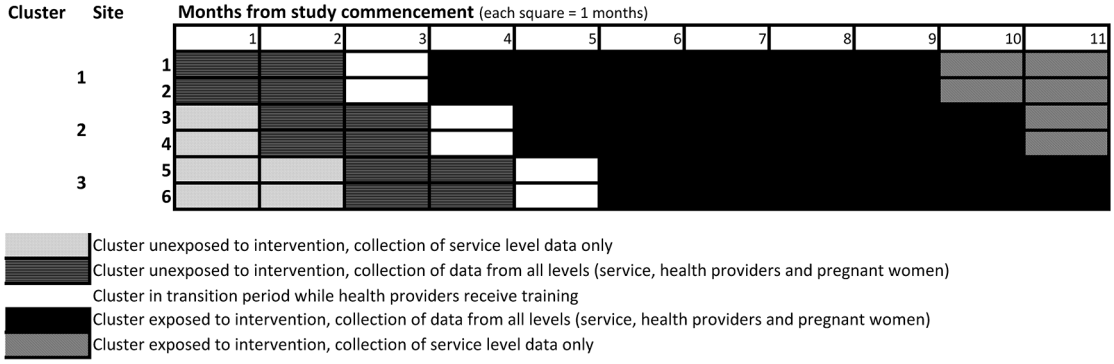

Figure 1 Schematic illustration of the step-wedge cluster study for the Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy Pilot Study.

design will ensure all sites receive the intervention which is important from an ethical viewpoint. The cluster design was chosen to prevent contamination, a problem identified in the Eades' study.[45]

Timeline of the study

November 2016 to September 2017.

Setting

Urban and regional AMSs in NSW, Queensland and South Australia. The AMSs include Aboriginal Community Controlled Health Services which are non-government organisations operated by local Aboriginal and Torres Strait Islander communities, to deliver holistic, comprehensive and culturally appropriate healthcare to the communities that control them through an elected board of management.[53]

Inclusion criteria

For participating services AMSs are included if they fulfil all of the following criteria:

1. Diagnose pregnancy or provide antenatal or routine care for pregnant Aboriginal or Torres Strait Islander women.
2. Employ at least one General Practitioner (GP).
3. Have contact with at least 20 pregnant women who smoke per year.
4. Are able to recruit and follow patients as required.

Participating health professionals are those who: consult with pregnant women either for confirmation of pregnancy, antenatal care and/or routine care.

Participating women will include those who fulfil all of the following criteria:

1. Pregnant, ≤28 weeks gestation.
2. Aboriginal and/or Torres Strait Islander or expectant mothers of Aboriginal and/or Torres Strait Islander babies.
3. Aged ≥16 years old.
4. Smoke tobacco at any level of consumption, including those that only smoke occasionally.

Intervention components

The ICAN QUIT in Pregnancy intervention includes:

- Training of health professionals in participating sites through webinar in three 60-min weekly sessions. The training will be delivered by two experienced tobacco treatment specialists. Content will include background on smoking in pregnancy including the Indigenous context; the ABCD approach, and the use of NRT in pregnancy (see online supplementary file for full description of webinar content). As an incentive to complete the training, all health professionals will be offered continuing professional development points (required as part of registration with the Australian Health Practitioner Regulation Agency).
- An educational resources package, to be used by both health professionals and pregnant women, has been developed collaboratively and includes a training manual for health professionals, and flip chart, patient booklet and educational posters for engaging with the pregnant women. Resources were developed by a medical doctor and tobacco treatment specialist (YBZ) and Aboriginal researcher (MB) in consultation with AMSs. These have been rigorously pretested using a four-step process, including review by an expert panel, assessment using a suitability of material score by two Aboriginal health workers, readability scores, and focus groups reviews with both health professionals, and female Aboriginal community members, in three states.[54]
- Oral forms of NRT for the pregnant women will be supplied to the sites free of charge, as these are not currently subsidised in Australia. All available forms in Australia will be included (gum, lozenge, mini lozenge, inhalator and spray). NRT will be dispensed through a voucher system. Sample packs will be provided directly to the sites to introduce patients to the selection available. If NRT patches are required, the GP at the service will write a government-subsidised prescription. NRT will be used according to product and Therapeutic Goods Administration instructions, as well as health professionals' judgement on a patient-by-patient basis. No study-specific protocol to NRT dispensing will be followed. As nicotine has potential effects on the fetus,[55 56] a risk-benefit analysis will be undertaken with each woman when NRT is offered, as recommended in clinical guidelines.[21] A participant not using NRT can remain in the study with behavioural support only.
- Audit and feedback regarding health professionals' performance will be via aggregated, deidentified, service-specific, monthly data collection, commencing in the pretraining phase and continuing through to study completion. Each service will receive feedback regarding their rate of NRT prescription to pregnant women who smoke compared with other study services.

Study implementation

A staff member will be nominated as a research facilitator by each service. The role of the research facilitator is to recruit patients, conduct surveys and evaluations, and collect feasibility data (table 1). The research facilitator will be trained by the research team in a face-to-face meeting and provided with supporting resources (detailed instructions and checklist) to assist them in their role. The research team will provide three site visits (before commencement, 1 month after commencement and end of study) and weekly telephone calls as implementation support. Additional support will be provided as needed by the research facilitator.

Recruitment and reimbursement

Services will be recruited through: (1) written invitation to all AMSs in NSW asking for expressions of interest, and (2) targeted invitations to services that worked previously with the researchers. The service will be reimbursed

Table 1 Feasibility and acceptability outcomes

Hierarchy of measurement (service, Health Professionals or pregnant women)	Outcome	Data collection method	Analysis	Time-points
Service	Recruitment rate (primary outcome)	Research facilitator log	Number of women recruited divided by number of women approached for each site, overall sites and stratified by site	End of study
Service	Follow-up rate	Participant survey	Percentage of women recruited who complete all follow-up surveys	4 weeks and 12 weeks
Service	Proportion of women's checklists completed	Women's checklist	Number of consultations with a completed checklist divided by the total number of consultations for each patient (designated and non-designated study visits)	End of study
Service	Provider training rate	Research facilitator log	Number of providers undergoing webinar training divided by the total number of providers, overall sites and stratified by site	End of training
Service	Webinar completion rate	Research facilitator log	Number of webinar sessions each provider attended	End of training
Health professionals and pregnant women	Acceptability of intervention and implementation	Interviews with staff and patients	Thematic analysis	End of study

$6000 in instalments, for the involvement of their nominated research facilitator.

Service staff will aim to recruit all pregnant smokers under their care when they attend for any type of service including confirmation of pregnancy, antenatal care or routine care. The study will be advertised through posters at the service.

The research facilitator will complete a one-page eligibility checklist with women interested in the study, and if they are eligible, will gain informed consent. Consenting women will be assigned a unique code to link the data collected to the same participant. Pregnant women recruited to the study will be asked to attend three designated study visits (baseline at recruitment, 4 weeks and 12 weeks postrecruitment). At each study visit, the participating women will be asked to fill out two to three online surveys and perform a breath carbon monoxide test. We estimate that each study visit will take between 30 min and 50 min.

Women will receive reimbursement for their time in the form of a $A20 shopping voucher for each visit (total $A60). Women attending all three study visits will enter into a draw for one baby pack (value $A50) per site.

Outcomes

Outcomes include feasibility and acceptability measures, and measures of effectiveness outcomes (detailed description of all the outcomes are presented in tables 1 and 2). The primary outcome will be the recruitment rate of participating pregnant women defined as the number of eligible women who consented to participate in the study.

Data collection and instruments

Data will be collected at three levels—(1) service (2) health professionals and (3) pregnant women (tables 1 and 2). Participant timelines are presented in table 3 (health professionals) and table 4 (pregnant women).

Service level

Research facilitator log

Feasibility data will be collected by the research facilitator using a designated log, including recruitment rate, follow-up rate, proportion of participant surveys completed and health professionals' training rate. Reasons for non-participation or withdrawal will not be collected routinely as part of the research facilitator designated log, but will be discussed with the research facilitator on an ongoing basis in the weekly implementation phone calls and at the end of the study interview.

Aggregated computerised data

Deidentified aggregated monthly computerised data will be collected from study commencement (figure 1), including: number of pregnant women attending the service; number of those that smoke; number referred to the Quitline and number of NRT prescriptions (including oral NRT vouchers).

Health professionals level

Health professionals' survey

A 102-item, 15 min, self-administered online survey will include questions about health professionals' demographic characteristics; self-reported knowledge, attitudes and provision of smoking cessation care; prescription

Table 2 Measures of effectiveness outcomes

Hierarchy of measurement (service, Health Professionals or pregnant women)	Outcome	Data collection method	Analysis	Time points
Service	Proportion of pregnant smokers that were given nicotine replacement therapy (NRT)	Audit of deidentified grouped data	Pharmaceutical Benefit Scheme (PBS)* prescriptions or vouchers for NRT	Monthly
Health professionals	Self-reported knowledge, attitudes and practices about managing smoking in pregnancy	Health Professionals surveys	Changes in knowledge, attitudes and practices comparing all time points	Pretraining, post-training and end of study
Health professionals	Behaviour change techniques (BCT)	Audio recording of consultations	Analysis of transcripts by trained BCT coders	Pretraining and post-training
Pregnant women	Self-reported smoking characteristics	Smoking characteristics survey	Changes in smoking characteristics	Baseline, 4 weeks and 12 weeks
Pregnant women	Women's perception of receiving smoking cessation care	Women's checklist	Composite scores on checklists	Exit from consultations with a Health Professional
Pregnant women	Self-reported quit rates	Smoking Characteristics Survey	7-day point prevalence and continuous abstinence[74]	Baseline, 4 weeks and 12 weeks
Pregnant women	Biochemically validated quit rates	Handheld CO metre	7-day point prevalence and continuous abstinence[74] using expired CO<6 ppm as reference point	Baseline, 4 weeks and 12 weeks
Pregnant women	Self-report of adherence to NRT	Smoking characteristics survey	Changes in adherence to NRT	4 weeks and 12 weeks
Pregnant women	Self-reported knowledge, attitudes and smoking behaviours	Smoking Characteristics Survey	Changes in knowledge, attitudes and smoking behaviours	Baseline, 4 weeks and 12 weeks
Pregnant women	Growth and empowerment	Growth and Empowerment Survey	Changes in growth and empowerment domains	Baseline, 4 weeks and 12 weeks
Pregnant women	Critical success measures	Critical Success Survey	Descriptive analysis of the nine critical success factors	End of study

*Pharmaceutical Benefit Scheme (PBS) is the Australian government scheme for prescription subsidy

Table 3 Schedule of assessments for health professionals receiving training for Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy Pilot Study

Assessment	Performed by	Pretraining _ _/_ _/_ _ _ _ (dd/mm/yyyy)	Post-training _ _/_ _/_ _ _ _ (dd/mm/yyyy)	End of study _ _/_ _/_ _ _ _ (dd/mm/yyyy)
Informed consent	Research facilitator	X		
Pretraining survey	Self-administered online	X		
Audio recording of smoking consultations (optional)	Health professional	X	X	
Post-training survey	Self-administered online		X	X
Interview	Research team			X

of NRT; self-assessment of the barriers and enablers to providing smoking cessation care; and perceived usefulness of educational resources. This survey is based on a previous survey from a national study of 378 GPs and obstetricians.[9] The survey will be sent pretraining and post-training, and at the end of the study (table 3).

Health professionals' demographic characteristics include: gender, age, years working as a health professional (less than 10 years; 10–19 years; 20 or more years), specialty (GP; midwife; nurse; Aboriginal health worker; other), smoking status (daily; occasionally, ex-smoker, never smoked) and average number of pregnant women who smoke seen per month (<5, 5–10,>10).

Self-reported provision of smoking cessation care: will be measured using 5-point Likert Scales (never (0%); occasional (1%–25%); sometimes (26%–50%); often (51%–75%); always (76%–100%)) on the various components of smoking cessation care ('How often do you provide the following types of cessation care with pregnant women?' ask; record smoking status; brief advice; assess nicotine dependence; measure carbon monoxide; cessation support; discuss psychosocial context; follow-up; referral to Quitline; referral to other specialist cessation support; involve family members).

Prescription of NRT and attitudes towards prescribing NRT during pregnancy: NRT prescription will be

Table 4 Schedule of assessments for pregnant women participating in Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy Pilot Study

Assessment	Performed by	Day 0 _ _/_ _/_ _ _ _ (dd/mm/yyyy)	Any additional follow-up* _ _/_ _/_ _ _ _ (dd/mm/yyyy)	4 weeks (+/−3 days) _ _/_ _/_ _ _ _ (dd/mm/yyyy)	12 weeks (+/−7 days) _ _/_ _/_ _ _ _ (dd/mm/yyyy)	End of study _ _/_ _/_ _ _ _ (dd/mm/yyyy)
Review eligibility for study	Health professional and/or research facilitator	X				
Informed consent	Research facilitator	X				
Smoking characteristics survey	Research facilitator	X		X	X	
Growth and Empowerment survey	Research facilitator	X		X	X	
Critical Success Measures survey	Research facilitator				X	
Breath carbon monoxide test	Research facilitator	X		X	X	
Patient checklist	Research facilitator	X	X	X	X	
Audio recording of smoking consultation (optional)	Health professional	X	X	X		
Interview	Research team					X

*Any additional follow-up (not part of designated study visits) including all of her visits to the service for usual care.

measured with the 5-point Likert Scale as for the other smoking cessation care components. Self-reported perceptions on NRT in pregnancy will include rating the safety for the fetus, effectiveness in aiding pregnant smokers to quit and perceived adherence.

Barriers and enablers to smoking cessation care: (5-point Likert Scales—strongly disagree, to strongly agree). This will be measured using 22 statements covering 13 domains from the Theoretical Domains Framework,[50] including: knowledge, reinforcement, role/identity, beliefs about capabilities, optimism, beliefs about consequences, social influence/subjective norm, goals/priority, memory/attention, environmental context and resources, emotions/stress, intentions, behavioural regulation. Most domains include one question regarding smoking cessation care during pregnancy in general, and one question specifically regarding the prescription or recommendation of NRT.

The 'Knowledge' domain will also be measured with one question about guidelines ('Have you read any of the following smoking cessation guidelines?' With a list of 3 different national guidelines, yes/no); and 24 true/false statements that will be computed to form a composite score. The 'Skills' domain will be measured with one question ('Have you received any training in tobacco management related to pregnancy? with a list of 4 training types' yes/no).

Usefulness of educational resources will be measured using 5-point Likert Scales (not useful at all to very useful) for each webinar session and each educational resource.

Interviews

At the conclusion of the study, one of each type of health professionals from each service (ie, a midwife, a GP and an Aboriginal health worker), including also the manager and research facilitator, will be interviewed. Recruitment will continue until saturation of themes. Estimated sample n=40. The objective of the interviews is to assess the feasibility of the intervention and the study, and gain valuable insights before commencing the cRCT. The semistructured interview guide will include questions based on the Theoretical Domains Framework and Behaviour Change Wheel,[49 50] and include topics such as the challenges to implementing the study, and what could have been done to improve the study.

Pregnant women level

Smoking characteristics survey

This 56-item, 15 min, survey will incorporate questions from a previously tested survey in Aboriginal pregnant smokers.[57] Demographic and smoking characteristics will include: age, Aboriginal and Torres Strait Islander status, partner status, parity, number of children, any child living at home, smoking status, measures of nicotine dependence (Fagerstrom Test of Nicotine Dependence,[58] Heaviness of Smoking Index,[59] strength and frequency of urges to smoke[60 61]), home smoking rules, intentions to quit smoking, number of previous quit attempts ≥24 hours, use of other smoking cessation resources (such as the Quitline), symptoms of nausea in pregnancy (morning sickness is a predictor of spontaneous quitting[62]), the Risk Behaviour Diagnosis Scale (previously validated in Aboriginal smokers, adapted here for pregnant smokers[63]), and attitudes to smoking and quitting. Adherence to NRT will be measured using a 5-item multichoice question (did not take it all; used occasionally 1–2 times a week; used 3–4 times but not all doses; occasionally missed a dose; used most doses, every day).

At the 4-week and 12-week follow-ups, the survey includes additional questions to determine 7-day point prevalence smoking abstinence and continuous abstinence rates.[64]

Growth and empowerment measure (GEM)

This survey has been previously validated with 184 Indigenous Australians, but has not been used specifically with Indigenous pregnant women[65] and includes two components:

1. 14-item Emotional Empowerment Scale which comprises two domains: inner peace and self-capacity.
2. 12 Scenarios with two domains: healing and enabling growth and connection and purpose.

These are accompanied by the 6-item Kessler Psychological Distress Scale supplemented by two questions assessing frequency of happy and angry feelings. Estimated completion time is 15 min.

Critical success measure

This measure was developed through analysis of six Indigenous youth social and emotional well-being programmes[66] and was previously used in the evaluation of an urban art-based community health programme with young Aboriginal and Torres Strait Islander parents.[67] This survey will be completed only once at the 12-week visit. This survey will measure nine factors relevant to an empowerment-based programme, including adopting full commitment to working from strengths; being patient to develop the relationship bond first; modelling reliability and being consistent; facilitating connection to culture; adopting a non-judgemental approach; setting rules and boundaries; modelling openness, honesty, hope and trust; maximising opportunity for choice making, self-motivation, feeling safe to try new things; celebrating small achievements and positive changes. For each factor, we will use 5-point Likert Scales to measure women's perception of the importance of the factor (from not at all to absolutely essential) and how well the intervention achieves this (from poorly to extremely well). Estimated completion time is 15 min.

Breath carbon monoxide

At the three study visits, a breath carbon monoxide test will be performed to validate smoking status, and estimate fetal carboxyhaemoglobin. Carbon monoxide level ≥5 ppm=96% sensitivity and 99.6% specificity for agreement of carbon monoxide readings and self-report of smoking in Aboriginal communities.[68]

Women's checklist

At the end of any visit to the service, from recruitment to the end of follow-up, including the designated study visits at 4 weeks and 12 weeks, the patient will be asked to complete a 1 min online checklist on a computer tablet. The survey will commence with a question regarding which health professional she saw on that occasion (GP/midwife/nurse/Aboriginal health worker/other). Eleven dichotomous questions (yes/no) will be used to form a composite score representing quality of smoking cessation care. For example: *Did any of the health professionals you saw today give you the following care: Asked you about smoking? Gave you advice to quit…? Assisted you with making a quit plan? Explained how smoking affects…? Offered you NRT…? Measured your breath…? /Discussed with you…? Gave you support…? Made arrangements for follow-up appointments or referral? Gave you resources…?* Two Likert Scales will be used to rate (1) her perceived involvement in making a decision about quitting (no involvement to very much involved) and (2) her overall satisfaction with the help she received (not satisfied at all to very satisfied).

Recording of consultations for behaviour change techniques analysis

A digital audio recording of provider-patient sessions relating to smoking cessation will be undertaken, including a mix of initial and follow-up consultations (ie, prequit attempt, and during or postquit attempt up to the 4-week follow-up point). A total estimate of 54 consultations will be recorded (nine consultations per service—three pregnant smokers from each service, for each woman, three consultations as outlined above).

Interviews

At the conclusion of the study, approximately three to four women from each service, will be interviewed to assess the feasibility of the intervention and related research in order to gain insights before the cRCT. Key topics to be discussed include their perceptions of the usefulness, acceptability and potential effectiveness of the support they received as part of the study, and what could have been done to improve this. Recruitment will continue until saturation of themes.

Sample size calculation

Health professionals' sample: expected sample size will be six services, training 5–10 per service, with total sample size of n=30–60 recruited health professionals. Expected completion of training is 80%.

Pregnant women's sample: expected recruitment is 10 eligible consenting women per service n=60 (range 50–80). Assuming a true recruitment rate of 50%, a sample of 200 eligible women will allow estimates of the true recruitment rate within a 7% margin of error.

Data analysis plan

Recruitment rates (and other feasibility outcomes specified in table 1) will be estimated as proportions (or percentages) with 95% CIs, SEs will be adjusted for the clustered design using the clustered jackknife.[69] All primary analysis will be according to the intention-to-treat principle, such that each site (and participants within) will be analysed according to the time at which the site crossed over to the intervention period.

Analysis of effectiveness outcome measures

1. Changes in the proportion of eligible women that were prescribed NRT from pretraining to post-training will be assessed using a logistic mixed effects regression model. The model will include a categorical effect of time, an indicator of period (pretraining vs postintervention) and a random intercept for each site.
2. Changes in provider knowledge/attitudes relating to smoking cessation in pregnant mothers measured by self-administered survey: pretraining to post-training and end of study will be investigated using generalised linear mixed effects models, with random effects for the site and the health professionals, and fixed effects for time. If the fraction of missing data is less than 5% the primary method will be based of those with completed surveys from both time points. Otherwise we will use multiple imputation under the missing at random assumption, with a sensitivity analysis using pattern mixture models to explore the potential that data is missing not at random.
3. Trends in smoking characteristics and growth and empowerment, and factors associated with smoking characteristics and growth and empowerment, will be assessed using generalised linear mixed models.
4. Two certified behaviour change techniques coders will independently code the transcribed audio recordings. Discrepancies will be resolved through discussion with a third coder. Coding will be based on the taxonomy of 44 smoking cessation behaviour change techniques.[15 16] Additionally, the two coders will independently code the training resources. Inter-rater agreement levels will be calculated. We will assess changes between behaviour change techniques present pretraining and post-training; and the fidelity between the behaviour change techniques present in the training resources and those present in the post-training recordings.
5. Interviews at the end of the study will be audio recorded, transcribed and analysed (using NVivo software) with a framework analysis[70] based on the Theoretical Domains Framework and Behaviour Change Wheel.[49 50] Two researchers will independently open code and index a 20% proportion of the transcripts line by line, using a predetermined coding matrix. After coming to consensus, one researcher will then complete the coding and indexing. If appropriate, inductive themes will be included after discussion between the two researchers.

Ethics and dissemination

We will follow Australian National Health and Medical Research Council ethical guidelines for research,

including Aboriginal and Torres Strait Islander research, consistent with the Declaration of Helsinki.[71]

The Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP) invites at least one member from each of the pilot study AMSs and will convene bimonthly. The role of the SCAAP will be to provide cultural consultation, advice and direction to ensure that the implementation of the ICAN QUIT in Pregnancy project pilot is acceptable and respectful to the Aboriginal communities involved. The SCAAP is instrumental in ensuring research practice, data collection and dissemination of findings is appropriate to each community. Members of SCAAP will be included in the writing and publication of research results.

Furthermore, an Aboriginal cultural liaison position is maintained throughout the study to ensure appropriate level of cultural safety, Aboriginal community ownership and engagement is upheld. The research team includes three Aboriginal chief investigators and four Aboriginal associate investigators who are involved in various aspects of the project, including the design, implementation, data analysis and interpretation.

Pregnant smokers who are mature minors (aged over 16 years but under 18 years) will be included if judged by the research facilitator able to give informed consent. Consent to the audio recording is an additional option for both health professionals and participating pregnant women, which they can agree to or decline.

All of the data collected, at all levels, are deidentified. Pregnant women participating in the study are given a unique code by the research facilitator. Any data collected are only identified with this code. Health professionals' surveys are linked using the date of birth and the last three digits of their surname.

All serious adverse events, and study related adverse events considered severe in nature that do not otherwise fulfil the definition of a serious adverse event, will be reported immediately by sites during follow-up. For the purposes of this study those events that will be considered severe study related adverse events include, but are not limited to, severe allergic reaction to NRT and clinical depression. A data monitoring committee will not be convened for this study and was not deemed necessary by the human research ethics committee, as NRT will be used according to current clinical guidelines.

Study outcomes will be discussed with participating services. Sites will receive a lay summary of the study outcomes, to be distributed to their community and participants of the study as they see fit. A policy brief will be distributed to Aboriginal and Government peak bodies.

Significance of the study

The ICAN QUIT in Pregnancy intervention trial was designed to overcome implementation problems identified in previous research.[45 46 72 73 74] This includes ensuring community representation in governance of the research; participant recruitment by known health staff from the service; adequate reimbursement for time and effort of the services and women participants. This pilot phase will enable us to test the feasibility and acceptability of the intervention, and make further adjustments as necessary, prior to the expense of a large cRCT. The ICAN QUIT in Pregnancy pilot trial will provide valuable information to advance the much needed reduction in smoking rates among pregnant Indigenous women.

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Collaborators Complete list of authors of the ICAN QUIT in Pregnancy pilot group is detailed in the acknowledgements.

Contributors YBZ wrote the manuscript and contributed to the design of the study. GG contributed to writing the manuscript, and designed and oversees the study. CO and KP advised on the study design, and statistical analysis. MB contributed to the design of the study and with MG advised on Aboriginal community consultations and adherence to ethical guidelines to research with Aboriginal communities. BB and JR advised on methodology and implementation of the research. LA advised on the design of the intervention using the Theoretical Domains Framework and Behavior Change Wheel. All authors critically reviewed the manuscript.

Competing interests None declared.

Patient consent Obtained.

Ethics approval University of Newcastle Human Research Ethics Committee (HREC) (REF #H-2015-0438). Aboriginal Health & Medical Research Council (AH&MRC) HREC (REF #1140/15). South Australia Aboriginal HREC (REF #04-16-652. Far North Queensland HREC (REF #16/QCH/34 – 1040). Note: The interviews at the end of the study were not included in the original ethics application and have recently been submitted as an amendment

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Data sharing statement This is a protocol manuscript therefore there is no additional unpublished data currently from this study.

REFERENCES

1. Australian Institute of Health and Welfare. *Australia's mothers and babies 2013—in brief*. Canberra: AIHW, 2015.
2. Australian Institute of Health and Welfare. *Australian burden of disease study: impact and causes of illness and death in Aboriginal and Torres Strait Islander people, 2011*. Canberra: AIHW, 2016.
3. Gould GS, McEwen A, Munn J. Jumping the Hurdles for Smoking Cessation in Pregnant Aboriginal and Torres Strait Islander Women in Australia. *The Journal of Smoking Cessation* 2011;6:33–6.
4. Gould GS, Munn J, Avuri S, *et al*. "Nobody smokes in the house if there's a new baby in it": Aboriginal perspectives on tobacco smoking in pregnancy and in the household in regional NSW Australia. *Women Birth* 2013;26:246–53.
5. Gould GS, Munn J, Watters T, *et al*. Knowledge and views about maternal tobacco smoking and barriers for cessation in Aboriginal

and Torres Strait Islanders: a systematic review and meta-ethnography. *Nicotine Tob Res* 2013;15:863–74.
6. Gould GS. Exploring the barriers and enablers to smoking cessation in Pregnant Aboriginal and Torres Strait Islander women with the behaviour change wheel. *Australasian Epidemiologist* 2014;21:31–5.
7. Gould GS, McEwen A, Watters T, *et al*. Should anti-tobacco media messages be culturally targeted for indigenous populations? A systematic review and narrative synthesis. *Tob Control* 2013;22:e7.
8. Passey ME, D'Este CA, Sanson-Fisher RW. Knowledge, attitudes and other factors associated with assessment of tobacco smoking among pregnant aboriginal women by health care providers: a cross-sectional survey. *BMC Public Health* 2012;12:165.
9. Zeev YB, Bonevski B, Twyman L, *et al*. Opportunities Missed: A Cross-Sectional Survey of the Provision of Smoking Cessation Care to Pregnant Women by Australian General Practitioners and Obstetricians. *Nicotine Tob Res* 2017;19:636–41.
10. Gould GS. Here's how to close the gap on indigenous women smoking during pregnancy. The Conversation (Iss. July 21). 2016. https://theconversation.com/heres-how-to-close-the-gap-on-indigenous-women-smoking-during-pregnancy-62347
11. Fiore MC. *Treating tobacco use and dependence: 2008 update. U.S. Department of Health and Human Services*. Public Health Service.
12. Chamberlain C, O'Mara-Eves A, Oliver S, *et al*. Psychosocial interventions for supporting women to stop smoking in pregnancy. *Cochrane Database Syst Rev* 2013;10:CD001055.
13. Michie S, Richardson M, Johnston M, *et al*. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013;46:81–95.
14. Michie S, Wood CE, Johnston M, *et al*. Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions (a suite of five studies involving consensus methods, randomised controlled trials and analysis of qualitative data). *Health Technol Assess* 2015;19:1–188.
15. Michie S, Hyder N, Walia A, *et al*. Development of a taxonomy of behaviour change techniques used in individual behavioural support for smoking cessation. *Addict Behav* 2011;36:315–9.
16. Lorencatto F, West R, Michie S. Specifying evidence-based behavior change techniques to aid smoking cessation in pregnancy. *Nicotine Tob Res* 2012;14:1019–26.
17. Coleman T, Chamberlain C, Davey MA, *et al*. Pharmacological interventions for promoting smoking cessation during pregnancy. *Cochrane Database Syst Rev* 2015;12:CD010078.
18. Stead LF, Perera R, Bullen C, *et al*. Nicotine replacement therapy for smoking cessation. *Cochrane Database Syst Rev* 2012.
19. Dempsey D, Jacob P, Benowitz NL. Accelerated metabolism of nicotine and cotinine in pregnant smokers. *J Pharmacol Exp Ther* 2002;301:594–8.
20. Mendelsohn C, Gould GS, Oncken C. Management of smoking in pregnant women. *Aust Fam Physician* 2014;43:46–51.
21. Zwar N, Richmond R, Borland R, *et al*. *Supporting smoking cessation: a guide for health professionals*. Melbourne, 2011. (updated July 2014).
22. NICE. *Smoking: stopping in pregnancy and after childbirth*, 2010.
23. McRobbie H, Bullen C, Glover M, *et al*. New Zealand smoking cessation guidelines. *N Z Med J* 2008;121:57–70.
24. Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment. *Canadian smoking cessation clinical practice guideline*. Toronto, Canada, 2011.
25. Okoli CT, Greaves L, Bottorff JL, *et al*. Health care providers' engagement in smoking cessation with pregnant smokers. *J Obstet Gynecol Neonatal Nurs* 2010;39:64–77.
26. The Agency for Health Care Policy and Research Smoking Cessation Clinical Practice Guideline. *JAMA* 1996;275:1270–80.
27. Chang JC, Alexander SC, Holland CL, *et al*. Smoking is bad for babies: obstetric care providers' use of best practice smoking cessation counseling techniques. *Am J Health Promot* 2013;27:170–6.
28. Price JH, Jordan TR, Dake JA. Obstetricians and gynecologists' perceptions and use of nicotine replacement therapy. *J Community Health* 2006;31:160–75.
29. Glover M, Paynter J, Bullen C, *et al*. Supporting pregnant women to quit smoking: postal survey of New Zealand general practitioners and midwives' smoking cessation knowledge and practices. *N Z Med J* 2008;121:53–65.
30. Cooke M, Mattick RP, Campbell E. The influence of individual and organizational factors on the reported smoking intervention practices of staff in 20 antenatal clinics. *Drug Alcohol Rev* 1998;17:175–85.
31. Condliffe L, McEwen A, West R. The attitude of maternity staff to, and smoking cessation interventions with, childbearing women in London. *Midwifery* 2005;21:233–40.
32. Grimley DM, Bellis JM, Raczynski JM, *et al*. Smoking cessation counseling practices: a survey of Alabama obstetrician-gynecologists. *South Med J* 2001;94:297–303.
33. Hartmann KE, Wechter ME, Payne P, *et al*. Best practice smoking cessation intervention and resource needs of prenatal care providers. *Obstet Gynecol* 2007;110:765–70.
34. Hickner J, Cousineau A, Messimer S. Smoking cessation during pregnancy: strategies used by Michigan family physicians. *J Am Board Fam Pract* 1990;3:39–42.
35. Jordan TR, Dake JR, Price JH. Best practices for smoking cessation in pregnancy: do obstetrician/gynecologists use them in practice? *J Womens Health* 2006;15:400–41.
36. Moran S, Thorndike AN, Armstrong K, *et al*. Physicians' missed opportunities to address tobacco use during prenatal care. *Nicotine Tob Res* 2003;5:363–8.
37. Mullen PD, Pollak KI, Titus JP, *et al*. Prenatal smoking cessation counseling by Texas obstetricians. *Birth* 1998;25:25–31.
38. Price JH, Jordan TR, Dake JA. Perceptions and use of smoking cessation in nurse-midwives' practice. *J Midwifery Womens Health* 2006;51:208–15.
39. Coleman-Cowger VH, Anderson BL, Mahoney J, *et al*. Smoking cessation during pregnancy and postpartum: practice patterns among obstetrician-gynecologists. *J Addict Med* 2014;8:14–24.
40. Stead LF, Buitrago D, Preciado N, *et al*. Physician advice for smoking cessation. *Cochrane Database Syst Rev* 2013;5:CD000165.
41. Gould GS, Watt K, McEwen A, *et al*. Predictors of intentions to quit smoking in aboriginal tobacco smokers of reproductive age in regional New South Wales (NSW), Australia: quantitative and qualitative findings of a cross-sectional survey. *BMJ Open* 2015;5:e007020.
42. Carson KV, Verbiest ME, Crone MR, *et al*. Training health professionals in smoking cessation. *Cochrane Database Syst Rev* 2012;5:CD000214.
43. Smith BJ, Carson KV. Methodological challenges and options for addressing them in Aboriginal and Torres Strait Islander health research. *Australasian Epidemiologist* 2014;21:47.
44. Gould GS, Watt K, Stevenson L, *et al*. Developing anti-tobacco messages for australian aboriginal and Torres Strait Islander peoples: evidence from a national cross-sectional survey. *BMC Public Health* 2014;14:250.
45. Eades SJ, Sanson-Fisher RW, Wenitong M, *et al*. An intensive smoking intervention for pregnant Aboriginal and Torres Strait Islander women: a randomised controlled trial. *Med J Aust* 2012;197:42–6.
46. Patten CA, Windsor RA, Renner CC, *et al*. Feasibility of a tobacco cessation intervention for Pregnant Alaska Native women. *Nicotine Tob Res* 2010;12:79–87.
47. Gould GS, Bittoun R, Clarke MJ. A Pragmatic Guide for Smoking Cessation Counselling and the Initiation of Nicotine Replacement Therapy for Pregnant Aboriginal and Torres Strait Islander Smokers. *J Smok Cessat* 2015;10:96–105.
48. NSW Ministry of Health. quit for new life NRT Protocol. *Centre for Population Health* 2013.
49. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci* 2012;7:37.
50. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;6:1–12.
51. Bovill M, Bar-Zeev Y, Gruppetta M, *et al*. Collective and negotiated design for a clinical trial addressing smoking cessation supports for Aboriginal and Torres Strait Islander mothers in NSW, SA and Qld ? developing a pilot study. *Aust J Prim Health* 2017. published online 31 March 2017.
52. Hemming K, Haines TP, Chilton PJ, *et al*. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ* 2015;350:h391.
53. Australian Institute of Health and Welfare. *Healthy Futures—Aboriginal Community Controlled Health Services: Report Card 2016*. Canberra, 2016.
54. Bar-Zeev Y, Bovill M, Gruppetta M, *et al*. Assessing and validating an Educational Resource Package for the management of Smoking Cessation in Indigenous Pregnant Women. *Asia-Pacific J Clin Oncol* 2016;12:11.
55. *The Health Consequences of Smoking-50 years of Progress: a Report of the Surgeon General*. Atlanta, 2014.

56. Benowitz N, Dempsey D. Pharmacotherapy for smoking cessation during pregnancy. *Nicotine Tob Res* 2004;6:189–202.
57. Gould G, Clarke M, Cadet-James M, *et al*. Our smoking and smoke-free stories" by Aboriginal women: a qualitative study. *GP16 Conference*, Perth, WA. 2016.
58. Heatherton TF, Kozlowski LT, Frecker RC, *et al*. The Fagerström Test for Nicotine dependence: a revision of the Fagerström tolerance questionnaire. *Br J Addict* 1991;86:1119–27.
59. Kwok TC, Taggar J, Cooper S, *et al*. Nicotine dependence and biochemical exposure measures in the second trimester of pregnancy. *Nicotine Tob Res* 2014;16:145–54.
60. 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.
61. Riaz M, Lewis S, Coleman T, *et al*. Which measures of cigarette dependence are predictors of smoking cessation during pregnancy? analysis of data from a randomized controlled trial. *Addiction* 2016;111:1656–65.
62. Kullander S, Källén B. A prospective study of smoking and pregnancy. *Acta Obstet Gynecol Scand* 1971;50:83–94.
63. Gould GS, Watt K, Cadet-James Y, *et al*. Using the risk behaviour diagnosis scale to understand australian aboriginal smoking - A cross-sectional validation survey in regional New South Wales. *Prev Med Rep* 2015;2:4–9.
64. West R, Hajek P, Stead L, *et al*. Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction* 2005;100:299–303.
65. Haswell MR, Kavanagh D, Tsey K, *et al*. Psychometric validation of the growth and Empowerment measure (GEM) applied with indigenous Australians. *Aust N Z J Psychiatry* 2010;44:791–9.
66. Haswell M, Blignault I, Fitzpatrick S, *et al*. *The Social and Emotional Wellbeing of Indigenous Youth: reviewing and extending the evidence and examining its implications for policy and practice*, 2013.
67. Jersky M, Titmuss A, Haswell M, *et al*. Improving health service access and wellbeing of young aboriginal parents in an urban setting: mixed methods evaluation of an arts-based program. *Aust N Z J Public Health* 2016;40:S115–S121.
68. Maclaren DJ, Conigrave KM, Robertson JA, *et al*. Using breath carbon monoxide to validate self-reported tobacco smoking in remote Australian indigenous communities. *Popul Health Metr* 2010;8:2.
69. Kott PS. The Delete-a-Group Jackknife. *J off stat* 2001;17:521–6.
70. Gale NK, Heath G, Cameron E, *et al*. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013;13:117.
71. NHMRC. *Values and ethics: guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*. Canberra, ACT: Commonwealth of Australia, 2003.
72. Liu H, Laba TL, Massi L, *et al*. Facilitators and barriers to implementation of a pragmatic clinical trial in aboriginal health services. *Med J Aust* 2015;203:24–7.
73. Marley JV, Kitaura T, Atkinson D, *et al*. Clinical trials in a remote aboriginal setting: lessons from the BOABS smoking cessation study. *BMC Public Health* 2014;14:579.
74. West R. *Assessing smoking cessation performance in NHS Stop Smoking Services: the Russell Standard (Clinical)- Version 2*, 2005.