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Complete List of Authors:	Bar Zeev, Yael; University of Newcastle, School of Medicine and Public Health Bonevski, Billie; University of Newcastle, School of Medicine & Public Health Bovill, Michelle; The University of Newcastle, School of Medicine and Public Health Gruppetta, Maree; University of Newcastle, School of Medicine and Public Health Oldmeadow, Christopher; Hunter Medical Research Institute Plaazzi, Kerrin; Hunter Medical Research Institute Atkins, Louise; UCL Reath, Jennifer; University of Western Australia Pilot group, ICAN QUIT in Pregnancy; University of Newcastle, School of Medicine and Public Health Gould, Gillian; The University of Newcastle, School of Medicine and Public Health;
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The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy Pilot Study Protocol: A Feasibility Step-Wedge Cluster Randomized Trial to Improve Health Providers Management of Smoking during Pregnancy

Title Page

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], ICAN QUIT in Pregnancy Pilot Group[5], Gillian S Gould[1]

[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]University of Western Australia, Perth, Western Australia, Australia, [5]Complete authors list of the ICAN QUIT in Pregnancy Pilot Group detailed in the acknowledgments.

Corresponding author: yael.barzeev@uon.edu.au

ABSTRACT

Introduction: Indigenous women have the highest smoking prevalence during pregnancy (47%) in Australia. Health providers (HPs) 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 HPs management of smoking in Indigenous pregnant women – The Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy. This intervention includes webinar training for HPs, an educational resources package for HPs and pregnant women, free oral nicotine replacement therapy (NRT) for pregnant women, and audit and feedback on HPs performance.

The aim of this study is to test the feasibility and acceptability of the ICAN QUIT in Pregnancy intervention to improve HPs provision of evidence-based culturally-responsive smoking cessation care (SCC) to Australian Indigenous pregnant smokers.

Methods and analysis: This protocol describes the design of a step-wedge cluster randomized pilot study. Six Aboriginal Medical Services (AMSs) are randomized into three clusters. Clusters receive the intervention staggered by one month. HPs report on their knowledge and skills pre and post intervention and at the end of the study. Pregnant women are recruited and followed up for three 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 HPs, measured using a designated log; and trends of effectiveness outcomes, including quit rates and NRT prescription rates.

Ethics and dissemination: In accordance with Aboriginal Health and Medical Research Council guidelines for research in Aboriginal health, this study has been developed in collaboration with a Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP). The SCAAP will advise on implementation, analyses, interpretation and dissemination to ensure they are respectful towards Indigenous culture. Results will be disseminated to AMSs, Aboriginal communities, National Aboriginal bodies, and through the scientific literature.

Registration details: This protocol is registered with the Australian and New Zealand Clinical Trials Registry (Ref #: ACTRN12616001603404)

Keywords: Step Wedge Randomized Controlled Trial; Smoking Cessation; Indigenous; Pregnancy

*The term Indigenous will be used in this document to refer to both Aboriginal and Torres Strait Islander peoples in Australia, but with recognition and respect of the autonomy of the two peoples.

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 re-imbursement for time and effort of the services and women participants.
- 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 ante-natal 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 to the general population (11% compared to 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 anti-tobacco messages, and inadequate access to targeted programs[4,5 7]. Health providers (HPs) report they are ill-equipped to tackle the complexities of smoking cessation care (SCC) for pregnant women, and lack resources and optimism[8,9]. First-line medications (oral nicotine replacement therapy (NRT)) are currently not subsidized 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 the general population who smoke[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 (BCTs)[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 1.03-1.93); The exclusion of non-placebo controlled trials resulted in a lower, non-significant increase in the cessation rate (RR 1.28, 95% CI 0.99-1.66)[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 not been successful in quitting unaided[21-24].

Need for HPs training

HPs report that they lack the knowledge, skills and confidence to effectively assist pregnant women to quit smoking. A recent national Australian cross-sectional survey[9] found that few General Practitioners (GPs) and Obstetricians always perform all of the required components of the clinical guidelines[11,25]. Furthermore, only 11% reported always prescribing NRT, 7% arranging follow-up, 22% discussing the psychosocial context of smoking, and 26% referring to a specialized cessation program (such as the national Quitline). Surveys with other antenatal HPs in Australia (Aboriginal Health Workers (AHW), midwifes, nurses) report similar findings[8].

These findings mirror surveys across different countries[26-39], portraying an evidence-practice gap in the way HPs currently manage smoking in pregnant women.

Addressing this gap is crucial, as it has been shown that advice from HPs increases the chances of a quit attempt in the general population (RR 1.66, 95% CI 1.42, 1.92)[40], and is positively associated with intentions to quit in Australian Indigenous smokers of reproductive age (OR 3.82, 95% CI 1.43, 10.2)[41]. Training HPs has been proven to increase rates of smoking cessation (OR= 1.60, 95% CI 1.26,2.03)[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]. Several implementation factors marred the outcomes of these studies, including low enrolment, high attrition, and potential contamination between study arms[45,46]. Patten's study included NRT only through referral to a separate program[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], but add a D component (Discuss the psychosocial context of smoking)[47]. A proactive approach is recommended – offering assistance to all pregnant smokers (regardless of readiness to quit), and an expedited offer of NRT after 1-2 days of an unsuccessful quit attempt[47].

On the basis of these ABCD guidelines[47], we used the Theoretical Domains Framework (TDF)[48], the Behaviour Change Wheel (BCW)[49], and Behaviour Change Techniques (BCTs) recommended in pregnancy[16], to develop a theory based behaviour change intervention aimed to improve HPs management of smoking in Indigenous pregnant women – ICAN QUIT in Pregnancy. The TDF and BCW are used to identify barriers and facilitators to achieving evidence-based care to inform intervention design[49].

We developed this intervention in collaboration with a Stakeholder and Consumer Aboriginal Advisory Panel (SCAAP), including staff and community members from two AMSs[50].

The aim of this study is to test the feasibility and acceptability of the ICAN QUIT in Pregnancy intervention to increase HPs provision of evidence-based, culturally-responsive SCC to Australian Indigenous pregnant smokers. This study will inform the final design and implementation of a clustered RCT (cRCT) aimed to study the effectiveness of training HPs 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 multi-component targeted intervention to train HPs 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 HPs' 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 the trained HPs.
4) Assess patients' perceived receipt and quality of SCC by the trained HPs.
5) Evaluate changes in the perceived wellbeing of pregnant patients
6) Evaluate BCT use by the trained providers.

Study design

This is a step-wedge cluster randomized pilot study with six participating sites randomized to three clusters. All sites will provide monthly aggregated computerized data. The intervention will be sequentially delivered two months following commencement of the study, staggered by one month between clusters. Two cohorts, one of HPs and one of pregnant women, will provide data with repeated measures: from two 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 reduce the cost and burden of simultaneous implementation, while also providing some control of confounding factors through randomisation[51]. Furthermore, this design will ensure all sites receive the intervention from an ethical view point.

Timeline of study: November 2016-September 2017.

Setting: Urban and regional AMSs in New South Wales (NSW), Queensland (QLD), and South Australia (SA). The AMS can either be run by government or non-government organizations, and 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 health care to the communities that control them through an elected board of management[52].

Inclusion criteria

For participating services AMSs are included if they:

1. Diagnose pregnancy or provide antenatal or routine care for pregnant Aboriginal or Torres Strait Islander women.
2. Employ at least one 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 HPs are those who:

1. Consult with pregnant women either for confirmation of pregnancy, ante-natal care, and/or routine care.

Participating women will include:

1. Pregnant women, ≤28 week's gestation.
2. Aboriginal and/or Torres Strait Islander or expectant mothers of Aboriginal and/or Torres Strait Islander babies.
3. Women aged ≥ 16 years old.
4. Those smoking tobacco at any level of consumption.

Intervention components

The ICAN QUIT in Pregnancy intervention includes:

1. **Training** of all HPs in participating sites through webinar in three 60-minute 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.

Continuing Professional Developments (CPD) points (required as part of registration with the Australian Health Practitioner Regulation Agency) will be applied for as an incentive.

2. **An educational resources package,** to be used by both HPs and pregnant women, was developed collaboratively with two participating sites in NSW, and includes a training manual for the HPs, and a flipchart, patient booklet and educational posters for engaging with the pregnant women. Resources were rigorously pre-tested by a 4 step process, including an expert panel, suitability of material score by two AHW, readability scores, and focus groups with both HPs, and female Aboriginal community members, in three states[53], and amended as required.
3. **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-subsidized prescription.
4. **Audit and feedback** regarding HPs performance will be via aggregated, de-identified, service specific, monthly data, commencing in the pre-training phase and continuing through to study completion. Each service will receive feedback regarding their rate of NRT prescription to pregnant women who smoke compared to the other study services.

Study implementation

A staff member will be nominated as a research facilitator (RF) by each service. The role of the RF is to recruit patients, conduct surveys and evaluations, and collect feasibility data (table 1). The research team will provide three site visits (before commencement, one month after commencement, and end of study) and weekly telephone calls as implementation support.

Recruitment and Reimbursement

Services will be recruited through: a) a written invitation to all AMSs in NSW asking for expressions of interest, and b) by contact with services that worked previously with the researchers. The service will be reimbursed $6000 in instalments, for the involvement of their nominated RF.

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, or routine care. The study will be advertised through posters at the service.

The RF will complete a one-page eligibility checklist with women interested in the study, and if eligible, gain informed consent. Consenting women will be assigned a unique code to link the data collected to the same participant without identifying her. Pregnant women recruited to the study will be asked to attend three designated study visits (baseline at recruitment, 4 and 12 weeks post recruitment). At each study visit, the participating women will be asked to fill out 2-3 online surveys and perform a breath carbon monoxide (CO) test. Women will receive reimbursement for their time in the form of a $20 shopping voucher for each visit (total $60 AUD). Women attending all three study visits will enter into a draw for one baby pack (value $50 AUD) per site.

Outcomes

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

Data collection and instruments

Data will be collected at three levels – 1) Service 2) HPs and 3) Pregnant women (Table 1 and 2). Participant time lines are presented in Table 3 (HPs) and Table 4 (participating pregnant women).

1) **Service Level**

Research Facilitator log:

Feasibility data will be collected by the RF using a designated log, including recruitment rate, follow up rate, proportion of participant surveys completed, and HP training rate.

Aggregated computerized data:

De-identified aggregated monthly computerized data will be collected from study commencement (Figure 1), including: number of pregnant women attending the service; number of those that smoke; and number of NRT prescriptions (including oral NRT vouchers).

2) **Health Professionals Level**

HPs survey

A 102-item, 15 minute, self-administered online survey will include questions about HPs demographic characteristics; self-reported knowledge, attitudes and provision of SCC;

prescription of NRT; self-assessment of the barriers and enablers to providing SCC; and perceived usefulness of educational resources. This survey is based on a previous survey from a national study of 378 GPs and Obstetricians[9]. Survey will be sent pre and post-training, and at the end of the study (Table 3).

HPs demographic characteristics: include gender, age, years working as a HP (less than 10 years; 10-19; 20 or more years), speciality (GP; Midwife; Nurse; AHW; 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 SCC: 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 SCC ("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 (CO); 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 measured with the 5-point Likert scale as for the other SCC components. Self-reported perceptions on NRT in pregnancy will include rating the safety for the foetus, effectiveness in aiding pregnant smokers to quit, and perceived adherence.

Barriers and enablers to SCC: (5-point Likert Scales - strongly disagree, to strongly agree). This will be measured using 22 statements covering 13 TDF domains[48], 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 SCC 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 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 HP from each service (i.e. a midwife, a GP and an AHW), including also the manager and RF, will be interviewed. Estimated sample N=40. The purpose is to assess the feasibility of the intervention and the study, and gain valuable insights before commencing the cRCT. The semi-structured interview guide will include questions based on the TDF and BCW[48,49].

3) Pregnant Women Level

Smoking characteristics survey:

This 56-item, 15 minute, survey will incorporate questions from a previously tested survey in Aboriginal pregnant smokers[54]. 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 (Fagestrom Test of Nicotine Dependence[55], Heaviness of Smoking Index[56], Strength and Frequency of Urges to

Smoke[57,58]), home smoking rules, intentions to quit smoking, number of previous quit attempts ≥24h, symptoms of nausea in pregnancy (morning sickness is a predictor of spontaneous quitting[59]), the Risk Behaviour Diagnosis Scale (previously validated in Aboriginal smokers, adapted here for pregnant smokers[60]), and attitudes to smoking and quitting. Adherence to NRT will be measured using a 5-item multi-choice 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 and 12 week follow up, the survey includes additional questions to determine 7-day point prevalence smoking abstinence and continuous abstinence rates[61].

Growth and Empowerment Measure (GEM)[62] which 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 Kessler 6 Psychological Distress Scale supplemented by two questions assessing frequency of happy and angry feelings.

Critical success measure: This survey will be completed only once at the 12 week visit. This survey will measure 9 factors relevant to an empowerment-based program, 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-judgmental 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 woman'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).

Breath carbon monoxide. At the three study visits, a breath CO test will be performed to validate smoking status, and estimate foetal carboxyhaemoglobin. CO ≥5 ppm=96% sensitivity and 99.6% specificity for agreement of CO readings and self-report of smoking in Aboriginal communities[63].

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 and 12 weeks, the patient will be asked to complete a 1 minute online checklist on a computer tablet. The survey will commence with a question regarding which HP she saw on that occasion (GP/Midwife/Nurse/AHW/Other). Eleven dichotomous questions (Yes/No) will be used to form a composite score representing quality of SCC. 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 a) her perceived involvement in making a decision about quitting (No involvement to Very much involved) and b) her overall satisfaction with the help she received (Not satisfied at all to Very satisfied).

Recording of consultations for BCT 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 (i.e. pre-quit attempt, and during or post-quit attempt up to the 4-week follow-up point). A total estimate of 54 consultations will be recorded (9 consultations per service – 3 pregnant smokers from each service, for each woman, three consultations as outlined above).

Interviews

At the conclusion of the study, a selection of women (N=20, estimate 3-4 from each service), will be interviewed to assess feasibility of the intervention and the study and to gain valuable insights before the cRCT.

Sample size calculation:

HPs sample: expected sample size will be six services, training 5-10 HPs per service, with total sample size of N=30-60 recruited HPs. 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 30%, a sample of 200 eligible women will allow estimates of the true recruitment rate within a 6% 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% confidence intervals, standard errors will be adjusted for the clustered design using the clustered jackknife.

Analysis of effectiveness outcome measures:

1) Changes in the proportion of eligible women that were prescribed NRT from pre 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 (pre vs post intervention) 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: pre to post-training and end of study will be investigated using generalised linear mixed effects models, with random effects for the site and the HPs, 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 the 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 BCT coders will independently code the transcribed audio-recordings. Discrepancies will be resolved through discussion with a third BCT coder. Coding will be based on the taxonomy of 44 smoking cessation BCTs[15,16]. Additionally, the two coders will independently code the training resources. Inter-rater agreement levels will be calculated. We will assess changes between BCTs present pre and post training; and the fidelity between the BCTs 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 with a framework analysis[64] based on the TDF and BCW[48,49]. 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 (NHMRC) ethical guidelines for research, including Aboriginal and Torres Strait Islander research, consistent with the Declaration of Helsinki[65].

The study has received the following ethics approvals*:

1. University of Newcastle Human Research Ethics Committee (HREC) (REF #H-2015-0438)
2. Aboriginal Health & Medical Research Council (AH&MRC) HREC (REF #1140/15)
3. South Australia Aboriginal HREC (REF #04-16-652
4. Far North Queensland HREC (REF #16/QCH/34 – 1040)

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

As NRT is being proposed as part of the intervention[21], and nicotine has potential effects on the foetus [66,67], 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. All of the data collected, at all levels, is de-identified.

The SCAAP will include at least one member from each AMS and will convene bi-monthly. The SCAAP will advise on implementation issues, analyses and interpretation to ensure they are respectful towards Indigenous culture. 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 Study

The ICAN QUIT in Pregnancy intervention trial was designed to overcome implementation problems identified in previous research[45,46,68,69]. This includes ensuring community representation in governance of the research; participant recruitment by known health staff from the service; adequate re-imbursement 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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The following collaborators are in the ICAN QUIT in Pregnancy Pilot Group: Gillian Gould, Billie Bonevski, Peter O'Mara, Marilyn Clarke, Chris Oldmeadow, Alan Clough, Kristin Carson, Jennifer Reath, Yael Bar Zeev, Michelle Bovill, Katherine Boydell, Maree Gruppetta, Roger Smith, Yvonne Cadet-James, Renee Bittoun, Lou Atkin, Brett Cowling, Lisa Orcher.

Authors' contributions

Dr Yael Bar Zeev wrote the manuscript with contribution from A/Prof Gillian Gould, who oversees the study. Dr Chris Oldmeadow and Kerrin Palazzi advised on the study design, and statistical analysis. Michelle Bovill and A/Prof Maree Gruppetta advised on Aboriginal community consultations and adherence to ethical guidelines to research with Aboriginal communities. Prof Billie Bonevski and Prof Jennifer Reath advised on methodology and implementation of the research. Dr Lou Atkins advised on the design of the intervention using the TDF and BCW. All authors critically reviewed the manuscript.

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Competing interest's statement

No authors have competing interests.

Figure 1: Schematic illustration of step wedge cluster study for ICAN QUIT in Pregnancy pilot study

Cluster	Site	Months from study commencement (each square = 1 months)										
		1	2	3	4	5	6	7	8	9	10	11
1	1											
	2											
2	3											
	4											
3	5											
	6											

	Cluster unexposed to intervention, collection of service level data only
	Cluster unexposed to intervention, collection of data from all levels (ser
	Cluster in transition period while health providers receive training
	Cluster exposed to intervention, collection of data from all levels (servic
	Cluster exposed to intervention, collection of service level data only

Table 1: Feasibility and Acceptability Outcomes

Hierarchy of Measurement (Service, HPs or pregnant women)	Outcome	Data collection method	Analysis	Time-points
Service	Recruitment rate (Primary outcome)	Research facilitator log	Number of woman recruited divided by number of woman 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 and 12-weeks
Service	Proportion of woman's checklists completed	Woman's checklist	Number of consultations with a completed checklist divided by the total number of consultation 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
HPs and pregnant women	Acceptability of intervention and implementation	Interviews with staff and patients	Thematic analysis	End of study

Table 2: Trends of Effectiveness Outcomes

Hierarchy of Measurement (Service, HPs or pregnant women)	Outcome	Data collection method	Analysis	Time-points
Service	Proportion of pregnant smokers that were given NRT	Audit of de-identified grouped data	Pharmaceutical Benefit Scheme (PBS)* prescriptions or vouchers for NRT	Monthly
HPs	Self-reported knowledge, attitudes and practices about managing smoking in pregnancy	HPs surveys	Changes in HPs knowledge, attitudes and practices comparing all time-points	Pre-training, post-training and end of study
HPs	Behaviour Change Techniques	Audio-recording of consultations	Analysis of transcripts by trained BCT coders	Pre and post training
Pregnant women	Self-reported smoking characteristics	Smoking characteristics survey	Changes in smoking characteristics	Baseline, 4-weeks and 12-weeks
Pregnant women	Woman's perception of receiving smoking cessation care	Woman's checklist	Composite scores on checklists	Exit from consultations with a HP
Pregnant women	Self-reported quit rates	Smoking characteristics survey	7-day point prevalence and continuous abstinence77	Baseline, 4-weeks and 12-weeks
Pregnant women	Biochemically validated quit rates	Hand-held CO meter	7-day point prevalence and continuous abstinence77 using expired CO <6ppm as reference point	Baseline, 4 weeks and 12 weeks
Pregnant women	Self-report of adherence to NRT	Smoking characteristics	Changes in adherence to NRT	4 weeks and 12 weeks

		survey		
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 9 critical success factors	End of study

* Pharmaceutical Benefit Scheme (PBS) is the Australian government scheme for prescription subsidy
HPs = Health Providers

Table 3: Schedule of Assessments for Health Providers receiving training for ICAN QUIT in Pregnancy pilot study

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

Table 4: Schedule of Assessments for Pregnant Women participating in ICAN QUIT in Pregnancy pilot study

Assessment	Performed by*	Day O _ _/_ _/_ _ _ _ (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 provider and/or Research facilitator	X				
Informed Consent	Research facilitator	X				
Smoking Characteristics survey	Research facilitator	X		X	X	
Growth and Empowerment survey		X		X	X	
Critical Success Measures survey					X	
Breath Carbon Monoxide test	Research facilitator	X		X	X	
Patient checklist	Research facilitator	X	X	X	X	
Audio-recording of smoking consultation (optional)	Self-administered online	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.

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. *Journal of Smoking Cessation.* 2011;6(1):33-36.
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(4):246-253.
5. Gould GS, Munn J, Watters T, McEwen A, Clough AR. 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(5):863-874.
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(2):31-35.
7. Gould GS, McEwen A, Watters T, Clough AR, van der Zwan R. Should anti-tobacco media messages be culturally targeted for Indigenous populations? A systematic review and narrative synthesis. *Tob Control.* 2013;22(4):e7.
8. Passey ME, D'Este CA, RW. S-F. 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. Bar Zeev Y, Bonevski B, Tywman 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 and Tobacco Research.* 2016. Accepted for publication 05/12/2016.
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, Chair GP. Treating Tobacco Use and Dependence: 2008 Update. In: Services. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service; 2008.
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(1):81-95.
14. Michie S, Wood CE, Johnston M, Abraham C, Francis JJ, Hardeman W. 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(99):1-188.
15. Michie S, Hyder N, Walia A, West R. Development of a taxonomy of behaviour change techniques used in individual behavioural support for smoking cessation. *Addict Behav.* 2011;36(4):315-319.
16. Lorencatto F, West R, Michie S. Specifying evidence-based behavior change techniques to aid smoking cessation in pregnancy. *Nicotine Tob Res.* 2012;14(9):1019-1026.

17. Coleman T, Chamberlain C, Davey MA, Cooper SE, Leonardi-Bee J. 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 of Systematic Reviews.* 2012(11).
19. Dempsey D, Jacob P, 3rd, Benowitz NL. Accelerated metabolism of nicotine and cotinine in pregnant smokers. *J Pharmacol Exp Ther.* 2002;301(2):594-598.
20. Mendelsohn C, Gould GS, Oncken C. Management of smoking in pregnant women. *Aust Fam Physician.* 2014;43(1):46-51.
21. Zwar N, Richmond R, Borland R, et al. *Supporting smoking cessation: a guide for health professionals* Melbourne2011 [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. *The New Zealand medical journal.* 2008;121(1276):57-70.
24. Canadian Action Network for the Advancement DaAoP-iTT. Canadian Smoking Cessation Clinical Practice Guideline. . Toronto, Canada2011.
25. The Agency for Health Care Policy and Research Smoking Cessation Clinical Practice Guideline. *Jama.* 1996;275(16):1270-1280.
26. Okoli CT, Greaves L, Bottorff JL, Marcellus LM. Health care providers' engagement in smoking cessation with pregnant smokers. *J Obstet Gynecol Neonatal Nurs.* 2010;39(1):64-77.
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(3):170-176.
28. Price JH, Jordan TR, Dake JA. Obstetricians and gynecologists' perceptions and use of nicotine replacement therapy. *J Community Health.* 2006;31(3):160-175.
29. Glover M, Paynter J, Bullen C, Kristensen K. 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(1270):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(2):175-185.
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(3):233-240.
32. Grimley DM, Bellis JM, Raczynski JM, Henning K. Smoking cessation counseling practices: a survey of Alabama obstetrician-gynecologists. *South Med J.* 2001;94(3):297-303.
33. Hartmann KE, Wechter ME, Payne P, Salisbury K, Jackson RD, Melvin CL. Best practice smoking cessation intervention and resource needs of prenatal care providers. *Obstet Gynecol.* 2007;110(4):765-770.
34. Hickner J, Cousineau A, Messimer S. Smoking cessation during pregnancy: strategies used by Michigan family physicians. *J Am Board Fam Pract.* 1990;3(1):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 (Larchmt).* 2006;15(4):400-441.
36. Moran S, Thorndike AN, Armstrong K, Rigotti NA. Physicians' missed opportunities to address tobacco use during prenatal care. *Nicotine Tob Res.* 2003;5(3):363-368.
37. Mullen PD, Pollak KI, Titus JP, Sockrider MM, Moy JG. Prenatal smoking cessation counseling by Texas obstetricians. *Birth.* 1998;25(1):25-31.
38. Price JH, Jordan TR, Dake JA. Perceptions and Use of Smoking Cessation in Nurse-Midwives' Practice. *Journal of Midwifery and Women's Health.* 2006;51(3):208-215.

39. Coleman-Cowger VH, Anderson BL, Mahoney J, Schulkin J. Smoking cessation during pregnancy and postpartum: Practice patterns among obstetrician-gynecologists. *Journal of Addiction Medicine.* 2014;8(1):14-24.
40. Stead LF, Buitrago D, Preciado N, Sanchez G, Hartmann-Boyce J, Lancaster T. Physician advice for smoking cessation. *Cochrane Database Syst. Rev.* 2013;5:CD000165.
41. Gould GS, Watt K, McEwen A, Cadet-James Y, Clough AR. 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(3):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(2):47.
44. Gould GS, Watt K, Stevenson L, McEwen A, Cadet-James Y, Clough AR. 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. *The Medical journal of Australia.* 2012;197(1):42-46.
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(2):79-87.
47. Gould GS, Bittoun R, MJ. C. 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.* 2014:1-10.
48. 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.
49. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science.* 2011;6(1):1-12.
50. Michelle Bovill YB-Z, Maree Gruppetta , Peter O'Mara , Brett Cowling , Gillian Gould. Collective and negotiated design for a clinical trial addressing smoking cessation supports for Aboriginal and Torres Strait Islander mothers in NSW, SA and QLD. *Aust J Prim Health.* 2017. Accepted for publication 16/01/2017.
51. Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ : British Medical Journal.* 2015;350.
52. Australian Institute of Health and Welfare. Healthy Futures—Aboriginal Community Controlled Health Services: Report Card 2016. Canberra.2016.
53. Bar Zeev Y BM, Gruppetta M, Bonevski B, Gould GS. . Assessing and Validating an Educational Resource Package for the Management of Smoking Cessation in Indigenous Pregnant Women. . *Asia-Pacific Journal of Clinical Oncology.* 2016;12 (Supp. 6):11.
54. Gould G, M., Clarke, M., Cadet-James, Y., Bonevski, B. . "Our smoking and smoke-free stories" by Aboriginal women: a qualitative study. GP16 Conference. ; 2016; Perth, WA.
55. Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire. *Br J Addict.* 1991;86(9):1119-1127.
56. Kwok TC, Taggar J, Cooper S, Lewis S, Coleman T. Nicotine dependence and biochemical exposure measures in the second trimester of pregnancy. *Nicotine Tob Res.* 2014;16(2):145-154.

57. Fidler JA, Shahab L, West R. Strength of urges to smoke as a measure of severity of cigarette dependence: comparison with the Fagerstrom Test for Nicotine Dependence and its components. *Addiction.* 2011;106(3):631-638.
58. 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 randomised controlled trial. *Addiction.* 2016.
59. Kullander S, Källén B. A Prospective Study of Smoking and Pregnancy. *Acta Obstet. Gynecol. Scand.* 1971;50(1):83-94.
60. Gould GS, Watt K, Cadet-James Y, Clough AR. Using the risk behaviour diagnosis scale to understand Australian Aboriginal smoking – a cross-sectional validation survey in regional New South Wales. *Preventive Medicine Reports.* 2015;2:4-9.
61. West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction.* 2005;100(3):299-303.
62. 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(9):791-799.
63. Maclaren DJ, Conigrave KM, Robertson JA, Ivers RG, Eades S, Clough AR. Using breath carbon monoxide to validate self-reported tobacco smoking in remote Australian Indigenous communities. *Popul Health Metr.* 2010;8(1):2.
64. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol.* 2013;13(1):117.
65. NHMRC. *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.* Canberra, ACT: Commonwealth of Australia; 2003.
66. *The Health Consequences of Smoking-50 Years of Progress: A Report of the Surgeon General.* Atlanta GA2014.
67. Benowitz N, Dempsey D. Pharmacotherapy for smoking cessation during pregnancy. *Nicotine Tob Res.* 2004;6 Suppl 2:S189-202.
68. 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(1):24-27.
69. Marley JV, Kitaura T, Atkinson D, Metcalf S, Maguire GP, Gray D. Clinical trials in a remote Aboriginal setting: lessons from the BOABS smoking cessation study. *BMC Public Health.* 2014;14:579.

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The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy Pilot Study Protocol: A Feasibility Step-Wedge Cluster Randomized Trial to Improve Health Providers Management of Smoking during Pregnancy

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Complete List of Authors:	Bar Zeev, Yael; University of Newcastle, School of Medicine and Public Health Bonevski, Billie; University of Newcastle, School of Medicine & Public Health Bovill, Michelle; The University of Newcastle, School of Medicine and Public Health Gruppetta, Maree; University of Newcastle, School of Medicine and Public Health Oldmeadow, Christopher; Hunter Medical Research Institute Plaazzi, Kerrin; Hunter Medical Research Institute Atkins, Louise; UCL Reath, Jennifer; Western Sydney University School of Science and Health Pilot group, ICAN QUIT in Pregnancy; University of Newcastle, School of Medicine and Public Health Gould, Gillian; The University of Newcastle, School of Medicine and Public Health;
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The Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy Pilot Study Protocol: A Feasibility Step-Wedge Cluster Randomized Trial to Improve Health Providers Management of Smoking during Pregnancy

Title Page

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], ICAN QUIT in Pregnancy Pilot Group[5], Gillian S Gould[1]

[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, [5]Complete authors list of the ICAN QUIT in Pregnancy Pilot Group detailed in the acknowledgments.

Corresponding author: 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 professional's 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 professional's 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 randomized pilot study. Six Aboriginal Medical Services (AMSs) are randomized into three clusters. Clusters receive the intervention staggered by one month. Health professionals report on their knowledge and skills pre and post training and at the end of the study. Pregnant women are recruited and followed up for three 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 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, 14/10/2016) is registered with the Australian and New Zealand Clinical Trials Registry (Ref #: ACTRN12616001603404)

Keywords: Step Wedge Randomized Controlled Trial; Smoking Cessation; Indigenous; Pregnancy

*The term Indigenous will be used in this document to refer to both Aboriginal and Torres Strait Islander peoples in Australia, but with recognition and respect of the autonomy of the two peoples.

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 re-imbursement 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 ante-natal 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 to the general population (11% compared to 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 anti-tobacco messages, and inadequate access to targeted programs[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 subsidized 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 1.03-1.93); The exclusion of non-placebo controlled trials resulted in a lower, non-significant increase in the cessation rate (RR 1.28, 95% CI 0.99-1.66)[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 women is still unsuccessful quitting smoking, adding an NRT patch. This is done to ensure that the lowest effective dose is used[22,26].

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[11,25]. Furthermore, only 11% reported always prescribing NRT, 7% arranging follow-up, 22% discussing the psychosocial context of smoking, and 26% referring to a specialized cessation program (such as the national

Quitline). Surveys with other antenatal health professionals in Australia (Aboriginal Health Workers, midwifes, nurses) report similar findings[8].

These findings mirror surveys internationally[26-39], 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, 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, 10.2)[41]. Training health professionals has been proven to increase rates of smoking cessation (OR= 1.60, 95% CI 1.26,2.03)[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 to 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 program[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 [50], the Behaviour Change Wheel [51], 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[51].

The intervention was developed in collaboration and negotiation with two 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[52].

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[52]. 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 multi-component 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 professional's 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 patient' perceived receipt and quality of smoking cessation care by the trained health professionals.
5) Evaluate changes in the perceived wellbeing of pregnant patients.
6) Evaluate behaviour change techniques use by the trained health professionals.

Study design

This is a step-wedge cluster randomized pilot study with six participating sites randomized 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 randomized using simple randomisation. Allocation concealment was not possible. All of the sites will receive the same intervention which will be sequentially delivered two months following commencement of the study, staggered by one month between clusters (the intervention is described below). Two cohorts, one of HPs and one of pregnant women, will provide data with repeated measures: from two 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 reduce the cost and burden of simultaneous implementation, while also providing some control of confounding factors through randomisation[53]. Furthermore, this design will ensure all sites receive the intervention which is important from an ethical view point. The cluster design was chosen to prevent contamination, a problem identified in the Eades' study[45].

Timeline of study: November 2016-September 2017.

Setting: Urban and regional AMSs in NSW, Queensland, and South Australia. The AMS 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 health care to the communities that control them through an elected board of management[54].

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 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:

1. Consult with pregnant women either for confirmation of pregnancy, ante-natal care, and/or routine care.

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

1. Pregnant, ≤28 week's 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:

1. **Training** of health professionals in participating sites through webinar in three 60-minute 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 supplemental file for full description of webinar content). As an incentive to complete the training, all health professionals will be offered Continuing

Professional Developments points (required as part of registration with the Australian Health Practitioner Regulation Agency).

2. **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 flipchart, 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 pre-tested 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[55]..

3. **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-subsidized prescription. NRT will be used according to product and Therapeutic Goods Administration instructions, as well as health professional's judgment on a patient-by-patient basis. No study-specific protocol to NRT dispensing will be followed. As nicotine has potential effects on the foetus[56,57], 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.

4. **Audit and feedback** regarding health professional's performance will be via aggregated, de-identified, service specific, monthly data collection, commencing in the pre-training phase and continuing through to study completion. Each service will receive feedback regarding their rate of NRT prescription to pregnant women who smoke compared to 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, one 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: a) written invitation to all AMSs in NSW asking for expressions of interest, and b) targeted invitations to services that worked previously with the researchers. The service will be reimbursed $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, 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 and 12 weeks post recruitment). At each study visit, the participating women will be asked to fill out 2-3 online surveys and perform a breath carbon monoxide test. We estimate that each study visit will take between 30-50 minutes.

Women will receive reimbursement for their time in the form of a $20 shopping voucher for each visit (total $60 AUD). Women attending all three study visits will enter into a draw for one baby pack (value $50 AUD) per site.

Outcomes

Outcomes include feasibility and acceptability measures, and measures of effectiveness outcomes (detail description of all the outcomes are presented in Table 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 (Table 1 and 2). Participant time lines are presented in Table 3 (Health professionals) and Table 4 (pregnant women).

1) 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 computerized data:

De-identified aggregated monthly computerized 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).

2) Health Professionals Level

Health professional's survey

A 102-item, 15 minute, self-administered online survey will include questions about health professionals demographic characteristics; self-reported knowledge, attitudes and provision of smoking cessation care; prescription 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]. Survey will be sent pre 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; 20 or more years), speciality (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 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 foetus, 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 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 (i.e. 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 semi-structured interview guide will include questions based on the Theoretical Domains Framework and Behaviour Change Wheel [50,51], and include topics such as the challenges to implementing the study, and what could have been done to improve the study.

3) Pregnant Women Level

Smoking characteristics survey:

This 56-item, 15 minute, survey will incorporate questions from a previously tested survey in Aboriginal pregnant smokers[58]. 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 (Fagestrom Test of Nicotine Dependence[59], Heaviness of Smoking Index[60], Strength and Frequency of Urges to Smoke[61,62]), home smoking rules, intentions to quit smoking, number of previous quit attempts ≥24h, use of other smoking cessation resources (such as the Quitline), symptoms

of nausea in pregnancy (morning sickness is a predictor of spontaneous quitting[63]), the Risk Behaviour Diagnosis Scale (previously validated in Aboriginal smokers, adapted here for pregnant smokers[64]), and attitudes to smoking and quitting. Adherence to NRT will be measured using a 5-item multi-choice 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 and 12 week follow up, the survey includes additional questions to determine 7-day point prevalence smoking abstinence and continuous abstinence rates[65].

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[66] 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 Kessler 6 Psychological Distress Scale supplemented by two questions assessing frequency of happy and angry feelings. Estimated completion time is 15 minutes.

Critical Success Measure:

This measure was developed through analysis of six Indigenous youth social and emotional wellbeing programs[67] and was previously used in the evaluation of an urban art-based community health program with young Aboriginal and Torres Strait Islander parents[68]. This survey will be completed only once at the 12 week visit. This survey will measure 9 factors relevant to an empowerment-based program, 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-

judgmental 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 woman'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 minutes.

Breath carbon monoxide. At the three study visits, a breath carbon monoxide test will be performed to validate smoking status, and estimate foetal 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[69].

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 and 12 weeks, the patient will be asked to complete a 1 minute 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 a) her perceived involvement in making a decision about quitting (No involvement to Very much involved) and b) 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 (i.e. pre-quit attempt, and during or

post-quit attempt up to the 4-week follow-up point). A total estimate of 54 consultations will be recorded (9 consultations per service – 3 pregnant smokers from each service, for each woman, three consultations as outlined above).

Interviews

At the conclusion of the study, approximately 3-4 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 professional's 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% confidence intervals, standard errors will be adjusted for the clustered design using the clustered jackknife[70]. 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 pre 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 (pre vs post intervention) 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: pre 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 the 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 pre 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[71] based on the Theoretical Domains Framework and Behaviour Change Wheel [50,51]. 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 (NHMRC) ethical guidelines for research, including Aboriginal and Torres Strait Islander research, consistent with the Declaration of Helsinki[72].

The study has received the following ethics approvals*:

1. University of Newcastle Human Research Ethics Committee (HREC) (REF #H-2015-0438)
2. Aboriginal Health & Medical Research Council (AH&MRC) HREC (REF #1140/15)
3. South Australia Aboriginal HREC (REF #04-16-652
4. Far North Queensland HREC (REF #16/QCH/34 – 1040)

The Stakeholder and Aboriginal Community Advisory Panel (SCAAP) invites at least one member from each of the pilot study AMSs and will convene bi-monthly. 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 the 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 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, is de-identified. Pregnant women participating in the study are given a unique code by the research facilitator. Any data collected is only identified with this code. Health provider's survey 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 a severe study related adverse events include, but are not limited to, severe allergic reaction to the 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 Study

The ICAN QUIT in Pregnancy intervention trial was designed to overcome implementation problems identified in previous research[45,46,73,74]. This includes ensuring community representation in governance of the research; participant recruitment by known health staff from the service; adequate re-imbursement 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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The following collaborators are in the ICAN QUIT in Pregnancy Pilot Group: Gillian Gould, Billie Bonevski, Peter O'Mara, Marilyn Clarke, Chris Oldmeadow, Alan Clough, Kristin Carson, Jennifer Reath, Yael Bar Zeev, Michelle Bovill, Katherine Boydell, Ling Li, Maree Gruppetta, Roger Smith, Yvonne Cadet-James, Renee Bittoun, Lou Atkin, Brett Cowling, Lisa Orcher.

Authors' contributions

Dr Yael Bar Zeev wrote the manuscript with contribution from A/Prof Gillian Gould, who oversees the study. Dr Chris Oldmeadow and Kerrin Palazzi advised on the study design, and statistical analysis. Michelle Bovill and A/Prof Maree Gruppetta advised on Aboriginal community consultations and adherence to ethical guidelines to research with Aboriginal communities. Prof Billie Bonevski and Prof Jennifer Reath advised on methodology and implementation of the research. Dr Lou Atkins advised on the design of the intervention using the TDF and BCW. All authors critically reviewed the manuscript.

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Competing interest's statement

No authors have competing interests.

Table 1: Feasibility and Acceptability Outcomes

Hierarchy of Measurement (Service, HPs or pregnant women)	Outcome	Data collection method	Analysis	Time-points
Service	Recruitment rate (Primary outcome)	Research facilitator log	Number of woman recruited divided by number of woman 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 and 12-weeks
Service	Proportion of woman's checklists completed	Woman's checklist	Number of consultations with a completed checklist divided by the total number of consultation 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

Table 2: Measures of Effectiveness Outcomes

Hierarchy of Measurement (Service, HPs or pregnant women)	Outcome	Data collection method	Analysis	Time-points
Service	Proportion of pregnant smokers that were given NRT	Audit of de-identified 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	HPs surveys	Changes in HPs knowledge, attitudes and practices comparing all time-points	Pre-training, post-training and end of study
Health professionals	Behaviour Change Techniques	Audio-recording of consultations	Analysis of transcripts by trained BCT coders	Pre and post training
Pregnant women	Self-reported smoking characteristics	Smoking characteristics survey	Changes in smoking characteristics	Baseline, 4-weeks and 12-weeks
Pregnant women	Woman's perception of receiving smoking cessation care	Woman's checklist	Composite scores on checklists	Exit from consultations with a HP
Pregnant women	Self-reported quit rates	Smoking characteristics survey	7-day point prevalence and continuous abstinence[75]	Baseline, 4-weeks and 12-weeks
Pregnant women	Biochemically validated quit rates	Hand-held CO meter	7-day point prevalence and continuous abstinence[75] using expired CO <6ppm as reference point	Baseline, 4 weeks and 12 weeks
Pregnant women	Self-report of adherence to NRT	Smoking characteristics	Changes in adherence to NRT	4 weeks and 12 weeks

		survey		
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 9 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 ICAN QUIT in Pregnancy pilot study

Assessment	Performed by	Pre-training _ _/_ _/_ _ _ _ (dd/mm/yyyy)	Post training _ _/_ _/_ _ _ _ (dd/mm/yyyy)	End of study _ _/_ _/_ _ _ _ (dd/mm/yyyy)
Informed consent	Research facilitator	X		
Pre training 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

Table 4: Schedule of Assessments for Pregnant Women participating in ICAN QUIT in Pregnancy pilot study

Assessment	Performed by*	Day O _ _/_ _/_ _ _ _ (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.

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. *Journal of Smoking Cessation.* 2011;6(1):33-36.
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(4):246-253.
5. Gould GS, Munn J, Watters T, McEwen A, Clough AR. 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(5):863-874.
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(2):31-35.
7. Gould GS, McEwen A, Watters T, Clough AR, van der Zwan R. Should anti-tobacco media messages be culturally targeted for Indigenous populations? A systematic review and narrative synthesis. *Tob Control.* 2013;22(4):e7.
8. Passey ME, D'Este CA, RW. S-F. 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. Bar Zeev Y, Bonevski B, Tywman 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 and Tobacco Research.* 2016 (accepted for publication).
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(1):81-95.
14. Michie S, Wood CE, Johnston M, Abraham C, Francis JJ, Hardeman W. 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(99):1-188.
15. Michie S, Hyder N, Walia A, West R. Development of a taxonomy of behaviour change techniques used in individual behavioural support for smoking cessation. *Addict Behav.* 2011;36(4):315-319.
16. Lorencatto F, West R, Michie S. Specifying evidence-based behavior change techniques to aid smoking cessation in pregnancy. *Nicotine Tob Res.* 2012;14(9):1019-1026.

17. Coleman T, Chamberlain C, Davey MA, Cooper SE, Leonardi-Bee J. 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 of Systematic Reviews.* 2012(11).
19. Dempsey D, Jacob P, 3rd, Benowitz NL. Accelerated metabolism of nicotine and cotinine in pregnant smokers. *J Pharmacol Exp Ther.* 2002;301(2):594-598.
20. Mendelsohn C, Gould GS, Oncken C. Management of smoking in pregnant women. *Aust Fam Physician.* 2014;43(1):46-51.
21. Zwar N, Richmond R, Borland R, et al. *Supporting smoking cessation: a guide for health professionals* Melbourne2011 [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. *The New Zealand medical journal.* 2008;121(1276):57-70.
24. Canadian Action Network for the Advancement DaAoP-iTT. Canadian Smoking Cessation Clinical Practice Guideline. . Toronto, Canada2011.
25. The Agency for Health Care Policy and Research Smoking Cessation Clinical Practice Guideline. *Jama.* 1996;275(16):1270-1280.
26. Okoli CT, Greaves L, Bottorff JL, Marcellus LM. Health care providers' engagement in smoking cessation with pregnant smokers. *J Obstet Gynecol Neonatal Nurs.* 2010;39(1):64-77.
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(3):170-176.
28. Price JH, Jordan TR, Dake JA. Obstetricians and gynecologists' perceptions and use of nicotine replacement therapy. *J Community Health.* 2006;31(3):160-175.
29. Glover M, Paynter J, Bullen C, Kristensen K. 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(1270):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(2):175-185.
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(3):233-240.
32. Grimley DM, Bellis JM, Raczynski JM, Henning K. Smoking cessation counseling practices: a survey of Alabama obstetrician-gynecologists. *South Med J.* 2001;94(3):297-303.
33. Hartmann KE, Wechter ME, Payne P, Salisbury K, Jackson RD, Melvin CL. Best practice smoking cessation intervention and resource needs of prenatal care providers. *Obstet Gynecol.* 2007;110(4):765-770.
34. Hickner J, Cousineau A, Messimer S. Smoking cessation during pregnancy: strategies used by Michigan family physicians. *J Am Board Fam Pract.* 1990;3(1):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 (Larchmt).* 2006;15(4):400-441.
36. Moran S, Thorndike AN, Armstrong K, Rigotti NA. Physicians' missed opportunities to address tobacco use during prenatal care. *Nicotine Tob Res.* 2003;5(3):363-368.
37. Mullen PD, Pollak KI, Titus JP, Sockrider MM, Moy JG. Prenatal smoking cessation counseling by Texas obstetricians. *Birth.* 1998;25(1):25-31.
38. Price JH, Jordan TR, Dake JA. Perceptions and Use of Smoking Cessation in Nurse-Midwives' Practice. *Journal of Midwifery and Women's Health.* 2006;51(3):208-215.

39. Coleman-Cowger VH, Anderson BL, Mahoney J, Schulkin J. Smoking cessation during pregnancy and postpartum: Practice patterns among obstetrician-gynecologists. *Journal of Addiction Medicine.* 2014;8(1):14-24.
40. Stead LF, Buitrago D, Preciado N, Sanchez G, Hartmann-Boyce J, Lancaster T. Physician advice for smoking cessation. *Cochrane Database Syst. Rev.* 2013;5:CD000165.
41. Gould GS, Watt K, McEwen A, Cadet-James Y, Clough AR. 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(3):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(2):47.
44. Gould GS, Watt K, Stevenson L, McEwen A, Cadet-James Y, Clough AR. 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. *The Medical journal of Australia.* 2012;197(1):42-46.
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(2):79-87.
47. Gould GS, Bittoun R, MJ. C. 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.* 2014:1-10.
48. NSW Ministry of Health. Quit for new life NRT Protocol. Centre for Population Health 2013.
49. Gould GS, Bittoun R, MJ. C. A Pragmatic Guide for Smoking Cessation Counselling and the Initiation of Nicotine Replacement Therapy for Pregnant Aboriginal and Torres Strait Islander Smokers *Journal of Smoking Cessation.* 2015;10:96-105.
50. 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.
51. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science.* 2011;6(1):1-12.
52. Michelle Bovill YB-Z, Maree Gruppetta , Peter O'Mara , Brett Cowling , Gillian Gould. Collective and negotiated design for a clinical trial addressing smoking cessation supports for Aboriginal and Torres Strait Islander mothers in NSW, SA and QLD. *Aust J Prim Health.* 2017 (accepted for publication).
53. Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ : British Medical Journal.* 2015;350.
54. Australian Institute of Health and Welfare. Healthy Futures—Aboriginal Community Controlled Health Services: Report Card 2016. . Canberra.2016.
55. Bar Zeev Y BM, Gruppetta M, Bonevski B, Gould GS. . Assessing and Validating an Educational Resource Package for the Management of Smoking Cessation in Indigenous Pregnant Women. . *Asia-Pacific Journal of Clinical Oncology.* . 2016;12 (Supp. 6):11.
56. *The Health Consequences of Smoking-50 Years of Progress: A Report of the Surgeon General.* Atlanta 2014.
57. Benowitz N, Dempsey D. Pharmacotherapy for smoking cessation during pregnancy. *Nicotine Tob Res.* 2004;6 Suppl 2:S189-202.

58. Gould G, M., Clarke, M., Cadet-James, Y., Bonevski, B. . "Our smoking and smoke-free stories" by Aboriginal women: a qualitative study. GP16 Conference. ; 2016; Perth, WA.
59. Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire. *Br J Addict.* 1991;86(9):1119-1127.
60. Kwok TC, Taggar J, Cooper S, Lewis S, Coleman T. Nicotine dependence and biochemical exposure measures in the second trimester of pregnancy. *Nicotine Tob Res.* 2014;16(2):145-154.
61. Fidler JA, Shahab L, West R. Strength of urges to smoke as a measure of severity of cigarette dependence: comparison with the Fagerstrom Test for Nicotine Dependence and its components. *Addiction.* 2011;106(3):631-638.
62. 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 randomised controlled trial. *Addiction.* 2016.
63. Kullander S, Källén B. A Prospective Study of Smoking and Pregnancy. *Acta Obstet. Gynecol. Scand.* 1971;50(1):83-94.
64. Gould GS, Watt K, Cadet-James Y, Clough AR. Using the risk behaviour diagnosis scale to understand Australian Aboriginal smoking – a cross-sectional validation survey in regional New South Wales. *Preventive Medicine Reports.* 2015;2:4-9.
65. West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction.* 2005;100(3):299-303.
66. 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(9):791-799.
67. Haswell M, Blignault I, Fitzpatrick S, Jackson Pulver L. The Social and Emotional Wellbeing of Indigenous Youth: Reviewing and Extending the Evidence and Examining its Implications for Policy and Practice. 2013.
68. 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 Suppl 1:S115-121.
69. Maclaren DJ, Conigrave KM, Robertson JA, Ivers RG, Eades S, Clough AR. Using breath carbon monoxide to validate self-reported tobacco smoking in remote Australian Indigenous communities. *Popul Health Metr.* 2010;8(1):2.
70. Kott PS. The Delete-a-Group Jackknife. *Journal of official statistics.* 2001;17(4):521-526.
71. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol.* 2013;13(1):117.
72. NHMRC. *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.* Canberra, ACT: Commonwealth of Australia; 2003.
73. 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(1):24-27.
74. Marley JV, Kitaura T, Atkinson D, Metcalf S, Maguire GP, Gray D. Clinical trials in a remote Aboriginal setting: lessons from the BOABS smoking cessation study. *BMC Public Health.* 2014;14:579.
75. West R. Assessing smoking cessation performance in NHS Stop Smoking Services: The Russell Standard (Clinical)- Version 2. April 2005.

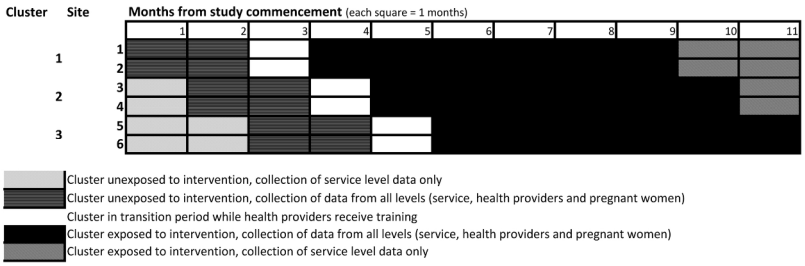

Figure 1: Schematic illustration of step wedge cluster study for ICAN QUIT in Pregnancy pilot study

209x148mm (300 x 300 DPI)

Supplemental File 1

Webinar content

Session 1:

- Background on smoking in pregnancy and relevance to vulnerable subgroups including the Indigenous context.
- Non-confrontational history taking.
- Engagement of vulnerable pregnant smokers.
- Assessment of smoking in Indigenous and vulnerable women - nicotine dependence and motivation.
- Assessing socio-cultural aspects and environmental smoking.
- Culturally competent care - importance and content.
- Non-didactic counselling styles.
- Concept and benefit of 'teachable moments'.

Session 2:

- The ABCD approach – Ask-Brief advice-Cessation medications-Discuss psychosocial context.
- Behaviour change techniques (BCTs) successful in pregnancy, e.g. goal setting, setting a quit date, problems solving, and boosting self-efficacy.
- How to tailor advice to the client.
- Interventions of differing intensity - brief to intensive.
- Involving the family in smoking management and smoke-free environments.
- Supportive counselling and follow up.
- Psychosocial support.
- Use of optimised resources.
- Referral mechanisms.
- Ancillary resources available: Quitline, on-line and mobile phone apps.

Session 3:

- Using NRT in pregnancy:
    - Initiating NRT, and how to advise about NRT - NRT algorithm for pregnancy – step-wise titration.
    - Dosage management
    - Side-effects
    - Indications/contra-indications
    - Promoting adherence
- Use of the CO meter as a motivational tool, and for monitoring and validating abstinence.
- Advising re cannabis and e-cigarettes.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 3
	2b	All items from the World Health Organization Trial Registration Data Set	Not relevant
Protocol version	3	Date and version identifier	Page 3
Funding	4	Sources and types of financial, material, and other support	Pages 26
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Pages 1 and 26
	5b	Name and contact information for the trial sponsor	Not relevant
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Not relevant
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Page 23

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Pages 5-9
	6b	Explanation for choice of comparators	Page 10
Objectives	7	Specific objectives or hypotheses	Page 9-10
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 10
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 11
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 11
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 10 and 12-13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Not relevant
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 13-14
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Not relevant
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Pages 15-23 and 28-30
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 10, 15, 27, and 31-32

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 21
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 25
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Not relevant
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Not relevant
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 13, 15-21
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 15

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 14 and 24
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Pages 21-23
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Not relevant
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 21
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Not relevant
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Not relevant
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 24
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not relevant
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 23
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 23-25

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 14
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not relevant
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 14 and 24
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 26
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Not relevant
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Not relevant
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 25
	31b	Authorship eligibility guidelines and any intended use of professional writers	Not relevant
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Not relevant
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Page 24
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not relevant

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.