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Feasibility and acceptability of Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy multicomponent implementation intervention and study design for Australian Indigenous pregnant women: A pilot cluster randomised step-wedge trial

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HIGHLIGHTS

- Resources targeted to Indigenous smoking cessation in pregnancy were well-received.
- Health staff were motivated by engagement with Indigenous pregnant women.
- Many Indigenous women made quit attempts, and 13.8% quit smoking.
- ICAN QUIT in Pregnancy was feasible and acceptable to Aboriginal Medical Services.
- Modifications were recommended by health staff to trial design and survey length.

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ABSTRACT

Background: Many health providers (HPs) lack knowledge, confidence, optimism and skills in addressing smoking with pregnant women. This study aimed to explore the feasibility and acceptability of a) a co-designed multi-component intervention for HPs at Aboriginal Medical Services (AMSs) in culturally-targeted pregnancy-specific smoking cessation care and b) the study design.

Methods: Using a randomised step-wedge cluster design, the Indigenous Counselling And Nicotine (ICAN) QUIT in Pregnancy Trial was evaluated across six AMSs in three Australian states. HPs were provided educational resource packages including live interactive webinars, treatment manuals, patient resources, carbon monoxide (CO) meters, and oral Nicotine Replacement Therapy (NRT). Feasibility was assessed through recruitment and retention rates of both pregnant women (12-weeks) and HPs (end of study) as well as the potential to improve women's quit rates. Qualitative interviews with staff post-trial explored acceptability of the intervention and study, based on capability, opportunity and motivation from the Behaviour Change Wheel.

Results: Pregnant women (n = 22; 47% (95% CI: 32%, 63%) eligible) and HPs (n = 50; 54% (95% CI: 44%, 64%) eligible) were recruited over 6 months with retention rates of 77% (95% CI: 57%, 90%) and 40% (95% CI:

Abbreviations: ICAN QUIT in Pregnancy, Indigenous Counselling And Nicotine Quit in Pregnancy.; HP/s, Health Providers.; CO, carbon monoxide.; SCC, Smoking Cessation Care.; NRT, Nicotine Replacement Therapy.; GEM, Growth and Empowerment Measure.; ACTRN, Australian and New Zealand Clinical Trials Registry.; AMS/s, Aboriginal Medical Service.; HREC, Human Research Ethics Committee.; GP, General Practitioner.; RF, Research Facilitator.; RCT, Randomised controlled trial.; TDF, Theoretical Domains Framework.; COM-B Model, Capability, Opportunity, Motivation, Behaviour Model.; BCW, Behaviour Change Wheel.; RR, Relative risk.; SISTAQUIT, Supporting Indigenous Smokers To Assist Quitting.

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28%, 54%) respectively. Self-reported 12-week 7-day point-prevalence abstinence was 13.6% (n = 3) and validated abstinent with CO readings ≤6 ppm. Staff interviewed regarding intervention implementation highlighted the importance of provision and use of resources, including training materials, patient resources, CO meters and oral NRT. Resources helped increase capability and opportunity, restructure the environment, and provided social comparison and modelling. Staff were motivated by greater engagement with pregnant women and seeing the women's reductions in CO readings. Having the intervention at the AMSs improved organisational capacity to engage with pregnant women. Staff reported changes to their routine practice that were potentially sustainable. Recommendations for improvement to the implementation of the intervention and research included reducing training length and the tasks related to conducting the study.

Conclusion: ICAN QUIT in Pregnancy was a pilot study with the ability to enrol Indigenous women. It was feasible to implement and acceptable to most staff of the AMSs in three states, with modifications recommended. Smoking in pregnancy is a key challenge for Indigenous health. The intervention needs to be evaluated through a methodologically rigorous fully-powered study to determine the efficacy of outcomes for women.

Trial registration: Australian and New Zealand Clinical Trials Registry, ACTRN12616001603404. Registered 21 November 2016 - retrospectively registered, https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=371778

1. Background

Tobacco smoking is diminishing among pregnant women globally, (Murthy, 2017; Reitan & Callinan, 2017) but smoking rates among Australian Indigenous pregnant women remain higher than their general population counterparts (age-standardised percentages of 44% compared to 12% respectively in the first 20 weeks of pregnancy). (Australian Institute of Health and Welfare, 2016) In some states, such as New South Wales, the gap is widening (a three-fold to six-fold increase over a decade), (Health, 2015) and smoking rates were reported as increasing among pregnant Aboriginal women in the Northern Territory (from 42% in 1997–1999 to 52% in 2009–2011). (Department of Health, 2014; Li & O'Neil, 2018) Smoking is a major reversible risk factor for obstetric complications. (Hofhuis, de Jongste, & Merkus, 2003) Maternal smoking in pregnancy is associated with multiple adverse health effects for the unborn baby and affects the early lives of the offspring. (Hofhuis et al., 2003) Many non-communicable diseases are associated with in utero exposure to chemicals from tobacco, such as chronic heart and lung diseases, cancer, obesity and diabetes. (Hofhuis et al., 2003) Tobacco smoking has also been identified as a major preventable cause of health inequities suffered by women experiencing psychosocial disadvantage. (Chamberlain et al., 2017)

Pregnancy has a unique set of circumstances that can make stopping smoking more difficult for women. Women from the general pregnant population report many barriers to quitting, including: lack of knowledge, stigma, partner smoking, fears that quitting risks disruption of social networks, boredom and isolation, need to balance own needs and that of the unborn baby, rebellion, belief that risks of smoking in pregnancy are exaggerated, psychosocial stress, financial stress, intimate partner violence, depression, half-hearted support from HPs, and negative attitudes towards pharmacotherapy. (Bottorf et al., 2014; Crane, Hawes, & Weinberger, 2013; Flemming, Graham, McCaughan, Angus, & Bauld, 2015; Flemming, Heirs, Fox, & Sowden, 2013; Flemming, Md, & Graham, 2014; Ingall, 2010; Rhodes-Keefe, 2015; S Schneider & Schuetz, 2010) Within the Indigenous context during pregnancy these barriers are compounded by additional factors, (Bovill et al., n.d.; Gould et al., 2013; Gould et al., 2017; Gould, Lim, & Mattes, 2017; Gould, Munn, Watters, McEwen, & Clough, 2013; Gould, Patten, Glover, Kira, & Jayasinghe, 2017) including social-cultural norms, smoking as a stress reduction and coping mechanism due to higher rate of multiple life stressors compared to the non-Indigenous population, lack of culturally-tailored content triggering fear control responses and avoidance or refutation of messages and inconsistent advice from HPs to quit versus cut down subsequently resulting in inconsistent application of evidence-based approaches such as nicotine replacement therapy (NRT). (Bar-Zeev et al., 2017; Bar-Zeev, Lim, Bonevski, Gruppetta, & Gould, 2018)

Systematic reviews on psychosocial interventions for smoking cessation in pregnancy have shown that interventions such as counselling (RR 1.44, 95% CI 1.19 to 1.73) (Chamberlain et al., 2017) and NRT (RR 1.41, 95 CI 1.03 to 1.93) (Coleman, Chamberlain, Davey, Cooper, & Leonardi-Bee, 2015) can be effective to aid quit attempts compared to usual care. However, a Cochrane review pooled results from four interventions (three were tailored counselling, and one used incentives) conducted with Indigenous pregnant women, and did not show a significant effect. (Chamberlain et al., 2017) Even though these four relatively small studies have been conducted world-wide among Indigenous pregnant women, this is considered a very limited amount of research compared to > 100 trials with over 28,000 women in the broader pregnant population. The Cochrane review highlights the importance of considering context in program design, as the very high baseline prevalence of smoking among Indigenous people, may overwhelm the capacity of individuals to quit smoking. Suggested are comprehensive approaches and concurrent environmental interventions, such as supporting smoke-free homes, and culturally-targeted support. Despite interventions being reported as feasible and acceptable to Indigenous communities, there have been challenges with implementation in the studies conducted to date.

Conversely, a Cochrane review of smoking cessation interventions culturally-tailored for smoking cessation among the general population of Indigenous adults demonstrated a positive effect on cessation (RR 1.43, 95% CI 1.03 to 1.98; p = 0.032). (Carson et al., 2012)

Unique barriers pregnant Indigenous women face for smoking cessation require unique interventions that consider these compounding factors. Cochrane and other authoritative reviews highlight the need for further research into targeted approaches for women in high priority groups, including women experiencing psychosocial disadvantage, and Indigenous pregnant women. (Chamberlain et al., 2017) Recommended approaches for further research stress the importance of considering cultural and other contexts to enable specific needs of subpopulations to be addressed and ensure intervention appropriateness for respective settings. Trials during pregnancy can also be challenging to implement as research needs to be conducted in a small window of time with other confounding factors such as women delivering early, or moving, or becoming unwell.

Pilot studies that describe intervention development are required to assess intervention feasibility, acceptability and potential for uptake prior to large investment into fully-powered studies. To date, few feasibility studies of smoking cessation for Indigenous women have been conducted. Of the available evidence from four feasibility studies among pregnant Indigenous women, recruitment rates range between 12%–58%, and retention rates from 37% to 86% and outcomes measures reported for feasibility and acceptability vary. (Glover, Kira, Walker, & Bauld, 2015; Passey & Stirling, 2018; Patten et al., 2010) Only one study, Passey et al., reported process measures in detail. (Passey & Stirling, 2018) A full randomised controlled trial (RCT) of

smoking cessation intervention in Australian Indigenous pregnant women had a high recruitment rate of 69% (n = 263/379 women) over a period of two years, and a 67% retention rate, yet a non-significant increase in quit rates. (Eades et al., 2012) Although this trial was feasible in relation to recruitment, the paper reported implementation problems, which may have impacted trial outcomes. These implementation issues for an intervention, and the research design may be picked up in a pilot study. This highlights the importance of understanding implementation and context of both an intervention and the research to maximise conditions for success, as both aspects may operate independently.

In the context of so few trials being conducted in an Indigenous setting for pregnant women who smoke, the seriousness of the effects of smoking across the lifespan for Indigenous Australians, and the need to develop more robust evidence about the implementation of smoking cessation during pregnancy for Indigenous women, we aimed to examine the feasibility and acceptability of a) a multi-component culturally-tailored smoking cessation intervention for Indigenous pregnant women called Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy, and b) the step-wedge trial design. A multi-component intervention was developed to simultaneously target services, HPs and end-users (pregnant women using the services), as multiple factors have been identified that are critical to address for a targeted approach to smoking cessation in this population. (Gould, 2014; Passey, Bryant, Hall, & Sanson-Fisher, 2013) This paper reports on the feasibility and acceptability of this intervention, the implementation issues encountered, and participant recommendations for a larger trial. (Gould, 2017)

2. Methods

2.1. Study design, setting and participants

This pilot study used a randomised step-wedge design in six Aboriginal Medical Services (AMSs) in Australia: four services in New South Wales, one in Queensland, and one in South Australia from November 2016 to September 2017. The published a priori protocol is described in brief. (Bar-Zeev et al., 2017) The AMSs were all primary health services that are controlled by an Aboriginal community board. An Aboriginal community-controlled health service aims to deliver holistic, comprehensive, culturally appropriate health care to the community that controls it.

A step-wedge design is an alternative to a parallel cluster trial design, which is commonly used for the evaluation of service delivery at the level of the cluster. (Hemming, Haines, Chilton, Girling, & Lilford, 2015) In a step-wedge design, each cluster provides before and after observations and switches from control to becoming exposed to the intervention, but the start times for the clusters are staggered (see schema in Fig. 1). (Hemming et al., 2015)This design was chosen as having potential for a full trial as an alternative to a standard randomised controlled trial (RCT). The advantage would be that all sites receive the intervention in a timelier fashion for example compared to a standard cluster RCT or wait-list intervention. If the pilot phase was feasible, the trial could continue to recruit more services under the same design. The services were randomised in pairs, to when they would receive treatment cross-over (see Fig. 1) using simple randomisation by a senior statistician (CO). The intervention was delivered for a period of 2-months, with delivery of the intervention staggered by one month between each step (see Fig. 1). Inclusion criteria for services were AMSs who consulted Indigenous pregnant women, employed at least one general practitioner (GP), had contact with 20 pregnant women who smoke per annum, and were able to recruit and follow-up patients for the study. There were no specific exclusion criteria for services. Each pair of services had a two-month pre-training period in which to recruit women and perform usual care, followed by a month designated for the training, and then a post-training period when they continued recruiting and following up pregnant women (see Fig. 1). All HPs at a service, and their managers or other staff were welcome to participate in the webinar training. Pregnant women were eligible provided they were current smokers, were up to 28-weeks' gestation, aged 16 years or over, and expecting an Indigenous baby. An exclusion criterion was if a woman was unable to give informed consent.

Expected sample size for HP was 30–60, with ~80% expected to complete the training. Expected sample for women was 60 (estimate of 10 women per service, range 50–80) with recruitment rate expected to be ~50%. (Bar-Zeev, Bonevski, Bovill, et al., 2017). There is limited data available to guide the estimation of a sample size for this study. Therefore, samples sizes were pragmatically estimated based on information obtained from colleagues who work within AMSs.

2.2. Intervention

The ICAN QUIT in Pregnancy study was collaboratively designed (Bar-Zeev, Bonevski, Bovill, et al., 2017; Gould et al., 2017) following in-depth community consultation. (Bovill et al., 2017) This occurred under the guidance of a Stakeholder and Consumer Aboriginal Advisory Panel to produce a suite of training and educational resources for HPs and the pregnant Indigenous women they consult, (Bar-Zeev et al., 2017) based on the Behaviour Change Wheel (BCW) and Theoretical Domains Framework (TDF). (Gould, Bar-Zeev, et al., 2017) The

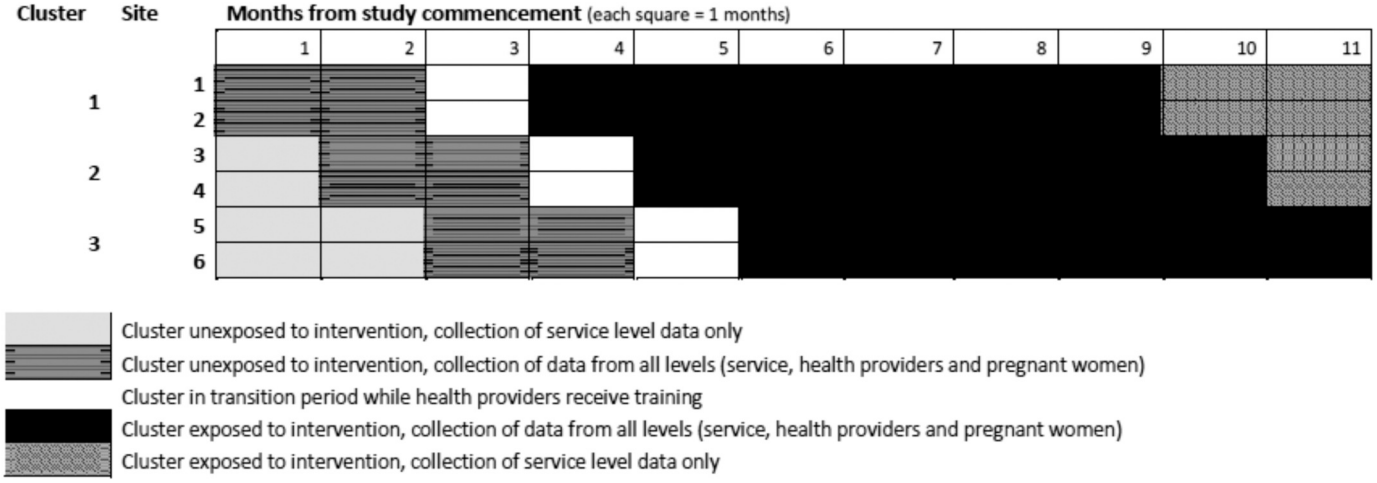

Fig. 1. Schema of Step-Wedge Cluster Randomised Design for ICAN QUIT in Pregnancy (reproduced with permissions from authors) (Bar-Zeev, Bonevski, Bovill, et al., 2017).

behaviour change targeted was HP provision of smoking cessation care for pregnant women. This was to be achieved through the intervention components at the HP level of: education, training and enablement, social modelling, environmental restructuring, incentivising (non-financial incentives) and persuasion. (Bar-Zeev, Bonevski, Bovill, et al., 2017; Gould, Bar-Zeev, et al., 2017)

Planned intervention components included:

1. An education resource package to support interactive webinar training delivered in real time by Tobacco Treatment Specialists via Zoom software (Zoom Video Communications, San Jose, California, U.S.A). Three one-hour sessions were delivered in a single 3-h period. Recorded sessions were available for HPs who missed live sessions. Supportive materials included a treatment manual, a desktop guide (as a mouse pad), a Flipchart to guide the HP-patient consultation, several educational posters, and a patient booklet. Development and pre-testing of these resources have been detailed elsewhere. (Bar-Zeev et al., 2017; Bovill et al., 2017; Gould, Bar-Zeev, et al., 2017)
2. Oral forms of NRT. As oral forms of NRT are recommended as a first option before NRT patches are prescribed, and not subsidised in Australia at the time of the study, AMS were provided with sample packs, and supplies to dispense on site, via a voucher system.
3. A carbon monoxide (CO) breath meter specifically designed for use with pregnant smokers (Bedfont Scientific piCOBaby™ Smokerlyzer®) to measure exhaled CO, as a biological indicator of tobacco smoking, and a computer tablet were supplied.
4. Audit and feedback to report to AMS their performance as a whole service on prescribing rates of NRT to pregnant patients who smoke during the study period

2.3. Recruitment and intervention delivery

A Research Facilitator (RF) was engaged at each service (selected by individual AMSs) to recruit women to the trial, collect data and follow up participants. Women were recruited to the trial by posters displayed in waiting room or clinic areas, a pamphlet on the trial given to interested women, and other local means, such as informing women about the trial through community events or newsletters, and word of mouth. Women were followed up by the RF by planned appointments, at routine clinic visits, or by contacting women via their preferred channels.

Shopping vouchers of Australian Dollar (AUD) $20 value each were given to women at each evaluation point of baseline, 4-weeks and 12-weeks (not able to be used to purchase tobacco or alcohol). Services were reimburse AUD $6000 in three installments of AUD $2000 to recompense the RFs time. The RFs were trained by YBZ face to face during site visits, and a study briefing via Zoom, and supported by a research assistant (LP) by weekly telephone calls and emails.

2.4. Outcome measures and data collection

The primary outcome measure was feasibility determined through recruitment rate (number of participants recruited divided by number deemed as eligible and therefore invited to the trial by the RF) and retention rates for pregnant women (completion of 12-weeks follow-up survey) and HPs (completion of one follow-up survey). We did not predetermine a recruitment threshold below which we considered the study not to be feasible but would use the information gained to make improvements to conduct a larger trial.

Secondary outcomes included:

a) Survey completion rates for pregnant women and HP participants;
b) Rate of agreement to audio-recording of consultations for women and health providers;
c) Acceptance and adherence of NRT among pregnant women;
d) Efficacy of ICAN QUIT in Pregnancy program measured by various indicators: self-reported; biochemically validated by CO readings ≤ 6 ppm indicating smoking abstinence; 7-day point prevalence; continuous abstinence using the Russell Standard Clinical – assessed as abstinent if 'not a puff' since quit date, or allowing slippage of 1–5 cigarettes, (West, 2005) at each time point, and number of women making a quit attempt;
e) Intervention adherence to training for the ICAN QUIT in Pregnancy program for both eligible HPs and consenting HPs and provision of NRT;
f) Use of research study forms;
g) Feasibility of obtaining monthly data on NRT prescriptions and smoking characteristics of pregnant women attending the service;
h) Fidelity of training timing (proportion of services trained as scheduled);
i) Views of pregnant women participants about critical factors for success (survey);
j) Views of staff from interviews post-study.

Data collection sources included study research logs and surveys collected by Qualtrics software (Provo, Utah, USA).

2.4.1. Surveys

The surveys included a 'smoking characteristics survey' (a 56-item survey collecting data on attitudes to smoking, intentions to quit smoking and smoking behaviours – with additional demographic questions at baseline), and a previously validated Growth and Empowerment Measure (GEM): these were completed at four and 12 weeks, as well as the 'women's checklist' (a 10-item survey asking about the smoking cessation care the woman had received that day) completed, after each consultation at the service and after study visits. The GEM is an instrument to measure dimensions of empowerment as defined and described by Aboriginal people, developed in collaboration with Aboriginal Australians and psychometrically validated in Aboriginal populations. (Haswell et al., 2010) The smoking characteristics survey was validated in an Aboriginal community-based study, (Gould, Watt, Cadet-James, & Clough, 2015; Gould, Watt, McEwen, Cadet-James, & Clough, 2014) and previously used with pregnant Aboriginal women. (Bovill et al., 2018; Gould, Bovill, et al., 2017) The women's checklist was used for the first time in this study. A 'health provider survey' (102-items completed pre-training included baseline demographic characteristics, and knowledge, attitudes and practices, and also at one-month post-training, and at the end of the study). The health provider survey was previously validated in a national study of Australian general practitioners and obstetricians. (Bar-Zeev et al., 2018; Bar-Zeev, Bonevski, Twyman, et al., 2017)

2.4.2. Critical factors survey

This was used to assess study acceptability from the women participants' viewpoint. The critical success survey was previously developed through an analysis of Indigenous youth social and emotional well-being programs. (Haswell, Blignault, Fitzpatrick, & Jackson-Pulver, 2013) Pregnant participants were presented with nine critical factors that are theorised to be important to a successful program, at the end of the study. This survey measures nine factors relevant to an empowerment-based program, including adopting a commitment to working from strengths; being patient to develop the relationship bond; modelling reliability and being consistent; facilitating connection to culture; adopting a non-judgemental approach; setting rules and boundaries; modelling openness, honesty, hope and trust; maximising opportunity for choice making, self-motivation, feeling safe to try new things; and celebrating small achievements and positive changes. For example, the first critical success factor was "Adopting full commitment to working from strengths, not seeking to correct deficits". For each critical factor participants were asked to indicate, using a five-point Likert scale: (Reitan & Callinan, 2017) how important they believed the

factor was in order for the program to work well, with response options including "not at all", "a little", "moderate", "very" and "absolutely essential"; and (Murthy, 2017) how well they thought the program achieved that factor, with response options including: "poorly," "slightly," "moderately," "very" and "extremely." For both questions, responses were dichotomised as "not at all/a little/moderate" vs. "very/absolutely essential", and "poorly/slightly/moderately" vs. "very/extremely", respectively.

2.4.3. Interviews

Study and intervention acceptability was assessed qualitatively using semi-structured moderator guides tailored for the manager of the AMSs, the RF or the HPs. The intention was to interview one of each HP type (GP, Aboriginal Health Worker, midwife or nurse) from each service to obtain a range of views about the intervention, implementation and design acceptability. Interviews were conducted between August 2017 and January 2018, either face-to-face during the final study visit by research staff, or by telephone if AMS staff were not available on that day. The interviews were audio-recorded and professionally transcribed (intelligent verbatim).

2.5. Analysis

Descriptive analyses reporting counts and proportions were used for recruitment and retention rates. Ninety-five percent confidence intervals were calculated for the main outcomes (recruitment and retention rates) using the Wilson method, as it is recommended for small sample sizes. (Brown, Cai, & Dasgupta, 2001) For the critical success factors, a cross-tabulation of the number and percentage of participants reporting each of the two categories for how important they believed the factor was (i.e. "not at all/a little/moderate" vs. "very/absolutely essential") compared to the two categories for how well participants thought the program achieved the factor (i.e. "poorly/slightly/moderately" vs. "very/extremely") were reported for each of the nine critical factors.

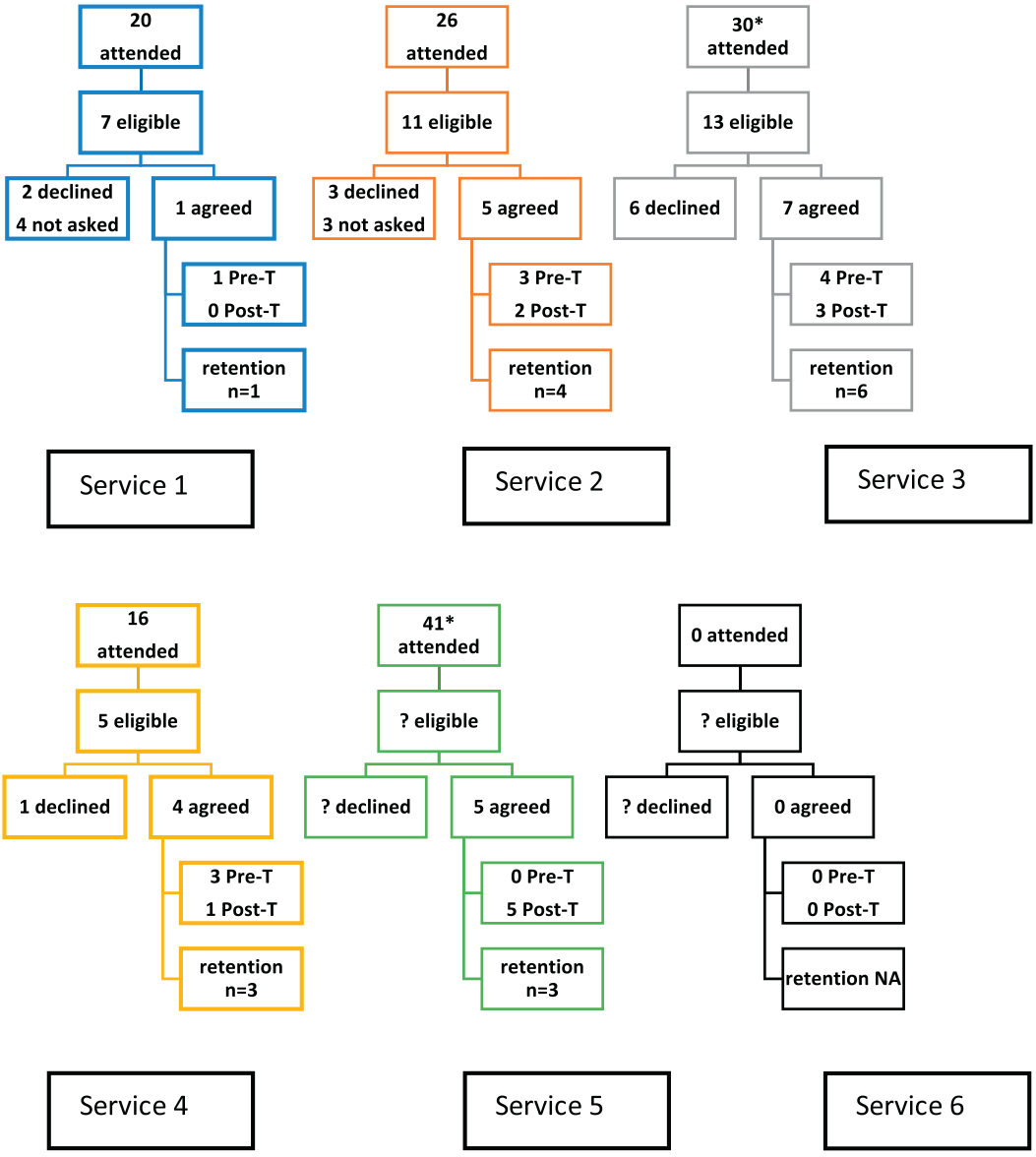

Fig. 2. Flow chart for each site of recruitment and retention of pregnant women participants.
Legend: *Estimated from service data.
Pre-T = Pre-training (women recruited prior to services receiving training).
Post-T = Post-training (women recruited after services received training).
NA = non-applicable.

Table 1
Secondary outcomes for ICAN QUIT in Pregnancy Pilot Study.

Outcome	Result
a.) Survey completion rates Pregnant women	Women's Smoking Characteristics Survey: 4-weeks: 68% (15/22) 12-weeks:77% (17/22) GEM survey (at least one follow-up): 77% (17/22) Critical Success Factors Survey: 45% (10/22) at end of study Women's Checklist: 45 checklists were completed in total by 19 participants (average 2 per participant, range 1–6) Note: one service did not collect the GEM or Critical Success Factors surveys due to their length.
Health Providers*	HP Pre-training survey: n = 45/50 = 90% HP Post-training survey (at least one survey completed): n = 20/50 = 40%
b.) Agreement to audio-recording Pregnant women	Overall agreement 67% (14/22) S1 n = 0/1 S2 n = 3/5 S3 n = 7/7 S4 n = 4/4 S5 n = 0/5 S6 n = 0 (NA none recruited)
Health providers	S1 n = (not known) S2 n = 0/3 S3 n = 6/8 S4 n = 10/12 (83%) S5 n = (not known) S6 n = NA
c.) Acceptance and Adherence to NRT	55% of women (12/22) accepted NRT 58% of these women (7/12) used the NRT, none took as directed: 2 took NRT ≥50% of the time; 5 < 50% of the time
d.) Efficacy of ICAN QUIT in Pregnancy for smoking cessation	Quit attempts: 41% (9/22) made a quit attempt by 12 weeks Quit rate at 12 weeks: 13.6% (3/22 – intention-to-treat analysis) 7-day point-prevalence and biochemically validated by exhaled CO readings ≤6 ppm Continuous abstinence was achieved by 9.1% (2/22) at 12 weeks (all reported 'not a puff' since quit date as per Russell Standard Clinical) An additional woman achieved CO validated ≤6 ppm 7-day point-prevalence and continuous abstinence at 4 weeks, but relapsed before 12 weeks
e.) Intervention adherence HP Training	Training rate 42% (39 out of 93 eligible HP at sites). HP training rates by service: S1 = 5/11 (45%) S2 = 3/9 S3 = 7/17(41%) S4 = 7/21 (33%) S5 = 6/18 (33%) S6 = 11/17 (65%)
Provision of NRT	55% (12/22) of women participants provided with NRT
f.) Use of research study forms by services	HP training forms: used by 1 service (out of 6) Eligibility forms for women: used by 1 service (out of 6) CO-reading forms: 4 services (out of 5) NRT vouchers: 2 services (out of 4 that dispensed oral NRT)
g.) Feasibility of monthly data (numbers of pregnant women smoking who attended the service during study period, and NRT prescriptions** to any pregnant woman attending the services, number of visits pregnant women made to the services)	S1 – provided data from May 2017, then monthly from November 2016 to April 2017, then monthly as required until Sept 17. During the study period no NRT prescribed S2 – as above for S1 (same IT person). During the study period no NRT prescribed S3 – provided data in February 2017 that included data from November 2016 to February 2017, then in October 2017 sent the rest of the data. Data included number of visits for women at the service and smoking status. Could not provide NRT prescription data. S4 – started providing data in March 2017 (included November 2016 to March 2017), after that monthly until September 2017. Five women in total prescribed NRT patch (1 before training, and 4 after), and 13 were offered a referral to the Quitline (4 prior to training, and 8 after). S5 - in September 2017 provided data from November 2016 to July 2017, then in October 2017 sent data from July to September 2017. Only provided smoking status monthly, and overall for all the study period (unsure if before training or after). One woman received an NRT prescription. S6 – did not provide any data.
h.) Fidelity of training timing by services	Three out of 6 services were trained in the month scheduled. One service was one month late due to the holiday period; two were two months late with training.

Legend: HP = Health Providers; S# is de-identified service number; NRT = Nicotine Replacement Therapy.
Percentages reported only where denominator > 10.

* Some HPs completed post-training form near end of study, thus protocol was changed to require only one follow-up survey.

** NRT prescriptions did not include the oral NRT vouchers given by the services, but Pharmaceutical Benefit Scheme prescriptions for NRT patches written by any HP in the AMS to a pregnant women irrespective if she was in the trial or not.

Table 2
Number of participants responding to each item of the Critical Factors survey.

Question	How important?	Total N (out of 10)	How well does the program do this? - Poorly/ slightly/moderately	How well does the program do this? - Very/extremely
Adopting full commitment to working from strengths, not seeking to correct deficits	Not at all/A little/ Moderate	3	3	0
	Very/Absolutely essential	7	1	6
Being patient to develop the relationship bond first, then using the relationship to move towards positive change	Not at all/A little/ Moderate	2	2	0
	Very/Absolutely essential	8	0	8
Modelling reliability and being consistent; staff doing what they say they will do to build and maintain trust and to show they care	Not at all/A little/ Moderate	2	2	0
	Very/Absolutely essential	8	0	8
Facilitating connection to culture, showing how to be strong Aboriginal or Torres Strait Islander person through individual, group and community engagement	Not at all/A little/ Moderate	3	3	0
	Very/Absolutely essential	7	1	6
Adopting a non-judgemental approach, using mistakes as a way to build new skills for better choices	Not at all/A little/ Moderate	2	2	0
	Very/Absolutely essential	8	0	8
Setting rules and boundaries around what's okay and what isn't in a way directly applicable to everyday life; e.g. respect, two-way accountability	Not at all/A little/ Moderate	2	2	0
	Very/Absolutely essential	8	0	8
Modelling openness, honesty, hope and trust	Not at all/A little/ Moderate	3	3	0
	Very/Absolutely essential	7	0	7
Maximising opportunity for choice making, self-motivation, feeling safe to try new things	Not at all/A little/ Moderate	2	2	0
	Very/Absolutely essential	8	0	8
Celebrating small achievements and positive changes, and using these as leverage towards autonomy	Not at all/A little/ Moderate	2	2	0
	Very/Absolutely essential	8	0	8

This provided an indication of whether those factors participants thought were important were also perceived to have been done well by the program.

Qualitative data was analysed using a framework analysis, (Gale, Heath, Cameron, Rashid, & Redwood, 2013) thus the data was coded under categories of TDF, (Cane, O'Connor, & Michie, 2012) and BCW (including the COM-B model i.e. Capability, Opportunity, Motivation - Behaviour), (Michie, Atkins, & West, 2014) in addition to a general inductive analysis to capture other emergent themes. (Thomas, 2006) Capability, according to the BCW, comprises physical and psychological components (such as physical and cognitive skills, knowledge and behaviour regulation); opportunity includes physical and social aspects; and motivation includes reflective (through cognitive processes and intentions), and automatic (via habits, emotions or reinforcement). Twenty per cent of the transcripts were independently coded line by line by two researchers (MB – a female Indigenous researcher) and GRG - a female non-Indigenous researcher. The two researchers came to a consensus for a coding book, then MB continued to code the remaining transcripts. Analytic progress was periodically overseen by GSG. GSG completed the framework analysis with the BCW and TDF. For additional analysis information refer to the published protocol (Bar-Zeev, Bonevski, Bovill, et al., 2017).

2.6. Ethics

The study was approved by the following Human Research Ethics Committees (HREC): University of Newcastle HREC (#H-2015-0438), Aboriginal Health & Medical Research Council HREC (#1140/15), South Australia Aboriginal HREC #04-16-652, Far North Queensland HREC (#16/QCH/34 – 1040).

2.7. Trial registration

This study was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12616001603404).

3. Results

Pregnant participants' flow through the study for each of the six AMSs is presented in Fig. 2. Reasons reported by the RFs for women declining (exact numbers not recorded by services): did not like RF, not interested in the study, partner did not know she smoked, and wanted to try to quit alone. Two reasons given were not actually exclusion criteria: one woman stated she did not want to quit smoking, and another woman was reported to not be Indigenous, (a woman was eligible providing she was pregnant with an Indigenous baby, and irrespective of her intentions to quit smoking).

3.1. Feasibility results

For the primary outcome of recruitment rate, sufficient data on the number of eligible women was only provided by four of six services. Services were given 6 months to recruit women and three months to follow them up, however a couple of services were allowed more time, in case they could increase their numbers. Recruitment rates could only be calculated in services one, two, three and four; these varied from 14% to 80%, with 47% (95% CI: 32%, 63%) overall (17/36). Service five recruited five women, and service six none. Documentation was problematic for service five due to a change in RF, and service six similarly did not provide documentation on eligibility, commenting that few eligible women attended in the time period of the study.

Recruitment for the HPs was calculated from services providing data that 93 HPs worked at the services. Fifty of these consented to the study, resulting in a recruitment rate of 54% (95% CI: 44%, 64%). Recruitment rate ranged from 33% to 72% at the sites. HP types recruited were: 17 GPs, 17 nurses/midwives, 10 AHWs, 6 others (e.g. family strengthening worker). Several HPs had multiple roles.

Retention rates for pregnant women were provided from five services (one not applicable), and varied from 60% to 100%, with an overall retention rate of 77% (95% CI: 57%, 90%) (17/22). HP retention rate was 40% (95% CI: 28%, 54%) overall (20/50). Secondary outcomes are reported in Table 1.

3.2. Acceptability results

3.2.1. Critical success factors

A total of 10 out of 22 pregnant participants completed the critical factors survey (45%). There were no duplicates or missing data points. For each of the nine items, Table 2 presents the percentage and frequency of participants who reported the level of importance as “not at all/a little/moderate” vs. “very/absolutely essential”, compared to whether they indicated that the program achieved the factor “poorly/slightly/moderately” vs. “very/extremely”. As shown in Table 2 > 50% of participants indicated that each of the nine factors were “very/absolutely essential” to the program's success. Similarly, > 50% of participants reported that the program achieved each factor “very/extremely” well. Furthermore, agreement between participants perceived level of importance and their perceptions of how well they believed the program addressed each factor was high (≥ 90% in all cases), with only two items “Adopting full commitment to working from strengths, not seeking to correct deficits” and “Facilitating connection to culture, showing how to be strong Aboriginal or Torres Strait Islander person through individual, group and community engagement”, illustrating a discordance in responses by one participant.

3.2.2. Qualitative data from interviews for acceptability

Eighteen interviews were conducted from six AMSs comprising: six RFs, four managers, four GPs, two HW, and two midwives. Interviews lasted from 7 to 72 min (mean 29 min). TDF findings are annotated with ‘TDF’ followed by the relevant domain. The analysis presented under the domains of the COM-B model considers both the feasibility and acceptability of the research study conducted at the AMSs, its intervention, and implementation. Analyses are presented below, and representative quotes are in Table 3.

3.2.2.1. Capability

3.2.2.1.1. Physical capability. Building capacity within the service was vital from a managerial level. Managers in particular highlighted the importance of physical capability for service and capacity on an organisational level.

3.2.2.1.2. Psychological capability3.2.2.1.2.1. Education and training

There was evidence of psychological capability increasing through the education and training, and that the content was acceptable to a wide range of staff. Conducting the training at the AMS was seen to increase service capability. It was also beneficial to have managers attend training, so they could understand required capacity from a service level. Staff, in general, highly praised what they had learnt through the webinar training and commented favourably on quality and comprehensiveness of the content. Even though the webinar was broken up with interactive sessions and videos, more of this type of content, including case studies were requested, supplemented with graphics and animation. There was evidence HPs were then able to offer an increased level of support to pregnant women who smoke and make changes to routine practice (TDF belief about capabilities). HPs and RFs expressed enhanced confidence in knowing how to use NRT and promote it to women. Whereas before they might not have been confident to demonstrate the products or challenge a woman if she expressed reluctance, HPs now felt enabled to provide NRT as an option and discuss its benefits and relative safety, compared to continued smoking (TDF memory, attention, decision-making processes).

Being involved in the research project and the intervention, enabled many HPs to take the new practices into routine care, thus giving

Table 3
Interview data categorised into the COM-B model with participant interview excerpts.

Capability	
Physical capability	
Capacity-building	*"..the aim is to help pregnant women quit, but it also - it's built in the capacity of the service to actually be able to do that…"* Manager
	"…Research doesn't have to be just taking from the organisation and us giving all of this time and all of this data. It can be something where the organisation can benefit as well." Manager
Psychological capability	
Knowledge and cognitive skills from the training	*"My senior social worker here and the social emotional wellbeing worker and, you know, the Aboriginal [HW] - the midwife and the GP, they all understood it [webinar] really good and they thought it was fantastic information."* RF
	"I participated in the training - you know, partly for my own benefit and to see what happens…but what I was interested in was increasing the capacity of the organisation really. So I looked at it as a capacity building exercise to have this training, get staff on board because they're all aware of smoking and how important it is to help women stop" Manager
	"And it's training that we can use again and again and again. It's not just a, yeah, once-off thing." RF
Decision processes and behavioural regulation	"So instead of talking to them and then saying 'Well, this is the sort of follow-up we've got', I found it a lot easier to have that conversation and to be able to offer them their support." GP
	"I was [offering NRT before], but most women say to me no, they'd rather do it without it, and I never presented them with an alternative argument as far as statistics go and the likelihood of success in quitting. So I'm more likely to challenge their understanding of NRT now." Midwife
	"… we've got her smoking status flagged now, which we didn't have before the project. So that's a change that will be ongoing." GP
	"… we've really increased the number of brief interventions that are recorded…" Manager
	"It made me more inclined to make smoking in pregnancy more of a priority when there's so many things to talk about at the start." GP
Research capability and impact of the RF role	*"She's [RF] just an exceptional person in being able to manage all this."* Manager
	"It was worth all that time and effort that took me away from my role." RF
	"It [RF role] hasn't really a major impact on what I do. It just gave me extra information which we pass on or that we can see if there's any changes." RF
	"I'd probably say be aware that it's going to take a bit of time and impact you a little bit…I think I probably had the busiest time I've had in five years over that whole period, so I think you have to be prepared for that really, for a bit of extra work…be prepared to put in a little bit of extra effort." RF
Opportunity	
Physical opportunity	
NRT supplies	*"There weren't a lot that took that offer up, but the ones that did, said, "Yeah, it might be a good idea to give that a shot." RF*
	"We even had people come – coming in and asking for them..So they were in the drawers here, we were able to say "What, do you want some – what would you rather? …the chewing gum? …the lozenges? …the patch?" Health Worker
	"I think if there were clinicians who were still on the fence it probably would have had a negative impact not having had the webinar training before the program started." GP
Environmental context and resources	*"…it enhanced our already existing service where we're trying to help women to quit. I think having the flipchart and having posters in the waiting room, having handouts in the waiting area before they see the doctor…. We did have some information, but probably it wasn't as good as what's been available through the research."* Midwife
	"I thought the flipchart was great. I thought it was excellent… a lot of women think that in pregnancy they can't have nicotine replacement therapy, so being able to say to them 'Yes, you can have this'." Midwife
	"… it puts a positive face of an Aboriginal woman, this is her place, this is her with her family and this is her using NRT…. GP
	"[Resources were]..really good, really informative and gave you lots of sort of answers to when you were asking questions, or when other people asked questions." Health Worker
Social opportunity	
Patient Journey	*"My role was, was that I would start discussions with women which I generally do when they're pregnant about … cessation of smoking, and then our midwife would be working hand in hand. So she would then see the patient and recruit the patient, sign the consent. Then we [doctors] would initiate the nicotine replacement therapy."* GP
	"I was not notified who was in the study and who wasn't, meaning even if on the day I could just get a little note in the chart before I open it to say 'This patient's enrolled' then I could potentially look at it with a different hat on than just the usual way…I would have liked to have been able to say 'Look, you signed up on this day and how is it going now?" GP
	I think giving me an opportunity to connect with the pregnant women through that role was really good, but also learning a lot from that in my - you know, to use with my current role as well. RF

(*continued on next page*)

Table 3 (*continued*)

Capability	
Social influences and social modelling	*It's only been from talking with [RF] that I've actually had the confidence to talk to people about using an oral spray ….if you can explain to someone this is how a product works and I have confidence in this product and you could use this product this way, I think they're more likely to take it up…."* GP
	"I think it was good to have you guys come back and give us the broader picture of what's happening in the other services, and I think it's quite valuable. … as you say, in your pilot you've got over a 10% quit rate. That's really meaningful, but at the time, when you say I've got eight women and seven of them didn't quit. Why are we doing this? It's so hard. I think giving that bigger picture that says the quit smoking rate in pregnancy is 3% you said today…We've only run this project for six months and one out of eight of our women quit, so that's more than the average. We're doing really well." GP
Motivation	
Reflective motivation	
Motivation for HPs to help pregnant women quit, and recommending NRT	*"I think - before having that conversation with [trainer], I probably was thinking more along the lines of 'how do you feel about quitting', whereas, yes, I have shifted to the, 'How do you feel about trying NRT now?'* "GP
Goals and intentions	*"…the project has made me more aware of being more rigorous, more systematic in terms of checking people's smoking status and intervening more often and we've now got our computer system assisted so that we're working on every single visit, checking where they're up to with their smoking. I think that's something that we've changed, because previously we would check in the beginning and then sporadically we would ask how things were going…"* GP
Automatic motivation	
Motivation and reinforcement for HPs and pregnant women	*"… the one pregnant mum that quit, seeing her realise that that number [on Smokerlyzer] was not a good thing and actually making that real effort to get that number down and seeing how proud she was at the end of that, I think was really good for me to see, like - and seeing all the babies born, of course, that's, you know - and all healthy. All, you know, beautiful, healthy little babies, which that was, yeah, fantastic, enjoyable."* RF *"The incentive of the gift card was fantastic, because quite often these women are, you know, living payday to payday and, you know, it comes in handy when you're expecting a new baby or when you've had a new baby. RF* *Another thing about it [booklet] that was good, it didn't throw up all the negatives. …'This is the problems that can happen.' But it was more of a positive thing, you know, 'This is what we've got to offer', 'This is what we can do for you', 'This is the support you can have', those sorts of things."* Midwife

Legend – GP = general practitioner; NRT = Nicotine Replacement Therapy; RF = research facilitator.

evidence of sustainability of implementing smoking cessation care more effectively. This ranged from being more systematic about recording smoking status and brief interventions, to counselling women and offering support (TDF memory, attention, and decision processes, and behavioural regulation). Attitudes to and mode of recommending NRT changed giving HPs a stronger knowledge base, and confidence (TDF knowledge and belief about capability).

> *"I have a much better understanding of the benefits of NRT and I'm much more likely to promote the use of it…"* Midwife

3.2.2.1.2.2. Research capability

Research was not the core business of the AMSs that participated. For several it was a new venture; some AMS reported having participated in prior research, and a few had not found it beneficial:

"I think that all of those things your project is trying to break down… because for a long time research has just been taking from organisations like this." Manager.

Staff from the services noted their experience with ICAN QUIT in Pregnancy was rewarding, and the research team provided an exemplary level of communication. It was vital to the smooth-running of the project that the person in the RF role had the capacity to take it on, was a good fit and had managerial support. Most RFs expressed they benefitted from being in the role, and built their own knowledge, experience and capability.

3.2.2.2. Opportunity

3.2.2.2.1. Physical opportunity. Webinar was chosen as the training delivery mode to accommodate challenges of rurality of many of the AMS. Managers appreciated the convenience of this mode of training, saving on costs of staff traveling to a main centre and days lost through absences. However, challenges remained in organising all staff to attend the webinars on one occasion. In some services doctors missed the training because they were not released from clinic time or could not be financially reimbursed for clinic time lost. In others, doctors did not feel sufficiently motivated or incentivised to attend.

Most services opted to have three one-hour sessions in a single sitting, because of challenges of getting staff together. This resulted in many staff commenting that the webinar was too long, or too much to take in one occasion. All services received individual recordings of their webinar sessions for staff to follow up and view later if they missed the training.3.2.2.2.1.1. NRT supplies

Oral NRT at the time was not subsidised in Australia. However, these forms are preferred as a first-line treatment for smoking cessation in pregnancy. (Zwar, Mendelsohn, & Richmond, 2014) Having oral NRT sample packs and supplies on site provided a major opportunity to improve access to NRT (TDF environmental context and resources) and was highly regarded by most. It facilitated women accepting NRT and being willing to give it a trial.

Alternately, HPs not attending the training (or not completing it) had an impact on women having access to NRT. Several interviewees at one service reported they became aware that a few women, who had been previously willing to take NRT, were then told by a doctor it was safer to continue to smoke at a low level than take NRT, and subsequently declined to accept the NRT supplies.3.2.2.2.1.2. Resources

Training resources were useful tools. The flipchart to guide the patient consultation was used in various ways by staff members, sometimes by showing a favourite page or two to reinforce discussions about NRT, or displaying a particular photo showing a woman using NRT which attracted interest from several pregnant women (TDF social influences).

Posters were provided showing different types of NRT or comparing chemicals in a cigarette to those in NRT and were often displayed around the AMS or within the HP offices. They served to educate women, restructure the environment and act as prompts (TDF environmental context and resources). Similar to the flipchart, posters modelled to women that NRT was safe by showing Indigenous women in the photos actively using NRT, for example an oral spray (TDF social influences). A mouse mat was intended to serve as a desktop prompt about the main ABCD features of the smoking cessation care and how to titrate NRT to patient's dependence indicators. However, it did not appear to be used as a prompt and found to be less useful. Overall the combined presence of resources had a powerful impact to restructure the AMS environment, towards the better provision of SCC in the

context of tackling Indigenous smoking during pregnancy.

3.2.2.2.2. Social opportunity. When staff saw others providing smoking cessation care, it enabled teamwork and a common purpose. Recruitment of the women was not seen as problematic in many of the services, who reported success from the flexible approach offered by the research team. Face-to-face recruitment of women was preferred. Several services planned ahead by looking at the antenatal clinic appointment list and screening that way for eligibility. Women who did sign up were said to be *"eager about it"* RF. Having a trusted relationship with the RF or other staff was a benefit for recruitment, but conversely personal barriers with staff and shyness were reported as barriers. In many cases, study recruitment provided an opportunity for a team approach, and helped navigate the patients' journey through the service, and their journey towards smoking cessation.

Some staff expressed their needs for social opportunity could have been further met within the service by having team meetings about the project, and briefings to understand how the women participants were going. Having a system that helped HPs know which women were in the project was valued, so they could make sure they would inquire about their progress. This was achieved in one AMS by organising before the antenatal patients came in who they would need to see on a particular visit and aiming for all required HPs and the RF to be seen before the patient left the service. In services where this did not occur there was a potential project disconnect. One service found communication about who was participating in the study a challenge, and the GP providing this information suggested ways this could be remedied.

Social modelling was achieved through whole of service training, and instruction on providing SCC by credible sources (Tobacco Treatment Specialists and Indigenous presenters). Webinar videos showed positive attitudes of other HPs providing SCC to Indigenous women in pregnancy and were intended to build optimism. There was also evidence of staff communicating with each other to improve their own knowledge and confidence for using different aspects of the intervention and promoting them to pregnant women.

The audit and feedback approach was hampered by delays getting service-level data from the AMSs in the time-frame of a short pilot study, thus was not feasible. However, interviewees did express wanting more social opportunities to reflect on their own performance and compare themselves to others. More social comparisons may have improved project understanding (TDF memory, attention and decision processes) and staff motivation (TDF beliefs about capabilities, and intentions). At the wrap-up site visits, the research team presented

Table 4
Suggested improvements for the intervention and the research.

Aspect of the study	Suggested improvement	Representative quote
Research related suggestions		
Research facilitator role	Train two staff as back-up for RF role or split the role, so one recruits another follows up.	*"So they look at the midwife more as being that therapeutic role, and being that support, doing the smoking cessation…You take away that coalface data stuff and give it to more another role that it then allows the person to separate it a bit."* Manager
	A good fit for role is important, and RF having time and motivation to do it.	*"…the staff needs to have that time available to be able to do it. Do it the right way. Not have someone that's got to wear a number of hats and then it falls over."* Manager
Overall management at AMS sites	Managerial support and oversight	*"To have one person overseeing the project and just making sure that things are running smoothly in terms of different points throughout the study."* RF *"…it's probably easier when there's a lot of managerial support behind a research project."* Manager
Research facilitator training	Dedicated workshop for RF training	*"You could improve it by…before you're rolling it out, having that workshop before, so whoever's going to be the facilitator – and with the facilitators, the doctors, the health workers and the midwife, maybe have a workshop beforehand, before actually running that, so everyone's on the same page…" RF*
Recruiting women	Alternate ways to recruit	*"I would probably actually host a day… To launch the project…I would have done it a bit differently. Because it's actually putting it out there and asking them to talk to the health worker themselves and let them know…"* RF
Following-up women	Recommended a method used in another pregnancy clinic to ensure women are seen by relevant HPs and the RF	*"…there's a slip that has a list of all possible providers that are part of that clinic and it's ticked which of the providers they need to see and then when those providers see them, they sign the slip and then the woman don't leave the building until all the people that they're supposed to see have signed off that they've seen them."* GP
Step-wedge design of study	Start the training at the beginning of the project: avoid step-wedge pre-post design	*"I think that was confusing for services in general, that they were - some just didn't know why they weren't getting it [training] straightaway because normally when a project starts you get it straightaway."* RF
Length of study	Study length should be at least 12 months: services were just getting into their stride when the study finished	*"…realistically you need a good 12 months from way to go, from start to finish. Having a nine month timeframe, just as long as a baby, is not enough, because it's got to build momentum."* RF
Surveys	Reduce length and repetitive nature of surveys.	*"Get rid of that checklist. Delete the checklist. I think everything else was really good."* RF *"I think they found them quite wordy and asking the same thing over and over again…" RF* *"… the GEM was so long and so big…'Now, this one is that long one. Do you remember? It's the heavy questions and that, so just take your time.' …I really had to just remind them to expect that… anything to do with social and emotional stuff is going to be challenging, especially… if you had a bad week."* RF
Intervention related suggestions		
Improving social modelling	Case-studies for training e.g., videos showing how to counsel and prescribe NRT. Also to convey others' experiences of the intervention. Newsletters with content to engender social comparisons. Link-ups with other AMS in the project for comparison and support.	*"'Here's a short video of where we've run this program before.' Let's talk to the midwives and the doctors and chat to – if patients wanted to talk about what they've been through and 'This is what they thought of what we were doing.'"* Midwife *"Sometimes I've found when I've been part of research projects before, that getting a newsletter and saying 'These are how many centres', having a picture 'X's doing really well' or 'So and so at Y'… it would probably be good to have ongoing emails with just a newsletter or project update."* Midwife

Legend: GEM – Growth and Empowerment Measure; NRT = Nicotine Replacement Therapy.

comparative data to the services and this was appreciated by AMS staff to understand their place in the research, assess what they had achieved, and feel optimistic about the future (TDF social influences, optimism and behavioural regulation).

3.2.2.3. Motivation

3.2.2.3.1. Reflective motivation. The first hour of the webinar training was explicitly aimed at motivating HPs and improving optimism for providing SCC to Indigenous pregnant women, and to improve HPs' belief in their capability to do so. There was evidence that smoking was re-framed as an addiction (TDF beliefs about consequences) by HPs, which was also one of the aims of the training. Staff reported that what motivated them during the project was seeing results (TDF beliefs about consequences) in two main ways:

1) Having the project at their AMS increased their engagement with pregnant Indigenous women who smoke, which in the past had been challenging:

   "…when I first started this, one of our priority groups that was highlighted was pregnant mothers who smoke. Getting in to - and, I guess, engaging with those women, is difficult…. A lot of the time they feel like they're being targeted, judged. You know, they feel like they're ashamed of their history of smoking or that they're still smoking in pregnancy… unfortunately, a lot of the pregnant women that we had here were past the 28-week line. But those pregnant were that were involved in the study said, 'You know, if you want to quit smoking, you can go and see the TIS team, even though you're not involved in the study.' So, for us, that was a really big benefit, because it gave us the opportunity to have connection with those pregnant women that we otherwise probably wouldn't have had." RF

2) Seeing women's success in quitting smoking. *"I think it was great that a couple of women gave up smoking. That was fabulous."* RF. The latter was also facilitated by the use of the CO meter to provide the women with self-monitoring, biofeedback and positive reinforcement.

3.2.2.3.2. Automatic motivation. Vouchers of AUD $20 value each were given to women at each evaluation point, but not contingent on quitting. Nonetheless, staff reported that the vouchers were considered an incentive and a re-enforcement for women to participate in the research.

Staff liked that resources did not overly promote negative aspects of smoking; messages were positively pitched, aiming to increase self-efficacy in pregnant women to quit smoking. ICAN QUIT in Pregnancy as a whole was seen to be a worthwhile experience by most staff interviewed. This quote emphasised the positive and meaningful nature of the benefits.

"I think learning about these things and getting some data and seeing where it goes is really, really positive, and if we can get women reducing or ceasing smoking in pregnancy, what a fantastic thing for the future for their children." Manager

3.2.2.4. Suggested improvements for the research. One emergent theme centred on how the research could be improved. These suggestions are outlined in Table 4.

4. Discussion

Feasibility and acceptability data obtained from six AMSs in three states were analysed from the ICAN QUIT in Pregnancy study. The numbers of women recruited at n = 22 was less than the 50–80 participants expected, partly due to a lack of eligible women at the time in some services, the short time-frame of the project, and services taking time to get familiar with the study. (Bar-Zeev, Bonevski, Bovill, et al., 2017) However, the recruitment rate of women was close to the expected 50% at 47% (determined from four of six services that tracked this data accurately). The planned patient recruitment for the larger trial will be 15 women per service over a period of two years, with an intension that 30 sites will be recruited, and a total sample of N = 450 women. We believe that allowing this extended recruitment time would account for seasonal variations in pregnancy rates, and thus be feasible.

The numbers of HPs recruited (n = 50) was in the expected range of 30–60. (Bar-Zeev, Bonevski, Bovill, et al., 2017) HP recruitment was satisfactory at 54% (50/93), and 39 HPs completed the training: 78% trained was close to the 80% predicted. (Bar-Zeev, Bonevski, Bovill, et al., 2017) Retention rates were 77% for women, and 40% for HPs. Survey completion rates varied by site from 45% to 77% for the women, and 40% to 90% for the HPs. Agreements to audio-record consultations varied among sites from 0% to 100% for women, and 0% to 83% for HPs. Some data collection tools for process measures were not used as intended. HPs' training forms and eligibility forms for women were each used by only one service; CO-reading forms were used by four services, and NRT forms were used by two services. These forms will need to either be replaced by more effective methods, or more emphasis given on data collection in the RF training.

The critical success factor survey results demonstrated, in the 10 women who completed them, that there was a concordance of over 90% between women who felt the factors were important, and the ability of the project to positively achieve that success factor. Qualitative interview data provided BCW and TDF commentary about how the intervention, its implementation, and the research process measured up according to capability, opportunity and motivation. Strong points for the implementation were the resources, including training materials, patient resources, equipment (CO meters) and oral NRT. These increased capability and opportunity, helped restructure the environment, and provided social comparison and modelling. Staff were motivated by greater engagement with pregnant women. They were also inspired by the women's CO readings decreasing (indicating less exposure to tobacco smoke), and some women stopping smoking completely (thus CO readings reducing to the non-smoking range). Having research at the AMSs on the whole improved organisational capacity and RF capability. Staff reported making changes to their routine practice that were potentially sustainable. Most services felt the extra workload was worthwhile to improve the health of mothers and infants in a very high-priority area. Valuable feedback was given for areas for improvement particularly for webinar training and reducing the volume and type of research data collected. For the larger trial, survey length will be reduced and surveys will be combined into a single instrument, for example the women's checklist incorporated in to the main surveys.

4.1. Comparison with other studies

Measuring recruitment rates is an important aspect of feasibility studies. Recruitment rates varied in previous feasibility studies of smoking cessation among pregnant Indigenous women, from 12% to 58%. (Glover et al., 2015; Passey & Stirling, 2018; Patten et al., 2010) Our recruitment rate of 47% is quite reasonable in this context. Retention rates in feasibility studies varied from 37% to 86%, compared to our relatively high retention rate for the women of 77%, although these figures are potentially imprecise due to low sample sizes. These feasibility studies varied in their measures of feasibility and acceptability, with our study being more detailed than most others to date.

Only one Australian study, conducted in 22 pregnant Indigenous Australian women in three rural Aboriginal Maternal and Infant Health Services in New South Wales in 2010–2012, reported additional measures. (Passey & Stirling, 2018) This study of a complex intervention had a recruitment rate of 58%, and a high retention rate of 86%. (Passey & Stirling, 2018) Feasibility was determined by implementation of the key components of the intervention, and acceptability by enrolment and completion, and interviews. Visual aids, resources and free NRT were well-received though implementation challenges were

described. One site withdrew due to lack of capacity and staff shortages, and engagement of some women was difficult. Recommendations for improvement centred around service capacity and sustainability.

Factors reported as being important in a 2012–2013 New Zealand with Maori pregnant women (n = 24; recruitment rate 32%; retention rate 37.5%), (Glover et al., 2015) included low recruitment when a HP was involved. The tenor of trial promotion may have influenced a pregnant woman's ability to enrol and stay engaged. (Kira, Glover, Walker, & Bauld, 2016). A 2007–2008 feasibility RCT for a complex intervention conducted among US Alaska Native pregnant women (n = 35) had a low recruitment rate of 12%; but high average retention rate of 84%. (Patten et al., 2010) Authors concluded that the low recruitment, hampered by women feeling stigmatised by the enrolment process and not having time to participate, suggested the program was not feasible or acceptable. (Patten et al., 2010)

The step-wedge design in our trial was confusing for services that were used to getting a new intervention straight away rather than having a period of usual care, followed by the intervention. Step-wedge designs have been reported as complex to execute in real-world settings especially when individual consent is required, and delays with recruitment can frequently impact study outcomes. (Heim et al., 2017) Routine data have previously been reported as less accessible than expected and retrieval of data highly delayed. (Heim et al., 2017) These issues combine to cause a lower than expected sample size. Only 12 cluster randomised step-wedge designed studies have been conducted previously in Australasia, and their practical challenges are rarely reported. (Grayling, Wason, & Mander, 2017)

4.2. Strengths and limitations

One strength of our study is its theoretical design, and planned approach to measuring feasibility.

and acceptability with a protocol paper published a priori. (Bar-Zeev, Bonevski, Bovill, et al., 2017) A RF who was an existing staff member of the AMSs likely helped engagement and retention rates. In recognition of the diversity of Australian Indigenous populations and contexts, the study was deliberately conducted in three Australian states to aid generalisability and transferability of findings, in preparation for a full trial. However, regional differences will occur in all states. New South Wales was better covered with four services enrolled; having only one service in South Australia and Queensland might limit generalisability for those states. The pilot feasibility study provided a wealth of data to inform the decisions needed for a full trial in five states (SISTAQUIT® – Supporting Indigenous Smokers To Assist Quitting trial registration ACTRN12618000972224). (Gould, 2017) Due to the feedback from this pilot, the SISTAQUIT® trial is planned as a cluster RCT using a standard design. Recruitment and retention rates are guiding decisions about the sample size required for the larger study.

The study length of nine months is typical for a pilot study, however in the context of pregnancy seemed short for the services, who gave feedback that they would have preferred a longer follow-up. This was an unforeseen response, as researchers were very conscious of not burdening the sites for longer than necessary. The women were only followed up for 12 weeks, as we considered most quitting activity would occur during that timeframe.

5. Conclusion

ICAN QUIT in Pregnancy as a complex implementation intervention was well-received, feasible and acceptable in AMSs across all three states, with modifications recommended for the length of webinar training. For the research itself, changes were recommended for data collection and the step-wedge design. Smoking in pregnancy is a key challenge for Indigenous health. Training HPs and providing resources has a high potential to improve outcomes for Australian Indigenous women and infants. This pilot study enabled implementation challenges to be addressed before initiation of a major study. This study appropriately considered cultural and other contexts of the services, so specific needs of the Indigenous community could be addressed. By assessing and reporting feasibility, acceptability and the measurement of process data, we can better account for the implementation of the intervention and the research.

Declarations

Ethics approval and consent to participate: The study was approved by the following Human Research Ethics Committees (HREC): University of Newcastle HREC (#H-2015-0438), Aboriginal Health & Medical Research Council HREC (#1140/15), South Australia Aboriginal HREC #04–16-652, Far North Queensland HREC (#16/QCH/34–1040). All participants gave informed consent to participate.

Consent for publication: Not applicable

Availability of data and materials: The datasets generated and/or analysed during the current study are not publicly available (due to permissions, protocols and ethics approvals required by the Aboriginal communities and partners prior to usage) but may available from the corresponding author on reasonable request.

Competing interests

YBZ has received fees for lectures in the past (years 2012–2015) from Novartis NCH (distributes NRT in Israel). She has not received any fees from pharmaceutical companies in Australia. No other authors have competing interests to declare.

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Authors' contributions

GSG designed the study, with assistance from YBZ and MB. GSG conducted the quantitative analysis (aided by AH for the critical success measure); with MB conducted interviews; conducted the qualitative analysis, aided by MB and GRG. KC and KB contributed to the qualitative analysis and interpretation. GSG wrote the manuscript. YBZ contributed to the quantitative analysis, oversaw and critically reviewed drafts of the paper, and managed the day-to-day conduct of the study. LP collected the feasibility data and aided in interpretation. MB and MG contributed Aboriginal cultural advice about the analysis. BB contributed to the design of the study and critically reviewed the paper. CO provided high-level statistical oversight. All authors read and approved the final manuscript. The ICAN QUIT in Pregnancy Pilot Group advised on the research design and implementation.

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