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The Incentives to Quit tobacco in Pregnancy (IQuiP) protocol: piloting a financial incentive-based smoking treatment for women attending substance use in pregnancy antenatal services

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ABSTRACT

Introduction While tobacco smoking prevalence is falling in many western societies, it remains elevated among high-priority cohorts. Rates up to 95% have been reported in women whose pregnancy is complicated by other substance use. In this group, the potential for poor pregnancy outcomes and adverse physical and neurobiological fetal development are elevated by tobacco smoking. Unfortunately, few targeted and effective tobacco dependence treatments exist to assist cessation in this population. The study will trial an evidence-based, multicomponent tobacco smoking treatment tailored to pregnant women who use other substances. The intervention comprises financial incentives for biochemically verified abstinence, psychotherapy delivered by drug and alcohol counsellors, and nicotine replacement therapy. It will be piloted at three government-based, primary healthcare facilities in New South Wales (NSW) and Victoria, Australia. The study will assess the feasibility and acceptability of the treatment when integrated into routine antenatal care offered by substance use in pregnancy antenatal services.

Methods and analysis The study will use a single-arm design with pre–post comparisons. One hundred clients will be recruited from antenatal clinics with a substance use in pregnancy service. Women must be <33 weeks' gestation, ≥16 years old and a current tobacco smoker. The primary outcomes are feasibility, assessed by recruitment and retention and the acceptability of addressing smoking among this population. Secondary outcomes include changes in smoking behaviours, the comparison of adverse maternal outcomes and neonatal characteristics to those of a historical control group, and a cost-consequence analysis of the intervention implementation.

Ethics and dissemination Protocol approval was granted by Hunter New England Human Research Ethics Committee (Reference 17/04/12/4.05), with additional ethical approval sought from the Aboriginal Health and Medical Research Council of NSW (Reference 1249/17). Findings will be disseminated via academic conferences, peer-reviewed publications and social media.

Strengths and limitations of this study

- ► Intervention development has been theoretically underpinned and based on current tobacco smoking-related evidence for pregnant women from high-priority groups.
- ► The intervention uses innovation and technology to remove barriers associated with the application of contingency management and research participation.
- ► The application of contingency management and its methodology in this study is labour intensive and provides implementation challenges in a public healthcare setting.
- ► Eligibility and abstinence are determined by breath carbon monoxide. This method is limited by the short half-life of carbon monoxide that is subject to individual variation and its difficulty detecting low levels of smoking.
- ► Follow-up is completed at 12 weeks postpartum—no long-term follow-up of smoking is provided.

Trial registration number Australia New Zealand Clinical Trial Registry (Ref: ACTRN12618000576224).

INTRODUCTION

Background

Tobacco smoking in pregnancy is the major modifiable contributor to adverse maternal, fetal and neonatal outcomes.[1 2] Maternal smokers are at increased risk of ectopic pregnancy, placental abruption, placenta praevia, miscarriage and stillbirth.[3 4] The consequences for their babies are far-reaching, with infants exposed to prenatal cigarette smoke more likely to experience low birth weight, attachment difficulties, chronic lung and cardiovascular disease, sudden unexpected

death in infancy, obesity, learning and behavioural difficulties. An increased likelihood of developing tobacco and other substance use disorders later in life also exists.[4–8]

While overall prevalence of tobacco smoking in pregnancy is declining in Australia,[9] prevalence rates in some high-priority subgroups remain disproportionately high.[10] Women who use alcohol and other psychoactive substances during pregnancy (including cannabis, opioids, stimulants and benzodiazepines) are one such group. Australian estimates of smoking prevalence in women from this group is 82.3%,[11] compared with 10.6% of the general population of pregnant women.[12] A 2016 attendance audit of an Australian health-based antenatal clinic for women who use substances during pregnancy corroborated these results, with 92% of attendees over a 12-month period reporting tobacco use during their pregnancy.[13] Internationally, similar prevalence rates have been reported in opioid-dependent pregnant women treated with methadone or buprenorphine.[14 15] In addition to problems caused by substance use, this population is often characterised by socioeconomic disadvantage,[10] concurrent mental health problems,[16] a history of trauma[17] and social challenges including intimate partner violence, unstable housing, child protection issues, legal problems and poverty.[18]

Barriers to smoking cessation

Pregnancy provides an important opportunity for women to stop tobacco smoking. This may be driven by a protective urge to safeguard the fetus and/or to avoid the social prejudice and discrimination associated with prenatal smoking.[2 19] Up to half of all pregnant women who smoke will quit spontaneously prior to their initial antenatal visit.[20] Unfortunately, pregnant women with other substance use problems are more likely to persist with tobacco smoking[21 22] despite strong aspirations to stop.[23 24] Their success is typically hampered by a combination of biological, psychosocial or systemic barriers.[10]

Physiological and genetic factors create difficulties in achieving cessation, some unique to women who use substances. Human and animal research suggests that nicotine and stimulation of the nicotinic acetylcholine receptor system may influence the rewarding or reinforcing effects of other addictive drugs. This can increase the consumption of nicotine and/or the other substances and may be mediated through the brain's dopamine reward pathway.[25 26] The combined exposure to nicotine and other substances is thought to produce behavioural consequences across a range of substances, including enhanced effect and reduced cognitive deficits in stimulant use,[27 28] increased consumption and tolerance of opioids, reduced withdrawal of opioids[26 29] and increased consumption of alcohol.[30] The metabolism of nicotine is also known to be increased during pregnancy.[31] Nicotine clearance in pregnant smokers is almost twice than that of non-pregnant smokers.[31] This increases demand for nicotine in the body and potentially jeopardises women's ability to abstain.

Mental health disorders and substance use occur together very frequently and in Australia, at least half those seeking treatment for substance use will have a mood-based or anxiety-based disorder.[32] Women who smoke tobacco during pregnancy are up to 2.5 times more likely to have depression or anxiety and 4.5 times more likely to have a substance use disorder than those who do not smoke.[21] Familial factors, particularly genetics, are thought to influence high rates of smoking by predisposing individuals to both smoking and mental illness, including substance use.[33] The neurological actions of nicotine can assist in relieving some of the symptoms associated with negative affect,[34] further contributing to the development of nicotine dependence.

Psychosocial factors that have been shown to impede cessation in this priority population include: a strong psychological dependence to nicotine, the struggle to stop or reduce multiple substances, a perceived lack of vulnerability to the damaging effects of maternal tobacco smoking and a belief that tobacco is legal and therefore not harmful.[10 23 24] Moreover, a lack of support from partners, having partners or other household members who smoke tobacco and high levels of smoking acceptability within close social networks are common and have a detrimental impact on tobacco smoking cessation efforts.[10 23 24 35 36]

Systemic barriers involving health policies and practices can also negatively influence cessation. Evidence suggests that antenatal healthcare providers perceive pregnant women with substance use problems as not wanting to stop smoking.[37] When asked, however, many do report a desire to quit but lack the resources and support required to do so.[23 24] Treatment providers may also prioritise alcohol and other drug cessation over tobacco[38–41] as concurrent cessation is considered overwhelming and thought to compromise substance treatment.[39] Current evidence is at odds with these views, suggesting that continuation of tobacco smoking can prompt relapse to other drug use[42] and that coordinated tobacco and psychoactive substance cessation can enhance long-term alcohol and other drug treatment outcomes.[43–45]

Available smoking cessation interventions

In this complex environment, few pregnant women with co-occurring substance use problems are successful at abstaining from tobacco. A lack of effective cessation treatments targeting this high-priority group has been documented.[46] A 2015 review of treatments for tobacco smoking in pregnant women receiving opiate agonist therapy found only three published studies.[22] Of these, two brief behavioural treatments were effective in reducing tobacco consumption but had little effect on abstinence.[47 48] The third, a randomised controlled trial incorporating contingency management, demonstrated significant positive effects on both smoking reduction and abstinence.[49]

The highest prevalence of smoking is now seen in groups vulnerable to social disadvantage, including

those with substance use disorders.[50] To shift this health disparity, tailored tobacco smoking treatments are clearly needed. Based on this demand, we have designed a comprehensive smoking cessation intervention that addresses the barriers facing women whose pregnancies are complicated by substance use. It will combine three evidence-based smoking cessation treatments: contingency management, nicotine replacement therapy (NRT) and behavioural counselling.

Study aims and objectives

The aim of the study is to measure the impact of this treatment when integrated into public health-based substance use in pregnancy antenatal services.

The primary objectives are to:

1. Assess the feasibility of addressing tobacco smoking among this population using a combination of contingency management, NRT and behavioural counselling.
2. Evaluate the acceptability of offering treatment for tobacco dependence, and of the intervention components, among participants and staff of substance use in pregnancy antenatal services.

The secondary objectives are to:

1. Examine changes in tobacco smoking behaviours of study participants. Behaviours include self-reported and carbon monoxide (CO) validated abstinence and reduction, quit attempts and home smoking bans.
2. Compare adverse maternal outcomes of study participants to those of a historical control group.
3. Compare neonatal outcomes of infants born to study participants with those of a historical control group.
4. Financially evaluate the costs and benefits of implementing the intervention.

METHODS AND ANALYSIS

The study protocol was developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement.[51]

Study design and setting

This is a single-arm pilot study, using pre–post comparisons. The intervention will be incorporated into the routine care of women attending substance use in pregnancy antenatal services offered at three major referral hospitals in Australia, two in New South Wales (NSW) and one in Victoria. These state government-run specialist services operate within the drug and alcohol and maternity services of individual local hospital networks, offering treatment to improve health outcomes for women and their babies.

Eligibility criteria

Pregnant women who meet the following criteria will be invited to participate:

1. Have been referred to, or attending, a participating substance use in pregnancy antenatal service prior to 33 weeks' gestation.
2. A daily tobacco smoker with a CO level >3 parts per million (ppm).
3. Aged ≥16 years.
4. Be willing and able to comply with requirements of the study.

Screening and recruitment

The intervention will be offered to women from study enrolment (any point from confirmation of pregnancy to 32 weeks' gestation) until the delivery of their baby. Based on an internal audit of client first appointments, we anticipate that approximately half of the participants will commence between 21 and 30 weeks' gestation and that recruitment of 100 women could be achieved in a 12-month period.

Women will be screened by antenatal clinicians (eg, addiction specialist or specialised drug and alcohol nurse) by verifying their tobacco smoking status using a validated, multichoice question: 'Which of the following best describes your smoking status?' selecting from 'I'm a smoker, I smoke daily', 'I'm a smoker, I smoke occasionally', 'I'm an ex-smoker, I never smoke now' or 'I'm a non-smoker, I have never smoked'. The use of this format to elicit smoking history has demonstrated accuracy in past research.[52] Interest and eligibility will be gauged before being referred to the research team for recruitment and informed consent.

The intervention

This smoking cessation intervention was developed using current evidence and supported by a taxonomy of behavioural change techniques (BCTs) for behavioural interventions. BCTs are the observable and replicable components of an intervention designed to alter or redirect the underlying causes of behaviour.[53] From a taxonomy of 43 evidence-based BCTs, developed to provide a consistent and reliable catalogue of methods used for smoking cessation,[54] 11 were identified as effective for smoking cessation in pregnancy.[55] These have been incorporated in the current treatment and include contingent rewards, measurement of CO levels, assessment of past and current smoking behaviour, assessment of readiness to quit smoking, provision of information on smoking consequences, facilitation of goal setting, identification of barriers to quitting, identification of relapse triggers, provision of written information, facilitation of relapse prevention and facilitation of social support.[55]

The intervention will provide a combination of the following:

1. Financial incentives for every instance of CO verified smoking abstinence or reduction in smoking consumption from study enrolment until the birth of their baby.
2. Counselling for smoking cessation as required from study enrolment to 12 weeks postpartum.
3. NRT from enrolment until birth as part of the intervention, then to 12 weeks postpartum to assist relapse prevention.

Contingency management

Contingency management offers incentives (financial, usually voucher-based or cash; or prizes) in return for biochemically verified abstinence from alcohol or other drug use. Incentives compete with the reinforcing effects of addictive substances and increase the likelihood of cessation by providing immediate, positive reinforcement for abstinence. Contingency management has a growing evidence base as a treatment for substance use, increasing cessation in cannabis, cocaine, opiates, stimulants, alcohol and tobacco treatments.[56–59]

The provision of rewards contingent on abstinence from tobacco is an endorsed BCT[55] and has been cited in the Cochrane Database of Systematic Reviews as the single most effective treatment for pregnant tobacco smokers (Risk Ratio 2.36, 95% CI 1.36 to 4.09).[20] Improvements in fetal growth, mean birth weight, proportion of low birthweight deliveries and breastfeeding duration have all been associated with contingency management-based smoking cessation.[60 61] Reductions in maternal mood and anxiety symptoms have also been noted.[62]

Verification of abstinence is critical to the success of contingency management treatments but often burdensome to clients and treatment providers. Frequent, objective measures of smoking abstinence are essential to prevent falsification of self-reported smoking status when incentives are offered.[63] Expired breath CO is an effective and non-invasive assessment method but its short half-life (2–8 hours)[64] necessitates twice daily monitoring to accurately measure smoking abstinence. The logistic and economic barriers of this regimen make implementation difficult; however, innovations in technology have helped overcome many of these challenges.[65]

Internet-based contingency management has been trialled in a US national sample of tobacco smokers[66] and subpopulations of tobacco smokers including those from rural areas,[67] those with attention-deficit hyperactivity disorder[68] and pregnant women.[69] Participants are required to self-assess breath CO levels using a CO detector. An internet-enabled device with video capability (eg, web camera or smart phone) can be used to video record a breath sample and corresponding CO reading, before being uploaded for verification.[70 71] This procedure is relatively simple, quick and convenient, with reported mean compliance for video submission ranging from 68% to 98%.[69 71] The procedure has been validated as an acceptable smoking cessation method among internet-based contingency management intervention participants, treatment naive smokers and healthcare providers.[72]

Incentives

Incentives will be in the form of electronic gift cards from a major retail outlet that may be exchanged for groceries and general merchandise but restricted for purchases of alcohol and tobacco products. Due to the frequency of sampling and constraints of fixed amount gift cards, participants will receive written notification of incentive amounts earned immediately after submission of each CO sample. This methodology provides the positive reinforcement required to maintain behavioural change and has been successfully employed in an incentive programme for adolescent smoking cessation.[73] Actual earnings may be distributed weekly or accumulated and redeemed at participant' request.

CO monitoring

Measuring expired-air CO is another BCT recommended for pregnant tobacco smokers,[55] offering the dual benefits of abstinence validation and biofeedback. Participants will self-monitor breath CO levels using internet-based verification methods, collected using a portable monitor (Bedfont Micro+ Smokerlyzer) provided by the study. A cut-off CO level of ≤5 ppm has been adopted to define abstinence, based on evidence that this cut-off results in the best sensitivity and specificity for determining pregnant non-smokers from pregnant smokers.[74]

CO samples are relatively easy to provide, with instructional guidance provided by the monitors' touchscreen. Samples will be recorded using participants' own video-enabled internet device and are expected to take 20–30 s. Results will be submitted by completing a short survey sent prior to each expected test. These require the samples' date, time, ppm value and confirmation of current smoking (yes/no) as well as the time-stamped and date-stamped video footage to be uploaded for confirmation by the research team.

Once submitted, the survey will provide a personalised response based on the results supplied. Feedback will include a congratulatory message for CO results below the required ppm cut-off or an encouraging message for those over. Additional information regarding the current incentive earned, accumulated incentive total and potential future earnings will be provided as immediate reinforcement for desired behavioural change.

Verification of the sample results and video will be undertaken by research staff. Should concern over the legitimacy of a CO result exist, an observed confirmation sample will be undertaken within 24 hours using videoconference facilities. Samples missed due to non-compliance will be presumed positive unless circumstances, substantiated by research staff, prevent their provision (eg, hospitalisation, technical fault or error).

Reinforcement schedule

A well-considered schedule of positive reinforcement is required to successfully condition behavioural change. Variables including how many instances of the target behaviour will be reinforced, reinforcer magnitude and delays in providing reinforcement can influence effectiveness.[75] The current schedule uses five phases of continuous reinforcement with escalating incentives, and a CO sampling regime that reduces over time. Table 1 outlines the aim and duration of each phase, including incentive amounts. The schedule, devised to maximise behavioural change, has been based on those from

Table 1 Aim, duration and procedures of phases used in the schedule of reinforcement

Phase	Aim and rationale	Duration	Procedure
Baseline	► Provides baseline data to evaluate changes in CO during the intervention period ► Serves as training for study monitoring procedures	Up to 5 days	► Samples to be submitted once daily ► Average CO level calculated from results ► Provision of baseline samples will not be incentivised
Shaping	► Provides incentives for intermediate criteria between tobacco smoking and abstinence ► Improves treatment effectiveness while fostering learning and reinforcement prior to quitting[100] ► This phase is optional for those not wishing to stop smoking immediately	Up to 4 weeks	► Weekly reduction of CO targets will be calculated using baseline CO levels and the estimated number of weeks until target abstinence ► Incentives for smoking reductions are based on a fixed schedule of $A2.50 per verified sample, with two submissions per day permitted (morning and afternoon) ► Participants are encouraged to set a quit date within 4 weeks of study enrolment
Abstinence	► Provides an incentive for every verified sample indicating a CO of ≤5 ppm ► High-frequency monitoring is required in the early stages of a quit attempt. Any smoking during the initial weeks of abstinence is predictive of negative long-term smoking outcomes in general populations and pregnant women[101 102] ► Higher magnitude incentives are provided for abstinence as these exert more influence over behavioural change than those of lower magnitude[103]	Period from post baseline or reduction phase through to commencement of thinning phase	► Incentives start at $A3.00, increasing by $A0.10 for every verified negative and are capped at $A20.00. Escalating schedules of reinforcement induce longer periods of continuous abstinence than fixed schedules[104 105] ► Samples to be provided twice daily (defined as 24:00 till 23:59) separated by a minimum of 8 hours[70] for the initial 4 weeks of non-smoking. After this time, they will reduce to once daily
Thinning	► Reduce incentives for abstinence and monitoring requirements ► The switch from continuous to intermittent reinforcement has been shown to reduce reliance on incentives and to prolong abstinence[106]	4 weeks prior to expected delivery date	► Samples to be completed every second day at varying time points to verify abstinence ► Due to varying treatment length, this will only apply to those who have been abstinent for 6 weeks (defined as completion of 4 weeks of twice daily + 2 weeks of once-daily CO samples)
Contingency reset	► Incentives will not be provided for missed samples or those >5 ppm and the value of subsequent samples <6 ppm will be reduced ► To encourage abstinence after relapse, incentive values can be reset after a period of abstinence[71 76]		► Following a positive sample, the reinforcement value of the next negative CO sample will be reset to its initial rate ($A3.00) ► Two consecutive negative samples will revert the incentive to its pre-reset value

CO, carbon monoxide; ppm, parts per million.

seminal contingency management studies.[71 76] Delays in reinforcement are overcome by the provision of immediate, incentive-based feedback after CO submission.

Behavioural counselling

Counselling for the treatment of tobacco smoking primarily focuses on increasing motivation, providing problem solving and coping skills and relapse prevention.[20] Psychological interventions that assist cessation in pregnant women show positive results when compared with usual care.[20 77] Unfortunately, counselling interventions have shown limited success in pregnant smokers with co-occurring substance use, with reduction of tobacco consumption (cutting down) more likely than cessation.[47 48] A review of effective psychosocial treatments for pregnant women found that individualised counselling strategies or those provided concurrently with other strategies, such as contingency management, had the best outcomes.[20] Counselling in the current study will be delivered by qualified drug and alcohol counsellors trained in nicotine addiction treatment. A counselling guide, developed for the intervention, was adapted from established guides for the provision of smoking cessation services to women.[78 79] The guide is based on the principles of motivational interviewing[80] and cognitive–behavioural therapy, while providing a women-centred, personalised approach to treatment.[81] It focuses on providing education and strategies to increase motivation, encouraging abstinence and promoting relapse prevention, incorporating the remaining BCTs identified as requirements for effective smoking cessation treatment in pregnancy.[55]

A non-prescriptive approach has been taken to encompass the individual needs and circumstances of participants and the varying time they will spend on the study. Instead of a predetermined number and structure of sessions, four half-hour sessions will be offered during the prenatal period and two postpartum to assist relapse prevention, with more or less support available as required. Sessions will be conducted using videoconferencing or audio-conferencing. Both are effective delivery methods for tobacco dependence treatment and reduce the burden associated with face-to-face attendance on research participants.[82]

Pharmacotherapy

Nicotine replacement therapy is a widely used pharmacotherapy in Australia to aid smoking cessation. In general populations, NRT combined with behavioural counselling is considered the gold standard for tobacco treatment.[83] In pregnant smokers, however, only borderline support from low-level evidence exists for the same combination (RR 1.43, 95% CI 1.03 to 1.93).[84] The use of NRT in pregnancy has been controversial[85] as the low dosages recommended are not able to counter the increase in nicotine metabolism that occurs during pregnancy.[31] This may account for the poor smoking cessation outcomes from trials of its use in pregnancy.[86] In Australia, practical guidelines have recommended higher dose NRT to be used in combination with behavioural counselling for pregnant women who are unable to abstain from smoking without medication.[85 87]

All oral forms of NRT currently available in Australia (gum, spray, inhalator, mist or lozenge), and nicotine patches, will be offered free of charge. Women will be provided with education to extend their understanding of the use and safety of NRT[88] and will be encouraged to use as much as needed to control urges to smoke.[89] The Royal Australian College of General Practice smoking cessation guidelines for pregnant women will be followed, whereby oral NRT will be used in the first instance, followed by a daytime (16 hours) patch or combined oral and patch if required.[90] In instances of heavy or overnight smoking, guidance will be sought by a specialised medical professional for appropriate NRT dosage. NRT will also be offered and supplied free-of-charge to partners and/or other household members who smoke. This will be available for the period of study enrolment and is aimed at encouraging cessation support and reducing the impact of partner's or family smoking on participants.[91 92]

Study participation

After informed consent, participant's access to an internet-enabled device will be assessed. If necessary, a suitable device will be provided for the duration of study, with data costs being the responsibility of the participant. Existing devices will be updated with applications to enable videoconferencing and timestamping and date-stamping of video. Email accounts will be verified or set up as required. Finally, women will receive a CO monitor with detailed instructions on how to provide, record and submit a CO sample as well as information regarding the sampling regime.

Patient involvement

Patient involvement is used in several stages of the study. Semistructured interviews with substance use in pregnancy antenatal clinic clients informed the intervention's initial acceptability and its implementation. In-depth interviews with participants will provide feedback on the intervention and suggest improvements for its potential future application across other health services. Participants will also be consulted about the most useful methods and specific detail required in the dissemination of study results.

Data collection

Table 2 details the procedures used for data collection. All data, with the exception of CO sample data, will be collected during interviews conducted by a research team member at weekly intervals through to delivery. Follow-up interviews at 12 weeks postpartum will incorporate weekly data collection as well as an audio-recorded qualitative interview to assess the acceptability of the intervention and its components to address smoking within this population of women.

With the exception of recruitment and consent, all interviews will be conducted over the phone or via a secure videoconference link. A $A20 electronic retail voucher will be provided on completion of each research interview, including those at baseline and follow-up. Identical to incentive vouchers, these will reimburse time and cover expenses associated with data and call costs.

All data collected for the study, including videos, online surveys and feedback used in CO monitoring, will be confidentially managed and stored using Research Electronic Data Capture (REDCap) data capture tools. REDCap is a secure, web-based application designed specifically for research studies, hosted by Hunter Medical Research Institute and the University of Newcastle.

Statistical analysis plan

Quantitative analysis

Table 3 defines the outcome measures required to capture the pilot study objectives. All outcomes will be assessed as percentages and proportions with 95% CIs; no inferential statistical analysis will be performed.

To avoid multiple comparisons with the repeated measures of expired CO (and risk of increased type I error), mixed models will be used to handle the repeated measures, with each individual treated as a random effect; the link function will be a logistic regression for the binary outcome of smoking abstinence, and linear regression for the continuous outcome of number of cigarettes smoked per day. Data will be graphed, and residuals assessed to see if the linear model is appropriate or if a non-linear function is needed.

Table 2 Detailed description of assessment items and procedures for data collection

Assessments	Description	Screen	Baseline	Daily	Weekly	Monthly	Follow-up	Support
Screening	Date of birth, expected due date of delivery, gestational age at screening, smoking status	x						
Informed consent	Patient information and consent form, photograph for identification purposes		x					
Demographics	Aboriginal and Torres Strait Islander status, education, income status, marital status, current living arrangements		x					
Smoking and household smoking	Number of household smokers, house and car smoking bans, changes to smoking during pregnancy, types of tobacco used, number of cigarettes smoked, Fagerström Test for Cigarette Dependence,[107] strength and frequency of urges to smoke, feelings about smoking, history of quit attempts, methods previously used to quit		x					
Childhood Trauma Questionnaire (CTQ)[108]	28-item assessment of five types of childhood trauma: physical, sexual and emotional abuse; physical and emotional neglect		x					
Alcohol Use Disorders Identification Test (AUDIT-C)[109]	3-item screen identifying hazardous drinking or alcohol use disorder		x			x	x	
Australian Treatment Outcomes Profile (ATOP)[110]	Screens 28-day use of a range of substances, health and well-being, housing, employment and study, violence, legal issues, child protection		x			x	x	
Generalized Anxiety Disorder (GAD-7)[111]	7-item screening and severity measure of generalised anxiety disorder		x			x	x	
Patient Health Questionnaire (PHQ-9)[112]	9-item screening, monitoring and severity measure of depression		x			x	x	
Treatment Acceptability Questionnaire	13 items adapted from prior internet-based contingency management studies.[72] Assesses acceptability and helpfulness of study components					x	x	
Counselling	Mode of delivery, phase and major topics of discussion, importance of quitting, confidence to quit							x
Nicotine replacement therapy (NRT)	Quantity of NRT used in past 7 days, concerns or problems using NRT, household member use of NRT				x		x	
7-day smoking status	Self-reported 7-day point prevalence abstinence and number of cigarettes smoked				x		x	
Expired air CO	CO ppm	x	x	x			x	

Table 3 Primary and secondary outcome measures

Outcome	Time point	Data collection	Variables/method
Primary outcomes—pilot study			
Feasibility	Study completion	Database + weekly interview	► Recruitment rate (number recruited/number screened) ► Retention rates (number completing last follow-up/number recruited) ► CO sample rate (actual COs completed/total possible COs) ► Number of counselling sessions completed ► Number of women taking NRT ► Adherence to NRT (proportion of dispensed NRT consumed)[113] ► Partners/household members receiving NRT
Acceptability	Study completion	In-depth interviews and focus groups	Qualitative interviews with participants and antenatal staff will explore: ► Acceptability of the intervention ► Perceived effectiveness of intervention components ► Attitudes toward addressing tobacco smoking ► Barriers and facilitators to the implementation of the intervention as routine antenatal care
	Monthly	Interview	Treatment Acceptability Questionnaire
Secondary outcomes—intervention effectiveness			
Changes in tobacco smoking	At birth	Weekly interview	► Number of abstinent days (≤5 ppm; actual number of days/total possible number of days) ► Self-reported 7-day point prevalence verified by CO at birth ≤5ppm ► Self-reported reduction in number of cigarettes smoked/day in past 7 days at 12 weeks postpartum ► Changes in management of smoke-free home/cars
Adverse maternal outcomes	During pregnancy and to 12 weeks postpartum	Medical chart review	Participant adverse maternal outcomes will be compared with those of historical controls. The outcomes will incorporate: ► Rates of miscarriage ► Ectopic pregnancy ► Preterm labour and birth ► Stillbirth ► Intrauterine growth restriction ► Placenta praevia ► Placental abruption and premature rupture of the membranes
Neonatal outcomes	At birth and at 12 weeks postpartum	Medical chart review	Participant newborn characteristics will be compared with historical controls, including: ► Birth weight ► Head circumference ► Gender ► Gestational age at delivery ► Malformations (including cleft lip/palate, gastroschisis, heart defects) ► Sudden infant death syndrome
Economic evaluation	Study completion	Cost-consequence analysis	Costs incurred: ► Financial incentives ► NRT and delivery ► CO monitoring equipment ► Counselling wages and other associated costs ► Administration wages and other associated costs ► Patient costs (out-of-pocket expenses) ► Overheads Offsets: ► Reductions in costs of smoking Outcomes: ► Abstinence at delivery ► Reductions in CO at delivery

CO, carbon monoxide; NRT, nicotine replacement therapy; ppm, parts per million.

Maternal and neonatal outcome comparison data will come from a retrospective medical record review of clients who attended the substance use in pregnancy antenatal clinic and given birth immediately prior to study commencement at participating hospitals.

Qualitative analysis

Interview and focus group data will be analysed under the framework of qualitative description.[93] This methodology, commonly used in health research, draws from a natural perspective and provides rich descriptions of the

perceptions and experiences of informants.[94] All data will be audio-recorded, professionally transcribed and entered into the qualitative software program NVivo.[95] Content analysis, along with constant comparison techniques, will be used to develop descriptions. Double coding will be completed on half of the interviews, with two researchers comparing and agreeing on codes developed. Based on these, a descriptive framework will be generated.

Economic evaluation

A cost-consequence analysis (CCA) will provide an evaluation of the intervention in financial terms. CCA is a descriptive approach that presents intervention costs and outcomes in a readily understandable, disaggregated form.[96] This transparent presentation offers easy application to healthcare decision-making and is particularly useful in pilot or feasibility research[97] and studies where a full comparative analysis presents challenges in terms of meaningful comparison data. All costs and outcomes that will form part of the CCA are provided in table 3.

ETHICS AND DISSEMINATION

The study protocol complies with the Australian policy reference, the National Statement on Ethical Conduct in Human Research. The protocol was approved by the Hunter New England Human Research Ethics Committee (Reference 17/04/12/4.05). Additional approval was sought by the Aboriginal Health and Medical Research Council of NSW (Reference 1249/17).

Consideration will be given when recruiting women identifying as Aboriginal or Torres Strait Islander peoples to ensure that they have the option of culturally appropriate support during the consent process. Pregnant smokers aged 16–17 years may be included in the study if assessed as mature minors with the ability to understand the research and capacity to express a choice about participation.

The findings will provide knowledge about the acceptance of contingency management for smoking cessation in the Australian public health arena, being of interest to stakeholders, funding bodies and participants. Feasibility results will be disseminated at local and international conferences via social media and published in peer-reviewed journals.

DISCUSSION

This study explores the feasibility of integrating an innovative, multicomponent smoking cessation intervention into the antenatal care offered to women whose pregnancy is complicated by drug and/or alcohol use. The contingency management strategy, supported by counselling and pharmacotherapy, has been tailored to meet the specific needs of this population. Its implementation into a healthcare setting, and the use of technology to remove barriers associated with research participation, makes this tobacco treatment unique and accessible.

The research provides an opportunity to assess potential recruitment and retention issues that are often associated with studies involving disadvantaged populations.[98] The potential uptake of tobacco treatments of this nature has received little attention in health-disparate Australian populations. Moreover, while internet-based contingency management has been successfully trialled across a variety of groups, the question about its acceptability among pregnant women with substance use concerns remains unanswered. Importantly for equity purposes, the single-arm design allows the offer of treatment to all eligible women. Not only does this mirror a real-world clinical setting, it maximises data collection and provides treatment exposure to as many clients as possible.

Additionally, study outcomes will be strengthened by piloting the treatment across three primary healthcare settings. This will maximise its potential to uncover procedural issues likely to impede its potential scalability to a randomised controlled trial. We expect to identify issues relating to the intervention, study procedures and their implementation and use the findings to inform implementation science and other future clinical research and practice.

The study has several limitations. For example, the differing CO cut-offs to determine eligibility and abstinence. Eligibility requires a CO of >3 ppm to ensure the inclusion of all self-reported smokers, while the CO to determine smoking status is ≤5 ppm. It is acknowledged that a small rise in CO may enable an incentive payment; however, it is considered this would only apply to a minority of cases. More generally, the study will be limited by those characteristics applicable to pilot studies in general.[99] An assessment of the tobacco dependence treatment's efficacy will not be made, due to the small sample size and lack of power. The measurement of outcomes, including changes in smoking behaviour, neonatal characteristics and adverse maternal outcome comparisons, are intended to identify trends rather than determine statistical inferences.

Finally, a pressing demand exists for targeted, effective tobacco dependence treatments for high-priority groups of women who use tobacco and other substances during the antenatal period. The importance of addressing maternal tobacco smoking in Australia is a state and national health priority in view of the serious but preventable impact it has on the health of tobacco-dependent mothers, and the life course of their infants and children.

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