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STUDY PROTOCOL

ADDICTION SSA

# The use of financial incentives for smoking cessation in pregnant women: A parallel-group randomised controlled trial protocol

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## Abstract

**Background and aims:** Smoking cessation during pregnancy results in short- and long-term health benefits for the mother and infant. Despite public health policies and initiatives to reduce smoking, smoking in pregnancy remains unacceptably high in Australia, particularly among populations of high disadvantage. Internationally, the use of financial incentives has shown some promise in assisting pregnant women to quit smoking, but more research is needed in different contexts. This study aims to determine the efficacy, cost-effectiveness and acceptability of the use of financial incentives in Australia.

**Design:** 2-arm parallel-group randomised controlled trial.

**Setting:** Australian antenatal care setting.

**Participants:** Pregnant women who smoke.

**Intervention:** Women randomised to the intervention group will receive financial incentives of increasing value at three time points throughout their pregnancy (4 and 12 weeks from the first antenatal visit and 37 weeks gestation) upon confirmation of smoking abstinence.

**Measurements:** The primary comparison outcome is a composite binary measure of abstinence at three time points during pregnancy (4, 12 and 37 weeks). Smoking abstinence will be determined by a carbon monoxide breath analysis reading of ≤3 ppm. The primary statistical analysis is estimation of the absolute difference in the prevalence of abstinence at all three time points based on the intention-to-treat groups. A cost-effectiveness analysis will be undertaken to quantify the social returns of the intervention. A qualitative process evaluation will also be conducted to determine fidelity, contextual factors and the acceptability of the intervention to pregnant women and healthcare workers.

**Comments:** This study will be the first Australian trial of financial incentives in reducing smoking in pregnancy. The findings will provide evidence on the acceptability, effectiveness and cost-effectiveness of financial incentives to reduce smoking in pregnancy in Australia.

KEYWORDS
Abstinence, acceptability, antenatal, cost-effectiveness, intervention, tobacco

## INTRODUCTION

Smoking during pregnancy has immediate and long-term effects on health, economic wellbeing and human capital accumulation [1, 2]. Health risks include spontaneous miscarriage, ectopic pregnancy, operative vaginal delivery/caesarean section, sudden infant death syndrome, asthma, low birth weight, stillbirth and infant obesity [3]. Low birth weight is associated with a higher risk of type 2 diabetes, coronary heart disease and hypertension [4]. In Australia in 2020, 8.8% of women smoked during the first 20 weeks of pregnancy [5]. Smoking follows a clear socio-economic gradient, with women living in areas of high socio-economic disadvantage more likely to smoke and less likely to quit during pregnancy than women living in more advantaged areas, and with smoking prevalence for women in the most disadvantaged quartile being 16.9% [6, 7]. Despite a gradual general decline in smoking, policies implemented in Australia, such as smoking bans in public places, plain cigarette packaging with graphic warnings, smoking harm advertisements and tobacco tax increases, appear to have had limited influence on smoking in pregnancy [8].

Smoking cessation during pregnancy is challenging. A systematic review reported that only 13% were successful in quitting during pregnancy through an intervention, and of those that quit, 43% resumed postpartum [9]. There appears to be a 'dose–response' benefit to the fetus, where the dose relates to the number of weeks of non-smoking [10]. Women who quit earlier have perinatal outcomes similar to those of non-smokers [10, 11]; therefore, engaging women with support services early is paramount in facilitating them to quit and remain abstinent.

Standard clinical practice in South Australia, the Australian state where this randomised controlled trial (RCT) will be conducted, involves a healthcare provider discussing smoking status during the first antenatal visit (at approximately 14 weeks of gestation) and referring to the 'Quitline' telephone support service if they are interested in quitting. However, few go on to access this service [12]. Healthcare providers might limit further support if they believe that people who do not use the service are not interested in quitting [13].

Financial incentives are a relatively novel approach to smoking cessation. Systematic reviews indicate that financial incentives are efficacious in improving quit rates among general [14–16] and socio-economically disadvantaged [17] populations. They are also efficacious in helping pregnant women quit smoking [14–16, 18]. A meta-analysis of 12 studies in pregnancy found that abstinence at the last assessment during pregnancy (5–8 months) was 2.43 times higher when financial incentives were offered [16]. Financial incentives that require individuals to demonstrate abstinence are more effective than those that require only attendance at scheduled appointments [14]. Interventions that increase the value of the financial incentive incrementally throughout pregnancy (to acknowledge the continued effort to remain abstinent) have also been more effective [18]. There is also evidence of long-term abstinence in response to financial incentives. A meta-analysis of five RCTs demonstrated that abstinence was 2.73 times higher when financial incentives were offered, where the incentives remained available postpartum. Where incentives are ceased postpartum, a meta-analysis of six studies found that abstinence was 1.93 times higher than in control participants [16]. Although the current evidence on efficacy is promising, only five studies have included cost-effectiveness analyses [18–22]. Systematic reviews have recommended higher quality trials, more cost-effectiveness analyses and evaluations of acceptability [14].

### Objectives

To determine whether carbon monoxide monitoring plus financial incentives will assist women in achieving abstinence from smoking tobacco during pregnancy, compared with carbon monoxide monitoring only. We will also conduct a qualitative exploration of the experiences and attitudes of participating mothers and health professionals regarding the intervention and the use of financial incentives to encourage women to quit smoking.

### Primary outcome

Smoking abstinence will be analysed as a binary measure derived from verified cumulative abstinence at all three measurement time points following the first antenatal visit, as assessed by piCO$^{baby_{TM}}$ carbon monoxide (CO) breath analysis of ≤3 ppm at 4 and 12 weeks after the first antenatal visit and at 37 weeks of gestation. Successful point-in-time abstinence will be determined by a CO breath analysis of ≤3 ppm at all three time points. If a measurement of >3 ppm is recorded at any single time point, the primary abstinence criterion will be deemed not met.

### Secondary outcomes

(1) Abstinence of smoking tobacco at 37 weeks of gestation, as assessed by piCO$^{baby_{TM}}$ CO breath analysis of ≤3 ppm.
(2) Abstinence of smoking at 6 months postpartum, as assessed by piCO$^{baby_{TM}}$ CO breath analysis of ≤3 ppm.

## METHODS

This protocol is written according to the SPIRIT (Standard Protocol Items: Recommendations for Intervention Trials) statement [23] and the CONSORT (Consolidated Standards of Reporting Trials) statement [24].

## Trial design

The study uses a two-arm parallel-group RCT design. The intervention group will be offered financial incentives for smoking abstinence, and the control group will not be offered financial incentives. Both arms will undergo carbon monoxide breath analysis at all measurement time points.

## Study setting

This study is being conducted in Australian antenatal care settings of the Northern Adelaide Local Health Network (NALHN). NALHN is the main provider of antenatal services in the northern suburbs of Adelaide (capital city of the state of South Australia). The catchment area is home to approximately 400 000 people, comprising some of the most disadvantaged urban populations in Australia, including the City of Playford, which is in the second highest decile of socio-economic disadvantage in Australia. Each year, there are approximately 4000 births in NALHN. Based on 2016–18 statistics, the prevalence of smoking during pregnancy was 20% [25].

## Participants

Participants will be pregnant women attending antenatal care who smoke.

## Eligibility criteria

Women will be eligible if they are pregnant and smoke tobacco (confirmed by CO breath analysis of ≥4 ppm at first antenatal visit), are ≥18 years of age and are ≤20 weeks pregnant at the first antenatal appointment. Women will be excluded if they are unable to communicate in English or are unable to provide informed consent.

## Procedure

Figure 1 illustrates the flow of participants through the study. Table 1 shows the enrolment, intervention and assessment schedule.

## Eligibility assessment, recruitment and consent

Participants will be screened for eligibility and recruited in two ways. Most will be screened and recruited in the first stage of a two-step admission process for pregnant women. Pregnant women enter socio-demographic and obstetric information (including smoking status) into an online platform before their first (in-person) antenatal visit, which is available to the midwife or obstetrician during the visit. Women who disclose smoking will receive brief information on the trial and a Participant Information Sheet and Consent Form. Midwives or obstetricians will then follow up about potential participation during the first antenatal visit. Women who have not filled out the online form will be screened during this visit. It is routine practice for the attending health worker (midwife or obstetrician) to enquire about smoking status. Women who disclose current smoking will be invited to participate.

Women provided with an information sheet will be given the opportunity to ask questions and to discuss the study with their partner, family and friends. If interested, they will be asked if they are willing to discuss their involvement with a researcher. Where possible, the discussion will take place in the antenatal care setting, ideally during the first visit.

Women who agree to participate will provide written consent. Upon consent, the health worker will request a CO breath sample taken with a CO monitor. CO is an exhaled by-product of smoking tobacco and can be used to confirm smoking status. The piCO$^{baby}$™ is a handheld CO breath analysis device that offers a rapid, simple and inexpensive point-of-care test of smoking status. The piCO$^{baby}$™ is commonly used in antenatal care settings to determine smoking status and as a means of engaging discussions about smoking and quitting. The manufacturer's recommendations [26] and midwifery resources from the UK apply a cut-off point of 4 ppm [27]. Thus, if the CO reading is 3 ppm or lower participants are categorised as non-smokers, and participants with readings of ≥4 ppm are categorised as smokers. A position statement by the Perinatal Society of Australia and New Zealand recommends CO monitoring as part of routine antenatal care [28]. CO monitoring is already part of routine care in the UK, where it has been demonstrated to assist pregnant women to quit [27]. Past research by our group indicates that midwives perceive that CO breath analysis would allow pregnant women to view a measure of their smoking that may facilitate discussions about smoking status and smoking cessation [13].

## Target population, sample size and study power

Estimates of the effects of incentive-based RCTs of interventions promoting smoking cessation among pregnant women range from a 14%–15% higher point prevalence of abstinence at 34–38 weeks of gestation (in two high-quality, well-powered RCTs in the UK) [18, 20] to 30% for sustained abstinence (from three trials of lower quality in the USA, with small sample sizes ranging 82 to 166) [14, 29–31]. It is planned to investigate the subgroup of nulliparous pregnant women because they are younger, more likely to smoke than older women [32], more likely to have more future children and represent the best opportunity for permanent smoking cessation.

Australian data indicate that, of the women who reported smoking during pregnancy in 2022, 77% of those from the most disadvantaged quintile (Q1) continued to smoke after 20 weeks of gestation, compared with 61% in the least disadvantaged quintile (Q5). This demonstrates that Australian women in a socio-economically disadvantaged position appear less likely to cease smoking [6]. We have

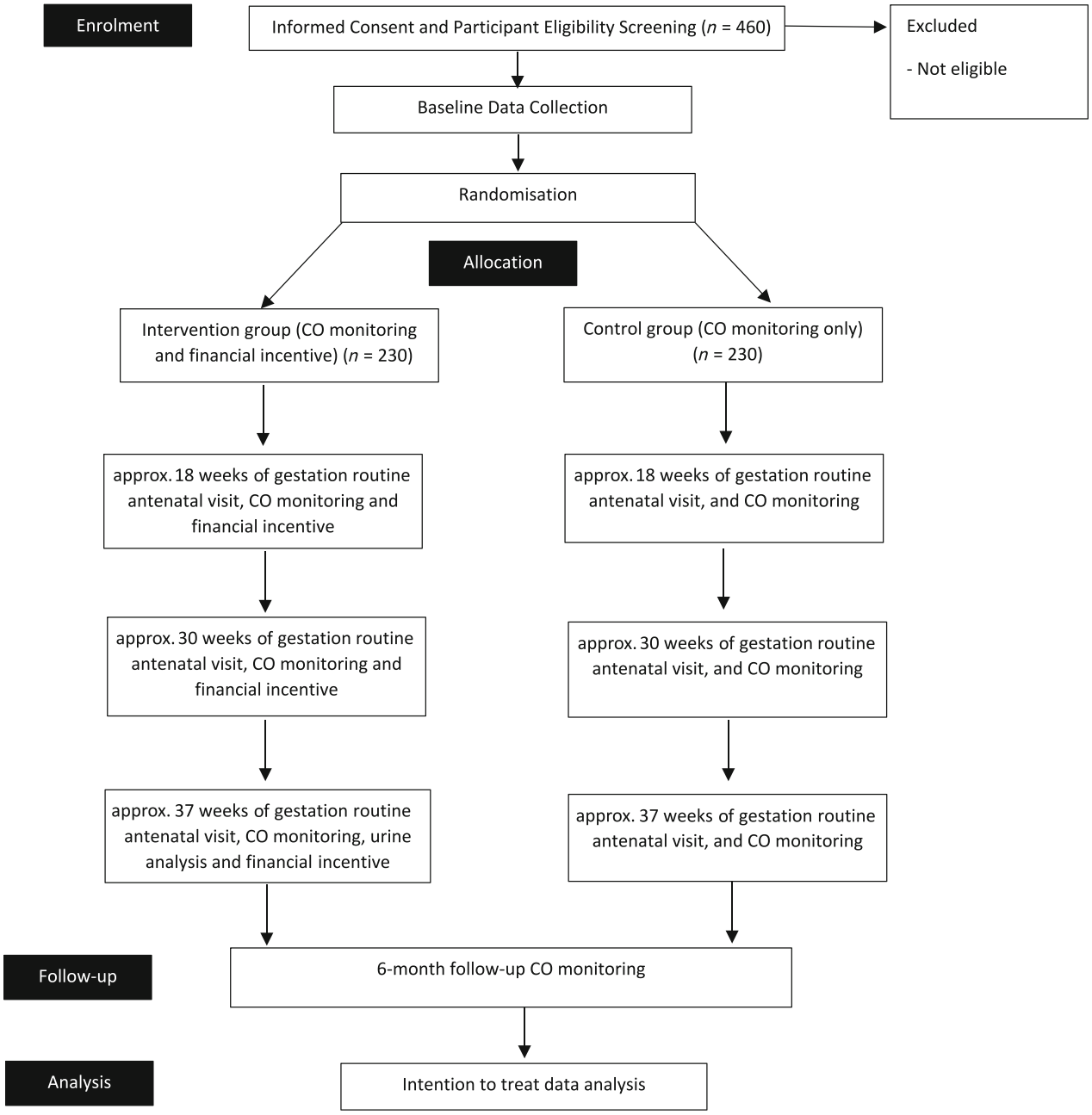


**FIGURE 1** Study flow chart.

therefore based our sample size calculations on a modest 10% improvement in point-in-time abstinence (from 5% to 15%), with 90% power (10% Type II error rate) and an alpha of 5% (5% Type I error rate). Using the *sampsi* function in the statistical package Stata (Version 18, Standard Edition) [33], we calculated the minimum required sample size of $n = 207$ in each of the intervention and control groups.

A low attrition rate is anticipated as the trial is embedded in routine care and it is likely that participants can be followed throughout pregnancy, even if they do not cease smoking. We assume, therefore, that no more than 10% of the final sample will drop out. To accommodate the potential for attrition, the sample size calculated above is multiplied by 10/9 (i.e. divided by 0.9). This results in a final sample size of $n = 207/0.9 = 230$ per randomisation group.

A stratum-specific analysis of nulliparous women (estimated to be 29% of the sample, so $n = 60$ per group) will allow the detection of 15% absolute improvement in point-in-time abstinence, from 5% to 20%, with 61% power and 5% Type I error. A stratum-specific analysis of multiparous women (estimated to be 71% of the sample, so $n = 147$ per group) will allow the same absolute improvement in point-in-time abstinence of 10% to be detected with 77% power.

For the qualitative evaluation component, women will be recruited purposively to gain insights about acceptability, experiences and subjective meanings tied to their engagement with the

**TABLE 1** Study schedule.

| | Enrolment | Baseline | Allocation | 4 weeks after enrolment (approx. 18 weeks of gestation) | 12 weeks after enrolment (approx. 30 weeks of gestation) | 37 weeks of gestation | 6 months postpartum |
|---|---|---|---|---|---|---|---|
| Eligibility screen | X | | | | | | |
| Informed consent | X | | | | | | |
| Random allocation | | | X | | | | |
| Financial incentive (intervention group) | | | | X | X | X | |
| Sociodemographic characteristics | | X | | | | | |
| Smoking history | | X | | | | | |
| Obstetric history | | X | | | | | |
| CO breath analysis | X | | | X | X | X | X |
| Urinary metabolites (anabasine and cotinine) | | | | | | X | |
| Smoking since last visit | | | | X | X | X | X |
| Smoking cessation aids | | X | | X | X | X | X |
| Smoking cessation support | | X | | X | X | X | X |
| Antenatal risk questionnaire | | X | | | | X | |
| Edinburgh Postnatal Depression Scale | | X | | | | X | |
| Multidimensional Scale of Perceived Social Support | | | | | | X | |
| Infant data | | | | | | | X |

intervention. Purposeful sampling aims to capture a range of experiences, including from women who do not quit. Interviews will be conducted at around 37 weeks of gestation and participants will receive a AU$50 voucher to compensate them for their time. The pragmatic Model of Information Power [34], which uses the dimensions of study aim, sample specificity, use of established theory, quality of dialogue and analysis strategy, will inform researchers when the sample holds sufficient information power for sampling to cease.

## Intervention

Women randomised to the intervention group will be offered financial incentives, in the form of voucher gift cards for a major supermarket chain and department stores, for point-in-time abstinence as measured by CO breath analysis values of ≤3 ppm. The vouchers will increase in value throughout the pregnancy from AU$50 to AU$150 and then to AU$400. Vouchers offer the greatest flexibility for individual needs, which may change throughout pregnancy [35].

The CO breath analyses will be conducted at routine antenatal appointments to avoid any additional burden from attending research appointments. Women will nominate a 'quit date' within 2 weeks of consenting (no later than 22 weeks of gestation). At 2 weeks following the quit date, women will receive an AU$50 voucher for a negative CO breath analysis at their next antenatal appointment. They will receive an AU$150 voucher for a negative CO breath analysis at 12 weeks after their quit date (antenatal appointment at approx. 30 weeks of gestation) and an AU$400 voucher at the antenatal appointment at 37 weeks of gestation, upon confirmation of negative CO breath analysis. CO monitoring was chosen over urinary analysis because it fits seamlessly into routine antenatal care, provides the immediate feedback essential for reinforcing smoking cessation behaviours [36], and is non-invasive, quick and easy to administer. Urinary analysis will also be conducted in batch testing at the completion of the trial, to enhance the validity of the results through biochemical verification. Although CO monitoring is used throughout the study for pragmatic benefits, urinary analysis is a robust secondary measure to confirm smoking abstinence. Only the breath analysis needs to be negative to receive the voucher. Abstinence will be rewarded at any stage but if participants had not quit at a previous appointment the reward will revert to the lower amount. For example, if a woman was not abstinent at 18 weeks ($0 reward), but was abstinent at 30 weeks and 37 weeks, they would receive $50 and then $150, respectively. The maximum value of the financial incentive is

$600, a non-trivial amount of money (equivalent to 53% of the median weekly earnings of women in Australia in 2024 and about 14 hours of pay at the total average hourly pay rate across all industries of $44) [37]. This amount is: (1) consistent in magnitude with Australian literature on the desired value of incentives [38]; (2) the midpoint of the range of other successful incentives (it is neither excessive nor trivial) [14]; (3) similar to the highest quality trial conducted among pregnant women [20]; and (4) meets the framework for designing incentives for health behaviours [36].

Women will be provided with a flyer outlining the standard quit support available, such as counselling services, their GP, nicotine replacement therapy (NRT) and smartphone apps. When designing this intervention, clinical staff were asked whether women should be offered NRT. Some clinicians reported that they would prefer to assess potential benefit from NRT on an individual basis and offer the women and their partners NRT prescriptions on a case-by-case basis. This aligns with current clinical practice. No participants will be denied NRT prescriptions if indicated and no participant will be excluded for using NRT.

## Control

Women randomised to the control group will be asked to provide CO breath analyses at routine (scheduled) antenatal appointments approximately 4 and 12 weeks after enrolment, as well as breath and urine samples at 37 weeks of gestation. They will receive an AU$50 gift voucher for participation. Women are also provided with standard care, including the provision of a flyer outlining the support available.

### Random allocation and blinding

Women will be randomly assigned to the intervention or control groups after the collection of baseline measures in a 1 : 1 ratio via the REDCap randomisation module [39]. The randomisation schedule will be prepared by a statistician (LG) who is not involved in the day-to-day operations of the trial, will be stratified by parity (0 vs ≥1) and will use random permuted blocks with lengths of 4 and 6. The randomisation schedule is hidden in REDCap until consent, eligibility and baseline data are collected. Randomisation occurs in the presence of the clinical trial officer, who then explains the assigned group to the participant.

## Data collection methods

### Baseline

At baseline, demographic data, including date of birth, education, employment status, paid working hours, postcode, ethnicity and Government-issued Health Care Card eligibility (proxy for welfare benefits), will be collected. Smoking history will be taken, including smoking status, age started smoking, recent use and nicotine addiction (assessed using the Fagerström Test for Nicotine Dependence) [40], motivation to stop [41], e-cigarette, vaping and cannabis use (using the Self-Report Habit Index) [42], quit attempts, and smoking cessation aids used by the mother and/or their partners and household members (e.g. NRT, medication, vaping and e-cigarettes, Quitline, etc.) [43]. Financial wellbeing will be assessed using questions from the Household Income and Labour Dynamics in Australia (HILDA) survey [44] (a nationally representative, longitudinal study), including current needs, financial responsibilities, financial constraints, the nature of problems in daily life arising from a shortage of money, ease of raising money in an emergency and how they might obtain that money.

### At 4 and 12 weeks after first antenatal appointment

At the 4- and 12-week antenatal clinic visits, trial staff will assess tobacco smoking abstinence using the CO breath analysis cut-off value of ≤3 ppm. If an woman in the intervention group has a breath analysis of ≤3 ppm, trial staff will provide them with the relevant AU $50 or AU$150 voucher.

Participants will also answer questions about smoking since the last visit, any smoking cessation aids they have used (e.g. NRT, medication, vaping and e-cigarettes, Quitline, etc.) and whether they sought cessation support from family, friends or services. Women will complete these questions confidentially using an iPad. Before concluding the visit, trial staff will ask the women whether they would like to speak with a health professional or smoking cessation expert. Women struggling to quit will be referred to an obstetrician for review and assessment for pharmaceutical support and/or consultation with a smoking cessation counsellor.

### At 37 weeks of gestation

At the antenatal visit conducted at 37 weeks of gestation, women will be asked for CO breath analysis and a urine sample for the analysis of tobacco by-products (anabasine and cotinine). They will answer questions about smoking since the last visit, any smoking cessation aids they have used (e.g. NRT, medication, vaping and e-cigarettes, Quitline, etc.) and whether they sought cessation support from family, friends or services. Women will complete three surveys to evaluate any psychological impacts of quitting: (1) the 12-item Antenatal Risk Questionnaire (ANRQ), which records psychosocial symptoms during routine care [45], and asks questions about the extent to which an issue affects them, with five response options ranging from ‘Not at all’ to ‘Very much’ (scores of ≥23 are considered high), and in accordance with current clinical practice guidelines will be referred to a health professional; (2) the 10-item Edinburgh Postnatal Depression Scale (EPDS), with four possible response options, measures depression in the antenatal and postpartum periods (scores exceeding 12 are suggestive of depression and require further assessment) [46]; and (3) the Multidimensional Scale of Perceived Social Support, which

measures the participant's perception of social support received from the three domains of family, friends and significant other (this tool has been validated for use in the Australian population) [47].

### At 6 months postpartum

At 6 months postpartum, participants will be contacted for a follow-up visit in their home or at another suitable location. Participants will be asked about postpartum tobacco use (relapse), use of smoking cessation supports (e.g. NRT, medication, vaping and e-cigarettes, Quitline, etc.) and undergo a CO breath analysis. Participants will be provided an AU$50 voucher for their time, which is not dependent on smoking status.

Women will complete questionnaires confidentially using an iPad. To minimise participant burden, the participant's consent will be obtained to extract relevant baseline and follow-up data from the medical records. These data include social history information, lifestyle-related information, labour and obstetric information from current and previous pregnancies, and infant information from current and previous pregnancies, such as Apgar score, resuscitation at delivery, time to establish regular breathing, birth injuries, congenital abnormalities, nursery admission and level of care, gavage feeding, supplementary feeding and treatments in the neonatal period. The ANRQ and EPDS are routinely used in antenatal care around the time of the first antenatal visit; where it is not possible to collect this information from medical records, it will be collected at baseline. High scores on the EPDS and the ANRQ will be followed up by clinical trial staff with the Midwifery Unit Managers and may also include follow up by the perinatal mental health service or other clinical care.

### Qualitative evaluation

A qualitative process evaluation will be conducted concurrently with the trial to understand whether the intervention was delivered as intended, identify contextual factors affecting implementation and outcomes, and how women and healthcare workers interact with the intervention. The evaluation will include women who enrolled in the intervention arm (who smoked and may or may not have quit) and healthcare providers (obstetricians and midwives, and any ancillary NALHN staff who engage with the trial, e.g. smoking cessation counsellors). Semi-structured interviews with the women participants will be conducted via phone or face to face, depending on preference, and the healthcare workers will be invited to participate in a focus group or interview.

## Data management

Trial data will be collected using REDCap software [39] and stored on the University of Adelaide's secure server. Upon publication, a redacted de-identified dataset will be deposited in an open data repository, such as the Centre for Open Science. This dataset will include the following variables: baseline characteristics (maternal age – categorised, parity) and trial outcomes (randomisation group, cumulative abstinence from recruitment until 37 weeks of gestation or end of pregnancy, single point-in-time abstinence at 37 weeks of gestation or end of pregnancy and at 6 months postpartum). The participant information sheet explains that a small quantity of de-identified data will be deposited in a repository, and thus participants need to give consent for their data to be included to be eligible to participate.

## Analysis

The main trial analyses and the cost-effectiveness analyses will be undertaken according to a Statistical Analysis Plan. Briefly, the primary statistical analysis is an estimation of the absolute difference in the prevalence of cumulative abstinence based on the intention-to-treat groups, that is, comparing average outcomes between the intervention and control groups to which participants were randomly allocated. Logistic regression analyses will be used to adjust the estimated prevalence difference for: (1) the parity strata within which randomisation took place; and (2) nicotine dependence at baseline based on the results of the Fagerström Test for Nicotine Dependence [40]. During the trial information will be collected that will enable an analysis of the sensitivity of results to assumptions about non-adherence (i.e. continued smoking) and loss to follow-up, both of which are post-randomisation events that may be influenced by time-varying confounding factors (e.g. financial events that might influence ongoing participation).

### Missing participant data

We anticipate that targeting a potentially vulnerable population is likely to result in participants for whom data collection is incomplete. The Russell Standard [48] will be adopted to account for missing outcome data on smoking cessation at trial completion. We note that this approach assumes that data are 'missing not at random', that is, the missingness may be related to the success or failure of the intervention. Following the guide proposed [49], we will report summary information on missing participant data and an examination of any differences in the distribution of baseline characteristics comparing participants with complete data against participants with any missing data in each randomisation group. Multiple imputation by chained equations (MICE), also known as the fully conditional specification (FCS) [50, 51], where separate, conditional univariate imputation models are specified for each variable with missing data, will be used to account for missing information in the statistical analysis (a strategy recommended in a recent review of approaches for handling missing data in RCTs) [52].

### Cost-effectiveness evaluation

A cost-effectiveness analysis will be undertaken to estimate the social returns of the intervention. Social returns will be calculated from the perspective of the Australian Medicare system as saved healthcare use expenditures for the cost year 2024–25. A within-trial analysis will be conducted by using data on healthcare resource use and quit outcomes to report the incremental cost per quitter and baby in the first year of life.

The cost of each arm of the trial will include referrals to the Quit program, breath and urine sample analyses, trial participation costs and financial incentives (AU$600). The costs of NRT will be included when prescribed by clinicians. NRT prescription and Quitline referral will be collected prospectively during routine antenatal care visits and documented in the medical record. We will use unit cost information with trial resource use data to estimate the mean cost per participant per arm. Administration costs (e.g. postage of vouchers, phone calls) will be included. We will use unit cost information from wage information from NALHN administrative records. We will include post-birth hospitalisation costs for preterm and low birth weight babies, constructed from administrative hospitalisation data and South Australia unit costing data. These data will be used to calculate the social return in terms of short-term healthcare expenditure savings relative to the cost of the intervention within the first year of life of the baby.

In an extension to this analysis, we will consider approximating the long-term cost savings that may occur through health gains of cessation for *both* the mother (e.g. improved respiratory and cardiovascular health) and baby (e.g. improved human capital through better birth outcomes), relying on typical estimates from the literature.

### Qualitative data analysis

The framework method of thematic analysis [53] will be used to analyse the qualitative data. This approach allows the analysis of some specific predetermined issues but also aims to leave space to explore other unexpected aspects of the participants' experiences or the way they assign meaning to phenomena [53]. This data analysis approach has been effectively used in health services research, especially with multidisciplinary teams, as it provides a systematic and transparent approach. The qualitative analysis findings will add value to the interpretation of the quantitative outcome measures generated. NVivo 12 software (QSR International Pty Ltd, Doncaster, Victoria, Australia) will be used to manage the analysis.

## DISCUSSION

This study will investigate the efficacy of financial incentives to support pregnant women in achieving abstinence from smoking tobacco, compared with usual care. Current support available to South Australian pregnant women who smoke has been poorly accessed and therefore ineffective in achieving high rates of smoking cessation, particularly in areas of high disadvantage [25], highlighting the need for innovative approaches.

A limitation of the study is the use of CO breath analysis as an indicator of current smoking status, compared with the more robust biochemical method of urinary analysis. Although CO breath analysis was chosen because of the pragmatic nature of this trial and the advantages of enabling the provision of an immediate financial reward to participants for smoking abstinence, it is acknowledged that it may not detect low levels of smoking, and it has a relatively short detection window compared with urinalysis. Furthermore, given the pragmatic nature of this trial, retention and loss to follow-up are potential limitations, particularly if there is a high rate of relapse postpartum. This could impact the completeness of the data.

The use of financial incentives is relatively novel and although showing promise [14–16], there have been recommendations for higher quality RCTs, more cost-effectiveness analyses and evaluations of acceptability [14]. This study fills these gaps and will provide efficacy and cost-effectiveness evidence in the Australian context, with the potential to inform future public health policy and practice. Possible challenges such as attrition may arise, but this has been considered in the sample size calculation and analysis plan.

## CONCLUSION

This article provides a comprehensive outline of the methods to be used to determine the efficacy, cost-effectiveness and acceptability of financial incentives in achieving smoking cessation in pregnant women. The study is unique to the Australian context and one of few to include a cost-effectiveness analysis, providing a valuable addition to the evidence base.

### AUTHOR CONTRIBUTIONS

**Megan L. Hammersley:** Writing—original draft (lead); writing—review and editing (equal); methodology (supporting). **Gustaaf A. Dekker:** Conceptualization (equal); funding acquisition (equal); methodology (equal); writing—review and editing (equal). **Lyle C. Gurrin:** Conceptualization (equal); funding acquisition (equal); methodology (equal); writing—review and editing (equal); analysis (lead). **Elizabeth A. Hoon:** Conceptualization (equal); methodology (equal); writing—review and editing (equal); analysis (lead). **Stefanie Schurer:** Conceptualization (equal); funding acquisition (equal); methodology (equal); writing—review and editing (equal); analysis (lead). **John W. Lynch:** Conceptualization (equal); funding acquisition (equal); methodology (equal); writing—review and editing (equal). **Marnie Aldred:** Writing—review and editing (equal). **Julia Dalton:** Writing—review and editing (equal). **Cherise J. Fletcher:** Writing—review and editing (equal). **Lisa G. Smithers:** Conceptualization (lead); funding acquisition (lead); methodology (lead); writing—review and editing (equal); project administration (lead).

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## DECLARATION OF INTERESTS

The authors have no conflicts of interest to declare.

## DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

## ETHICS STATEMENT

This study was approved by the Central Adelaide Local Health Network Human Research Ethics Committee (2022/HRE00310). Site-specific approvals were obtained from Lyell McEwin Hospital (2022/SSA00710) and Modbury Hospital (2022/SSA00711).

## CLINICAL TRIAL REGISTRATION

Australian and New Zealand Clinical Trials Registry (ACTRN12623000922673).

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