SMOKING CESSATION IN PREGNANCY

INVESTIGATING THE FEASIBILITY AND ACCEPTABILITY OF CARBON MONOXIDE (CO) MONITORING AND FINANCIAL INCENTIVES TO ENCOURAGE SMOKING CESSATION

Contents

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Summary

Smoking throughout pregnancy causes irreversible harm to both the mother and fetus. Although smoking rates have declined considerably, rates of smoking during pregnancy remain steady among socioeconomically disadvantaged populations [1]. The Northern Area Local Health Network (NALHN) serves a substantially disadvantaged population with approximately 1 in 4 women smoking during pregnancy [2]. Standard practice at NALHN is to refer women to the Quitline, yet it is widely acknowledged by women and health professionals that women rarely engage with the service (Unpublished data from research project 'Women's experiences of smoking and quitting in pregnancy' CALHN HREC approval Q20190304). Studies exploring the use of carbon monoxide (CO) monitoring and financial incentives in antenatal care to encourage smoking cessation have shown promising results [3-6]. This project will explore the feasibility and acceptability of using CO monitoring and financial incentives in antenatal care at the NALHN antenatal services.

Background

Women frequently under-report smoking to health care providers during antenatal care due to social stigma [7-10] (Unpublished data from research project 'Women's experiences of smoking and quitting in pregnancy' CALHN HREC approval Q20190304). Our recent research with antenatal care providers at NALHN has also revealed that staff can be hesitant to discuss the issue. This can be because they feel challenged approaching the subject as well as confirming that women are reluctant to discuss the issue (Unpublished data from research project 'Women's experiences of smoking and quitting in pregnancy' CALHN HREC approval Q20190304) [11]. Their greatest fear is that discussing smoking in pregnancy may harm the professional relationships they have with women resulting in abandonment of antenatal care [11]. Consequently, one of the most serious and preventable causes of intergenerational ill health remains largely unaddressed by the healthcare system.

In Australia, rates of smoking during pregnancy are high among socioeconomically disadvantaged populations [12, 13]. NALHN serves a substantially disadvantaged community. Areas in this catchment, have the second lowest Index of Relative Socioeconomic Disadvantage (IRSD) score for a capital city in Australia. [13, 14] Antenatal care provides an important opportunity to address smoking as women have close contact with the healthcare system for a protracted period. Currently, standard practice at NALHN is to refer women smoking in pregnancy to Quitline. However, women within the NALHN catchment area rarely engage with this service and find it unsuitable (Unpublished data from research project 'Women's experiences of smoking and quitting in pregnancy' CALHN HREC approval Q20190304). Data supplied to us *in confidence* from Quitline indicated that in the 2019 year there were only 31 referrals from NALHN. Therefore, this project is exploring different ways that health professionals might engage in conversations about smoking with pregnant women and assist with smoking cessation, specific to this highly vulnerable population.

The exploratory research described in this project involves introducing CO monitoring and financial incentives, both of which have been raised in our previous research involving pregnant women's lived experience of smoking (Unpublished data from research project 'Women's experiences of smoking and quitting in pregnancy' CALHN HREC approval Q20190304). Monitoring CO in expired air provides an opportunity for healthcare workers to discuss smoking and quitting support options with women who smoke during pregnancy [12, 15]. It can therefore be a motivating factor to quit and progress can be mapped with every quit attempt [16]. One Australian pilot study reported that CO readings were the most encouraging factor for cessation, more so than the offer of Nicotine Replacement Therapy (NRT) and a Quitline referral [16]. Other studies have reported that CO monitoring is a potentially cost-

effective means of encouraging smoking cessation, resulting in projected future savings for the healthcare system for smoking-related morbidity and mortality [17]. Similarly, women receiving financial incentives had higher rates of smoking cessation than those not receiving incentives [18]. Our previous research has revealed that women and midwives are interested in the potential for CO breath testing to facilitate conversations about smoking during pregnancy, and women are receptive to the idea of financial incentives (Unpublished data from research project 'Women's experiences of smoking and quitting in pregnancy' CALHN HREC approval Q20190304) [11]. The consensus was that incentives should be in voucher form, rather than cash.

Aim

Our aims are to conduct two qualitative pilot studies:

1. The first pilot study, will examine the feasibility and acceptability of CO monitoring during antenatal care.
2. The second pilot study, will examine the feasibility and acceptability of offering financial incentives.

Hypothesis

As this is a qualitative exploratory research project, we hypothesise that pregnant women will be willing to participate in the pilot trials and will share experience and attitudes about these motivating cessation interventions.

Outcomes

Primary Outcome

As these pilot studies are from a predominantly qualitative perspective, the primary outcome for this project is understanding the attitudes and lived experience/s of women who engage with CO monitoring and financial incentive interventions in antenatal care.

Project Design

Study Setting

Lyell McEwin Hospital (LMH) and Modbury Hospital antenatal clinics, NALHN

Participants for Pilot Trials

Inclusion criteria

- Women who are currently pregnant (any gestation) and smoke tobacco
- Aged 18 years or over
- Communicate in English without difficulty
- Receiving antenatal care from health professionals at NALHN
- Willing and able to give informed consent for participation in the study

Exclusion criteria

- Aged under 18 years
- Unable to communicate in English
- Are not able to provide informed consent for participation in the study
- Any pregnant woman who does not smoke tobacco or who quit smoking in pregnancy prior to meeting the researcher in the antenatal clinic

Anticipated start & finish dates

March 2021 – March 2023

Pilot Study 1: CO Monitoring (n=15)

Staff (obstetricians and midwives) in the antenatal clinic or Midwifery Group Practice (MGP) will conduct a brief eligibility screen of pregnant women who present for antenatal care. If a pregnant woman is identified by antenatal clinic staff as being a current smoker, they will be asked whether they consent to a conversation with the researchers about the project. The researchers will confirm a potential participant's eligibility and explain the nature of the study including what a CO monitor is and the information that can be obtained from CO breath analysis. The researchers will also answer any questions that may arise. It will be explained to women that they do not have to participate in the study and that their antenatal or general health care at NAHLN will not be affected by their decision to participate. It will also be stated that the participant is free to withdraw from the study at any time, for any reason, without prejudice to future care, and with no obligation to give the reason for withdrawal.

If a woman agrees to participate in the study, her contact details will be obtained, and she will be asked to read and sign a Participant Information Sheet and Consent Form (PICF). Electronic consent will be obtained by means of dated signature on a study tablet. A copy of the PICF will be given to the participant.

Participants will be asked to complete a 5-minute questionnaire including sociodemographic information and smoking history (Appendix 'Questionnaire Pilot Trials'). Once consent has been given and the questionnaire completed, an audio recorder will record the interaction that follows.

Women will be asked to use a calibrated CO monitor (PiCO Baby Smokerlyzer). CO breath analysis involves the person taking a breath and holding it for 15 seconds, then blowing into a mouthpiece attached to the CO monitor to empty their lungs. CO readings are then displayed on the monitor for both the mother and the fetus. The CO level will be explained to the participant with a poster (visual aid) provided by the manufacturer, which shows maternal and fetal CO content of blood. CO readings will be documented and researchers will discuss the following with participants:

- How did you find using the CO monitor?
- How did you find reading the output on the monitor and poster? Did it make sense?
- What is your understanding of why we are using a CO monitor?
- What are your thoughts having seen your and your baby's CO amount?
- How were you feeling about smoking before the reading? What about after?
- Does using the monitor make you feel like you want to change your smoking?

It is possible that women will be concerned about the CO in their or their baby's blood and/or their smoking. The researcher will then discuss with participants and provide information on supports available to women. This will take two forms. The first refers to mental health services available to women at NALHN and in the community. The second refers to smoking cessation strategies and supports available to pregnant women should the participant make the decision to quit smoking. These supports will also be provided in a handout for women to take home with them (Appendix 'Smoking Cessation & Support Resource'). Researchers will be available to assist women with accessing mental health supports and taking steps to initiate smoking cessation should they desire to do so. Participants will also be asked if they would like the research team to contact their GP about their involvement in the study. This would involve a letter sent to the GP by mail or email (see Appendix 'GP Letter Template') explaining the study and indicating one of their patients is enrolled and would like follow up care. Verbal consent will be obtained from the participant to take GP contact

details in order to send the letter. The audio recording will cease at this point and arrangements will be made for the 4 week follow up appointment with researchers. Women will have the option of meeting with the researcher at NALHN at their next antenatal appointment, at a local community centre, or having a home visit in the community from the researcher (see 'Researcher Safety' in ethical considerations). The time, date and place will be organised at this time. If the location organised to meet the researcher at the 4 week follow up is at a community centre participants will be offered Cab-Charge vouchers for their return trip.

Two to three days after the CO monitoring discussion in the antenatal clinic, participants will receive a courtesy call from the researcher. This call is to check on the participant and determine if they require additional support. We will attempt to contact women for a maximum of 3 occasions. If there is no answer a voicemail message will be left (if available) or a follow up text message will be sent in which women will be encouraged to contact researchers or the health service if they are having difficulty organising support for mental health problems related to using the monitor or if they are having difficulty with quitting.

At the 4 week follow up appointment, researchers will meet participants at NALHN, community centre, or the participant's home. This follow up will allow women time to reflect on the CO monitoring previously conducted and to see if changes in smoking behaviour had been attempted as a result. At this appointment participants will be asked to use the CO monitor for a second time and answer follow up questions. This interaction will also be audio recorded. CO readings will be documented and researchers will discuss the following with participants:

- Have you reflected on the initial CO monitor reading in the last 4 weeks? What are your thoughts?
- Is the second reading what you expected?
- Has anything changed in terms of your smoking in the last 4 weeks? Was this prompted by your initial CO reading?
- If you have changed your smoking, what has this involved? What worked best? What didn't? Do you think you would have made these changes had you not used the CO monitor?
- What do you think of the idea of using the CO monitor more broadly, in the antenatal clinic here?
- How do you propose we use the CO monitor in antenatal care?

The interviews will be audio recorded with explicit consent of participants. The data collected will be transcribed by CI Fletcher or a transcriber who has signed a confidentiality agreement with the University. Transcriptions will be analysed using thematic analysis [19]. This will allow the researchers to identify and interpret important themes and differences from this data, and to understand women's experiences, meanings, and realities. Personal identifiers will be removed and replaced by a pseudonym. Participants will receive a $50 reimbursement in the form of a voucher for time given to participate in the study. This will be given to participants at the 4 week follow up appointment.

Pilot Study 2: Financial Incentives (n=15)

Staff (obstetricians and midwives) in the antenatal clinic or Midwifery Group Practice (MGP) will conduct a brief eligibility screen of pregnant women who present for antenatal care. If a pregnant woman is identified by antenatal clinic staff as being a current smoker, they will be asked whether they consent to a conversation with the researchers about the project. The researchers will confirm a potential participant's eligibility and explain the nature of the study including what a CO monitor is, how it can be used with financial incentives to encourage smoking cessation. The researchers will also answer any questions that may arise. It will be explained to women that they do not have to

participate in the study and that their antenatal or general health care at NALHN will not be affected by their decision to participate. It will also be stated that the participant is free to withdraw from the study at any time, for any reason, without prejudice to future care, and with no obligation to give the reason for withdrawal.

If a woman agrees to participate in the study, her contact details will be obtained, and she will be asked to read and sign a Participant Information Sheet and Consent Form (PICF). Electronic consent will be obtained by means of participant dated signature on a study tablet. A copy of the PICF will be given to the participant.

Participants will be asked to complete a 5-minute questionnaire including sociodemographic information and smoking history (Appendix 'Questionnaire Pilot Trials'). Once consent has been obtained and the questionnaire completed, an audio recorder will record the interaction that follows. Participants will be asked the following:

- How do you feel about being offered money to quit smoking?
- How were you feeling about smoking before being offered a financial incentive to quit? What about after?
- What do you think about the value of $100 after 4 weeks for quitting? Do you think it should be more or less?

Women will then be asked to use a calibrated CO monitor (PiCO Baby Smokerlyzer). Baseline CO readings for all women will be documented.

To support women with quitting and be able to receive the incentive, the researcher will then discuss quitting options with participants. They will also be given a brochure (Appendix 'Smoking Cessation & Support Resource') with information about smoking cessation strategies and supports available to pregnant women for quitting (Appendix 'Smoking Cessation & Support Resource'). This brochure also includes mental health supports available at NALHN and in the community. Researchers will be available to assist women with accessing mental health supports and taking steps to initiate smoking cessation should they make the decision to do so. Participants will be asked if they would like the research team to contact their GP about their involvement in the study. This would involve a letter sent to the GP by mail or email (see Appendix 'GP Letter Template') explaining the pilot study and indicating one of their patients is enrolled and would like follow up care. Verbal consent will be obtained from the participant to take GP contact details in order to send the letter. The researcher will also discuss that environmental factors and second-hand smoke (SHS) can affect the results of the CO monitor. The audio recording will cease at this point and arrangements will be made for the 4 week follow up with researchers. Women will have the option of meeting with the researcher at NALHN at their next antenatal appointment, at a local community centre, or having a home visit by the researcher (see 'Researcher Safety' in ethical considerations). The time, date and place of the follow up appointment will be organised at this time. If the location organised to meet the researcher at the 4 week follow up is at a community centre participants will be offered Cab-Charge vouchers for their return trip.

Two to three days after the first meeting with the researcher in the antenatal clinic, participants will receive a phone call from the researcher. This call is to check on the participant and determine if they require additional support. We will attempt to contact women for a maximum of 3 occasions. If there is no answer a voicemail message will be left (if available) or a follow up text message will be sent in

which women will be encouraged to contact researchers if they are having difficulty organising support for mental health or if they are having difficulty with initiating quitting.

At the 4 week follow up appointment, researchers will meet participants as organised at the first meeting (at NALHN, community centre or the participant's home). At this appointment participants will be asked to use the CO monitor for a second time and answer follow up questions. Manufacturers recommendations and midwifery resources from the United Kingdom consider readings of 4ppm as a cut-off, with a published sensitivity of 0.89 and specificity of 0.86 [20]. Thus, if the CO reading for a participant is 4ppm or less, the participant will receive a $100 gift voucher for successfully quitting. If the CO reading for a participant is 5ppm or above, then the participant will receive a $50 gift voucher for their involvement in the study. This interaction will also be audio recorded. CO readings will be documented and researchers will discuss the following with participants:

- Is the second reading what you expected?
- If CO reading ≤4ppm
    - How did being offered the financial incentive affect your decision to quit?
    - Which cessation techniques (if any) did you try?
    - Which of these helped?
    - How did your family and friends respond?
    - What do you plan to do about smoking in the future?
- If CO reading ≥5ppm
    - Did your smoking change in the last 4 weeks?
    - Did being offered the incentive affect your smoking?
    - Did you attempt/try any cessation techniques? Did any help?
    - What supports do you have from family or friends?
    - If you wanted to quit but couldn't, what barriers existed for you in trying?
    - What do you plan to do about smoking in the future?
- What do you think about the health service offering financial incentives to encourage pregnant women to quit? How do you think pregnant women would respond?
- After your experience in the last 4 weeks, how much money you think is the right amount to help pregnant women to quit?
- Should that be given in one amount or at different times during pregnancy?

The interviews will be audio recorded with explicit informed consent of participants. The data collected will be transcribed by CI Fletcher or a transcriber who has signed a confidentiality agreement with the University researchers. Transcriptions will be analysed using thematic analysis [19]. This will allow the researchers to identify and interpret important themes, and differences from this data and to understand women's experiences, meanings, and realities. Personal identifiers will be removed and replaced by a pseudonym.

Feasibility and time period for recruitment

NALHN has ~4,000 births per year, 20% of which are to smokers (800 smokers per annum: 67 per month). We will recruit a total of 30 women across the two pilot trials. CI Dekker has previously recruited over 50% of eligible participants in other pregnancy studies, indicating the 30 proposed here is feasible.

We are liaising with the following staff at NALHN to support the recruitment into the pilot trials: Directors of the Women's and Children's Division, Meredith Hobbs and Dr Martin Ritossa, Academic Head of Obstetrics, Professor Gus Dekker, and Nursing Unit Managers.

Sample size

This is a pilot (feasibility) study. In our previous work on the lived experiences of smoking in pregnancy we recruited and interviewed 17 women and reached saturation. We anticipate recruiting 15 women for each of the pilot trials (30 women in total) though the final numbers will be driven by reaching saturation and by funding available. Low attrition is anticipated as the trial is embedded in routine care. Women are highly motivated to attend antenatal clinics with women who smoke attending an average of 10 antenatal visits.

Withdrawal of Participants

Participants are free to withdraw from the study at any time, for any reason, without prejudice to their future care, and with no obligation to give the reason for withdrawal. In case of withdrawal, the participant will be asked whether they would be willing to sign a withdrawal form and whether the data collected can still be used in the trial.

COVID-19 Precautions

Contact with trial participants will follow and be consistent with the most current public health advice on behavioural responses to the pandemic (e.g. social distancing, optimal hygiene practices). The research team will not attend NALHN if they are unwell, have a fever, cough and/or sore throat, have been in contact with any person/s with a respiratory illness (e.g. cough, shortness of breath) in the last two weeks, or are required to be in social isolation, as per the government regulations.

Researchers will be provided with a detailed orientation to the antenatal clinics and assessed to demonstrate competence in all local infection control, isolation, 5 moments of hand hygiene, Personal Protective Equipment use and escalation practices.

While recruiting and conducting the study, the research team will practice social distancing (minimum of 1.5 m between people and no more than one person per 2 m^2 in larger spaces). The researchers may be required to undertake additional direction as advised by the Nursing Unit Manager or their delegate on the ward at any time, this may include but not be limited to, the use of non-sterile gloves during the CO monitoring procedure and/or the wearing of a surgical mask by the researcher during the CO procedure. Prior to using the CO monitor, the researcher and pregnant woman will perform hand hygiene using an alcohol-based hand sanitiser. A new mouthpiece is used with the CO monitor for each person on each occasion. The mouthpieces are hygienically wrapped and single use only. Following each use, the external surfaces of the monitor and D-Piece will be wiped with neutral detergent wipes. The D-Piece will be visually inspected after each use and cleaned. If visibly soiled or contaminated it will be discarded and replaced by a new D-Piece. According to the manufacturer, the Bedfont piCO baby Smokerlyzer D-Piece has been tested to filter viruses as small as 24 nanometres in diameter. The COVID-19 virus particle has an approximate diameter of 125 nanometres. The manufacturer has concluded that bacterial and viral pathogens (including COVID-19) will be effectively removed by the D-Piece filter. The monitor and D-Piece will be allowed to air dry prior to its next use.

If restrictions prevent research staff from accessing the clinic, hospital staff will provide eligible participants with a study iPad containing the electronic participant information and consent form. If the participant would like further information, then a research staff member can discuss the trial with the participant over the phone. The iPad will be cleaned with alcohol-based wipes before and after every use. In times where restrictions to research staff do not apply, the trial coordinator will meet with participants as per protocol requirements and answer any questions they may have in person.

Data Handling, Confidentiality and Management

Baseline data will be collected using REDCap software and stored on the University's password-protected server. In-depth interviews will be captured on a voice-recording device. The recording will be uploaded to a University password-protected server, transcribed, and then deleted. The audio recordings of interviews will be transcribed by CI Fletcher or a paid transcriber who will have signed a confidentiality agreement that acknowledges participants' names, identifying details and the content of the interview must remain confidential. Identifying details (such as participant names) will be removed from the transcriptions at the earliest time point. Only the researchers will have access to identifiers which will be securely stored separately from the transcripts and audio recordings on the University of Adelaide's secure server. The investigators named in the application will take all reasonable steps as outlined in the Privacy Act, the NHMRC Australian Code for the Responsible Conduct of Research, and Code of Fair Information Practice to protect the information from misuse and loss, and from unauthorised access, modification or disclosure.

All study data will be captured using REDCap (Research Electronic Data Capture), a secure web application for building and managing online questionnaires and databases. Baseline data will be entered onto a study specific, web-based module within REDCap via study computers or electronic tablets (iPad). No participant identifiers will be entered in REDCap. All data will be linked to a unique trial number within REDCap. Data from here can be exported to statistical software for analysis.

The electronic device will be password protected and data will be uploaded to a protected directory on the University of Adelaide's secure server, in a folder accessible only via a university log-on and password. Access to the data will be restricted to the named investigators. Any written data will be scanned and securely stored electronically. Paper records containing sensitive information will be disposed in secure waste. Electronic data will be stored on password-protected computers on the University of Adelaide's secure network that also utilises anti-hacking software to prevent unauthorized access. Records and materials will be retained for seven years after the publication of research findings. After this, all copies of the participant identifiers will be deleted. Any sensitive paper output generated during the trial will be kept in locked filing drawers and offices and will be disposed in a confidential waste bin that is securely destroyed by cross-shredding.

At the end of every day of use, the CO monitors will be calibrated and stored securely in a locked filing cabinet in the University of Adelaide precinct, Level 2, Women's Health building at the Lyell McEwin Hospital.

Individual participants will not be identified in any publications, quotes from participants will be identified using pseudonyms, and reporting of potentially identifying events will be avoided.

Data may otherwise be discoverable through processes of law or for assessing compliance with research procedures. Participants will have the right to access the information collected and stored by researchers about their own data. Participants will also have the right to request that any information with which they disagree be corrected.

Due to time and budget constraints, participants will not be offered the option of reviewing transcripts or report drafts prior to publication. However, a summary of key findings will be made available to participants via email or mail.

Ethical Considerations

The applicants have no financial, private, professional or insitutional conflicts to declare.

Participant Safety

As detailed above, when a participant has enrolled in either of the trials, signed consent and used the CO monitor, the researcher will discuss cessation methods available for use in pregnancy and provide information of the mental health supports available through NALHN and in the local community, should they require them. All participants will be given the 'Smoking Cessation & Support Resource' (Appendix 'Smoking Cessation & Support Resource') and will have the opportunity to discuss with a researcher the content of this information. Researchers will be available to assist women with accessing mental health supports and taking steps to initiate smoking cessation should they make the decision to do so.

Also, three days after the first meeting with the researcher in the antenatal clinic, participants will receive a phone call from the researcher. This call is a welfare check to determine if additional support is required. Women will again be encouraged to contact researchers if they are having difficulty organising support for mental health or if they are having difficulty with initiating quitting. Three attempts to contact participants will be made.

Researcher Safety

At the 4 week follow up appointment in both pilot trials, the option of a home visit for participants will be offered. This will only be offered if meeting at NALHN or a community centre cannot be arranged. If a home visit is to occur, two researchers will be present. Researchers will not enter a participants' dwelling. Use of the CO monitor, follow up questions and receiving the voucher will occur outside the home. The researchers conducting the home visit will text a member of the research team (i.e. researcher not participating in the home visit) on arrival to the destination (including the address of the home visit) and on departure from the destination. If an hour has passed from the arrival text message and the external researcher has not received a text from the home visiting researchers, they will attempt to call the researchers. If this call is not answered then police will be contacted and asked to attend the address.

Data Ownership

Data that is generated from this study, as well as the protocol will be owned by the University of Adelaide. The University of Adelaide will also be responsible for fund management of this project.

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