PARTICIPANT INFORMATION SHEET

PROJECT TITLE: Smoking in Pregnancy: a randomised controlled trial to test whether financial incentives will help women to quit.

ETHICS APPROVAL NUMBER: 2022/HRE00310

Coordinating Principal Investigator: A/Prof Lisa Smithers
University of Adelaide
lisa.smithers@adelaide.edu.au

LOCATION: Northern Area Local Health Network (NALHN; Lyell McEwin and Modbury Hospitals)

You are invited to take part in this research project, which is called 'Smoking in Pregnancy: a randomised controlled trial to test whether financial incentives will help women to quit'. You have been invited to participate because you are pregnant, currently smoking cigarettes and accessing antenatal care with NALHN. Your contact details were obtained from staff at NALHN with your consent.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with your partner, a relative, friend or a health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide to take part on the research project, you will be asked to sign the consent section.

By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the use of your personal and health information as described

You will be given a copy of this Participant Information and Consent Form to keep.

Why am I being invited to participate?
We are testing whether financial incentives might help pregnant women quit smoking. As you are currently pregnant and a smoker, we would like to know if offering you a series of vouchers (total value $600) antenatally helps you successfully quit smoking.

What is the project about?
In the northern suburbs of Adelaide, a high proportion of pregnant women who receive antenatal care at NALHN smoke cigarettes. Midwives and doctors ask women about their smoking and routinely provide Quitline referrals, but not many women use this service. In the United States of America, Scotland and New Zealand financial incentives have helped pregnant women to quit smoking. Our initial research has shown that financial incentives may be strategy that is acceptable to pregnant women. We are interested to see if offering a financial incentive to pregnant women might help them to quit.

If you agree to participate in this study, we will first ask you to breathe into a carbon monoxide (CO) monitor. Smoking tobacco increases the amount of CO in your blood. The CO monitor measures the CO levels in your blood and confirms your smoking status. Using the CO monitor involves taking a breath and holding it for 15 seconds, then blowing into a mouthpiece attached to the monitor to empty your lungs. A new mouthpiece is used for each person on each occasion. The mouthpieces are hygienically wrapped and single-use only. A reading will be displayed on the monitor of how much CO is in your breath. If your CO reading is 3 ppm or lower, you will take no further part in the study. A reading of 4 ppm or above shows you are a smoker. If your reading is 4 ppm or higher you will then complete a questionnaire asking you some demographic information. You will also be asked about your smoking history and current use of tobacco, e-cigarettes and cannabis, previous quit attempts, what things you have tried to quit, and whether you intend on quitting. Questions about your financial wellbeing will also be asked. It is estimated that this questionnaire will take approximately 15 minutes to complete.

We will then discuss and provide you with some information about supports available and quitting methods you can use in pregnancy. It is important for you to know that secondhand smoke (cigarette smoke you inhale from people smoking close to you) can affect the result of the CO monitor. If you have quit smoking, but have been around people who smoke, this could affect the reading of the CO monitor.

You will then be randomly allocated to the intervention or control group. If you are allocated to the control group, you will be asked to breathe into a CO monitor at your regularly scheduled antenatal appointments approximately 4 and 12 weeks after you enrol in the study. At 37 weeks of pregnancy, you will again be asked to breathe into a CO monitor as well as provide a urine sample (which will also check your nicotine levels and smoking status). You will be provided a $50 gift voucher for your participation.

If you are randomised to the intervention group, you will also be asked to breathe into a CO monitor at your regularly scheduled antenatal appointments approximately 4 and 12 weeks after you enrol in the study. At 37 weeks of pregnancy, you will again be asked to breathe into a CO monitor as well as provide a urine sample (which will also check your nicotine levels and smoking status). If you successfully quit smoking (determined by a negative CO breath analysis of ≤3 ppm), you will be offered a series of gift vouchers. These will be provided at 3 visits if you remain abstinent. At 2 weeks following your quit date, you will be provided with a $50 voucher if you have a negative CO breath analysis. At 12 weeks following your quit date, you will be provided with a $150 voucher if you have a negative CO breath analysis. At your appointment at 37 weeks of pregnancy, you will be provided with a $400 voucher if you have a negative CO breath analysis. If you do not successfully quit straight away, you will be provided with a voucher if you quit in a later point of your pregnancy, but it will start at the lower amount e.g. if you quit 12 weeks after your quit date, you will receive $50 and if you remain abstinent at 37 weeks of pregnancy, you will receive $150. To receive the maximum amount of $600 in vouchers, you must be abstinent on all 3 visits when CO is tested.

At the antenatal visits, you will also be asked to complete questionnaires. At the 4- and 12-week visits, you will be asked if you have smoked since your last visit and what things you have used to help you quit. At the visit at 37 weeks of pregnancy, you will also be asked if you have smoked since your last visit and what things you have used to help you quit. Additionally, you will be asked a series of questions which record anxiety (Antenatal Risk Questionnaire), and depression in the antenatal

period (Edinburgh Postnatal Depression Scale), and questions which measure your social support (Multidimensional Scale of Perceived Social Support). The anxiety and depression questionnaires include some sensitive items that may raise concerns for some people. If you have high scores on the anxiety or depression questionnaires you will be contacted by a member of NALHN staff for further consultation and you may be offered additional health care or services.

Relevant information from your electronic medical records will also be obtained from a trained researcher who is part of the study team. This will include information on your pregnancy, labour, birth and your child (including past pregnancies) which is relevant to the study. Obtaining the information in this way will mean that we don't have to ask you unnecessary questions. This will reduce the amount of time needed to participate in the study.

If you are assigned to the intervention group, you will also be asked to take part in an interview at around 37 weeks of pregnancy or earlier. You would be asked questions about your experiences of the intervention and would be provided with a $50 gift voucher for your time.

If you are allocated to the control or intervention group, the trial coordinator will contact you 6 months after your baby is born to organise an appointment in your own home or a location in the community. At this appointment, you will be asked to provide a further CO breath sample at this appointment, and you will be asked some questions about smoking and your child's height, weight and head circumference. You will be provided with a $50 gift voucher for attending the appointment.

How much time will my involvement in the project take?

In terms of time commitment for the appointments, the initial appointment should take approximately 30 minutes. The 4-week and 12-week appointments 10 minutes each, where you will be asked to answer some brief questions and provide a CO breath sample. You will be issued a voucher if your CO breath analysis is ≤ 3 ppm. The 37-week appointment is 30 minutes, where you will be asked to answer additional questions and provide a CO breath sample and a urine sample. You will again be issued a voucher if your CO breath analysis is ≤ 3 ppm. The 6-month follow-up appointment should take no longer than 15 minutes, where you will be asked to provide another breath sample and will be issued a $50 voucher. If you are in the intervention group and take part in the interview, this should take no longer than 15-30 minutes.

Who is undertaking the project?

This project is being undertaken by NALHN (Lyell McEwin and Modbury Hospital) in collaboration with the University of Adelaide, School of Public Health, Prof. Lisa Smithers, Prof. Gus Dekker, Prof. John Lynch, Prof. Lyle Gurrin, Prof. Stefanie Schurer, Dr. Elizabeth Hoon, Dr. Megan Hammersley, Ms. Marnie Aldred, Dr. Julia Dalton, and Ms Cherise Fletcher.

This project is being funded by the Medical Research Future Fund.

What are the potential benefits of the research project?

The benefit of being involved in this study is it may give you an opportunity to think differently about your smoking. You will also be able to help others in the community by reflecting and sharing your views on being offered a financial incentive to quit smoking.

What are the potential disadvantages of the research project?

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may withdraw from the discussion, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team.

Can I withdraw from the project?

Participation in this project is completely voluntary. If you do not wish to take part, you do not have to. If you agree to participate, you can withdraw from the study at any time. Either agreeing or disagreeing to participate in this study will not affect any future health treatment or care, or any relationships with professional staff at NALHN or community organisations. Also, you can choose not to answer a question from the interviews at any time. However, following participation in the interviews you will not be able to withdraw your contribution. Individual contributions will not be able to be identified.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results.

What will happen to my information?

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. All study data will be stored on a secure web application. No personally identifying information will be entered into this application. Audio recordings and data from interviews will be transcribed by a paid transcriber who has signed a confidentiality agreement. Any identifying information will be removed from the transcription. The transcription will be kept confidential and stored securely by the researchers on the University of Adelaide server for at least 15 years. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law. A dataset containing information only about quitting status (yes or no), age and number of pregnancies will be posted on a scientific website to allow independent confirmation of the study findings. All personally identifying information will be removed.

The results of this study may be presented and published in academic journals and presented at conferences. You will not be identified in any publications. We may use quotes from the recordings but all identifying information or events will be removed.

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

At the end of the study, we will send you a summary of the findings via email or mail.

Who do I contact if I have any questions about the project?

If you are interested in participating, or have any questions or would like additional information, please contact the Principal Investigator.

Principal Investigator	Associate Professor Lisa Smithers
Telephone	0466 458 274
Email	lisa.smithers@adelaide.edu.au

What if I have a complaint or any concerns?

The study has been approved by the Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee. This research will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research (2007). If you have questions or problems associated with the practical aspects of your participation in the project, or wish to raise a concern or complaint about the project, then you should consult the Principal Investigator. If you wish to speak with an independent person regarding concerns or a complaint, SA Health's policy on research involving human participants, or your rights as a participant, please contact the CALHN Human Research Ethics Committee.

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Support Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

CONSENT FORM

PROJECT TITLE: Smoking in Pregnancy: a randomised controlled trial to test whether financial incentives will help women to quit.

ETHICS APPROVAL NUMBER: TBC

Coordinating Principal Investigator: A/Prof Lisa Smithers
University of Adelaide
lisa.smithers@adelaide.edu.au

LOCATION: Northern Area Local Health Network (NALHN; Lyell McEwin and Modbury Hospitals)

Declaration by Participant

I have read the Participant Information Sheet

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without it affecting my future care.

I understand that I will be given a signed copy of this document to keep.

☐ I understand that by participating in this study, my medical records will be accessed to obtain information relevant to the trial including current and any past pregnancies, labour, birth and my child **(please tick).**

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe the participant has understood the explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

WITHDRAWAL OF PARTICIPATION

PROJECT TITLE: Smoking in Pregnancy: a randomised controlled trial to test whether financial incentives will help women to quit.

ETHICS APPROVAL NUMBER: TBC

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University of Adelaide
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LOCATION: Northern Area Local Health Network (NALHN; Lyell McEwin and Modbury Hospitals)

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or NALHN.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the researcher must provide a description of the circumstances below.

Declaration by Researcher

I have given a verbal explanation of the implications of withdrawal from the research project and I believe the participant has understood the explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.