Teaching by Texting to Promote Health Behaviours in Pregnancy

Principal Investigator: Dr. Patricia Janssen, PhD
Professor, School of Population and Public Health.
University of British Columbia
604-875-2345 ext. 2314

Sponsor(s)/Funder: Canadian Institutes of Health Research.

Contact Information

You can contact the Research Manager, Dita Puspitarani, toll free at 1-855-871-BABY (2229) or by email at contact@smartmomcanada.ca.

Invitation

You are being invited to take part in this research study because you are 15 weeks pregnant or less, carrying only one baby, are 15 years of age or older, able to read and understand English and living in Canada, outside of British Columbia. We expect to have 3160 participants in the study overall.

Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving. Please review the consent form carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant. Please take time to read the following information carefully and to discuss it with your family, friends, and care provider(s) before you decide.

Who is conducting this study?

The study is led by Dr. Patricia Janssen, a registered nurse and Professor at the UBC School of Population and Public Health.

Study investigators include:
Dr. H. Bayrampour, PhD, an Associate Professor in the UBC Midwifery program with expertise in perinatal mental health
Dr. J. Coleman, PhD, a technical assistant at the Centre for International Child Health at BC Children's Hospital
Dr. C.-L. Dennis, PhD, Professor in Nursing and Psychiatry at the University of Toronto

Dr. N. Fairbrother, PhD, a perinatal psychologist and Clinical Associate Professor in the UBC Department of Psychiatry
S. McDonald, PhD, Adjunct Assistant Professor in the Departments of Paediatrics & Community Health Sciences at the University of Calgary
Dr. N. Muhajarine, PhD, Professor and Chair, Community Health and Epidemiology, University of Saskatchewan
Dr. S. Munro, PhD, Co-Applicant, an Assistant Professor in the UBC Department of Obstetrics and Gynecology
J. Murray, MPH, a doctoral student and former Research Manager for the First Nations Health Authority
Dr. W. Norman, MD, MHSc, an Associate Professor in the UBC Department of Family Practice
Dr. R. Renner, MD, MPH, FRCSC, a practicing obstetrician and Clinical Associate Professor in the UBC Department of Obstetrics and Gynecology
Dr S. Tough, PhD, a Professor with the Departments of Paediatrics and Community Health Sciences at the University of Calgary.
Dr. W. Zhang, PhD, an Assistant Professor at the UBC School of Population and Public Health and the Program Head of Health Economics at the Centre for Health Evaluation and Outcome Sciences

Who is funding this study?

This study is funded by the Canadian Institutes of Health Research.

Background

SmartMom is a prenatal education program in which research -based texts are sent to parents to guide them through each week of pregnancy. Messages are specific to each week of pregnancy and contain links to websites, phone numbers and videos on topics such as fetal growth and development, options for screening in pregnancy, and being prepared for labour and delivery. The SmartMom program was developed to support expectant parents with making healthy choices for pregnancy and childbirth.

What is the purpose of the study?

The purpose of this study is to determine if healthy pregnant people participating in the SmartMom prenatal texting program experience improved knowledge about healthy pregnancy, labour and birth and improved pregnancy outcomes compared to those who are not in the program.

We aim to learn if participation in SmartMom improves mental health outcomes, decreases fear of childbirth, supports appropriate weight gain and attendance at prenatal care

appointments, improves understanding of choices for screening tests in pregnancy, supports avoidance or reduction of tobacco, alcohol, and cannabis use, and results in better infant health outcomes. We will post the study results on our website, through our social media, and in newspapers.

Who can participate in this study?

You may be able to participate in this study if you are pregnant and:

- are 15 weeks pregnant or less
- are carrying one baby
- are 15 years of age or older
- have a cell phone with cell and internet access
- can read and understand English at a grade 8 level and are comfortable completing online surveys
- live in Canada (excluding British Columbia)

We may request documentation showing your name and due date and/or gestational age such as an ultrasound report or document from your care provider. You may block any other information on these documents that you do not wish to share. If we cannot determine you are eligible, you will not be enrolled in the study or you will be withdrawn if already enrolled.

Who should not participate in this study?

You will not be eligible to participate in this study if you have a health condition that existed prior to your current pregnancy that require individualized care including medication, such as:

- high blood pressure
- heart disease
- diabetes

or if you have previously had a baby while participating in the SmartMom program.

What does the study involve?

Overall design of the study

This is a two-arm randomized controlled trial, meaning that participants will be randomly assigned to one of two study arms: an intervention arm and a control arm.

Participants enrolled in the intervention arm will receive the SmartMom program, which sends three SMS text messages each week for 41 weeks.

Participants in the control arm will receive weekly messages about general interest topics related to pregnancy and updates about the study progress.

Participants in both study arms will be assisted to enroll in our SmartParent program after having the baby, if they so choose. SmartParent is a text messaging program similar to

SmartMom, but delivers messages for the first year of parenting. Participation in SmartParent is optional and not a requirement of participation in the study.

If You Decide to Join This Study

If you agree to take part in this study, you will be asked to complete three questionnaires:

- one at the time you enroll
- one when you are 38 weeks pregnant
- one after you give birth.

These should each take approximately 10 minutes or less to complete. You do not have to answer any question you do not wish to. Our study questionnaires ask questions about general knowledge related to pregnancy, lifestyle choices, and pregnancy outcomes and include questions from standardized measures of anxiety, depression and fear of childbirth.

Only study staff and investigators, will have access to your questionnaire answers. Answers provided to study investigators for analysis will not be linked to your personal information. This means that study staff will not be able to see or link your personal identifying information to you or your answers.

Remuneration

The study will provide Amazon or similar gift cards for $15, $20 and $25 for completing the enrollment, 38-week and follow-up survey, respectively. The gift cards will be sent by text within 4 weeks of completing the survey.

Use of Data from Secondary Data Sources that Use Identifiable Information

As part of this study, we are also requesting that you provide your personal health number (PHN) through a secure online portal. Your PHN would allow us to measure health outcomes such as number of prenatal visits attended, and interventions in labour and delivery, such as caesarean delivery rates, and infant outcomes, such as premature birth, in an anonymous fashion.

To do this, we will send your PHN and your study allocation (which trial arm you are in) in a safe, encrypted fashion to your province's perinatal data registry and the Canadian Institute for Health Information. Data about your pregnancy and birth will then be sent to the research team but without your PHN attached. Only the study staff and investigators will have access to your PHN and it will not be linked to your study data, survey answers, or health outcomes.

Memotext

Memotext is the Canadian tech company that delivers the SmartMom program via SMS texting. Memotext will have access to your phone number to deliver the program and will hold data about your participation (e.g. messages received, estimated due date) on their servers in Ontario. Their data storage policies are compliant with Canadian privacy regulations. Canadian policy requires that data, be stored for 15 years then destroyed. Memotext is not owned or governed by the University of British Columbia or any Health Authority. Memotext will not be using the stored data for any purpose other than what is described in the consent form.

What are the possible harms or discomforts?

We have not identified any risks associated with receiving text messages or completing study questionnaires. Participants will receive their scores after completing questionnaires that measure anxiety, depression, and fear of childbirth, along with interpretation of these scores and resource information if scores are concerning. In particular, if a participant indicates a severe degree of depression with the potential of self-harm, they will receive a text message, urging them to seek help accompanied by links to online information about resources and an invitation to call our study coordinator on our toll free number for assistance in accessing resources. The response to a call to the toll-free number may take up to 24 hours, however, the text with the resource list will be immediate. The study staff respondent will not offer direct aid, but will help you to use the list of resources already provided. There is a risk, as with all research, that participants' personal information is accidentally released, but measures are in place to prevent this and this risk is quite small.

What are the possible benefits of participating?

There may not be direct benefit to you from taking part in this study. We hope that the information learned from this study can be used in the future to benefit other pregnant people.

What are the alternatives to the study treatment?

If you choose not to participate in this study or to withdraw at a later date, you may attend prenatal education classes in your community or seek pregnancy information on publicly available websites or apps. Participation in the study does not prevent you from accessing prenatal education classes or other sources of pregnancy-related information online. You can discuss these options with your maternity caregiver before deciding whether or not to participate in this research project.

After the study is finished.

We will make available the results of the study on our website and in press releases as well as in academic publications. If the study results are positive, we may choose to undertake commercialization of SmartMom. It is possible that a product may be created or re-developed from the results of this study. The product may be sold and the researchers might make

money. You will have no rights to receive payments or money from any products that may be created from this study or any future research studies using this research data. Dr. Patricia Janssen and Sara Leckie are owners of a newly created business, called SmartParent Mobile Health Inc, which is involved in the commercialization of SmartMom. If you have any concerns or questions about this, please contact study team member Dita Puspitarani at dita.puspitarani@ubc.ca

What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the study team will have a discussion with you about what will happen to the information about you already collected. You have the right to request the destruction of your information collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note, however, that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please contact the study team.

How will my taking part in this study be kept confidential?

Your confidentiality is respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the University of British Columbia/Children's and Women's Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

Answers to questionnaires will be reported in aggregate—that is, results will be reported for groups and not for individuals. You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number or your name, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. Further details about these laws are available from study staff. Federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. We will not give information that identifies you to anyone without your permission, except as required by law.

For the current study, your phone number, answers to your questionnaires and your PHN will be stored in a secure server hosted by the BC Children's Hospital Data Management Team in Vancouver, BC in a manner compliant with Canadian privacy regulations. To transfer your PHN numbers to provincial or national data registries, we will encrypt them and send them using a dedicated secure file transfer server. Your health data will then be sent back to the researchers using the secure server in an encrypted file with the PHN removed and no identifying information attached.

Disclosure of Race/Ethnicity
Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence how people respond to different medications. You should be aware that providing this information is not mandatory.

What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights.

If I have questions about the study procedures during my participation, who should I speak to?

If you have any questions or desire further information about this study before or during participation, you can contact Dr. Patricia Janssen at 604-875-2345 ext. 2314.

Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, or privacy-related complaints, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598.) Please reference the study number (H22-00603) when calling so the Complaint Line staff can better assist you.

Signatures

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Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.

I will receive a dated copy of this consent form for my own records.

{Tickbox} I consent to participate in this study.

First Name_____**Last Name**_____