PARTICIPANT INFORMATION AND CONSENT FORM: HOUSEHOLD MEMBER - ENHANCED USUAL CARE GROUP

SMARThealth Caribbean Cluster Randomised Trial

Title of Study: A cluster randomised type 2 implementation-effectiveness trial of a community based digital intervention to improve cardiovascular health in the first year after birth in women who experience a high-risk pregnancy and their household members in the Caribbean

Short Title: SMARThealth Caribbean Cluster Randomised Trial: [COUNTRY]

Principal Investigator: [Insert COUNTRY PI name, institutional address, phone number and email]

Co-Investigators: [Insert COUNTRY Co-Investigators names, institutional address, phone number and email]

Funding Source: RIGHT 7, National Institute of Health Research, UK

INTRODUCTION

You are invited to participate in this research study because you are an adult member of the household of a woman who recently had a pregnancy affected by a high-risk condition known as an adverse pregnancy outcome (APO). These conditions may increase her risk of heart disease later in life. Because cardiovascular risk factors often affect families, this study also includes household members to better understand and support the health of the whole household.

This information is provided to help you understand the study, including its risks, benefits, and what participation involves, so that you can decide whether or not to take part. After reviewing and understanding the details, you choose to sign it if you wish to participate. Take your time with your decisions and consider your options. Additionally, feel free to discuss the details of this study with your family members or friends. You may also be asked if you would like to nominate an adult household member to participate in related aspects of the study.

WHY IS THIS RESEARCH BEING DONE?

Heart disease is the leading cause of death among women, yet it is often overlooked, especially after pregnancy. In addition, many adult family members may also have risk factors for heart disease. This study is being done to find out whether an added program of screening, follow-up, and lifestyle support can improve heart health in women after pregnancy and in their household members.

In this study, health centres (not individual participants) are randomly assigned to different groups. This means that the type of support you receive depends on the health centre where you receive care, not on your personal choice. This helps the researchers understand what works best to improve follow-up care and cardiovascular health after pregnancy. The results of this study will help determine whether this program can be used more widely to improve long-term health for women and their families.

WHAT DOES MY PARTICIPATION INVOLVE?

If you choose to participate, the study will last about 12 months and includes a baseline visit, a 6-month assessment, and a 12-month assessment.

Study Visit	**Timing**	**What will happen**
Baseline Visit	6-12 weeks after birth	Consent confirmation; questionnaires (health, lifestyle, mental health); physical measurements (blood pressure, weight, height, waist); blood sample
6-Month Visit	Around 6 months after baseline	Repeat questionnaires; physical measurements; blood sample
12-Month Visit	Around 12 months after baseline	Repeat questionnaires; physical measurements; blood sample; final assessment

At these visits, we will:

- ask questions about your health (physical and mental), wellbeing, lifestyle (such as sleep, diet, exercise, alcohol/tobacco use, etc.), and medical history
- conduct physical measures such as blood pressure, weight, height, waist circumference, etc.
- collect blood samples at specific timepoints (baseline, 6 months, and 12 months) to measure blood sugar and lipids (fat and cholesterol)

You will continue to receive the usual healthcare available in your community. You may also receive general health information as part of the study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks include:

- Mild pain, bruising, or discomfort from blood draws
- Feeling uncomfortable answering personal or mental health questions
- Time required to attend visits

If your responses suggest serious health concerns (e.g., high blood pressure or severe distress), the study team may advise you to seek care from a healthcare provider.

WHAT ARE THE POSSIBLE BENEFITS FOR ME?

You may not receive a direct medical benefit from participating. However, as part of this study you will receive health assessments during study visits and information about your health measurements. The information from this study may also help improve health programs for women and families in the future.

WHAT INFORMATION WILL BE KEPT PRIVATE?

Your study data will be collected and stored electronically using secure systems such as REDCap and the SMARThealth platform. You will be assigned a unique study identification number. Your name and contact details will be stored separately from your study data in a password-protected database that is accessible only to authorised study staff for participant follow-up.

McMaster University will be responsible for overall data management and secure storage of study data. Blood samples collected during the study will be used to measure markers related to heart and metabolic health, such as blood sugar and cholesterol. Samples will be labelled with a code number and will not include your name or identifying information. Some samples will be securely transferred to a laboratory in Canada for analysis and long-term storage.

With your permission, leftover samples may be stored and used for future health research, including studies that may involve genetic or other biological analyses. Any future use of your data or samples will be in a de-identified form (without your name or direct identifiers) and may be shared with approved researchers.

By agreeing to participate, you allow authorised individuals (such as members of the research team, study monitors, auditors, ethics committees, and regulatory authorities) to review your study records for monitoring and verification purposes. These individuals will not have access to information that directly identifies you unless required.

All reasonable steps will be taken to protect your privacy. If the results of this study are published or presented, your identity will not be disclosed.

CAN PARTICIPATION IN THE STUDY END EARLY?
Your participation is completely voluntary. You may refuse to join or withdraw at any time without affecting your access to usual healthcare. You can also choose to stop participation but allow existing data to be used or request removal of identifiable data (where possible).

WILL I BE COMPENSATED FOR MY PARTICIPATION IN THIS STUDY?
You will receive reimbursement for each study visit. Reimbursement is provided per visit and may include support for time, transportation, and childcare. [INSERT LOCAL CONTEXT] Choosing not to participate, or withdrawing later, will not affect your access to regular health services.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?
If new information becomes available that may affect your decision to continue, we will inform you. You may be asked to sign an updated consent form.

WHAT HAPPENS IF I AM INJURED?
We do not expect research-related injury. However, if injury occurs, you will receive appropriate medical care. Signing this form does not waive your legal rights.

IF I HAVE ANY QUESTION OR PROBLEMS, WHOM CAN I CALL?
For study-related questions, contact the study team INSERT LOCAL INFORMATION. For rights-related questions, contact the national ethics committee or institutional review board. INSERT HERE

CONSENT

I have read (or had read to me) and understood the information provided about this study. I have had the opportunity to ask questions and have my concerns addressed. I understand that my participation is voluntary and that I may withdraw at any time without affecting my access to healthcare.

Please indicate your choices below:

- ❑ I agree to participate in this study
- ❑ I agree to have blood samples collected as part of this study

Optional choices:

- ❑ I agree to allow my blood samples to be transferred outside of my country for analysis and storage

- ❑ I agree to allow my blood samples to be stored and used for future health research
- ❑ I agree to allow my samples to be used for genetic research
- ❑ I agree to be contacted about future research studies
- ❑ I agree to receive reminders or messages related to the study (if applicable)

I understand that I may choose not to agree to optional items above and still take part in the main study.

You will receive a copy of this signed consent form.

Participant Name (Print)	Signature	Date

Investigator Name (Print)	Signature	Date