CONSENT TO TAKE PART IN A RESEARCH STUDY

Protocol Title: mHealth for Gestational Diabetes (PHASE 2: Clinical Trial)
Principal Investigator: Shristi Rawal PhD (Rutgers University); Archana Shrestha, PhD (Site-PI) (KU-Dhulikhel Hospital) Faculty Advisor (if PI is a student):
Co-investigators: Jean-francois Daneault, PhD (Rutgers University); Abha Shrestha, MD (KU-Dhulikhel Hospital); Shrinkhala Shrestha, MPH (KU-Dhulikhel Hospital); Prabin Shakya, PhD candidate (KU-Dhulikhel Hospital); Meghnath Dhimal (Nepal Health Research Council)
Description of Study Population: Women attending ANC visit at Dhulikhel Hospital and diagnosed with Gestational Diabetes
Version Date: 9. 7.2023
Study Method: Quantitative
Study Type: Interventional (Exploratory Clinical Trial)

GENERAL OBJECTIVE: About this consent form

Please read this form carefully. This form provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. You may discuss your decision with your family, your friends, and/or your doctor. If you have any questions about the research or any portion of this form, please ask us. If you decide to participate in this research, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

STUDY SUMMARY: The **purpose of the research** is to test a mobile application (app) that supports self-management and treatment of gestational diabetes mellitus (GDM). We also want to better understand how telemonitoring can be used for self-management and treatment of gestational diabetes mellitus (GDM). If you take part in this research, depending on which research group you are assigned to, you may be asked to download the app on your smartphone and provide feedback about the app and answer some questionnaires. You will also be asked to use a blood pressure machine and a glucometer at home, both of which will be provided to you. You will participate in this study from around 30 weeks of gestation to 6 weeks after delivery. **Possible harms or burdens** of taking part in the study is minimal. There is no direct benefit to you for taking part. **An alternative to taking part in the research study** is not to take part in it.

Participation is voluntary

We invite you to take part in this research study because you receive antenatal care at the Dhulikhel hospital, and you have high Glucose Challenge Test (GCT) or have been diagnosed with gestational diabetes. The goal of this study is to test the benefits of a telemonitoring system and/or a smartphone application (app) designed to support self-management and treatment of gestational diabetes mellitus (GDM) among patients in a suburban hospital setting in Nepal. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

What you should know about a research study

- Someone will explain this research study to you.
- A research study is something you volunteer for.
- Whether or not you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

What is the purpose of this research?

The main objective of this study is to test a smartphone application (app) designed to support self-management and treatment of gestational diabetes mellitus (GDM) among patients in a suburban hospital setting in Nepal. We also want to test the implementation of the first natal telemedicine program in Dhulikhel Hospital and test its implementation, feasibility and acceptability among patient and healthcare providers.

Who is conducting this research?

This research is a collaboration between Dhulikhel Hospital – Kathmandu University Hospital, Nepal and researchers at Rutgers University, USA.

Dr. Shristi Rawal is the Principal Investigator of this research study. Dr. Rawal is an Assistant Professor in the Department of Clinical and Preventive Nutritional Sciences at the Rutgers School of Health Professions. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Rawal may be reached at 973-972-2710 or by mail: 65 Bergen, Suite 157, Newark, NJ 07107

Dr. Rawal or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: National Institute of Health

The National Institute of Health is the sponsor of this research study. Dr. Rawal is being paid to conduct this study according to a budget that will cover the costs of the study.

Who may take part in this study and who may not?

You are eligible to take part in this study if you are a pregnant woman who i) receives antenatal care at Dhulikhel Hospital, ii) receives a GDM diagnosis or have a high GCT iii) owns a smartphone, iv) has internet connectivity at home, v) can understand and read Nepali, vi) is less than 30 gestational weeks into pregnancy, and vii) is 18 years of age or older.

If you chose to participate in the study, you will be randomly assigned to either control or intervention group. If you are in the intervention group, you will receive usual standard care from Dhulikhel Hospital and also have to download the GDM app and use it, whereas if you are in the control group, you will only receive usual standard care from Dhulikhel Hospital. In addition to that, upon diagnosis of GDM (both in control and intervention group), you will receive a glucometer and blood pressure machine to monitor blood glucose and blood pressure at home.

How many people will take part in this research?

Approximately 120 participants diagnosed with GDM and 100 participants with high GCT only will take part in this study.

DURATION AND FREQUENCY OF PARTICIPANT INVOLVEMENT: How long will you take part in this research?

We expect that upon enrollment you will be in this study throughout the rest of pregnancy and until 6 weeks postpartum. We will collect data from you when you come to the hospital for regular antenatal checkup.

PROCEDURES AND PROTOCOL: What are your responsibilities?

As a participant, you may be asked to do the following:

- Use the telemonitoring system to communicate with healthcare providers on a bi-weekly basis (only if you are diagnosed with GDM)
- Use and provide feedback on the self-monitoring devices provided to you (only if you are diagnosed with GDM)
- Download, use and provide feedback for an app for GDM management.
- Consent to venous glucose testing biweekly and give access to retrieve information on GDM and associated health outcomes including neonatal birthweight.
- Rate the telehealth system and/or app using the usability evaluation questionnaire, system usability scale and Diabetes treatment satisfaction questionnaire (telehealth only if you are diagnosed with GDM)
- Participate in interviews with the study team to give information about your experience
- Answer some questions regarding your socio-demographic characteristics

What are the risks and possible discomforts?

We do not expect that your participation will bring you any harm. Taking the time to respond to the questionnaires and use the mobile app may be an inconvenience. We will not ask you any questions that are sensitive. You do not have to answer any questions that make you uncomfortable.

Are there any benefits from being in this research study?

There is no direct benefit to you. The information obtained through this study will potentially benefit the health of other pregnant women and their children.

What are my alternatives to participating in this research?

The alternative to participating in this research study is not to participate.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I be compensated for participating in this research?

You will not be paid for participating in the study, but you will receive a small appreciation gift ($10 in the form of pre-paid internet data package) at the end of the study.

What will I have to pay for if I participate in this research study?

There is no cost to you.

Who Might Benefit Financially From This Research?

Investigator Is an Inventor/Could Receive Royalties on a Product: Research studies like this one are designed to determine whether the smartphone app is safe and effective. Dr. Jean-Francois Daneault, one of the investigators in this study, is the founder of Medapplets, a company created to develop and promote smartphone applications such as the ones in this study. If research shows that the smartphone app being tested is safe and effective, Dr. Jean-Francois Daneault could potentially receive royalties on a product on the smartphone app utilized in this study in the future".

Can my taking part in the research end early?

You may decide not to continue in the research at any time without it being held against you. The person in charge of the research can remove you from the research at any time without your approval for any reason. Participation will not affect the health care you receive at Dhulikhel Hospital.

CONFIDENTIALITY: If I take part in this research, how will my privacy be protected? What happens to the information you collect?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Confidentiality will be maintained by assigning a code to disguise any identifying information that you provide. All research information will be kept in locked file drawers. Electronic data will also be stored in a password protected computer. All information obtained from you and other participants will be accessible only to research staff. We will also have private rooms available to conduct research activities. After data collection is complete, the dataset file will be sent to Rutgers University via encrypted email.

If you withdraw your permission, we will not be able to take back any information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

What will happen to my information collected for this research after the study is over?

The information collected about you for this research will not be used by or distributed to investigators for other research.

Right to Refuse or Withdraw: What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.
If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Shristi Rawal, PhD, Clinical and Preventive Nutritional Sciences, School of Health Professions, Rutgers Biomedical and Health Sciences at 65 Bergen St, Suite 923c, Newark, NJ 07107, USA.

If I have any questions, concerns, or complaints about this research study, who can I talk to?

You can call us with any concerns or questions. Our telephone numbers are listed below: You can ask questions as often as you want.

- Dr. Archana Shrestha (9840764738)
- If you have questions, concerns, or complaints,
- If you would like to talk to the research team,
- If you think the research has hurt you, or
- If you wish to withdraw from the study.

If I have questions about my rights as a research participant, whom can I contact?

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

You can contact

1. Kathmandu University School of Medical Sciences, IRC
   Dhulikhel, P.O. Box: 11008, Nepal
   Tel: 977-11-490497, Fax: 977-11-490707
   Email: irc@kusms.edu.np

2. Rutgers University IRB
   65 Bergen Street, Suite 511
   Newark, NJ 07102
   Tel: 973-972-3608
   Email: irbnwk@ored.rutgers.edu

3. Nepal Health Research Council
   Ramshah Path, Kathmandu, Nepal
   P.O.Box 7626
   Tel: 977-1-4254220
   Fax : 977-1-4262469 / 977-1-4268284
   Email : nhrc@nhrc.gov.np

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Participating in Future Research Studies:

We would like to contact you in the future to see if you would be interested in participating in another research study. Please indicate below if you are willing to be contacted about any future research studies.

____ Yes, I agree to be contacted about future research studies.

____ No, I do not want to be contacted about future research studies.

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent Name (Print):_____

Signature:_____ Date: _____

The consent form has been read to the participants. The participant was encouraged to ask questions and all questions has been answered to his/her satisfaction
Name of witness

Signature of witness Date

Signature of person obtaining consent Date

Printed name of person obtaining consent and assent

My signature and date indicate that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally authorized representative, and that informed consent was freely given by the participant or the legally authorized representative.