Participant Information Sheet

Redland Hospital, Logan Hospital and Beaudesert Hospital

**Research Project Title:**

A Smartphone and Internet-based interactive system to support the management of women with a diagnosis of Gestational Diabetes Mellitus (GDM)- Multi-site, real world implementation study

**Principal Investigator:**

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**Co-investigators:**

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1. **Introduction and purpose of research project**

You have been invited to participate in this research project as you have been diagnosed with Gestational Diabetes mellitus (GDM).

This research project has criteria for choosing potential research participants, which has been approved by the Metro South Health Human Research Ethics Committee (HREC). If you have been offered involvement in this research project, you have met these established inclusion criteria which are:

* You have a confirmed diagnosis of GDM
* You are at least 16 years of age
* You were referred by your General Practitioner (GP) for ante-natal care at Redland Hospital, Logan Hospital, Beaudesert Hospital
* You own and use a smart mobile phone (Both Androids or Apple Phones)
* You are able and willing to upload data into your smart mobile phone either via Wi-Fi or mobile data. Some of the data can be uploaded through Bluetooth, example the Roche glucometer and some of the data requires manual entry and upload

The aim of this research project is to study the real-world use of a smartphone application (App) through which you can record your blood glucose levels (BGLs) and other health measures during your treatment for GDM. Also being researched is the use of an internet-based portal, which will be viewed by your health care team, to monitor the health measures you record in your smartphone via the App. The smartphone App is called mobile health technology for a mother or ‘M♡THer GDM App’.

This Participant Information Sheet tells you about the research project and what is involved. Please read the information carefully and ask any questions about anything that you do not understand or that you wish to know more about.

Participation in this research project is voluntary and you do not have to participate. If you commence in the study and change your mind about your participation at any time, you can stop your involvement and there will be no change to your care that you have been receiving.

If you wish to participate in this research project, you will be asked to sign the Consent Form. By signing the Consent Form, you are telling us that you:

* Understand what you have read
* Consent to be a participant in this research project and to undertake the usual care measurements described for GDM management. These measurements will be captured via the smartphone M♡THer GDM App instead of a paper-based diary
* Consent to the health care team viewing your recorded health information via the internet-based portal which is updated from the smartphone M♡THer GDM App

You will be given a copy of this Patient Information Sheet and signed Consent Form for your records.

1. **What does participation in this research project involve?**

You will receive usual GDM care as well as access to the M♡THer GDM App if you agree to participate in the research study.

At the initial GDM group education session with the Diabetes Educator and the Dietitian, you will be assisted to download the App from the Apple App store or the Google Play store and you will automatically receive login details. A video embedded in the App will show you how to use all the features of the App and you will also receive an illustrated user manual.

At this session you will also be provided with a Bluetooth enabled blood glucose meter and you will learn how to self-monitor your blood glucose levels (BGLs), using this meter.

This GDM Group Education session, will take approximately 1.5 to 2 hours.

You will be asked to measure your BGLs four times per day which is usual care for women with GDM. This will be:

1. First thing in the morning when you wake up, before you eat or drink (also called ‘fasting BGL’)
2. One or two hours after each meal (that is, after breakfast, after lunch, and after dinner (also called the ‘post prandial BGL’).

The M♡THer GDM App will read your BGLs from your Bluetooth enabled blood glucose meter. You will also be asked to record any exercise you participate in, any medication for GDM that you are taking, any symptoms you may have (for example nausea) and your weight when it is measured at your ante-natal clinic appointments.

You will be asked to carry your smartphone with you throughout the day so that you can record your BGLs and health measurements into the M♡THer GDM App. Entering this information should take no more than 10 minutes, total, each day.

The smartphone M♡THer GDM App will also deliver reminder messages to you, such as blood glucose measurement alerts. The smartphone M♡THer GDM App will also have links to the educational material explained by the Diabetes Educator and Dietitian and will be able to graph your individual health measurements, so you can track your progress (for example your daily step count).

The health measurements recorded in the M♡THer GDM App will be automatically uploaded to the secure internet-based portal and will be viewed by the health care team involved in your GDM care. Your attendance at antenatal clinic appointments will be approximately every two weeks as advised by your health care team (dependant on your BGLs) up until week 36 of your pregnancy, then generally weekly thereafter until you give birth.

If you have used the M♡THer GDM App from diagnosis to birth, you will be asked to complete two short patient surveys. This survey asks about your experience of using the M♡THer GDM App and you will be asked to complete the survey four weeks after you start using the App and again within two weeks after you give birth.

There are no additional costs associated with being involved as a participant in this research project, nor will you receive any payment for your participation.

1. **Do I have to take part in this research?**

Participation is voluntary. If you do not wish to participate, you will still receive usual care for the treatment of your GDM.

1. **What are the possible benefits of participating in this research?**

The blood glucose meter used will transmit, via Bluetooth, your blood glucose results to the M♡THer GDM App on your smartphone. As a result, you will not have to manually record your blood glucose results into a paper-based diary. You also will not have to carry the paper-based diary with you, nor will you be required to bring the diary along to your appointments. All your health care measures in the App will automatically be transferred into the internet-based portal for your health care team to view.

The App will include links to the educational material (versus usual hard copy) discussed and referred to at the GDM Group Education session and by members of your health care team. There will be links to other useful and recommended websites for management of your GDM. You therefore will not have to carry hard copy formats of these educational guides with you, only your smartphone.

An additional benefit is that the health care team will be able to look at your BGL and health measurements regularly via the secure internet-based portal.

1. **What are the possible risks and or/disadvantages of taking part in this research?**

There are no identified risks to taking part in this research project, as you will be advised to undertake the same health measurements that all women diagnosed with GDM are routinely advised to do.

This includes self-blood glucose monitoring four times a day, dietary modifications as suggested, undertaking a suitable exercise program and possible commencement of medication (as required). This is routine and usual care for GDM. In addition, you will continue to attend routine antenatal clinic appointments, approximately every two weeks for the remainder of your pregnancy after your diagnosis of GDM up until week 36 of your pregnancy and generally weekly thereafter.

1. **What if I want to withdraw from the research project?**

If you agree to participate and later change your mind, you are free to withdraw from the research project at any time.

You will also be provided with a paper-based diary with your illustrated manual for the M♡THer GDM App. This is provided in case you have problems with the technology recording your BGLs and if you wish to withdraw from the research study. You will simply swap to recording your BGLs in the paper-based diary and then you will need to bring that diary along to all of your ante-natal clinic appointments.

If you do decide to withdraw, please contact the M♡THer GDM App Project Officer (details at the end of this Participant Information Sheet) to let the team know that you wish to withdraw from the research project and that you will be using the paper-based diary from that point onwards.

There will be no other change to your GDM care.

Any information received or collected from you during the research project prior to your withdrawal will not be used for research publication or presentation purposes, unless you provide written approval for this to occur.

1. **What happens when the research project ends?**

As GDM is only for the duration of your pregnancy, the research study for you will conclude when you give birth. The M♡THer GDM App is still under trial and its efficacy will not be known until our results are collated, at which point we will look at the options for future deployment if appropriate.

At this time, you will receive usual post natal care and advice for women who have had GDM during their pregnancy.

1. **What involvement does the Australian e-Health Research Centre, CSIRO have with this research project?**

Australian e-Health Research Centre, CSIRO, have been involved in:

* Developing the smartphone M♡THer GDM App used in this research project in collaboration with the health care team
* Providing the software server which will store information generated from the smartphone M♡THer GDM App to the internet-based portal

They will also assist in de-identified group data analysis and reporting.

It is important for you to understand, that the M♡THer GDM App and internet-based portal are hosted by CSIRO and their engineers will have access to these systems for the purpose of maintenance. These members of the CSIRO engineering team are bound by the CSIRO Terms of Use and work within this ethical framework.

It is because of this involvement of CSIRO that you will be asked when setting up the App to agree to their Terms of Use.

1. **What will happen to the information collected from me?**

Any information collected about you via the M♡THer GDM App uploads, as part of usual GDM care, will be kept in your Metro South Health hospital medical record (Redland, Logan or Beaudesert Hospital), as is usual practice for the recording of clinical information for women with GDM. The CSIRO will collect de-identified data to analyse the association between BGL readings and other health measures that you have unloaded such as steps, blood pressure and symptoms, the data will have no reference to you and the researchers will not be able to identify any individual woman in the study.

Although members of the health care team will look at this information for the clinical care of your GDM, no information about you will be identifiable to members of the research team who analyse the data collected for this research project. The information that the research team will have access to will be coded so that it does not have your name on it and hence will not be identifiable.

It is anticipated that the results of this research project will be published in peer reviewed scientific journal(s) and presented at scientific meetings. No individual participant will be identified in any publication and/or presentation, as group results only will be reported.

1. **Who has reviewed this research?**

This research project has been reviewed by the Metro South Health HREC.

This project will be carried out in accordance with research involving pregnant women as outlined in the *National Statement on Ethical Conduct in Human Research (2015)*. This statement was developed to protect the interests of people who agree to participate in human research studies.

1. **Who to contact for further information?**

If you have any concerns or enquiries about the App, please contact the M♡THer GDM App Project Officer

Phone: 07 3488 3111

If you have any complaints about any aspect of this research project, the way it is being conducted or any questions about being a research participant in general, you can contact:

Position: Metro South HREC Co-ordinator

Telephone: 07 3443 8047

Email: MSH-Ethics@health.qld.gov.au