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PARTICIPANT INFORMATION SHEET

DESIGN AND EVALUATION OF THE EFFECTIVENESS OF AN ADAPTIVE DIGITAL HEALTH INTERVENTION IN IMPROVING SELF-EFFICACY FOR WOMEN DIAGNOSED WITH GESTATIONAL DIABETES.

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We invite you to participate in a research study, which assesses if a digital mode of delivering (i.e. by smartphone app) a gestational diabetes mellitus (GDM) self-efficacy program is effective at improving self-confidence thereby mitigating future health risk.

Background

Women with GDM and their children are at a higher risk of other short-term health conditions, such as a higher morbidity rates, spontaneous or late miscarriage, preeclampsia, diabetic ketoacidosis, birth trauma or postpartum haemorrhage; and long-term health conditions, such as T2DM. When GDM is well-managed, risk of adverse outcomes is greatly reduced. The management of GDM is largely self-managed, which requires understanding, motivation and health literacy. However, many studies have reported the difficulties women with GDM experience when adopting these self-management practices, which is exacerbated by a lack of emphasis on empowering and equipping women to take on these tasks. Improving self-efficacy, defined as the belief in one's ability to successfully carry out a task, health knowledge, and empowering patients with GDM to take control of their health has been shown to improve health outcomes and mitigate long-term risk of type 2 diabetes mellitus.

While there are a host of mobile phone or internet health applications, these are rarely vetted by health care professionals, nor are they personalised or necessarily useful in information dissemination or education, which can negatively impact health outcomes. In this study, a smartphone application has been developed and vetted by qualified dieticians, diabetes educators and endocrinologists. This study will evaluate the effectiveness of a smartphone application for education in improving self-efficacy to support GDM management and mitigate long-term risk.

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What to Expect

Your participation will involve using a smartphone application that will contain educational material, covering a range of topics related to GDM. As part of the study, you will be encouraged to review the material provided to you on a weekly basis. You will be encouraged via the use of notifications to engage with the app, by means of visiting and completing at least one educational module, per week. This will involve viewing the entire educational module. The application will be provided to you free of cost and there are no additional expected costs to using the application.

You will complete a questionnaire upon registration in the trial. After having the application installed on your phone, you will be guided in-app on how to use the app and its features.

The application will outline an education program covering topics from self-monitoring, health-related and emotional counselling. Before birth, you will be asked to re-take these questionnaires. After the study is completed, the results of the digital health intervention will be published, and a copy will be provided to you, if requested.

Who can participate?

Women diagnosed with GDM who meet the following criteria are eligible for participation in this study:

- Aged 18 – 50 years
- Clinically stable and able to perform light physical activity
- Own a smartphone and have access to the internet
- Women with GDM who are deemed severely ill, are unable to use the application effectively, are intellectually impaired, have a mental health condition or who are not fluent in English will not be eligible for participation.

Benefits to You

You will receive a benefit from access to GDM-specific educational content that has been vetted by healthcare professionals and that is delivered to them in a convenient manner. Furthermore, by studying the use of telehealth interventions, this study could benefit remote or rural patients who do not have regular access to healthcare facilities. You will also have the experience of participating in research that could facilitate feelings of satisfaction by contributing to an area that empowers women with GDM and can lead to a better understanding of interventions for GDM and serve as a foundation for future research.

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Risks and Discomfort

There are no anticipated risks of participating in this study. You can expect to spend up to 5 minutes completing each lesson from the intervention content. Your involvement is completely voluntary, and you may withdraw from this study at any time by emailing the Principal Investigator.

Confidentiality

All of the information you have provided today will be treated at strictly confidential. All your information and data will be collected securely and will be de-identified. The findings of this study may be published as a research publication, conference proceedings, used to improve a future digital health intervention or model of care, and as part of the principal investigator's PhD thesis. Any issue revealed requiring mandatory reporting will be actioned by the Principal Investigator, who will report it to the necessary authority as required by law.

As part of the data analysis, the researchers will collect the following de-identified, non-personal information, including your

- Age,
- BMI,
- Ethnicity,
- Parity,
- History of GDM,
- Your current GDM management strategy, and
- Gestational age

Withdrawing from the study

You may withdraw from this study at any point before birth by emailing the Principal Researcher. Upon withdrawal, your data will be destroyed with a level of security and intention to safeguard your interests and well-being. Furthermore, your data will be excluded from the final analysis.

Study-specific information

This study is being conducted as part of the Principal Investigator's Doctor of Philosophy degree and is funded in-part by the University of Queensland. This is an educational intervention and your data will be collected in a means that will not identify you. However, this de-identified data may be used for better health promotion and for the design of future research that may benefit health outcomes for women with GDM.

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Consent

Upon installation and entry into the smartphone application, your written consent will be obtained.

Final report

Please indicate if you would like to receive a copy of the final report by emailing your interest to the principal investigator, Ms Uthara Nair, via email: u.nair@uqconnect.edu.au.

Concerns

If you have any concerns regarding your participation in this study at any time, you may contact the principal investigator, Ms Uthara Nair, via email: u.nair@uqconnect.edu.au to discuss your concerns.

This study has been cleared by the UQ HREC in accordance with the National Health and Medical Research Council's guidelines. If you would like to speak to an officer of the ethics office, you may contact the Ethics Officer at:

T (07) 3365 3571
E humanethics@research.uq.edu.au
W https://research.uq.edu.au/research-support/ethics-integrity-and-compliance/human-ethics

Sincerely,
Ms Uthara Nair
Centre for Online Health
The University of Queensland

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