Informed Consent

Trial Title: Digital therapeutics-based lifestyle intervention for gestational diabetes mellitus prevention of high-risk pregnant women

Informed Consent Form Version No.: 1.1, Version Date: 4/18/2023

Institution: Fujian Maternity and Child Health Hospital

Principal Investigator: Lihua Lin

Patient's name:

Dear Ms:

We hereby invite you to participate in a medical research study. This informed consent form provides you with information to help you decide whether or not to participate in this study. Please take some time to read the following carefully and discuss any unclear questions or terms with the appropriate physician. You can discuss your decision to participate in this study with your family and friends before making it. If you are taking part in another study, please let us know.

I. Background

1. Nature of the project: This study is sponsored by Fujian Maternity and Child Health Hospital (FMCHH) as a "Digital therapeutics-based lifestyle intervention for gestational diabetes mellitus prevention of high-risk pregnant women", which is led by FMCHH in conjunction with six medical institutions in the Fujian province, and the principal researcher is Li-Hua Lin, and the project will start and end from October 2023 to September 2026.

2.Background significance: Gestational diabetes mellitus is one of the most common comorbidities in pregnancy, often leading to an increased risk of short- and long-term complications for the pregnant woman herself and her offspring, including type II diabetes mellitus and cardiovascular disease in the distant future in the mother, as well as an increased risk of metabolic disorders, such as obesity and type II diabetes mellitus, in her offspring. Several studies have demonstrated that following a healthy lifestyle during pregnancy can reduce the incidence of gestational diabetes by about 40%.

3. This study was reviewed and approved by the Ethics Committee of Fujian Maternity and

Child Health Hospital.

II. Research Process

In this study, pregnant women with high risk factors for gestational diabetes mellitus were enrolled in the obstetrics clinic after filing and were assigned to the intervention group and the standardized management group in the regular nutrition clinic based on their voluntary choice of whether to receive the digital therapy management program by the doctor's detailed explanation of the digital therapy intervention program. The intervention group provides data-driven personalized diagnosis and treatment services for the subjects based on remote monitoring and intelligent feedback to pregnant women through APP. This study is expected to involve 800 participants in this research program with a follow-up period starting from early pregnancy until oral glucose tolerance measurement at 24-28 weeks.

This study requires the combination of routine clinical data to generate a personalized prescription for the management of people at risk for gestational diabetes mellitus. Your information and personal data will be kept strictly confidential and will not be shared with anyone outside the group without the consent of the principal investigator.

III.Risks and discomforts of participating in the study

In addition to the regular medical treatment, this study will conduct additional questionnaires for you, the content of the survey does not involve sensitive issues, if there is discomfort in the questionnaire, you can refuse to answer. During the study period, pregnant women will be required to use the sports bracelet at home to collect home health data. The sports bracelet is branded by Huawei, and according to Huawei's quality inspection report, it will not be harmful to pregnant women.

IV. Benefits of participating in the study

If you agree to participate in this study, you can receive timely feedback and better answers to your questions about nutritional care during pregnancy and other areas.

V. Costs associated with participation in the study

You do not need to pay any additional fees to participate in this study.

VI.Right to refuse to participate or withdraw from the study

Participation in this study is completely voluntary. You may choose not to participate in this study, or you have the right to withdraw from the study at any stage of the trial without any reason, and none of your medical treatment or rights will be affected as a result. However, the investigator's processing of your data prior to withdrawal is lawful, and it is unlikely that the data prior to withdrawal will be erased or processed if it has been integrated into the research program, and it may continue to be used in this study, provided that your privacy is protected. Once you have decided to participate in this study, please sign this informed consent form to indicate your agreement. Prior to entering the study, you will be screened by your physician to confirm that you are a suitable candidate.

VII.Privacy and Confidentiality

During the study, your name, gender and other personally identifiable information will be replaced with codes or numbers, and will be kept strictly confidential. Only the physician concerned will know your personal information, and your privacy will be well protected. The results of the study may be published in journals, but will not reveal any of your personally identifiable information.

If you agree to participate in this study, all of your medical information will be accessed by the investigator, the research authority, and the ethics committee to check the appropriateness of the operation of the study. If you sign the informed consent form, it also means that you agree to be accessed by the above people. Your medical records will be kept at the hospital, and any public reporting of the results of this study will not disclose the subject's personal identity. The investigator will make every effort to protect the privacy of subjects' personal medical information to the extent permitted by law.

VIII.How to get help in the study

You can keep yourself informed of information materials and research progress related to this study. If you have questions related to this study, please contact Leah Lin at 0591-87279153.

If you need to know about the rights and interests of the participants in this study, you can

contact the Ethics Committee of Fujian Maternity and Child Health Hospital at 0591-88312052.

Consent Signature Page

If you fully understand the content of this research project and agree to participate in this study, you will sign this informed consent form in duplicate, with one copy to be retained by the researcher and one copy to be retained by the subject or delegate.

Signed by the subject himself/herself or his/her legal representative:

Statement of Consent:

1. I acknowledge that I have read and understood the informed consent form for this study, that problems and solutions that may arise during the course of the study have been explained to me, and that I have had the opportunity to ask my own questions.

2. I have made it clear that participation in the study is voluntary and that refusal to participate will not jeopardize any benefits to which I am entitled.

3. I have been informed that the team members involved in this study and the Ethics Committee of Fujian Provincial Maternal and Child Health Hospital have the right to review the study records and case information, and I agree to the direct access to my study records by the abovementioned personnel, with the understanding that the abovementioned information will be treated in a confidential manner.

4. I agree to participate in this study

Your full name: Date:

The following will be completed by the physician performing the informed consent process:

INVESTIGATOR'S DECLARATION: I confirm that the nature, purpose, requirements, and possible risks of this study have been explained and discussed with the patient, and that other available treatment options have been explored at the same time, and I ensure that a copy of this Subject Informed Consent Form has been given to the subject for safekeeping.

Full name of researcher: Date:

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