Title：Dietary Management of Gestational Diabetes Mellitus

NCT ID not yet assigned

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Study protocol

Participants

The target population was selected from 48 patients with gestational diabetes mellitus attending the obstetrics outpatient clinic of the Affiliated Hospital of XXX. The study objects were selected by non synchronous control, for example, patients who visited the hospital in the first week were included in the control group, and patients who visited the hospital in the second week were included in the experimental group until saturation.

Intervention

The intervention group

The intervention group received a 12-week dietary management intervention based on the nudge strategy. The MINDSPACE framework was used, which has nine intervention categories. Face-to-face intervention and telephone follow-up were used to provide targeted dietary management.

The control group

During the intervention, patients in the control group received routine obstetric health education and instruction under contamination, but no additional information on dietary management based on nudge strategies.

Statistical analysis plan

Data collection

From October 21, 2022 to December 31, 2022 (prospective), data was collected. At the time of enrollment, demographic information about the study participants was gathered. Pre-intervention, 1-month post-intervention and 3-months post-intervention, patients' glucose level indicators (FPG, 2hPG) and pregnancy outcomes were collected. The study subjects had no knowledge of group assignments.

Statistical analysis

All statistical analyses were carried out using SPSS, version 26.0 (SPSS Inc., Chicago, IL, USA). Continuous variables with normal distributions were expressed as $x \pm s$ and compared between groups using the independent samples t-test; continuous variables with non-normal distributions were expressed as M (Q1, Q3) and compared

between groups using the Wilcoxon rank sum test; categorical variables were expressed as cases (%) and compared between groups using χ2 test and categorical variables were described as percentages and compared using chi-square test. Metrics that are repeated the time effect, the main effect of the intervention, and the interaction effect of both FBG and 2hPG before, 1 month after, and 3 months after the intervention were all compared in the two groups using ANOVA. P＜0.05 with two tailed significance was considered statistically significant.

Informed consent form

Dear lady!

We are researchers from Qingdao University. We invite you to participate in a study called "Research on Diet Management for Pregnant diabetes Patients Based on Nudge Strategy". Project leader Wenyao Geng.

Before you decide whether to participate in this study, we will introduce you to the purpose, procedure, possible risks and benefits of this study. Gestational diabetes is a type of diabetes that occurs or is diagnosed only during pregnancy when the glucose metabolism is normal or there is potential impaired glucose tolerance before pregnancy. Research shows that there is a relationship between diet management and GDM. The purpose of this study was to provide nutritional guidance on diet and behavior of pregnant women with diabetes during pregnancy, so as to prevent and reduce the possible abnormalities of glucose metabolism in the second trimester of pregnancy. The effect of nutritional guidance during pregnancy on reducing the risk of GDM was evaluated through the glucose tolerance screening test. By participating in this study, you can provide an important basis for the implementation of the nutrition intervention model during pregnancy, and you can also get your own professional medical knowledge and health guidance on nutrition during pregnancy.

All your data and personal information will be identified by number, your personal information will not be disclosed, and we will keep your medical examination results and records confidential to the maximum extent permitted by law. The research results of this project may be published in medical journals, and your personal information and data will remain confidential. You have the right to refuse to participate in or withdraw from this survey at any time without being discriminated against or unfairly treated. Your right to seek medical treatment will not be affected in any way. If you have any questions about this study or the discomfort caused by the study, please contact the following personnel:

Geng Wenyao, Qingdao University

After you fully understand and understand this study, if you agree to participate, please sign this Informed Consent Form.

I am willing to participate in this research.

Defendant: Date:

Informed by:Wenyao Geng