ISRCTN59044843 https://doi.org/10.1186/ISRCTN59044843

A smartphone application providing diet and physical activity information for the prevention of gestational diabetes

Submission date
05/04/2021

Recruitment status
No longer recruiting

Registration date
12/04/2021

Overall study status
Completed

Last Edited
14/02/2023

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The study aims to evaluate a specific behavioral intervention for the prevention of the development of gestational diabetes during 24-28 weeks of gestation among pregnant women whose initial screening before 20 weeks of gestation does not show gestational diabetes.

Who can participate?
Pregnant women aged 18-50 years who previously received gestational diabetes screening before 20 weeks of gestation according to institutional guidelines with normal results.

What does the study involve?
Participants will either receive standard antenatal care or individual counseling on diet and physical activity and weekly information on behavioral modification will be provided via the LINE smartphone application. Participants will be followed to determine the development of gestational diabetes at 24-28 weeks of gestation as well as other pregnancy outcomes.

What are the possible benefits and risks of participating?
Participants would benefit by reducing the risk of gestational diabetes along with developing healthier behavior during pregnancy.

Where is the study run from?
Faculty of Medicine Siriraj Hospital (Thailand)

When is the study starting and how long is it expected to run for?
From July 2020 to February 2023

Who is funding the study?
Thailand Research Fund (Thailand) and the Medical Research Council (UK)

Who is the main contact?
Dr Dittakarn Boriboonhirunsarn, dittakarn.bor@mahidol.ac.th

Contact information

Type(s)
Scientific

Contact name
Dr Dittakarn Boriboonhirunsarn

ORCID ID
https://orcid.org/0000-0002-5901-5923

Contact details
2 Wanglang Road
Siriraj
Bangkoknoi
Bangkok
Thailand
10700
+66 818085718
dittakarn.bor@mahidol.ac.th

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
TCTR20210317002

Study information

Scientific Title
Behavioral intervention for prevention of gestational diabetes

Study objectives
Behavioral intervention can prevent development of GDM during 24-28 weeks of gestation in women with normal initial GDM screening before 20 weeks of gestation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/11/2019, Siriraj Institutional Review Board (SIRB) (Human Research Protection Unit, Faculty of Medicine Siriraj Hospital, Mahidol University, His Majesty the King's 80th Birthday Anniversary 5th December 2007 Building, 2nd floor, Room 210, 2 Wang Lang Road Bangkoknoi, Bangkok 10700, Thailand; +662419 2667 - 72; siethics@mahidol.ac.th), ref: Si 796 /2019

Study design

Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gestational diabetes during 24-28 weeks of gestation in women with normal initial GDM screening

Interventions
The intervention group receives individual counseling on nutrition and physical activity together with weekly information about behavioral modification via smartphone (LINE application) until gestational diabetes mellitus (GDM) screening at 24-28 weeks of gestation. The control group receives standard antenatal care.

Intervention Type
Behavioural

Primary outcome(s)
Development of gestational diabetes mellitus (GDM) during 24-28 weeks of gestation measured using GDM screening at 24-28 weeks

Key secondary outcome(s))
Pregnancy outcomes related to gestational diabetes mellitus (GDM), such as preterm delivery, Large for Gestational Age (LGA), macrosomia, or cesarean section measured from participant notes at delivery

Completion date
28/02/2023

Eligibility

Key inclusion criteria
1. Aged between 18 and 50 years
2. Gestational age <20 weeks
3. Received gestational diabetes mellitus (GDM) screening according to institutional guideline
4. Have a smartphone with the LINE application

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
820

Key exclusion criteria
1. Pre-pregnancy diabetes
2. Intrauterine fetal death or major anomalies or any conditions that pregnancy termination is indicated
3. Do not agree to participate

Date of first enrolment
31/07/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Thailand

Study participating centre
Faculty of Medicine Siriraj Hospital
2 Wanglang Road
Siriraj
Bangkoknoi
Bangkok
Thailand
10700

Sponsor information

Organisation
Thailand Research Fund

Funder(s)

Funder type

Government

Funder Name
Thailand Research Fund

Alternative Name(s)
TRF

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Thailand

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other