

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

<b>Submission date</b> 05/04/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/04/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 14/02/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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](mailto:dittakarn.bor@mahidol.ac.th)

# Contact information

**Type(s)**

Scientific

**Contact name**

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# Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/06/2019

**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

## Age group

Adult

## Lower age limit

18 Years

## Sex

Female

## Target number of participants

820

## 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

### Sponsor details

14th Floor SM Tower  
979/17-21 Phaholyothin Road  
Samsan Nai  
Phyathai  
Bangkok  
Thailand  
10400  
+66 2278 8200  
callcenter@trf.or.th

### Sponsor type

Government

### Website

<http://www.trf.or.th/eng/>

## 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, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-review journals.

**Intention to publish date**

31/12/2023

**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