

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

**Evaluation of the effect of educational intervention with mobile health technology and based on the theory of planned behavior on sleep quality, anxiety and perceived stress caused by the Covid-19 pandemic in pregnant women referred to urban health centers.**

### Protocol summary

#### Study aim

- Determining the demographic characteristics of the people under study Determining the mean sleep quality score of pregnant women in the intervention group before, immediately and 1 month after the TPB-based educational intervention.

#### Design

Clinical trial with control group, with parallel groups, without blinding, random allocation using blocking, on 80 samples

#### Settings and conduct

Educational intervention in the form of 5 30-minute sessions in the intervention group in Gonabad city. Meetings will be held virtually with mobile health technology for both control and intervention groups in WhatsApp. Educational materials will be provided as a PDF file to both intervention and control groups. TPB-based educational materials will be only offered to the intervention group in the form of video and recorded audio.

#### Participants/Inclusion and exclusion criteria

Gestational age more than 12 weeks; Suffer from proper sleep; Mother age 15-45 years; Minimum literacy; No complications and diseases during pregnancy, including preeclampsia, eclampsia, gestational diabetes, and hydramnios; lack of experience of a stressful event other than Covid-19 disease for at least the last 6 months; lack of employment of the pregnant mother in the hospital and lack of employment in the night shift (due to the effect on sleep disorders); Do not suffer from mental-physical illness; Do not use tobacco, drugs, and sleeping pills; no history of infertility; the pregnant mother does not have Covid-19 disease now and in the past; Having the consent to enter the study; having a WhatsApp messenger or the possibility of installing this software on a mobile phone.

#### Intervention groups

The intervention group receives TPB-based training. The control group of the trainings in PDF format

#### Main outcome variables

Sleep quality; stress; coronary anxiety.

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20210801052045N1**

Registration date: **2021-08-08, 1400/05/17**

Registration timing: **prospective**

Last update: **2021-08-08, 1400/05/17**

Update count: **0**

#### Registration date

2021-08-08, 1400/05/17

#### Registrant information

##### Name

zohreh rostamikia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5224 1954

##### Email address

z.rostamikia72@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-09-02, 1400/06/11

**Expected recruitment end date**

2021-09-07, 1400/06/16

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of educational intervention with mobile health technology and based on the theory of planned behavior on sleep quality, anxiety and perceived stress caused by the Covid-19 pandemic in pregnant women referred to urban health centers.

**Public title**

Evaluation of the effect of educational intervention with mobile health technology and based on the theory of planned behavior on sleep quality, anxiety and perceived stress caused by the Covid-19 pandemic in pregnant women referred to urban health centers.

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Gestational age is more than 12 weeks (at the same time as the beginning of the 12th week of pregnancy and up to 2 months after delivery, women suffer from sleep problems and poor sleep quality.) Mothers aged 15-45 years Ability to read and write No complications and diseases during pregnancy, including preeclampsia, eclampsia, gestational diabetes, and hydramnios No experience of a stressful event other than Covid-19 disease during the past 6 months Unemployment of the pregnant mother in the hospital and unemployment in the night shift (due to the effect on sleep disorders) No mental or physical illness No smoking, drugs, and sleeping pills No history of infertility Pregnancy of a pregnant mother with Covid-19 disease now and in the past Having the consent to enter the study Having a WhatsApp messenger or the possibility of installing this software on a mobile phone

**Exclusion criteria:**

Incidence of acute mental and physical illness Premature rupture of membranes and preterm delivery Abnormal fetal presentation Pregnant mother with Covid-19

**Age**From **15 years** old to **45 years** old**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

**Randomization description**

The research units will be randomly assigned to the intervention or control group using quadruple

permutation blocks. In this way, the first six possible modes of blocks (AABB, ABAB, BBAA, BABA, ABBA, BAAB) are listed and each block will be assigned a number from one to six. Then, a number between one and six will be randomly selected using a table of random numbers, and then people will be assigned to the test group (A) and control (B) based on the block corresponding to the selected number. This will continue until the sample size is complete.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Training in this study is mobile health method and based on the theory of planned behavior.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Gonabad University of Medical Sciences

**Street address**

57.beheshti5.5, beheshti

**City**

Torbatehedyariyeh

**Province**

Razavi Khorasan

**Postal code**

9543119689

**Approval date**

2021-07-13, 1400/04/22

**Ethics committee reference number**

IR.GMU.REC.1400.055

**Health conditions studied****1****Description of health condition studied**

Sleep quality

**ICD-10 code****ICD-10 code description****2****Description of health condition studied**

Corona stress

**ICD-10 code****ICD-10 code description**

### 3

#### Description of health condition studied

Corona anxiety

#### ICD-10 code

#### ICD-10 code description

### 4

#### Description of health condition studied

Behavior-based education

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Sleep quality

#### Timepoint

Before intervention, immediately after intervention, 1 month after intervention

#### Method of measurement

Pittsburgh Sleep Quality Questionnaire

### 2

#### Description

Corona stress

#### Timepoint

Before intervention, immediately after intervention, 1 month after intervention

#### Method of measurement

Corona-related stress scale questionnaire

### 3

#### Description

Corona Stress Scale: CSS

#### Timepoint

Before intervention, immediately after intervention, 1 month after intervention

#### Method of measurement

Corona Disease Anxiety Scale(CDAS)

### 4

#### Description

Training based on the theory of planned behavior

#### Timepoint

Before intervention, immediately after intervention, 1 month after intervention

#### Method of measurement

Researcher-made questionnaire on the theory of planned behavior

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: Tashkia is an intervention group in WhatsApp software. 5 sessions of educational intervention in 2 sessions per week, each session for half an hour in the form of video and audio with pdf sessions. Educational materials based on the latest instructions of the Department of Maternal and Newborn Health of the Ministry of Health

#### Category

Behavior

### 2

#### Description

Control group: Control group: Form a control group in WhatsApp software. Only PDF tutorials are included in this group and also three questionnaires to complete

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gonabad Urban Community Health Centers

##### Full name of responsible person

Gonabad University of Medical Sciences

##### Street address

Asian Roadside - University Campus-Gonabad

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

1256897451

##### Phone

+98 51 5722 4083

##### Email

z.rostamikia72@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Full name of responsible person

Fariba Askari

##### Street address

Gonabad University of Medical Sciences

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9156137374

**Phone**

+98 51 5722 0575

**Email**

faribaaskari10@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Gonabad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Zohreh Rostamikia

**Position**

Graduate student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

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Fariba Askari

**Position**

Faculty member of Gonabad University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

## Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available