Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
Torbateheydariyeh
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
Sleap 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

Street address
57. beheshti5.5

City
Torbatehedariyeh

Province
Razavi Khorasan

Postal code
9543113689

Phone
+98 51 5224 1954

Email
z.rostamikia72@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Fariba Askari

Position
Faculty member of Gonabad University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Asian Roadside - University Campus-Gonabad

City
Gonabad

Province
Razavi Khorasan

Postal code
000000000000000

Phone
+98 51 5722 0575

Email
faribaaskari10@yahoo.com

Person responsible for updating data

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

Street address
57.Beheshti5.5

City
Tovbat-Heydariyeh

Province
Razavi Khorasan

Postal code
9543113689

Phone
+98 552241654

Email
z.rostamikia72@gmai.com

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