

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Investigating the effectiveness of tele-counselling on perinatal mental health during SARS-COV-2 pandemics

#### Protocol summary

##### Study aim

Effectiveness' determination of psychological interventions on the mental health of women referred to hospital and health centres affiliated to the Kerman University of Medical Science in pregnancy, delivery and the postpartum period in the Coronavirus epidemic in 2020

##### Design

Empirical intervention-based educational research, With pre-test and post-test, control and intervention groups and simple randomization with a sample size of 60 people

##### Settings and conduct

The present study is an empirically-based educational intervention with a pretest-posttest and intervention and control group design which will be done by ethic code achieved by Kerman University of Medical Sciences. Women satisfied to participate in the study will be randomly divided into intervention and control groups. The intervention group will attend 6 psychological counselling group sessions through virtual networks such as WhatsApp or Skype for 90 to 120 minutes. The post-test will be offered to the two groups after the sessions.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: satisfaction to participate in the study, being in a time period of 28 weeks of pregnancy to 28th of postpartum day for women referring for postpartum services, not receiving psychiatric medication, not attending in counselling sessions at the same time of study period

##### Intervention groups

Intervention group: Psychological counselling sessions consists of 6 weekly virtual sessions through virtual networks such as WhatsApp or Skype For 90 to 120 minutes. Control group: There is no intervention.

##### Main outcome variables

Anxiety, depression, health anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170611034452N12**

Registration date: **2020-12-20, 1399/09/30**

Registration timing: **retrospective**

Last update: **2020-12-20, 1399/09/30**

Update count: **0**

##### Registration date

2020-12-20, 1399/09/30

##### Registrant information

##### Name

Atefeh Ahmadi

##### Name of organization / entity

Kerman University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 5205

##### Email address

a.ahmadi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-05-10, 1399/02/21

##### Actual recruitment start date

2020-04-20, 1399/02/01

##### Actual recruitment end date

2020-05-14, 1399/02/25

##### Trial completion date

2020-05-14, 1399/02/25

**Scientific title**

Investigating the effectiveness of tele-counselling on perinatal mental health during SARS-COV-2 pandemics

**Public title**

Tele-counselling on perinatal mental health during pandemics

**Purpose**

Education/Guidance

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

satisfaction to participate in the study being in a time period of 28 weeks of pregnancy to 28th postpartum day for women referring for perinatal services Not consuming psychiatric medication

**Exclusion criteria:**

loss of pregnancy (fetal death)

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **60**

Actual sample size reached: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization in this study is a simple randomization. It is a personal randomization unit. Layering (strata) is not done. Women under the affiliation of health care centres who fill informed consent forms mean that they agree to participate in the study. for the division of them into two groups of intervention and control, statistical software will usedThe tool used in randomization is Randomizer software (www.randomizer.org) which also performs random sequences. Allocation concealment does not apply to this counselling intervention.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Education 6 sessions, Twice a week

**Secondary Ids**

empty

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

Deputy of Research

**Street address**

Haft Bagh Square

**City**

kerman

**Province**

Kerman

**Postal code**

7616913555

**Approval date**

2020-06-19, 1399/03/30

**Ethics committee reference number**

IR.KMU.REC.1399.134

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

anxiety

**ICD-10 code**

F41

**ICD-10 code description**

Other anxiety disorders

**2****Description of health condition studied**

depression

**ICD-10 code**

F32.8

**ICD-10 code description**

Other depressive episodes

**3****Description of health condition studied**

health anxiety

**ICD-10 code**

F45.8

**ICD-10 code description**

Other somatoform disorders

**Primary outcomes****1****Description**

Anxiety

**Timepoint**

Before and 3 weeks after intervention

**Method of measurement**

Modified to COVID-19 Hospital Depression and Anxiety Scale

**2****Description**

Depression

**Timepoint**

Before and 3 weeks after intervention

**Method of measurement**

Modified to COVID-19-Hospital Depression and Anxiety

Scale

### 3

#### **Description**

health anxiety

#### **Timepoint**

Before and 3 weeks after intervention

#### **Method of measurement**

Health anxiety questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: Intervention consists of 6 weekly group counselling sessions through virtual networks such as WhatsApp or Skype For 90 to 120 minutes Session Content: 1-Training of how to prevent the COVID-19 and provision of information about the disease, familiarity with practical solutions to a healthy lifestyle according to the condition of women (healthy diet, exercise, adequate sleep), dysfunctional cognitions related to COVID-19, muscle relaxation technique, conscious eating technique, assignment 2-Reviewing assignments, defining mindfulness and its benefits in coping with COVID-19 anxiety, training and performing mindfulness on breathing and senses, expressing personal boundaries and limitations, assignments 3-Review of assignments, familiarity with the physical, mental, emotional, and behavioral symptoms of stress and anxiety, introduction of cognitive errors related to COVID-19 from Ellis and Beck's perspectives, training of ways to overcome pregnancy and postpartum fatigue, training of yoga and aerobic exercise to increase respiratory capacity, assignments 4-Review of assignments, seated meditation with focus on breathing, body sounds and thoughts (four-dimensional meditation), definition of autopilot mind, familiarity with coping styles in the face of stressors, assignments. 5-Reviewing assignments, re-discussing cognitive errors, expressing the disadvantages and advantages of worries and fears, promoting family relationships and making love to the fetus and neonate, defining the pleasant and unpleasant life events, and ways to change feelings and attitudes towards events, assignments. 6-Accepting conditions and commitments by relying on self-care, being at the present (quitting daydreaming), discussing one's fears about one's vulnerability to disease, doing a body scan, reviewing and concluding.

#### **Category**

N/A

#### 2

#### **Description**

Control group: There is no intervention for the control group

### **Category**

Prevention

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

hospitals and health centers care affiliated to Kerman University Medical Science

##### **Full name of responsible person**

Atefeh Ahmadi

##### **Street address**

Haft Bagh Square

##### **City**

kerman

##### **Province**

Kerman

##### **Postal code**

7616913555

##### **Phone**

+98 34 3132 5179

##### **Email**

atefeahmadi59@gmail.com

#### 2

#### **Recruitment center**

##### **Name of recruitment center**

Kerman University of Medical Sciences

##### **Full name of responsible person**

Sahebeh dadshahi

##### **Street address**

Haft bagh, KMU Pardis

##### **City**

Kerman

##### **Province**

Kerman

##### **Postal code**

741

##### **Phone**

+98 34 3132 5220

##### **Email**

sahebeh68.dadshahi@gmail.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Kerman University of Medical Sciences

##### **Full name of responsible person**

Atefeh Ahmadi

##### **Street address**

Haft Bagh Square

##### **City**

kerman

##### **Province**

Kerman

##### **Postal code**

7616913555

**Phone**

+98 34 3132 5179

**Email**

atefeahmadi59@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kerman 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

**2**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Sahebeh Dadshahi

**Street address**

Haft Bagh. KMU Pardis

**City**

Kerman

**Province**

Kerman

**Postal code**

741

**Phone**

+98 34 3132 5180

**Email**

sahebeh68.dadshahi@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Atefeh Ahmadi

**Position**

Assistant professor in Kerman University of Medical Sciences, Midwifery Department and Nursing Resea

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Haft Bagh Square

**City**

kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3132 5179

**Email**

atefeahmadi59@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Atefeh Ahmadi

**Position**

Assistant professor in Kerman University of Medical Sciences, Midwifery Department and Nursing Resea

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Haft Bagh Square

**City**

kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3132 5179

**Email**

atefeahmadi59@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Atefeh Ahmadi

**Position**

Assistant professor in Kerman University of Medical Sciences, Midwifery Department and Nursing Resea

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Haft Bagh Square

**City**

kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3132 5179

**Email**

atefeahmadi59@gmail.com

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available