

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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)

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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

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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

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2

Recruitment center

Name of recruitment center

Kerman University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

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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

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Person responsible for scientific inquiries

Contact

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Kerman University of Medical Sciences

Full name of responsible person

Atefeh Ahmadi

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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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