Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 questionnnaire

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

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Other areas of specialty/work

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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
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Province
Kerman
Postal code
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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