Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of telemedicine-based massage training in spouses on the resilience of pregnant women during the Coronavirus pandemic

Protocol summary

Study aim
Determining the effect of telemedicine-based massage training in spouses on the resilience of pregnant women during the Coronavirus pandemic

Design
A clinical trial with a control group, with parallel groups, without blinding, randomized, is performed on 120 pregnant women, and the center name lottery method was used for randomization.

Settings and conduct
Individuals with the research units' characteristics, which refer to Mashhad health centers for pregnancy care, are randomly selected from the health care providers' list to the researcher by easy sampling method. They are assigned in WhatsApp into two groups, intervention and control.

Participants/Inclusion and exclusion criteria
The informed consent form has been signed. Iranian and resident of Mashhad. One fetus in the present pregnancy. The mother's age is between 18 to 35. The least literacy of the mother and her husband is about fifth-grade at the elementary school. She has access to the internet and WhatsApp. She lives with her husband. She has a landline or cell phone number. The gestational age is between 28 and 34 weeks. In response to the DASS 21 questionnaire, she obtained less than 10, 14, 17, after depression, anxiety, and stress, respectively.

Intervention groups
After obtaining the informed consent and completing the research tools in the intervention group, a training session is held on cyberspace. Using a whiteboard, the researcher will teach the massage technique to the spouses and answer their questions. Re-contact is established two weeks after the start of the research. No training will be given in the control group, and contact will be re-established two weeks after the start of the research. Immediately after the intervention and four days after that, the research tool will be completed.

Main outcome variables
Determining the resilience

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170607034378N2**
Registration date: **2020-11-19, 1399/08/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-19, 1399/08/29**
Update count: **0**

Registration date
2020-11-19, 1399/08/29

Registrant information

Name
Fatemeh Jalalmarvi

Name of organization / entity
Islamic Azad University of Mashhad

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Iran (Islamic Republic of)

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jalalmarvif941@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-04, 1399/08/14

Expected recruitment end date
2021-03-04, 1399/12/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of telemedicine-based massage training in spouses on the resilience of pregnant women during the Coronavirus pandemic

Public title
The effect of massage training on the resilience of pregnant women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
The informed consent form has been signed. Iranian and resident of Mashhad. One fetus in the present pregnancy. The mother's age is between 18 to 35. The least literacy of the mother and her husband is about fifth-grade at the elementary school. She has access to the Internet and WhatsApp. She lives with her husband. She has a landline or cell phone number. The gestational age is between 28 and 34 weeks. In response to the DASS21 questionnaire, she has obtained less than 10, 14, 17, after depression, anxiety, and stress, respectively.

Exclusion criteria:
An important and horrible event happened to her during the last 6 months. She has a medical history. She has a history of infertility or the current pregnancy is a result of infertility treatment. She or her husband has an addiction to tobacco (hookah, cigarettes, cheeks, drugs) or alcohol and psychosocial medications during the research. She has had the night shifts at work during the research. Skin problems such as scorch, skin wounds or bone problems such as fractures in the neck and back or legs. She has a speech, hearing or accent problems. She does not have the gynecological problems. She does the exercise regularly. She has a history of mental disorder.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Health Center No. 2 of Mashhad was selected from the five centers by cluster sampling method based on a lottery. Then, they were selected from the available health centers that were available and due to the possibility of information leakage, random assignment to two groups of intervention and control based on the names of the centers by lottery. Research units will also be randomly assigned so that mothers whose case number is even.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad university-mashhad Branch

Street address
Tehran - Ghods Town (West) - Between South Flamek and Zarafshan, Iran TV St. - Central Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th floor

City
Tehran

Province
Tehran

Postal code
9164697515

Approval date
2020-09-30, 1399/07/09

Ethics committee reference number
IR.IAU.MSHD.REC.1399.159

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Resilience

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Resilience

Timepoint
Before the intervention, immediately after the intervention and 4 days after the intervention.

Method of measurement
Connor- Davidson Resilience Scale (CD-RISC)

Secondary outcomes

1

Description
Stress-Anxiety-Depression
Timepoint
Before the intervention, immediately after the intervention and 4 days after the intervention
Method of measurement
Stress-Anxiety-Depression scale

Intervention groups

1

Description
The intervention group: After obtaining the informed consent and completing the research tools in the intervention group, a training session is held on cyberspace. Using a whiteboard, the researcher will teach the "Aflorage" massage technique to the spouses and answer their questions. The participants will be asked to do a back massage by the spouse after establishing a calm environment and the mother's correct position for 10 minutes and each limb for 5 minutes (30 minutes in total). It is also asked to do the massage technique at nights before going to bed, three times a week every other day for 4 weeks (12 times in total). Re-contact is established two weeks after the start of the research. Immediately after the intervention and four days after that, the research tool will be completed.
Category
N/A

2

Description
The control group: No training will be given, and contact will be re-established 2 weeks after the start of the research. Before the intervention, immediately after the intervention, and 4 days after, the research tool will be completed.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Center No. 2
Full name of responsible person
Ali Asghar Mahmudi
Street address
Mashhad Health Center Street No. 2. Panjrah Paeen Khiaban.
City
Mashhad
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Razavi Khorasan
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Phone
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2

Recruitment center
Name of recruitment center
14 Maesum Health Center
Full name of responsible person
Mahdi Sayad Kame Olya
Street address
North Tabarsi 35. 14 Maesum Health Center
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Mashhad
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Razavi Khorasan
Postal code
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Saeed Khayat Moghadam
Street address
Vice Chancellor for research and technology , Islamic Azad University,Imamamiye Aven,Ghasem Abad, Mashhad
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Province
Razavi Khorasan
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9234567124
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+98 51 3620 4001
Email
research@mshdiau.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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

Islamic Azad University

Full name of responsible person

Fatemeh Jalal Marvi

Position

science Committee (coach)

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Postal code

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

Title and more details about the data/document

Only those parts of the data, such as the information about the main outcome or such things, can be shared.

When the data will become available and for how long

"Access period starts 6 months after the results are published"

To whom data/document is available

Only for researchers working in the academic and scientific institutions

Under which criteria data/document could be used

send mail Identify the person

From where data/document is obtainable

Send email to jalalmarvif9@gmail.com

What processes are involved for a request to access

data/document

send mail Identify the person after one month

Comments