

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

Country

Iran (Islamic Republic of)

Phone

+98 51 3751 5211

Email address

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.

AgeFrom **18 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget 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.

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Province

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9153913153

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2

Recruitment center

Name of recruitment center

14 Maesum Health Center

Full name of responsible person

Mahdi Sayad Kame Olya

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North Tabarsi 35. 14 Maesum Health Center

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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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9234567124

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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
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Person responsible for updating data

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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