

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation of the effectiveness of progressive muscle relaxation technique on the level of covid-19 anxiety of pregnant women covered by the Ayat Comprehensive Health Services Center of Tehran University of Medical Sciences

Protocol summary

Study aim

Determining the Effectiveness of Progressive Muscle Relaxation Technique on Coronary Anxiety in Pregnant Women Covered by the Ayat Comprehensive Health Service Center of Tehran University of Medical Sciences

Design

Clinical trial with control group, with parallel group, double-blind, randomized, on 126 patients. A random sequence generated by computer software was used for randomization.

Settings and conduct

Eligible individuals are selected from Ayat Health Center. Intervention group: Receiving routine pregnancy care with training in progressive muscle relaxation technique in 6 sessions of 40 minutes. Control group: receiving routine pregnancy care. Pregnancy Anxiety Questionnaire and Covid-19 Anxiety Scale are completed by the participants before the intervention, at the end of the intervention and two weeks after the intervention.

Participants/Inclusion and exclusion criteria

Admission requirements: Satisfaction for research, gestational age less than 32 weeks, literacy, access to smartphone, computer or laptop on the web, mild to moderate covid-19 anxiety level Conditions of non-admission: history of confirmed psychiatric illness, history of receiving any psychotherapy in the last 6 months, high-risk pregnancy, mothers with severe covid-19 anxiety, visual and hearing impairment,, migration in the last 6 months, hospitalization in the last 6 months, Loss of family member in the last 6 months, suicidal thoughts, history of poor pregnancy outcomes such as preterm delivery, miscarriage, stillbirth and fetal abnormalities in the past year

Intervention groups

Intervention group: routine prenatal care with virtual training of progressive muscle relaxation technique in 6

sessions (each session 40 minutes at a rate of 3 times a week)/Control group: routine pregnancy care

Main outcome variables

Covid-19 anxiety pregnancy anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200630047962N1**

Registration date: **2020-08-21, 1399/05/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

Name

Mojgan Zendehtdel

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4433 7260

Email address

mojgan.zendehtdel@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-07, 1399/05/17

Expected recruitment end date

2020-09-21, 1399/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of progressive muscle relaxation technique on the level of covid-19 anxiety of pregnant women covered by the Ayat Comprehensive Health Services Center of Tehran University of Medical Sciences

Public title
The effect of progressive muscle relaxation on covid-19 anxiety in pregnant women

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Satisfaction to participate in research Gestational age less than 32 weeks Literacy for reading and writing Access to a smartphone, computer or laptop on the web Mild to moderate covid-19 anxiety levels

Exclusion criteria:
History of a confirmed psychiatric illness History of receiving any psychotherapy in the last 6 months High risk pregnancy Severe covid-19 anxiety level Visual and auditory impairment Immigration in the last 6 months Hospitalized in the last 6 months Loss of a family member in the last 6 months Suicidal thoughts History of poor pregnancy outcomes such as preterm labor, miscarriage, stillbirth and fetal malformations in the past year

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling is done by simple random method. The samples are divided into two groups A and group B based on a random sequence produced by computer software. Each patient receives a code. The pairing or individuality of the intervention or control group is determined by drawing lots. One group receives progressive muscle relaxation intervention with routine pregnancy care and one group receives only routine pregnancy care.

Blinding (investigator's opinion)
Double blinded

Blinding description

Participants receive prenatal care without knowing if they are in the intervention or control group. The outcome assessor also has no knowledge of assigning individuals to intervention and control groups.

Placebo
Not used

Assignment
Parallel

Other design features
The intervention is done in the form of virtual training by Skyroom

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical sciences

Street address

No. 13, 7th floor east, block 18, opj town, Koohsar St., Shahrn Square

City

Tehran

Province

Tehran

Postal code

1478894438

Approval date

2020-08-03, 1399/05/13

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.287

Health conditions studied

1

Description of health condition studied

Covid-19 anxiety

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Covid-19 disease anxiety

Timepoint

Before the intervention - immediately after the intervention - two weeks after the intervention

Method of measurement

Filling the Corona Disease Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine prenatal care with 6 sessions of virtual intervention including information and awareness about coronavirus and anxiety-causing factors for pregnant mothers during coronavirus pandemics and training and practice of progressive muscle relaxation technique (each session 40 minutes) 3 times a week for each group) via Skyroom software

Category

Other

2

Description

Control group: Routine pregnancy care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayat Comprehensive Health Services Center of
Tehran University of Medical Sciences

Full name of responsible person

Mojgan Zendehtdel

Street address

Ayat comprehensive Health Service Center, Shahid
Zolfi St., Shahid Kazemi St., Ayatollah Saeedi Highway

City

Tehran

Province

Tehran

Postal code

1478894438

Phone

+98 21 4433 7260

Email

Mojgan.zendehtdel@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Sahrayian

Street address

Keshavarz Boulevard and Ghods St. intersection,
central building of Tehran University of Medical

Sciences

City

Tehran

Province

Tehran

Postal code

1416663361

Phone

+98 21 8163 3600

Email

research@tums.ac.ir

Grant name

99-2-152-48830

Grant code / Reference number

99-2-152-48830

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mojgan Zendehtdel

Position

Jobholder

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

No. 13, 7th floor east, block 18, opj town, Koohsar St.,
Shahran Square

City

Tehran

Province

Tehran

Postal code

1478894438

Phone

+98 21 4433 7260

Email

Mojgan.zendehtdel@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mojgan Zendehtdel

Position

Jobholder

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

No. 13, 7th floor east, block 18, opj town, Koohsar St.,
Shahran Square

City

Tehran

Province

Tehran

Postal code

1478894438

Phone

+98 21 4433 7260

Email

Mojgan.zendehtdel@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mojgan Zendehtdel

Position

Jobholder

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

No. 13, 7th floor east, block 18, opj town, Koohsar St.,
Shahran Square

City

Tehran

Province

Tehran

Postal code

1478894438

Phone

+98 21 4433 7260

Email

Mojgan.zendehtdel@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to
make this available