

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of muscle relaxation training in both face-to-face and distance methods on stress, anxiety and sleep quality in pregnant women with hypothyroidism

Protocol summary

Study aim

Determining and comparing the effectiveness of muscle relaxation training in both face-to-face and distance methods on stress, anxiety and sleep quality in pregnant women with hypothyroidism

Design

A clinical trial with a control group, random sampling, phase 1 on 66 pregnant women with hypothyroidism, a table of numbers was used for randomization.

Settings and conduct

Muscle relaxation training in both face-to-face and distance Place of study: In coordination with the management of the Free Technical and Vocational Training Center, the House of Skills, which is a specialized center for massage and temperament training; This place was intended for face-to-face training of the samples.

Participants/Inclusion and exclusion criteria

Entry requirements Pregnant women with hypothyroidism, Do not use other pharmacological and non-pharmacological methods of anti-anxiety, anti-stress No entry conditions Absence from more than one session in class Non-pregnancy with assisted reproductive techniques Creating high-risk pregnancy conditions Dissatisfaction or unwillingness to continue reading

Intervention groups

Face-to-face training group, Distance education group

Main outcome variables

Stress level of individuals based on perceived stress questionnaire Anxiety level based on Spielberger overt and covert anxiety questionnaire People's score based on the Petersburg Sleep Quality Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220427054683N1**

Registration date: **2022-05-07, 1401/02/17**

Registration timing: **prospective**

Last update: **2022-05-07, 1401/02/17**

Update count: **0**

Registration date

2022-05-07, 1401/02/17

Registrant information

Name

afsaneh emanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4264 3000

Email address

in.sodako@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-10, 1401/02/20

Expected recruitment end date

2022-05-31, 1401/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of muscle relaxation training in both face-to-face and distance methods on

stress, anxiety and sleep quality in pregnant women with hypothyroidism

Public title
Comparison of the effectiveness of muscle relaxation training in both face-to-face and distance methods on stress, anxiety and sleep quality

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Having hypothyroidism Not suffering from mental disorders and diseases Non-use of other pharmacological and non-pharmacological methods of anti-anxiety, anti-stress and the absence of effective crises in the last 6 months (loss of parents, divorce) For face-to-face training group: Ability to attend classes in terms of physical and family conditions For distance education group: having a smart phone and the ability to work with virtual networks
Exclusion criteria:
Absence of more than one session in class Non-pregnancy by assisted reproduction methods No history of Anomalous baby birth Having high-risk pregnancy conditions such as diabetes or miscarriage while studying Reluctance to continue cooperation

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **33**

Randomization (investigator's opinion)
Randomized

Randomization description
The names were arranged alphabetically and each person was assigned a number and were divided into two groups, one in person and one in absentia.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Najafabad Azad University
Street address

University Blvd, Najafabad.

City
Najafabad

Province
Isfahan

Postal code
581413131

Approval date
2020-09-09, 1399/06/19

Ethics committee reference number
IR.IAU.NAJAFABAD.REC.1399.124

Health conditions studied

1

Description of health condition studied
Hypothyroidism

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Stress level of individuals based on perceived stress questionnaire

Timepoint
Before intervention and after intervention

Method of measurement
Perceived stress questionnaire (pass14)

2

Description
Anxiety level based on Spielberger overt and covert anxiety questionnaire

Timepoint
Before intervention and after intervention

Method of measurement
Spielberger overt and covert anxiety questionnaire

3

Description
People score on the Petersburg Sleep Quality Questionnaire

Timepoint
Before intervention and after intervention

Method of measurement
Petersburg Sleep Quality Questionnaire

Secondary outcomes
empty

Intervention groups

1

Description

Face-to-face training group: Pregnant women with hypothyroidism were asked to visit twice a week and perform movements in person and in the presence of a researcher. The exercise was repeated two to three times for each muscle group for 20 minutes. Practice was accompanied by listening to soothing music. The defects of the samples in performing the exercises were solved with the help of a researcher.

Category

Treatment - Other

2

Description

Distance education group: Pregnant women with hypothyroidism were asked to carefully view and implement the educational content that the researcher has already prepared for them and sent to the WhatsApp group at home. This group also performed the movements twice a week and sent some of their movements as a video to the researcher. Exercise was repeated for each muscle group two to three times for 20 minutes. Practice was accompanied by listening to soothing music. Exercises were followed up by the researcher on a weekly basis through phone calls and messages on WhatsApp, and the problems in performing the exercises were solved.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hassan Asgari (AS) Health Center in Najafabad

Full name of responsible person

fateme Nasaj

Street address

Health Alley, Imam Street, Najafabad.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mansoor Ahmadi Faraz

Street address

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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

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

Mina Jouzi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mina Jouzi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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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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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