

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effect of relaxation educational intervention on Stress, Anxiety and Depression in female primary school teachers in education district 3 of Isfahan.

Protocol summary

Study aim

Determining the effect of relaxation educational intervention on Stress, Anxiety and Depression in female primary school teachers in education district 3 of Isfahan.

Design

Two Groups, Single-Blind, Sample Size of 100, Randomized (Randomly Simple).

Settings and conduct

The intervention is in the form of face-to-face and virtual training. In 6 face-to-face sessions, the relevant theoretical concepts and relaxation exercises are presented. The virtual part is used to provide educational messages, provide summaries of exercises and reminders to do exercises at home. Single-blind was performed for participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Participants should get a score of 43 and above from the questionnaire. 2. Participants trend to participate in the study. Exclusion criteria: 1. Participants have major mental and physical diseases that prevent them from engaging in training.

Intervention groups

Intervention is in both face-to-face sessions and virtual education. In-person sessions consist of six in-person training sessions. Each session includes both theoretical concepts and relaxation training exercises. WhatsApp will be used in the virtual training. In addition, a reminder message will be sent every day to people to do the exercises. The group will also be used to track participants and solve their educational problems. No educational interventions will be performed for the control group about the research topic, and they will do their routine work.

Main outcome variables

Stress, Anxiety and Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200312046754N1**

Registration date: **2020-11-25, 1399/09/05**

Registration timing: **retrospective**

Last update: **2020-11-25, 1399/09/05**

Update count: **0**

Registration date

2020-11-25, 1399/09/05

Registrant information

Name

Zahra Aboutalebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 3081

Email address

zahra73abid@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-03, 1399/02/14

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of relaxation educational intervention on Stress, Anxiety and Depression in female primary school teachers in education district 3 of Isfahan.

Public title

The Effect of Educational Relaxation on Stress, Anxiety and Depression among Woman Teachers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having a score of 43 and more from the DASS-42 questionnaire Willingness to participate in the study

Exclusion criteria:

Having major mental and physical disease that barrier training

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, teachers will be included who according to the DASS-42 questionnaire have a score of 43 and more than 43. After selecting the teachers, the list of their names will be provided respectively for the researcher in numbers (1 to 100), and each of them will be randomly divided into two groups of intervention (even numbers) and control (odd numbers). None of them will be informed about their situation and others situation in each group and they will not have any connection with each other.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the researcher is aware of who is in the intervention group and who is in the control group. And participants are completely unaware of which intervention and control groups they belong to and they are kept blind. Relaxation exercises will be provided to those who will be in the intervention group. persons who are in the control group after the intervention, sample collection, and post-test will receive educational content.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Assistance for research and technology, Building No. 4, Isfahan University of Medical Sciences, Hezar Jerib St.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2020-08-11, 1399/05/21

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.204

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

Z56.3

ICD-10 code description

Stressful work schedule

2

Description of health condition studied

ICD-10 code

-

ICD-10 code description

-

3

Description of health condition studied

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Stress

Timepoint

Measurement of stress score before intervention, 55 and 85 days after intervention

Method of measurement

The Depression, Anxiety and Stress Scale-(DASS)42

2

Description

Anxiety

Timepoint

Measurement of anxiety score before intervention, 55 and 85 days after intervention

Method of measurement

The Depression, Anxiety and Stress Scale-(DASS)42

3

Description

Depression

Timepoint

Measurement of depression score before intervention, 55 and 85 days after intervention

Method of measurement

The Depression, Anxiety and Stress Scale-(DASS)42

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: Intervention is in both face-to-face sessions and virtual education. In-person sessions consist of six in-person training sessions (one training session per week) by a health educator and psychosomatic specialist. The duration of each training session is one and a half hours. Each session includes both theoretical concepts and relaxation training exercises. Relaxation exercises include diaphragmatic breathing, tension release, control keys, vibrating gestures, establishment and meditation, and each session provides one of its exercises with related theoretical concepts. In each session, first the theoretical concepts are taught for one hour, then 30 minutes for relaxation exercises. WhatsApp will be used by the health educator in the virtual training program, with one or two training messages per week about relaxation and summarize training sessions in person (in audio or text message) in the group. In addition, a reminder message will be sent every day to people to do the exercises and people tell the health educator if they do the exercises. The group will also be used to track participants and solve their educational problems.

Category

Behavior

2

Description

Control group: From the beginning to the end of the training interventions, no educational interventions will be performed for the control group about the research topic, and they will do their routine work. The samples in this study are teachers and they perform activities that related to their job, but they do not receive any intervention in the field of research plan such as referring to a counselor, psychologist or receiving medication related to treatment in the field of psychology. After collecting data from both groups in the post-test, educational files will be provided to control group for use.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan District 3 Public Primary Schools

Full name of responsible person

Zahra Aboutalebi

Street address

Education Department District 3 Isfahan, next to Saadi School, non-level Intersection of Gaza Martyrs, Army Blvd

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Province

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Postal code

8174773111

Phone

+98 31 3620 1901

Email

www.zahra73abid@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Assistance for Research and Technology, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib Ave.

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8174673461

Phone

+98 31 3668 8138

Email

www.research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Aboutalebi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

Street address

No. 4, Shahid Mohammadi Alley, Keshavarzi Avenue,
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City

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8174898131

Phone

+98 31 3776 3081

Email

zahra73abid@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Aboutalebi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Aboutalebi

Position

Student

Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Yes - There is 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

Study protocol, statistical analysis and statistical methods used, informed consent form, analysis codes will be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

Researchers interested in mental health-related factors, as well as researchers working in academic and scientific institutions, can apply to receive the mentioned data and documents.

Under which criteria data/document could be used

There are no other special conditions for using the

mentioned and sendable documents.

From where data/document is obtainable

1-email: zahra73abid@gmail.com 2-
phone:09130908563-09135676253 3-Department of
Health Education and Health Promotion, Faculty of
Health, Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

The applicant for the mentioned documents can receive the requested documents after a few days after submitting his / her application in the ways mentioned in the previous section, such as sending an email or calling the phone number.

Comments