

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effectiveness of stress inoculation training on individual sense of coherence and psychological distress in pregnant women

Protocol summary

Study aim

The aim of the present study will be examining the training of immunization against the stress on the individual's sense of cohesion and the psychological distress in pregnant women

Design

This study is a nonblinded clinical trial. The research population will be included all pregnant women referred to Imam Sari hospital. 30 pregnant women will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct

The study will be conducted in Imam Sari hospital. The control group and the experimental group will complete psychological distress and sense of coherence questionnaire.

Participants/Inclusion and exclusion criteria

Entry requirements to study would be to earn a score down in the individual sense of cohesion and earn a high score on the scale of psychological distress

Intervention groups

The experimental group was given a stress inoculation training about 8 sessions, once a week for 90 minutes and the control group did not receive training

Main outcome variables

psychological distress and sense of coherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190319043092N1**

Registration date: **2019-08-03, 1398/05/12**

Registration timing: **retrospective**

Last update: **2019-08-03, 1398/05/12**

Update count: **0**

Registration date

2019-08-03, 1398/05/12

Registrant information

Name

Ghodratollah Abbasi

Name of organization / entity

Islamic Azad University, Sari Branch

Country

Iran (Islamic Republic of)

Phone

+98 11 3444 5863

Email address

gh_abbasi@iausari.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2019-04-09, 1398/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of stress inoculation training on individual sense of coherence and psychological distress in pregnant women

Public title

effectiveness of stress inoculation on individual sense of coherence and psychological distress

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

low score on the scale of sense of coherence high score on the scale of psychological distress Pregnancy week 31 or 32 The lack of experience in training classes The lack of physical disease The lack of a history of psychiatric illness

Exclusion criteria:

High risk pregnancy (preeclampsia, hemorrhage, miscarriage risk) preterm delivery (delivery earlier than 37 weeks of pregnancy)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Pregnant women were replaced by simple random

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

Islamic Azad University- Sari Branch

Street address

Floor 5, Medical Bldgs, Azad University, Farah Abad Rd., Khazar Sq, Sari

City

Sari

Province

Mazandaran

Postal code

19318-48161

Approval date

2019-01-29, 1397/11/09

Ethics committee reference number

IR.IAU.SARI.REC.1397.029

Health conditions studied

1

Description of health condition studied

Distress in pregnancy

ICD-10 code

O75.0

ICD-10 code description

Maternal distress during labor and delivery

Primary outcomes

1

Description

sense of coherence

Timepoint

Before the study and immediately after the intervention

Method of measurement

Antonovsky's sense of coherence scale

2

Description

psychological distress

Timepoint

Before the study and immediately after the intervention

Method of measurement

The scale of psychological prishani Kessler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group will receive stress inoculation training about 8 sessions, once a week for 90 minutes.

Category

Behavior

2

Description

Control group: The control group will receive the ward usual care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sari hospital

Full name of responsible person

Farah masihpor

Street address

Floor 2, Imam Khomeini Hospital, Amir Mazandarani St.

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3304 4000

Email

fmasihpour19@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

mohamad farsi

Street address

Floor 5, Office Bldgs, Azad University, Farah Abad Rd, Khazar Sq

City

Sari

Province

Mazandaran

Postal code

19318-48161

Phone

+98 11 3303 2891

Email

moh_farsi@iausari.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

Private

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

Ghodratollah Abbasi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Floor 5, Human Sciences Bldgs, Azad University, Farah Abad Rd, Khazar Sq

City

Sari

Province

Mazandaran

Postal code

19318-48161

Phone

+98 11 3444 5836

Email

abasighodrat@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ghodratollah Abbasi

Position

Sari

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Mazandaran

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+98 11 3444 5836

Email

abasighodrat@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ghodratollah Abbasi

Position

Associate professor

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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

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

Title and more details about the data/document

The main outcomes of the study will be shared

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments