

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effectiveness of Stress Inoculation Training (SIT) on Anxiety and Sleep quality of Pregnant women in third trimester

Protocol summary

Summary

The aim of the present study was to examine for the effects of stress inoculation training (SIT) on anxiety and sleep quality of pregnant women in third trimester. Inclusion criteria were: located at week 31 or 32 of pregnancy and lack of psychiatric history, also exclusion criteria were: becoming the pregnancy as a high risk pregnancy (threatened miscarriage, bleeding, preeclampsia), preterm birth (delivery before 38 weeks of pregnancy). Among the study population (n = 436 pregnant women referred to health centers and health posts in Bushehr city), 40 subjects were selected. then they were allocated to one of the experimental and control groups by random. The experimental group subjected to 7 sessions of SIT training and the time of research was winter 2012.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031716093N1**

Registration date: **2014-03-17, 1392/12/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-17, 1392/12/26

Registrant information

Name

Elahe Jokar

Name of organization / entity

Shahid Bahonar University of Kerman

Country

Iran (Islamic Republic of)

Phone

+98 34 1322 0041

Email address

jokarelahe@ymail.com

Recruitment status

Recruitment complete

Funding source

Shahid Bahonar University of Kerman

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-01-03, 1391/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Stress Inoculation Training (SIT) on Anxiety and Sleep quality of Pregnant women in third trimester

Public title

The effect of stress on anxiety and sleep in women

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Having the ability and interest for taking part in the training program; located at week 31 or 32 of pregnancy; lack of participation in similar classes and methods; the lack of stress in the family in the last 3 months; a satisfying marital relationships; economic status; satisfaction sector; lack of physical illness that makes anxiety and a sleep disorder; no psychiatric history; education level degree or higher; minimum of 23 participants and a maximum of 33 years. Exclusion criteria: By discretion of the participant or the inability to sustain in training program; becoming the pregnancy high risk pregnancy (threatened miscarriage, bleeding,

preeclampsia); preterm birth (delivery before 38 weeks of pregnancy)

Age

From **23 years** old to **33 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Shahid Bahonar University of Kerman

Street address

22 Bahman Blvd, Kerman

City

Kerman

Postal code

Approval date

2013-11-24, 1392/09/03

Ethics committee reference number

350/1732

Health conditions studied

1

Description of health condition studied

Sleep disorder

ICD-10 code

G47.0

ICD-10 code description

Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes

1

Description

anxiety

Timepoint

before the intervention and a week after intervention

Method of measurement

Beck Anxiety Inventory

2

Description

sleep disorder

Timepoint

before the intervention and a week after intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

7 session stress inoculation training for the intervention group, which included training in muscle relaxation and challenge negative automatic thoughts and replace logical thinking, coping strategies, self-guided dialogue, learning meditation, diaphragmatic interpretation, social support

Category

Other

2

Description

The control group did not receive the intervention and questionnaires have been completed only

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Meraj Health Center

Full name of responsible person

Maryam Hydrshnas

Street address

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Bahonar University of Kerman

Full name of responsible person

Elahe Jokar
Street address
22 Bahman Blvd, Kerman
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Bahonar University of Kerman
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Bahonar University of Kerman
Full name of responsible person
Abbas Rahmati
Position
PH.D. in counseling / Associate Professor of Shahid Bahonar University of Kerman
Other areas of specialty/work
Street address
22 Bahman Blvd, Kerman
City
Kerman
Postal code
Phone
+98 34 1322 0041
Fax
Email
abrahmata@uk.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Bahonar University of Kerman
Full name of responsible person

Elahe Jokar
Position
Master of General Psychology
Other areas of specialty/work
Street address
22 Bahman Blvd
City
Kerman
Postal code
Phone
+98 34 1322 0041
Fax
Email
jokarelahe@ymail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Bahonar University of Kerman
Full name of responsible person
Elahe Jokar
Position
Master of General Psychology
Other areas of specialty/work
Street address
22 Bahman Blvd, Kerman
City
Kerman
Postal code
Phone
+98 34 1322 0041
Fax
Email
jokarelahe@ymail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty