Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Elahe Jokar
Name of organization / entity
Shahid Bahonar University of Kerman
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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 Unversity of Kerman

Full name of responsible person

Elahe Jokar
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22 Bahman Blvd, Kerman
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Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Bahonar Unversity 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
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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