Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of relaxation on stress, anxiety and depression of pregnant women in health centers of Kashan city

Protocol summary

Summary

Aims: This study was conducted to determine the effect of relaxation training on stress, anxiety and depression in pregnant women. Material and Methods: This quasi-experimental study was done on women refer to health centers of city of Kashan in the third trimester. At onset of study, if the woman was consent, was completed demographic questionnaire, Edinburgh Depression Scale and questionnaire of stress, anxiety and depression-21. Providing obtaining score of mild to moderate in the stress, anxiety and depression scale and score of 10 or higher in Edinburgh Depression Scale, individuals were divided randomized to the intervention group (n= 33) and control group (n= 33). In the intervention group in the first two weeks, relaxation exercises were taught to women and after 4 weeks, these exercises were carried out by the CD at home.Scale of stress, anxiety and depression-21 was again completed in the fourth and seventh weeks of beginning of study by all women.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112220035N1**
Registration date: **2015-04-22, 1394/02/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-22, 1394/02/02

Registrant information

Name

Saeideh Nasiri

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

saeideh.nasiri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2013-03-31, 1392/01/11

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of relaxation on stress, anxiety and depression of pregnant women in health centers of Kashan city

Public title

The Effect of Relaxation On Stress, Anxiety And Depression

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: 18-35 years, At least Elementary Education, living in Kashan, Iranian, Singleton Pregnancy
Exclusion Criteria: Neurological Disease, Drug Abuse, Stressful Events During the last Six Months, Complications During Pregnancy

Age

From **18 years** old to **35 years** old

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Kashan University of Medical Sciences
Street address
Qhotb Ravandi BLV- Kashan- Iran
City
Kashan
Postal code
Approval date
2013-03-10, 1391/12/20
Ethics committee reference number
26/1/5/29/ب

Health conditions studied

1

Description of health condition studied
Stress
ICD-10 code
F43.0
ICD-10 code description
Acute stress reaction

2

Description of health condition studied
Anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

3

Description of health condition studied
Depression
ICD-10 code
F32.0
ICD-10 code description
Mild depressive episode

Primary outcomes

1

Description
Stress
Timepoint
Start of Intervention, After Three weeks, After 6 weeks
Method of measurement
Questionnaire of Stress, Anxiety and Depression-21

2

Description
Anxiety
Timepoint
Start of Intervention, After 3 weeks, After 6 weeks
Method of measurement
Questionnaire of Stress, Anxiety and Depression-21

3

Description
Depression
Timepoint
Start of Intervention, After3 weeks, After 6 weeks
Method of measurement
Questionnaire of Stress, Anxiety and Depression-21

Secondary outcomes

1

Description
Demographic Variables
Timepoint
Start of Study
Method of measurement
Questionnaire of Demographic Information

Intervention groups

1

Description
Intervention Group: Relaxation training during 2 weeks Consecutively and then performing homeworks during 4 weeks and attendance at health center for performing Guided imagery one day in week
Category
Behavior

2

Description
Control Group: Performing routin cares for pregnant

women According to nation instructions of safe motherhood

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Golabchi Healthy Center

Full name of responsible person

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Nadi

Street address

Qhotb Ravandi BLV- Research Deputy of University- Kashan-Iran

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan University of Medical Sciences

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

Kashan University of Medical Sciences

Full name of responsible person

Saeideh Nasiri

Position

MSC. Midwifery

Other areas of specialty/work

Street address

Qhotb Ravandi BLV- Faculty of Nursing and Midwifery- Kashan-Iran

City

Kashan

Postal code

Phone

+98 31 5554 0021

Fax

Email

saeideh.nasiri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Saeideh Nasiri

Position

MSC

Other areas of specialty/work

Street address

Qhotb Ravandi BLV- Faculty of Nursing and Midwifery- Kashan- Iran

City

Kashan

Postal code

8715981151

Phone

+98 31 5554 0021

Fax

+98 55546633

Email

saeideh.nasiri@yahoo.com

Web page address

Person responsible for updating data

Contact

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