Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Benson Relaxation method on stress, anxiety and depression in pregnant women

Protocol summary

Summary

because relaxation is an essential interventions for removal stress, anxiety and depression based on psychoneuroimmunology science and haven't any research about effect of Benson relaxation on stress, anxiety and depression in pregnant women until now, we want to assess this very Inexpensive, effective,efficient and convenient method on stress, anxiety and depression in pregnant women. this research is randomized clinical trial with case and control groups that assess effect of Benson relaxation on foregoing cases, participants division is randomized using Table of random numbers. research area is health centers of varamin-pishva.in this research pregnant women that are in third trimester are assessed. in two groups all women that have mild stress, anxiety and depression are assessed. in case group in one month 2 times daily, morning & evening became relaxed and in next month & 2 month later is assessed with using of DASS-21 questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306069463N14**
Registration date: **2017-08-16, 1396/05/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-16, 1396/05/25

Registrant information

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Benson Relaxation method on stress, anxiety and depression in pregnant women

Public title

Effect of Benson Relaxation method on stress, anxiety and depression in pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

INCLUSION criteria:nuli parity, without history of abortion or infertility, women in third trimester of pregnancy, be literacy, ability to use CD of Benson Relaxation and didn't pass similar relaxation course, not using alcohol & opioid, without history of chronic disease, without history of psychologic disorders,without history of using psychoactive drugs, EXCLUSION criteria: without tendency of participants to follow research, pregnancy

disorders (e.g: placenta abruption, abnormal presentation and so on), decrease of fetal movement that needs intervention

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: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Tehran 16 Azar Street

City
Tehran

Postal code

Approval date
2017-04-15, 1396/01/26

Ethics committee reference number
IR.TUMS.FNM.REC.1396.2078

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
depression

Timepoint
befor & after intervention

Method of measurement
DASS-21 questionnaire

2

Description
stress

Timepoint
befor & after intervention

Method of measurement
DASS-21 questionnaire

3

Description
anxiety

Timepoint
befor & after intervention

Method of measurement
DASS-21 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
CD of Benson relaxation is gave to case group. after training, case group in one month 2 times daily, morning & evening became relaxed and is assessed in next month & 2 month later with using of DASS-21 questionnaire and compared with control group.

Category
Behavior

2

Description
CD of Benson relaxation isn't gave to control group.

anxiety, stress and depression is assessed in first visit and in next month & 2 month later with using of DASS-21 questionnaire and compared with case group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Varamin Health Care Centers

Full name of responsible person

Azade Zenouzi

Street address

Varamin, Bahonar Bulvar

City

Varamin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ziba Taghizade

Street address

Tehran, keshavarz, 16 Azar Street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University Of Medical Science,Faculty of Nursing & Midvifery

Full name of responsible person

Azade Zenouzi

Position

MS of Midvifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person

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Other areas of specialty/work

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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