

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of relaxation training on anxiety of pregnant women in high risk groups

Protocol summary

Summary

Abstract Background and Objectives: Prenatal maternal anxiety has adverse effects on the mother and fetus and child. Use of anxiety-reducing techniques for pregnant mothers plays an important role in decreasing maternal and child Psychological problems. Relaxation exercise could be improve pregnancy outcome in High Risk pregnancy and High Risk Delivery. This study aimed to determine the effect of relaxation training on anxiety in High risk mothers. **Methods :**The present study was done as a clinical trial on 150 High Risk Pregnant Women 32-35week (75 subjects as relaxation group,75 subjects as control group)referred to Health and Medical Center in Shahreza city.Data were collected using personal data form and Spielberger anxiety Inventory questionnaire .In addition to routine pregnancy care, four 90minute sessions of relaxation active Jacobson training courses were held during 4weeks (once a week). The control group only received routine pregnancy care .Anxiety score before the intervention and at the end of the intervention were analyzed in all two groups .Data analysis was done using Chi-square,T-test , exact 'fisher analysis. **Results:** In this study, the mean anxiety scores were not significantly different in the two groups before the intervention ,but there was significant differences in relaxation group after the intervention (p-value<0/001). There was a decrease in the mean anxiety score in relaxation group after the intervention whereas there was a slightly increase in the control group. **Conclusion:** The results of this study indicated that relaxation training could reduce anxiety in Pregnant High Risk Women.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121015737N1**

Registration date: **2014-04-27, 1393/02/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-27, 1393/02/07

Registrant information

Name

farzah rahimi

Name of organization / entity

Martyr Beheshti University of Medical Sciences
International Branch

Country

Iran (Islamic Republic of)

Phone

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Email address

m.ahmadi@sbm.u.ac.ir

Recruitment status

Recruitment complete

Funding source

International Branch of Shahid Beheshti University of
Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of relaxation training on anxiety of pregnant
women in high risk groups

Public title

Effect of relaxation training on anxiety of pregnant
women in high risk groups

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having the ability to read and write ; no history of mental illness ; not taking Anti-anxiety drugs; a gestational age between 32-35weeks (the exact date of the first day of the last menstrual period or ultrasound 20 weeks) ; Having low to moderate anxiety score (21-60) on the STAI anxiety scale ; lack of relaxation before or during the study ; the pregnant mother is high risk pregnancy groups.Exclusion criteria: non-compliance with the study protocol (the absence of a training session or non-performance of Relaxation at home for more than two days a week)

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

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

International Branch of Shahid Beheshti University of
Medical Sciences

Street address

No19,Shahid Abbassour Street,Vali asr Street,Tehran
,Iran

City

Tehran

Postal code

141553693

Approval date

2013-09-30, 1392/07/08

Ethics committee reference number

116/2682

Health conditions studied

1

Description of health condition studied

pregnancy anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Pregnancy anxiety

Timepoint

Before and after intervention

Method of measurement

Questionair

Secondary outcomes

empty

Intervention groups

1

Description

Intervention groups: receive routine care during pregnancy and four sessions of relaxation Control groups: receive routine care during pregnancy

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahreza Health centers

Full name of responsible person

Farzaneh rahimi

Street address

Shahreza

City

Shahreza

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

International Branch Shahid Beheshti University of
Medical Sciences

Full name of responsible person

Farzaneh rahimi

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No19,Shahid Abbaspour street, vali asr
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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

International Branch Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahbobeh ahmadi

Position

Master of Midwifery

Other areas of specialty/work**Street address**

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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