Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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
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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 Abbasspour street,vali asr street,Tehran,Iran
City
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
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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