

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effectiveness of Jacobsen relaxation training on the level of anxiety of pregnant women hospitalized in the complicated pregnancy department

Protocol summary

Study aim

Determining the effectiveness of Jacobsen relaxation training on the level of anxiety of pregnant women admitted to the complicated pregnancy ward

Design

The clinical trial has a control group with parallel groups. The participants are randomly allocated to two intervention groups and control groups through the online software (www.Random.org/sequences). The sample size is 44 people. There is no trial phase.

Settings and conduct

Complicated pregnancy department of Shahid Sadoughi Hospital in Yazd is the place of study. Jacobson relaxation training is conducted in 4 sessions of 60 minutes, twice a week, in person, and an educational pamphlet is provided to the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Having informed consent and willingness to participate in the study • Diagnosis of complicated pregnancy and prediction of at least two weeks hospitalization in the complicated pregnancy department of Shahid Sadoughi Hospital by a gynecologist. • Women of reproductive age • Pregnancy age 14-34 weeks (based on the exact date of the first day of the last menstrual period or ultrasound under 20 weeks) • Iranian nationality • Ability to understand and speak Persian language and cooperate in exercises
Exclusion criteria: • Participating in mental health-related intervention studies at the same time • Existence of various types of mental disorders • Existence of stressful events during the last 6 months such as immigration, death of relatives, divorce and financial problems • Smoking, drugs and alcohol

Intervention groups

For the intervention group, the Jacobson method of relaxation technique training is conducted in 4 sessions of 60 minutes twice a week and in person. For the control

group, an educational pamphlet is provided on the importance of stress control during pregnancy.

Main outcome variables

The level of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230725058915N1**

Registration date: **2023-09-24, 1402/07/02**

Registration timing: **prospective**

Last update: **2023-09-24, 1402/07/02**

Update count: **0**

Registration date

2023-09-24, 1402/07/02

Registrant information

Name

Fateme Jamashi

Name of organization / entity

Shahid sadoghi

Country

Iran (Islamic Republic of)

Phone

+98 35 3828 2718

Email address

fatemejamashi0072@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-21, 1402/08/30

Expected recruitment end date

2024-04-19, 1403/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of Jacobsen relaxation training on the level of anxiety of pregnant women hospitalized in the complicated pregnancy department

Public title

Effectiveness of Jacobsen relaxation training on the level of anxiety of pregnant women hospitalized in the complicated pregnancy department

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of complicated pregnancy and prediction of at least two weeks hospitalization in the complicated pregnancy department of Shahid Sadoughi Hospital by a gynecologist. Willingness to participate in the study Having informed consent to participate in the study Women of reproductive age Gestational age 14-34 weeks Iranian nationality Ability to understand and speak Persian and cooperate in doing exercises

Exclusion criteria:

Participating in concurrent mental health-related intervention studies Existence of various types of mental disorders such as psychosis, schizophrenia, anxiety which is under medical treatment based on the information of the medical record or the patient's own statements. Existence of stressful events during the past 6 months Smoking, drugs and alcohol

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random number sequence and online software (www.Random.org/sequences), research units are assigned to two groups of 30 people: motivational interview and pelvic floor exercises group.

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**

Research Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Bahonar square, the central building of Shahid Sadoughi University of Medical Sciences, Yazd Town

City

Yazd

Province

Yazd

Postal code

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Approval date

2023-06-14, 1402/03/24

Ethics committee reference number

IR.SSU.REC.1402.034

Health conditions studied**1****Description of health condition studied**

Anxiety during pregnancy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The level of anxiety

Timepoint

First and immediately and two weeks after the intervention

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Jacobson relaxation training is conducted in 4 sessions of 60 minutes and twice a week

Category

Prevention

2

Description

Control group: An educational pamphlet is provided for the control group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Complicated Pregnancy, Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Fatemeh Jamashi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. seyed mehdi hashemi bajgani

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Zaremobini

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable