

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of relaxation technique on preeclampsia and its consequences in high risk pregnant mothers referred to Selected comprehensive Health centers of Isfahan

Protocol summary

Study aim

aim of investigating was the effect of body relaxation technique on PES

Design

Clinical trial with control group, randomized, on 100 high-risk pregnant mothers, randomized based on random number table and even and unit numbering

Settings and conduct

In this clinical trial, the effect of relaxation technique on preeclampsia investigated in Isfahan. These mothers were divided into intervention and control groups and were evaluated for preeclampsia at the end of the study. The statistical analyzer did not know the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria were as follows: pregnant mothers from 20-24 weeks of gestation, literacy, first or second pregnancy, PES background in previous pregnancy or chronic hypertension in previous pregnancy, lack of smoking, alcohol and psychotropic substances using history, high proteinuria up to Trace level, blood pressure less than 140/90 mm Hg, no psychiatric disorders and severe anxiety (person who scored above 26 on DASS21 questionnaire), having CD player, a computer or an Android mobile phone in order to listen to the audio of relaxation file at home. Exclusion criteria Exclusion criteria were as follows: absence of more than two consecutive sessions in relaxation sessions, failure to perform more than three consecutive relaxation sessions at home, lack of willingness to continue the study, symptoms of PES, eclampsia, HELLP syndrome or performing a preterm delivery or severe anxiety before completing 4 sessions of relaxation technique

Intervention groups

All high-risk pregnant women referred to selected comprehensive health centers in Isfahan. In the intervention group, they performed 16 relaxation sessions and in the control group, they received only

clinical care.

Main outcome variables

stress score, preeclampsia, birth weight at delivery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091219002889N11**

Registration date: **2021-01-07, 1399/10/18**

Registration timing: **retrospective**

Last update: **2021-01-07, 1399/10/18**

Update count: **0**

Registration date

2021-01-07, 1399/10/18

Registrant information

Name

Mahboubeh Valiani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

2018-11-06, 1397/08/15
Actual recruitment end date
2019-02-04, 1397/11/15
Trial completion date
2020-02-10, 1398/11/21

Scientific title

The effect of relaxation technique on preeclampsia and its consequences in high risk pregnant mothers referred to Selected comprehensive Health centers of Isfahan

Public title

Body Relaxation techniques and Pre-eclampsia Syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

pregnant mothers from 20-24 weeks of gestation, literacy, first or second pregnancy, PES background in previous pregnancy or chronic hypertension in previous pregnancy, lack of smoking, alcohol and psychotropic substances using history, high proteinuria up to Trace level, blood pressure less than 140/90 mm Hg, no psychiatric disorders and severe anxiety (person who scored above 26 on DASS21 questionnaire), having CD player, a computer or an Android mobile phone in order to listen to the audio of relaxation file at home. Age range 16 to 43 years

Exclusion criteria:

Stress score obtained from the questionnaire is more than 26 Proteinuria over trace Blood pressure over than 140/90

Age

From **16 years** old to **43 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **98**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The initial selection of pregnancy records of pregnant women was done randomly based on a table of random numbers. Samples were randomly divided into experimental (even numbers) and control (unit numbers) groups. This numbering was done up to 100.

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Avenue, Isfahan University of Medical Sciences, Faculty of Nursing and Midwifery .

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Postal code

81746-73461

Approval date

2018-11-18, 1397/08/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.312

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

O10.412

ICD-10 code description

Pre-existing secondary hypertension complicating pregnancy, second trimester

Primary outcomes

1

Description

Blood pressure

Timepoint

Blood pressure was measured and recorded before and after the intervention in experimental and control group from the beginning and 36 weeks of pregnancy.

Method of measurement

Digital Blood Pressure Monitor

2

Description

stress score

Timepoint

stress score was measured and recorded before and after the intervention in experimental and control group from the beginning and 36 weeks of pregnancy.

Method of measurement

Dass21 Questionnaire,

3

Description

infant weight

Timepoint

After delivery, birth weight was measured and recorded.

Method of measurement

scales

4

Description

gestational age

Timepoint

After delivery, gestational age was measured and recorded.

Method of measurement

Gestational age based on LMP or the first sono of pregnancy

5

Description

proteinurine

Timepoint

proteinurine was measured and recorded before and after the intervention in experimental and control group from the beginning and 36 weeks of pregnancy.

Method of measurement

Roshe Laboratory Kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the experimental group participated in 16 sessions(8 sessions in the class and 8 sessions at home) of 30-minute relaxation with the Jacobson and Benson methods. Thus, the first session was at 20 to 24 weeks of pregnancy. Next, at 24 to 34 weeks of pregnancy, there were five sessions every two weeks. Then, at 34 to 36 weeks of pregnancy, there were two sessions every a week. Mother blood pressure was recorded before and after each session using a microlife.digital device. Then each participant in the first session was given a CD and relaxation technique training. At the first 10 minutes of relaxation technique, the following actions were performed to physically relax. At first, the mother was in a relaxed position (Semi-prone position) and after concentration, deep breathing and abdominal breathing exercises were performed. BRT was performed with Jacobson's method of contraction (5 seconds) and then conscious muscle release (30 seconds) to consciously relieve muscle tension (14). Then, at the final 20 minutes, visualization and mind imagery were carried out (with Benson's method), which contained three fictional content and at each session, a story content was performed. As such, after three

sessions, all three contents were performed.

Category

Prevention

2

Description

Control group: underwent routine medical care and Participate in PLC, the blood pressure, the Dass21 Stress Questionnaire, urine protein were measured once in the entrance to the study in the same manner as the experimental group, and re-examined at 36 weeks of pregnancy. Only Banson's relaxation was performed for 10 minutes with completely different content without Jackson's relaxation and deep relaxation. for the control group, by Perform a kind of Benson relaxation, is considered as a placebo for Body Relaxation technique. After 36 weeks of pregnancy, the mothers were followed up weekly by telephone. Furthermore, the researcher was present at the hospital during delivery and the mother was evaluated for gestational age, maternal hypertension, and PES. Maternal PES was diagnosed based on the approval of a gynecologist.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Navab Safavy Comperhensive Center

Full name of responsible person

Mahboubbeh Valiani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjo

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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Mahboubeh Valiani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available
Title and more details about the data/document
The end result of the data is anonymously shared.
When the data will become available and for how long
After being published in the magazine
To whom data/document is available
Researcher
Under which criteria data/document could be used

Executors of research project
From where data/document is obtainable
Ministry of Health, Deputy Minister of Education
What processes are involved for a request to access data/document
Data will be sent via email and data request and consultation with the implementers of this project.
Comments