

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of relaxation on blood sugar and blood pressure in pregnant women with gestational diabetes mellitus, referring to selective centers of Shiraz University of Medical Sciences- 1392

Protocol summary

Summary

The purpose of the study and study design: to survey the effect of relaxation on blood glucose and blood pressure changes in pregnant women with gestational diabetes- Random -not blinded- placebo not used- The study population: Volunteers who aged between 18 to 40 years and eligible for inclusion. Inclusion criteria: having gestational diabetes not overt diabetes; Gestational diabetes diagnosed by a gynecologist; being literate; age between 18 to 40 years; having ability to understand Persian language; living in Fars province; having ability to participate in educational programs, follow-up and implementation of the training program; gestational age between 24 to 30 weeks; no previous training about the subject; no severe mental illness and insanity. exclusion criteria: lack of willingness to continue in every phase of the study; refusing to participate in more than one session of training classes; not performing more than five days of relaxation at home; and the women who experience complication of pregnancy during the study. Sample: 8 eligible participants was selected from the population and randomly divided into two equal groups of 29 (Relaxation training group and the control group) Intervention: Educational Relaxation sessions (five sessions over three weeks) in training group - control group (not intervention)-Completion of the questionnaires: beginning of the intervention and Completion the experiment results prior to the intervention, immediately after intervention and one month after intervention in both groups. Study Outcome: the effect of Relaxation on four variables (Fasting plasma glucose, 2-hour postprandial blood glucose, systolic and diastolic blood pressure) in pregnant women with gestational diabetes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091014612N1**
Registration date: **2013-11-21, 1392/08/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-21, 1392/08/30

Registrant information

Name

Niloofar Bahoosh

Name of organization / entity

Shiraz University Of Medical Sciences

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+98 71 1623 8872

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Recruitment status

Recruitment complete

Funding source

Shiraz University Of Medical Sciences

Expected recruitment start date

2013-05-20, 1392/02/30

Expected recruitment end date

2013-08-21, 1392/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of relaxation on blood sugar and blood pressure in pregnant women with gestational diabetes mellitus,referring to selective centers of Shiraz University of Medical Sciences- 1392

Public title

The effect of relaxation on blood glucose and blood pressure changes in pregnant women with gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having gestational diabetes not overt diabetes; Gestational diabetes diagnosed by a gynecologist; being literate; age between 18 to 40 years; having ability to understand Persian language; living in Fars province; having ability to participate in educational programs, follow-up and implementation of the training program; gestational age between 24 to 30 weeks; no previous training about the subject; no severe mental illness and insanity. exclusion criteria: lack of willingness to continue in every phase of the study; refusing to participate in more than one session of training classes; not performing more than five days of relaxation at home; and the women who experience complication of pregnancy during the study.

Age

From **19 years** old to **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

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

Shiraz University Of Medical Sciences

Street address

Shiraz, Zand Ave, Shiraz University Of Medical Science Building

City

Shiraz

Postal code

7193613119

Approval date

2013-07-16, 1392/04/25

Ethics committee reference number

CT-92-6614

Health conditions studied

1

Description of health condition studied

gestitinal diabetes mellitus

ICD-10 code

o24.9

ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description

fasting blood sugar

Timepoint

Prior to the intervention, immediately after intervention and one month after the intervention

Method of measurement

Blood tests

2

Description

2-hour postprandial blood glucose

Timepoint

Prior to the intervention, immediately after intervention and one month after the intervention

Method of measurement

Blood tests

Secondary outcomes

empty

Intervention groups

1

Description

intervention groups: Relaxation Training session for 5 sessions 45 minute over3 weeks and Relaxation at home ,daily within 1 month

Category

Treatment - Other

2

Description

control group:with out intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez hospital

Full name of responsible person

Niloofer Bahoosh Student, MSc in Midwifery

Street address

Abiverdi street, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Shiraz University Of
Medical Sciences

Full name of responsible person

Dr. Gholam Reza Hatam

Street address

7th Flat, Central department of Shiraz University Of
Medical Sciences, Zand Street, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

ct-92-6614

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

Yes

Title of funding source

Vice chancellor for Research, Shiraz 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

Fatemeh (PBUH) College of Nursing and Midwifery

Full name of responsible person

Maasumeh kaviani

Position

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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