

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1623 8872

##### Email address

bahoosh@sums.ac.ir

##### 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

Faculty Member, MSc in Midwifery

#### Other areas of specialty/work

#### Street address

Namazi square, Shiraz

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Fatemeh College of Nursing And Midwifery

#### Full name of responsible person

Niloofer Bahoosh

#### Position

Student, MSc in Midwifery

#### Other areas of specialty/work

#### Street address

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**Fax**

**Email**

bahooshn@yahoo.com bahooshn@gmail.com

**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*