Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of relaxation on fasting blood glucose and blood pressure in women with gestational diabetes mellitus

Protocol summary

Summary

Main goal: determining the effects of relaxation on the fast blood sugar, systole and diastole blood pressure among women with pregnancy diabetes Design of study conduction: non-randomized, not blinding, single-centered, with control group Way of performing: the intervention group will be offered a training session for relaxation for 45 minutes. They will receive a manual book of relaxation method with a CD and a checklist of activities. Criteria of inclusion: diagnosis of pregnancy diabetes by specialist physician; gestational age more than 24 weeks and lower than 26 weeks, without illnesses such as asthma, chronic hypertension, epilepsy and etc, lack of taking special drugs of pregnancy Criteria of exclusion:excessive stress, the risk of pregnancy complications such as preeclampsia,the necessity of performing other psychiatric intervention, using sedative and antianxiety, initiating insulin shot Study population: 80 individuals Body mind and mind body as studied intervention: relaxation technic Intervention term: 10 weeks Studied consequences: fast blood sugar (gr/dL). systole and diastole blood) Millimeters of mercury(Control group: this group will obtain routine clinical health care. Intervention group: In technic classes the relaxation will be trained by the researcher in the form of role paly and CD play .The mother is asked in this method to lie and close eyes in the best position. In this position bringing her relaxation and initiates to breath deeply and regularly relaxes here muscles . they will receive a manual and CD of relaxation and a checklist for practice exercises.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071222943N2**
Registration date: **2015-12-31, 1394/10/10**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-12-31, 1394/10/10

Registrant information

Name
Sara Bikdelo
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6692 7171
Email address
sbigdelo@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Tehran University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of relaxation on fasting blood glucose and blood pressure in women with gestational diabetes mellitus

Public title

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

mellitus

Purpose

Supportive

Inclusion/Exclusion criteria

Criteria of inclusion in the study: diagnosis of pregnancy diabetes by specialist physician; gestational age more than 24 weeks and lower than 26 weeks, lack of identified mental disorders, without illnesses such as asthma, chronic hypertension, kidney, heart, epilepsy which affects the blood sugar and pressure, lack of taking special drugs of pregnancy which affects blood sugar and pressure, ability to understand and speak Persian, literacy read and write; no history of stillbirth and infertility. Criteria of exclusion from the study: missing pregnancy, excessive stress such as the death of someone close, intense family conflicts, accident and surgery operation during the research, nor performing relaxation exercises more than three consecutive days and lack of desire to cooperate, the risk of pregnancy complications such as preeclampsia, bleeding during the third trimester of pregnancy and infection during pregnancy, the necessity of performing other psychiatric intervention including necessity of visiting a psychiatrist, using sedative and antianxiety and doing hypnotism during research, initiating insulin shot during current pregnancy.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Since sampling has been performed just in Imam Khomeini Hospital and was single- centered and for avoiding conflict of samples of control and intervention groups, we first will perform sampling in control group followed by the intervention group.

Secondary Ids

1

Registry name

.

Secondary trial Id

.

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

The Street Qhods, Blvd Keshavarz, Tehran. Tehran University of Medical Sciences

City

Tehran

Postal code

1419733171

Approval date

2015-05-26, 1394/03/05

Ethics committee reference number

IR.TUMS.REC.1394.9111373010-145793

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

O24.4

ICD-10 code description

Diabetes mellitus arising in Pregnancy

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

fast blood sugar (gr/dL) which will be measured prior to the intervention and after the intervention session will be finished through a laboratory method

Method of measurement

laboratory method and In gram per dc litr

2

Description

Systolic and diastolic blood pressure

Timepoint

systole and diastole blood pressure will be measured prior to the intervention and after the intervention session will be finished by a mercury sphygmomanometer

Method of measurement

mercury sphygmomanometer and Millimeters of mercury and

Secondary outcomes

1

Description
.
Timepoint
.
Method of measurement
.

Intervention groups

1

Description
Control group: first, we will take samples of systole and diastole blood pressure and blood sugar for women with pregnancy diabetes and during study period this group will obtain routine clinical health care. In the end of the study, they will receive a CD and a manual of relaxation
Category
Other

2

Description
Intervention group: this group will take a session for 45 minute training relaxation and they will attend relaxation class next sessions. There are 1-4 attendant each session. In technic classes the relaxation will be trained by the researcher in the form of role paly and CD play and the mod is from mind-body and body mind type. The mother is asked in this method to lie and close eyes in the best position. In this position, she selects a word (such as Good, Love and etc.) bringing her relaxation and initiates to breath deeply and regularly such that inhales through nose and exhale from the mouth and repeats the word and in the same time relaxes here muscles starting from toes' tip toward upper muscles until all muscle to be fully expanded and keep this state 20 minutes and then opens her eyes. Then, all subjects are asked to practice the technic to obtain enough skill. After the technic is being thought, they are asked to act this technic twice a day at home and they will receive a manual and CD of relaxation and a checklist for practice exercises. The term of this technic is 10 weeks and the subjects will be contacted through telephone once a week.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini Hospital
Full name of responsible person
Sara Bikdeloo
Street address
End Of keshavarz BLvd, Tehran, Imam khomeini hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Tehran University of Medical Sciences
Full name of responsible person
Research assistant Tehran University of Medical Sciences
Street address
The Street Qhods, Blvd Keshavarz, Tehran. Tehran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research Tehran 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
Tehran School of Nursing and Midwifery
Full name of responsible person
Sara Bikdeloo
Position
Master degree midwifery student
Other areas of specialty/work
Street address
Street Nosrat Eastern(Avenue Doctor Myrkhany), Tohid Square, Tehran School of Nursing and Midwifery
City
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Fax
Email

bigdelys@gmail.com; sbigdelo@razi.tums.ac.ir

Web page address

http://fnm.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran School of Nursing and Midwifery

Full name of responsible person

Mehrnaz Geranmaye

Position

Department of faculty members

Other areas of specialty/work

Street address

Street Nosrat Eastern (Avenue doctor Myrkhany), Tohid Square,Tehran

City

Tehran

Postal code

Phone

+98 21 6693 7120

Fax

Email

Geranmay@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran School of Nursing and Midwifery

Full name of responsible person

Sara Bikdeloo

Position

Masrer degree midwifery student

Other areas of specialty/work

Street address

City

Postal code

Phone

+98 21 5633 3511

Fax

Email

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