

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of acupressure on the rate and severity of anxiety in women with gestational diabetes in intervention and placebo group

Protocol summary

Summary

Pregnancy is the most stressful period in women's life. One of the issues that affect the phenomenon of pregnancy and can lead to adverse pregnancy outcomes is gestational diabetes mellitus (GDM). On the other hand, anxiety and stress as the psychological problems can cause negative effects on pregnant mother with GDM and their fetuses. In this regard, acupressure as a branch of acupuncture is a non-pharmacological approach that was used for relieving some symptoms including anxiety. Therefore, this study was performed, to determine the effect of acupressure on severity of anxiety in women with GDM. A randomized controlled trial was used in this study. The eligible subjects of this clinical trial (the women with GDM, the age of 15-42 years old, and the feeling of anxiety) were randomly assigned into the experimental or acupressure group (n=30), which received acupressure at the true point (P7), and the placebo group (n=30), which received the intervention of touching (instead of acupressure) at true point (P7). The instrument for data collection in relation to measuring maternal anxiety and the severity of anxiety in the participants consisted of a questionnaire and the Visual Analogue Scale (VAS) respectively. Anxiety and its severity were measured in both groups before and after intervention. In the experimental group, the intervention (acupressure) was pressed about five minutes at the point of P7 for each side of the body three times a day for four consecutive days by the participants. The same procedure regarding touching at the point of P7 was used for the placebo group. The women who did not continue the trial for any reason, or the participants in the experimental group who did not feel the heavy and numbness feelings during the acupressure at the selective point were excluded. Finally, the data from pre-test (before the intervention) and post-test (at the end of the fourth day of the intervention) were compared and analyzed by the descriptive and inferential statistics between and within the two groups with SPSS (Statistical

Package for the Social Sciences, Chicago, Illinois) version 16.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206246247N8**

Registration date: **2012-09-15, 1391/06/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-09-15, 1391/06/25

Registrant information

Name

Farideh Bastani

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2011-10-23, 1390/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acupressure on the rate and severity of anxiety in women with gestational diabetes in intervention and placebo group

Public title

Acupressure and anxiety in women with gestational diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: All women aged between 15 and 42 years old, who attended and hospitalized in the Akbarabadi Hospital, the High Risk Obstetrical Unit between August 23, 2011, and October 23, 2011, for treatment of gestational diabetes, who mentioned the feeling of anxiety and no previous experience of acupressure, and signed the written informed consent. Exclusion criteria: not participating in the trial for any reason, and the subjects in the experimental group who did not feel the heavy and numbness feelings during the intervention (acupressure) at the selective point.

Age

From **15 years** old to **42 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

In this study, we had a supportive care not a pharmacological intervention. The patients, as the study participants, who were hospitalized in a similar high risk obstetrical unit, were blinded to group allocation. In other words, the experimental group individuals, who received the intervention (acupressure at the P7 point), and the control or placebo group individuals, who received superficial touching at the same point, had no information regarding their allocation to different groups for controlling their anxiety. Therefore, the participating patients were blinded in this way.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2011-01-18, 1389/10/28

Ethics committee reference number

12269

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

Anxiety-Post-traumatic stress disorder

ICD-10 code

F43.0, F41

ICD-10 code description

F43.0 (Post-traumatic stress disorder) and F41.1 (Generalized anxiety disorder)

Primary outcomes**1****Description**

anxiety and its severity

Timepoint

at pre-test (before the intervention) and post-test (at the end of the fourth day of the intervention)

Method of measurement

a questionnaire of maternal anxiety and the Visual analogue scale (VAS)

Secondary outcomes

empty

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

The intervention in the experimental group was acupressure at the point of P7 for five minutes on each side of the body, three times a day for four consecutive days.

Category

Other

2

Description

The intervention on the control or placebo group was touching instead of acupressure at the point of P7 for five minutes on each side of the body, three times a day for four consecutive days.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar-Abadi Hospital

Full name of responsible person

Dr.Kashanian

Street address

Akbar-Abadi Hospital, Molavi st., Tehran, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd.

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

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Dr. Farideh Bastani

Position

PhD-Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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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