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

Country

Iran (Islamic Republic of)

Phone

+98 21 8857 2278

Email address

f-bastani@sina.tums.ac.ir

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
Tehran

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
Street address
Nosrat St., Tohid Sq., 1419733171, Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran. Iran.
City
Tehran
Postal code
Phone
+98 21 6105 4102
Fax
+98 21 6694 1668
Email
f-bastani@sina.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Farideh Bastani
Position
PhD, Associate Professor
Other areas of specialty/work
Street address
Nosrat St., Tohid Sq., 1419733171, Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran. Iran.
City
Tehran
Postal code
Phone
+98 21 6105 4102
Fax
Email
f-bastani@sina.tums.ac.ir
Web page address

Person responsible for updating data

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

Street address
Nosrat St., Tohid Sq., 1419733171, Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran. Iran.
City
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Postal code
Phone
+98 21 6105 4102
Fax
Email
f-bastani@sina.tums.ac.ir
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