Clinical Trial Protocol
Iranian Registry of Clinical Trials
19 Apr 2022

The effectiveness of Emotional Freedom Technique on fear of childbirth in nulliparous women

Protocol summary

Study aim
Determining the effectiveness of Emotional Freedom Technique on fear of childbirth in nulliparous women

Design
Clinical trial with control and intervention group, one-way blind, randomized, on 116 nulliparous women, permutation blocks with block size 6 were used for randomization.

Settings and conduct
Clinical trial in Shahid Shafiei and Sadoughi health centers in Yasouj is in the form of two intervention and control groups. The order of the researcher and the participants will be unaware of who is in which group until the beginning of the study. Intervention in this study from the age of 28 to 30 weeks of pregnancy, beginning and end of postpartum intervention The questionnaire that is completed at the beginning of the study (fear of childbirth Vijma version A) to study will be a pre-test for both intervention and control groups, then the intervention group and the control group in the same way using points False for two sessions of face-to-face training and 10 weeks of face-to-face training and follow-up, the researcher learns the technique of mind liberation.

Participants/inclusion and exclusion criteria
include: Gestational age 28 to 30 weeks; primiparous; scoring more than 37 in the Vijma questionnaire
Exclusion : suffering from mental illness during the last year and taking psychotropic drugs

Intervention groups
Intervention group: tapping the parts of the face and body with the fingertips, which include: the beginning of the eyebrows, around the eyes, under the eyes, under the lips, chin, clavicle and armpits. Control group: They also hit in the same way by using false points, ie points other than the points of the introduced acupressure.

Main outcome variables
Fear of childbirth

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20210622051671N1
Registration date: 2021-07-31, 1400/05/09
Registration timing: registered_while_recruiting

Last update: 2021-09-29, 1400/07/07
Update count: 1
Registration date
2021-07-31, 1400/05/09
Registrant information
Name
Fatemeh Emadi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 31 5351 5216
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Pharmaceuticals
Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-07-24, 1400/05/02
Expected recruitment end date
2021-12-21, 1400/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of Emotional Freedom Technique on fear of childbirth in nulliparous women

Public title
The effectiveness of Emotional Freedom Technique on fear of childbirth in nulliparous women

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Minimum primary education Gestational age 28 to 30 weeks Nulliparous Earn more than 37 points in the Vijama questionnaire

Exclusion criteria:
Chronic diseases such as heart disease, high blood pressure, diabetes History of abortion Placenta previa Suffering from mental illness during the last year and taking psychotropic drugs Drug and smoking addiction Pregnancy complications such as preeclampsia, bleeding, intrauterine death, preterm delivery

Age
From 15 years old to 40 years old

Gender
Female

Phase
N/A

Groups that have been masked
• Participant

Sample size
Target sample size: 116

Randomization (investigator's opinion)
Randomized

Randomization description
The method of assigning the intervention to individuals is random and in the method of random permutation blocks with block size 6 (using the table related to random permutations) and with a ratio of 1: 1. The randomization list is prepared by a statistician. The codes assigned to the eligible individuals will be placed in sealed envelopes by an out-of-study person who is unaware of the research objectives and will be provided to the secretary of the clinic. They will not know who is in which group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The codes assigned to the eligible individuals will be placed in sealed envelopes by an out-of-study person who is unaware of the research objectives and will be provided to the secretary of the clinic. They will not know who is in which group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences

Street address
Golestan St., Ahvaz Jundishapur University of Medical Sciences, Razi School of Nursing and Midwifery

City
Ahvaz

Province
Khuzestan

Postal code
61357-15794

Approval date
2021-06-15, 1400/03/25

Ethics committee reference number
IR.AJUMS.REC.1400.192

Health conditions studied

1

Description of health condition studied
Fear of childbirth

ICD-10 code
F40

ICD-10 code description
Phobic anxiety disorders

Primary outcomes

1

Description
Fear of childbirth score in Vijma childbirth fear questionnaire

Timepoint
At the beginning of the study (before the intervention) with Vijma Maternity Fear Questionnaire version A and at the end of the intervention (first postpartum visit) with Vijama Maternity Fear Questionnaire version B

Method of measurement
Vijma Childbirth Fear Questionnaire version A and B

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: Tapping the parts of the face and body with the fingertips, which include: the beginning of the eyebrows (above the nose), the sides of the eyes (on the outer bone of the eye), the under eyes (on the cheeks and 2-3 cm Meters below the eye socket), under
the lips (in the short distance between the nose and the upper lip), chin (in the middle of the distance between the chin and the lower lip), clavicle (from the U-shaped bone below the throat 2-3 cm down and 2-3 cm Meters to the sides) and armpits (10 cm below the armpits).

**Category**
Other

**2**

**Description**
Control group: This group also strikes with their fingers using false points, i.e. points other than the points of acupressure introduced.

**Category**
Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**
Health centers 2 and 3 west of Ahvaz

**Full name of responsible person**
Khadijeh Hekmat

**Street address**
The end of Bani Hashem street, South Soroush street - the end of Kian, the first of Alavi alley, corner of Farahani

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**
Ahvaz University of Medical Sciences

**Full name of responsible person**
Kourosh Zarea

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Golestan Road, Shahr-e-Daneshgahi, Ahvaz School of Nursing and Midwifery, Vice Chancellor for Research, Second Floor

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**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**
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**Position**
Student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Midwifery

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**Position**
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**Latest degree**
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**Other areas of specialty/work**
Midwifery

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Person responsible for updating data

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Ahvaz University of Medical Sciences

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Seyyedeh Fatemeh Emadi

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Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
I do not have a plan at the moment

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available