Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of self-acupressure education on blood glucose index and anxiety in patients with pre-diabetes

Protocol summary

Study aim
The effect of self-acupressure education on blood glucose index and anxiety in patients with pre-diabetes

Design
Three-group randomized controlled clinical trial

Settings and conduct
The ST36 - LIV 3 - K 3 - SP 6 points of both feet are by the fingers of the patient in the acupuncture group. For reduce anxiety, massage the p6 point for 5 minutes daily. Pressure duration of 12 weeks and 5 minutes for each point and each day of the week with 10 seconds of massage and 2 seconds of rest, totaling 21 minutes.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Having definitive diagnosis of pre-diabetes, Written and oral consent, Over18 years of age , Ability to communicate Exclusion criteria:absence of clear and clinically approved neuropathy - No known psychiatric illness under treatment - Absence of wounds, organ failure, allergies And fractures in acupressure points - failure to participate in other interventional studies - no pregnancy and lactation (there is a risk of miscarriage) - no other infectious diseases

Intervention groups
Acupressure with metformine group:ST36 - LIV 3 - K 3 - SP 6 points with both fingers determined by the patient's own finger.Pressure duration of 5 minutes for each point and daily for 5 weeks.10 minutes of massage and 2 seconds of rest for a total of 21 minutes.For reduce anxiety, massage the p6 point for 5 minutes daily. Blood glucose and hemoglobin glycolysis and anxiety are measured and recorded in all 2 groups before the start of the intervention and after the end of the 12 weeks. Sham with metformine group:Routine training will be given for diabetes and the procedure will be exactly the same as for the test group, except that pressure is not applied to acupuncture points according to acupuncture specialists at a specific meridian within 1.5 cm.

Main outcome variables
Glycemic and HA1C and anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110906007494N36**
Registration date: **2021-01-31, 1399/11/12**
Registration timing: **prospective**

Last update: **2021-01-31, 1399/11/12**
Update count: **0**

Registration date
2021-01-31, 1399/11/12

Registrant information

Name
Masoumeh Bagheri Nesami

Name of organization / entity
Mazandaran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of self-acupressure education on blood glucose index and anxiety in patients with pre-diabetes

Public title
Acupressure in patients with pre-diabetes

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Having a definitive diagnosis of pre-diabetes - Having written and verbal consent to participate in the study - Over 18 years of age - Ability to communicate, absence of clear and clinically confirmed neuropathy - Not known mental illness under treatment - Absence of ulcer, Defects, allergies, and fractures in acupuncture targeted areas - Failure to participate in other interventional studies - Pregnancy and lactation (risk of miscarriage) - No other serious illnesses - No liver disease, kidney disease And heart failure

Exclusion criteria:
Desire to Exclude from the Study - Improper Massage - Illness and Patient Death During Study - Hospitalization and Change of Medication - Presence of Clear and Confirmed Neuropathy During Study - No adherence of Metformin Pills

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients were randomly assigned to two groups of 44 acupressure with metformin, sham with metformin , groups using random numbers provided with computer software and Randomization Permuted Block. 22 blocks with size 4 so that there are 2 people in each block. Therefore, 88 envelopes are designed and embedded inside based on information obtained from the computer program of letters A of acupressure group, B of sham group. The priority of opening the envelope is executed on the order of the number based on the patient's admission date.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences

Street address
Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square, Sari, Mazandaran, Iran.

City
SARI

Province
Mazandaran

Postal code
4816715793

Approval date
2020-02-26, 1398/12/07

Ethics committee reference number
IR.MAZUMS.REC.1398.1393

Health conditions studied

1

Description of health condition studied
Pre-diabetes and Anxiety

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Blood sugar indices

Timepoint
Before and 12 weeks after intervention

Method of measurement
Anxiety questionnaire and blood test

Secondary outcomes

empty

Intervention groups

1

Description
Acupressure with metformine group: After introducing and stating the aims of the study and obtaining written informed consent and patient cooperation to complete the study and after filling out the questionnaire, the researcher will learn how to pressure the points of interest. In this study a demographic and medical information questionnaire and a blood glucose index checklist were recorded. Then the subjects are

positioned backwards, with the head 30 degrees above the shoulders, and the thumbs are positioned bilaterally on the SP6 point (4 fingers above the medial ankle). Massage in a clockwise and counterclockwise manner. For reduce anxiety, massage the p6 point for 5 minutes daily. Then, to ensure patient learning, the patient is massaged several times to allow the researcher to learn from the patient, and the rest is massaged. Pressure duration of 5 minutes for each point and every day of the week (5 minutes on both feet) with 10 seconds of massage and 2 seconds of rest, totaling 21 minutes (1 minute of 2 seconds rest between Massage is the point), performed for 12 consecutive weeks (18). Blood glucose and hemoglobin glycolysis and anxiety indices were measured and recorded in a laboratory before and after the intervention for 12 weeks.

Category

Prevention

2

Description

Intervention group2: In the sham with metformine group, the procedure will be exactly the same as that of the test group, except that pressure is applied at points close to the acupressure points according to accredited acupuncture specialists in the field, who do not place this on the meridian. The order of pressure, mode of pressure, position of the patient, time, and amount of pressure in the test and sham groups were the same. It should be noted that in both groups, the pressure procedure will be taught by one person (the researcher). Blood glucose and glycated hemoglobin are then measured before and 12 weeks after baseline.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafavian Diabetes Clinic of Imam Khomeini Hospital in Sari

Full name of responsible person

sahar haghighat

Street address

Mazandaran University of Medical Sciencesvaliye asr highway,Joybar 3way,Imam ،Sari. Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sari University of Medical Sciences

Full name of responsible person

University researches Assistance-Traditional Medicine Research Center

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sari University of Medical Sciences

Full name of responsible person

Dr. Masoumeh Bagheri Nasami

Position

PhD of nursing education

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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
The research team has not yet made a decision on this issue.
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