

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effects of anti-inflammatory diet alone or in combination with acupuncture on mental health, advanced glycation end products (AGEs), anthropometric indices and metabolic status in diabetic patients with depression: A randomized, controlled clinical trial

Protocol summary

Study aim

1) Determination and comparison the effects of anti-inflammatory diet with/without acupuncture vs. control group on mental health (depression, anxiety) in diabetic patients with depression 2) Determination and comparison the effects of anti-inflammatory diet with/without acupuncture vs. control group on metabolic status (AGE, FBS, HbA1c, TC, TG, LDL-C, HDL-C, IL-6, hs-CRP) in diabetic patients with depression

Design

Randomized controlled clinical trial

Settings and conduct

Eligible patients will be selected by the announcement and referring by physicians among those referred to Diabetic clinics affiliated to Tehran University of Medical Sciences. Before starting the trial, the study will be explained to eligible individuals and if they have the tendency to participate, they will sign the written informed consent. Due to the type of intervention in this study, complete blindness is not possible. However, a colleague who will analysis data is not aware of the groups. Finally, encoded data will be provided to the data analysis team.

Participants/Inclusion and exclusion criteria

Inclusion criteria: suffering from T2DM for more than 6 months, taking oral anti-diabetic medications, and and suffering from mild-to-moderate depression. Exclusion criteria: injection insulin or liraglutide, taking medicinal herbs or herbal medicine, antibiotics, antioxidant supplements , suffering from severe depression, having chronic diseases, severe depression

Intervention groups

(i) an individualized anti-inflammatory diet with acupuncture therapy, (ii) an individualized anti-inflammatory diet alone, (iii) common diet alone (control group).

Main outcome variables

mental health (depression, anxiety)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110314006065N3**

Registration date: **2021-10-31, 1400/08/09**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-31, 1400/08/09**

Update count: **0**

Registration date

2021-10-31, 1400/08/09

Registrant information

Name

Nazli Namazi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

nazli.namazi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-24, 1400/08/02

Expected recruitment end date

2022-01-22, 1400/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of anti-inflammatory diet alone or in combination with acupuncture on mental health, advanced glycation end products (AGEs), anthropometric indices and metabolic status in diabetic patients with depression: A randomized, controlled clinical trial

Public title

Anti-inflammatory diets & mental health

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Suffering from type 2 diabetes mellitus for more than 6 months. taking oral anti-diabetic medications suffering from mild-to-moderate depression

Exclusion criteria:

injection of insulin or liraglutide taking medicinal herbs or herbal medicine, antibiotics, antioxidant supplements (multivitamins & minerals, vitamin E, vitamin C, Zinc), suffering from severe depression, having chronic heart - vascular diseases, severe depression, chronic liver chronic liver and kidney disease, uncontrolled thyroid and any other diabetes complications leads to inflammatory and oxidative conditions, other types of diabetes taking psychiatry medications. Pregnancy and lactation

AgeFrom **20 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

Eligible volunteers will be randomly allocated (1:1:1) into one of the three following groups: (i) receiving an individualized anti-inflammatory diet with acupuncture therapy (n=30), (ii) receiving an individualized anti-inflammatory diet alone (iii) receiving common diet (control group) (n=30). It is notable that volunteers will be randomized and allocated in each group based on the severity of depression (mild, moderate), age, and sex. The randomization will be carried out using an online system (<https://www.sealedenvelope.com/>). Once the randomization has been made, each patient is given a code with that she/he will be identified throughout the study. The randomization number will be assigned in a consecutive way. Randomization will not be exposed to those conducting the study and will be provided in

sealed opaque envelopes with successive numbers. The envelope will be opened after signing the informed consent form and complying with the eligibility criteria by the patients.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

National Institute for Medical Research Development

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Iran National Institute for Development of Medical Research (NIMAD), No. 21, beginning of Besat St., West Fatemi St., Tehran, Iran

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Postal code

۱۴۱۹۶۹۳۱۱۱

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.NIMAD.REC.1398.340

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

Type 2 diabetes mellitus

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

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

depression

Timepoint

Baseline, after 8 weeks of the intervention (At the end of the intervention)

Method of measurement

Montgomery-Asberg Depression Rating Scale (MADRS)

2

Description

fat mass

Timepoint

Baseline, after 4 weeks of intervention and At the end of the intervention

Method of measurement

Bio-Electrical Impedance Analysis

3

Description

fat free mass

Timepoint

Baseline, after 4 weeks of intervention and At the end of the intervention

Method of measurement

Bio-Electrical Impedance Analysis

4

Description

HbA1c

Timepoint

Baseline, At the end of the intervention

Method of measurement

Chromatography

Secondary outcomes

1

Description

advanced glycation end products

Timepoint

Baseline, At the end of the intervention

Method of measurement

ELISA kit

2

Description

FBS

Timepoint

Baseline, At the end of the intervention

Method of measurement

Autoanalyzer

3

Description

Total cholesterol

Timepoint

Baseline, At the end of the intervention

Method of measurement

Autoanalyzer

4

Description

low-density lipoprotein

Timepoint

Baseline, At the end of the intervention

Method of measurement

Autoanalyzer

5

Description

High-density lipoprotein

Timepoint

Baseline, At the end of the intervention

Method of measurement

Autoanalyzer

6

Description

high-sensitivity C-reactive protein

Timepoint

Baseline, At the end of the intervention

Method of measurement

ELISA kit

Intervention groups

1

Description

An individualized anti-inflammatory diet with acupuncture therapy. All three groups will receive common treatment (medications, weight-loss diet in overweight and obese subjects, healthy dietary recommendations) throughout the study. dietary inflammatory index score in accordance to 24-h dietary recall and FFQ will be calculated. In general, considering pro- and anti- inflammatory food parameters and their food sources, participants' characteristics, and an individualized anti-inflammatory diet will be prepared for both intervention groups. Our designed protocol for "Diabetic patients with Depression" emphasizes on treating different dimensions, etiologies, and symptoms of depression, and we will avoid those points which are proven to have blood sugar increasing effects. For instance, ST36 (ZuSanLi), ST25 (TianShu),etc, would not be punctured for diabetic patients.

Category

Treatment - Other

2

Description

An individualized anti-inflammatory diet alone. All three groups will receive common treatment (medications, weight-loss diet in overweight and obese subjects, healthy dietary recommendations) throughout the study. dietary inflammatory index score in accordance to 24-h dietary recall and FFQ will be calculated. In general, considering pro- and anti- inflammatory food parameters and their food sources, participants' characteristics, and an individualized anti-inflammatory diet will be prepared for both intervention groups.

Category

Treatment - Other

3

Description

Common diet. All three groups will receive common treatment (medications, weight-loss diet in overweight and obese subjects, healthy dietary recommendations) throughout the study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology and Metabolism Research Institute

Full name of responsible person

Nazli Namazi

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Endocrinology & Metabolism Research Institute,
Shariati Hospital, North Kargar Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Development of Medical Research in Iran

Full name of responsible person

Farid Najafi

Street address

National Institute for the Development of Medical
Research in Iran, between Gharib and Eskandari,
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Development of Medical Research in Iran

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nazli Namazi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available