Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 reffering 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
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Iran (Islamic Republic of)
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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
Age
From **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
Street address
Iran National Institute for Development of Medical Research (NIMAD), No. 21, beginning of Besat St., West Fatemi St., Tehran, Iran
City
Tehran
Province
Tehran
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

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

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Tehran

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Tehran

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1411713137

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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, Azadi St

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

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

Contact

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Latest degree

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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