Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

To investigate the effect of acupuncture plus standard care with standard care alone for liver chemistries and metabolic, systemic markers in adults with nonalcoholic fatty liver disease or metabolic dysfunction associated steatotic liver disease.

Protocol summary

Study aim

To compare acupuncture plus standard care with standard care alone for liver chemistries and metabolic, systemic markers in adults with nonalcoholic fatty liver disease or metabolic dysfunction associated steatotic liver disease.

Design

Single center, two arm, parallel, randomized, single blind trial with 56 participants; phase is not applicable. Allocation is 1 to 1 using variable blocks of 4 and 6 and opaque sealed envelopes. Participants and the acupuncturist are not blinded; outcome assessors and the data analyst are blinded.

Settings and conduct

The trial is conducted in the gastroenterology, acupuncture, and PERSIAN Cohort units of Imam Reza Hospital, Mashhad. Assessments occur at baseline and weeks 6 and 18.

Participants/Inclusion and exclusion criteria

Eligible participants are adults aged 18 years or older with grade 2 or 3 hepatic steatosis on ultrasonography. Main exclusions are grade 0 or 1 steatosis, advanced or other liver disease, significant alcohol use, a bleeding risk precluding acupuncture, pregnancy or breastfeeding, advanced malignancy, and regular acupuncture in the previous 3 months.

Intervention groups

Both groups receive standard lifestyle care for 6 weeks. The intervention group also receives 12 manual acupuncture sessions during these 6 weeks. Both groups receive identical weekly safety calls from weeks 1 to 18; week 18 is for follow up only.

Main outcome variables

The primary outcome is change in serum alanine aminotransferase from baseline to week 6. Secondary outcomes include alanine aminotransferase at week 18; other liver, metabolic, inflammatory, renal, and hematologic markers; Fibrosis 4; ultrasonography; quality of life; weight; body mass index; blood pressure; and adverse events during 18 weeks.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230626058585N3**
Registration date: **2026-08-31, 1405/06/09**
Registration timing: **prospective**

Last update: **2026-08-31, 1405/06/09**
Update count: **0**

Registration date

2026-08-31, 1405/06/09

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To investigate the effect of acupuncture plus standard care with standard care alone for liver chemistries and metabolic, systemic markers in adults with nonalcoholic fatty liver disease or metabolic dysfunction associated steatotic liver disease.

Public title

Effect of adding acupuncture to standard care in patients with fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of MASLD/NAFLD based on clinical, laboratory, and imaging criteria by a gastroenterologist/hepatologist. Grade 2 or 3 hepatic steatosis on baseline B-mode ultrasonography. Age 18 years or older. Clinically stable condition without acute hepatitis, acute liver failure, or current hospitalization for an acute liver condition. Stable main disease-related treatments without major changes during the previous 4 to 6 weeks, according to the treating physician. Ability to attend all scheduled study visits and follow-up assessments and, if allocated to the intervention group, the acupuncture sessions. Willingness to participate and provision of written informed consent.

Exclusion criteria:

Grade 0 or 1 hepatic steatosis on baseline ultrasonography according to the protocol-defined criteria, because only participants with grade 2 or 3 steatosis are eligible for this study. Evidence of cirrhosis, advanced hepatic fibrosis, liver failure, or hepatic decompensation. Other causes of liver disease, including active viral hepatitis, autoimmune hepatitis, biliary disease, Wilson disease, or hemochromatosis. Significant alcohol consumption exceeding 20 g/day in women or 30 g/day in men. Use of potent anticoagulants such as warfarin or direct oral anticoagulants, or severe coagulopathy making acupuncture unsafe. Severe thrombocytopenia or another bleeding disorder preventing safe needling. History of severe hypersensitivity or marked intolerance to needling, or extensive skin lesions at the intended acupuncture sites. Pregnancy or breastfeeding. Advanced malignancy or an incurable systemic disease with a life expectancy of less than 6 months. Regular acupuncture treatment for a related condition during the previous 3 months.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be individually allocated to the intervention and control groups in a 1:1 ratio using permuted block randomization with variable block sizes of 4 and 6. No stratification will be used. The random allocation sequence will be generated using the Sealed Envelope online randomization service. Allocation concealment will be performed using opaque, sealed envelopes prepared by an independent person who is not involved in delivering the intervention or assessing the outcomes. After confirming eligibility and obtaining written informed consent, the next envelope in the predetermined order will be opened and the participant will be assigned to the indicated group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, participants and the acupuncturist will not be blinded. The clinical outcome assessor, laboratory personnel handling coded samples, telephone safety monitor, ultrasonography reader, data-entry personnel, and statistical analyst will remain blinded to group allocation. The telephone safety monitor will receive a coded list containing participants from both groups without group labels. Participants will be instructed not to disclose their group allocation or type of intervention during blinded assessments or telephone calls, and any unblinding will be documented. Group codes will be revealed only after completion of the primary statistical analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Imam Reza Hospital, Mashhad University of Medical Sciences

Street address

Imam Reza Clinical Research Development Unit, Educational Complex Building, Basement Floor, Imam Reza Hospital, Ebne Sina Street, Mashhad, Iran

City

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Razavi Khorasan
Postal code
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Approval date
2026-08-10, 1405/05/19
Ethics committee reference number
IR.MUMS.IRH.REC.1405.115

Health conditions studied

1

Description of health condition studied
Metabolic dysfunction associated steatotic liver disease (nonalcoholic fatty liver disease)
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Change in serum alanine aminotransferase level
Timepoint
At baseline before the intervention and at the end of week 6 after the start of the intervention
Method of measurement
Serum alanine aminotransferase will be measured in units per liter by a standard enzymatic laboratory method using an automated clinical chemistry analyzer.

Secondary outcomes

1

Description
Change in serum aspartate aminotransferase level
Timepoint
At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention
Method of measurement
Serum aspartate aminotransferase will be measured in units per liter in the central laboratory using a standard kinetic enzymatic method and an automated clinical chemistry analyzer.

2

Description
Change in serum alkaline phosphatase level
Timepoint
At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention
Method of measurement
Serum alkaline phosphatase will be measured in units per liter in the central laboratory using a standard enzymatic method and an automated clinical chemistry analyzer.

3

Description
Change in serum gamma glutamyl transferase level
Timepoint
At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention
Method of measurement
Serum gamma glutamyl transferase will be measured in units per liter in the central laboratory using a standard enzymatic method and an automated clinical chemistry analyzer.

4

Description
Change in serum albumin level
Timepoint
At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention
Method of measurement
Serum albumin will be measured in grams per deciliter in the central laboratory using a standard colorimetric method and an automated clinical chemistry analyzer.

5

Description
Change in serum total bilirubin level
Timepoint
At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention
Method of measurement
Serum total bilirubin will be measured in milligrams per deciliter in the central laboratory using a standard colorimetric method and an automated clinical chemistry analyzer.

6

Description
Change in prothrombin time
Timepoint
At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention
Method of measurement
Plasma prothrombin time will be measured in seconds using a standard coagulation assay and an automated coagulation analyzer.

7

Description
Change in international normalized ratio
Timepoint
At baseline before the intervention, at the end of week 6,

and at the week 18 follow-up after the start of the intervention

Method of measurement

The international normalized ratio will be calculated from the participant's prothrombin time, the laboratory control prothrombin time, and the international sensitivity index of thromboplastin using the standard formula.

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Description

Change in fasting blood glucose level

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Fasting plasma glucose will be measured in milligrams per deciliter after an overnight fast using a standard enzymatic laboratory method and an automated clinical chemistry analyzer.

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Description

Change in glycated hemoglobin level

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Blood glycated hemoglobin will be measured as a percentage using a standardized laboratory method and an automated analyzer.

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Description

Change in fasting serum insulin level

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Fasting serum insulin will be measured in micro-international units per milliliter using a standardized immunoassay and an automated immunoassay analyzer.

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Description

Change in the homeostatic model assessment of insulin resistance score

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

The homeostatic model assessment of insulin resistance score will be calculated by multiplying fasting serum insulin in micro-international units per milliliter by fasting plasma glucose in milligrams per deciliter and dividing the result by 405.

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Description

Change in serum triglyceride level

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Serum triglyceride will be measured in milligrams per deciliter in the central laboratory using a standard enzymatic colorimetric method and an automated clinical chemistry analyzer.

13

Description

Change in serum total cholesterol level

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Serum total cholesterol will be measured in milligrams per deciliter in the central laboratory using a standard enzymatic colorimetric method and an automated clinical chemistry analyzer.

14

Description

Change in serum high-density lipoprotein cholesterol level

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Serum high-density lipoprotein cholesterol will be measured in milligrams per deciliter in the central laboratory using a standard laboratory method and an automated clinical chemistry analyzer.

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Description

Change in serum low-density lipoprotein cholesterol level

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Serum low-density lipoprotein cholesterol will be determined in milligrams per deciliter in the central laboratory using its standard validated laboratory procedure.

16

Description

Change in serum thyroid-stimulating hormone level

Timepoint

At baseline before the intervention, at the end of week 6,

and at the week 18 follow-up after the start of the intervention

Method of measurement

Serum thyroid-stimulating hormone will be measured in milli-international units per liter using a standardized immunoassay and an automated immunoassay analyzer.

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Description

Change in serum high-sensitivity C-reactive protein level

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Serum high-sensitivity C-reactive protein will be measured in milligrams per liter using a standardized high-sensitivity immunoassay and an automated analyzer.

18

Description

Change in the fibrosis four index score

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

The fibrosis four index will be calculated using the following formula: age in years multiplied by serum aspartate aminotransferase in units per liter, divided by the product of platelet count in ten to the ninth power per liter and the square root of serum alanine aminotransferase in units per liter.

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Description

Change in liver steatosis grade assessed by ultrasonography

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Liver steatosis will be assessed by B-mode abdominal ultrasonography using the same ultrasound device and a trained operator at all three assessments. Images will be coded and de-identified and will be read by an ultrasonography reader blinded to group allocation and the temporal order of the images. Steatosis will be classified from grade 0 to grade 3 based on hepatic echogenicity and visualization of the intrahepatic vessels, diaphragm, and posterior part of the right hepatic lobe.

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Description

Change in the physical health domain score of the World Health Organization Quality of Life Brief Version questionnaire

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

The validated Persian 26-item World Health Organization Quality of Life Brief Version questionnaire will be administered by a blinded outcome assessor. The physical health domain score will be calculated according to the standard scoring instructions and transformed to a scale from zero to 100, with higher scores indicating better quality of life.

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Description

Change in the psychological health domain score of the World Health Organization Quality of Life Brief Version questionnaire

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

The validated Persian 26-item World Health Organization Quality of Life Brief Version questionnaire will be administered by a blinded outcome assessor. The psychological health domain score will be calculated according to the standard scoring instructions and transformed to a scale from zero to 100, with higher scores indicating better quality of life.

22

Description

Change in the social relationships domain score of the World Health Organization Quality of Life Brief Version questionnaire

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

The validated Persian 26-item World Health Organization Quality of Life Brief Version questionnaire will be administered by a blinded outcome assessor. The social relationships domain score will be calculated according to the standard scoring instructions and transformed to a scale from zero to 100, with higher scores indicating better quality of life.

23

Description

Change in the environment domain score of the World Health Organization Quality of Life Brief Version questionnaire

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

The validated Persian 26-item World Health Organization Quality of Life Brief Version questionnaire will be administered by a blinded outcome assessor. The environment domain score will be calculated according to the standard scoring instructions and transformed to a scale from zero to 100, with higher scores indicating better quality of life.

24

Description

Change in body weight

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Body weight will be measured in kilograms using a calibrated scale, with the participant wearing light clothing and no shoes.

25

Description

Change in body mass index

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Body mass index will be calculated as body weight in kilograms divided by the square of height in meters. Height will be measured at baseline using a stadiometer.

26

Description

Change in platelet count

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Platelet count will be measured in ten to the ninth power per liter as part of the complete blood count using an automated hematology analyzer.

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Description

Change in blood hemoglobin concentration

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Blood hemoglobin concentration will be measured in grams per deciliter as part of the complete blood count using an automated hematology analyzer.

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Description

Change in total white blood cell count

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Total white blood cell count will be measured in ten to the ninth power per liter as part of the complete blood count using an automated hematology analyzer.

29

Description

Change in serum sodium level

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Serum sodium will be measured in millimoles per liter in the central laboratory using the ion-selective electrode method and an automated electrolyte analyzer.

30

Description

Change in serum urea level

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Serum urea will be measured in milligrams per deciliter in the central laboratory using a standard enzymatic method and an automated clinical chemistry analyzer.

31

Description

Change in serum creatinine level

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Serum creatinine will be measured in milligrams per deciliter in the central laboratory using a standard laboratory method and an automated clinical chemistry analyzer.

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Description

Incidence of adverse events during the study

Timepoint

Throughout the 18-week study period; during every acupuncture session for the intervention group and at all scheduled contacts and follow-up visits for both groups

Method of measurement

Adverse events will be actively assessed at each contact and recorded on a standardized adverse event form. The number and proportion of participants experiencing at least one adverse event will be calculated for each study

group.

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Description

Severity of adverse events during the study

Timepoint

Throughout the 18-week study period; during every acupuncture session for the intervention group and at all scheduled contacts and follow-up visits for both groups

Method of measurement

Each recorded adverse event will be classified by the investigator as mild, moderate, or severe according to its clinical intensity and the need for medical intervention. The distribution of severity categories will be reported for each study group.

34

Description

Change in serum alanine aminotransferase level

Timepoint

At baseline before the intervention and at the week 18 follow-up after the start of the intervention

Method of measurement

Serum alanine aminotransferase will be measured in units per liter by a standard enzymatic laboratory method using an automated clinical chemistry analyzer.

35

Description

Change in systolic blood pressure

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Systolic blood pressure will be measured in millimeters of mercury after at least 5 minutes of rest using a standard clinical method. The same measurement method used at baseline will be repeated at weeks 6 and 18.

36

Description

Change in diastolic blood pressure

Timepoint

At baseline before the intervention, at the end of week 6, and at the week 18 follow-up after the start of the intervention

Method of measurement

Diastolic blood pressure will be measured in millimeters of mercury after at least 5 minutes of rest using a standard clinical method. The same measurement method used at baseline will be repeated at weeks 6 and 18.

37

Description

Total number of adverse events during the study

Timepoint

Throughout the 18-week study period; during every acupuncture session for the intervention group and at all scheduled weekly telephone contacts and follow-up visits for both groups

Method of measurement

All adverse events will be actively assessed and recorded on a standardized adverse event form. Each distinct adverse event will be counted separately, allowing more than one event per participant. The total number of adverse events will be calculated for each study group.

38

Description

Seriousness of adverse events during the study

Timepoint

Throughout the 18-week study period; during every acupuncture session for the intervention group and at all scheduled weekly telephone contacts and follow-up visits for both groups

Method of measurement

Each recorded adverse event will be classified as serious or non-serious. A serious adverse event is an event resulting in death, a life-threatening condition, hospitalization or prolongation of hospitalization, persistent or significant disability, a congenital anomaly, or another medically important event. The number and proportion of serious adverse events will be reported for each study group.

39

Description

Timing of adverse events during the study

Timepoint

Throughout the 18-week study period; during every acupuncture session for the intervention group and at all scheduled weekly telephone contacts and follow-up visits for both groups

Method of measurement

For each adverse event, the date or study week of onset, date or study week of resolution, and its temporal relationship to an acupuncture session or scheduled study contact, when applicable, will be recorded on the standardized adverse event form.

40

Description

Relationship of adverse events to the study intervention

Timepoint

Throughout the 18-week study period; during every acupuncture session for the intervention group and at all scheduled weekly telephone contacts and follow-up visits for both groups

Method of measurement

The relationship of each adverse event to the study intervention will be assessed by the investigator using a standardized causality assessment and classified as unrelated, unlikely, possible, probable, or definite. The distribution of causality categories will be reported for each study group.

Intervention groups

1

Description

Intervention group: During weeks 1 to 6, participants in this group will receive standard conventional care for non-alcoholic fatty liver disease/metabolic dysfunction-associated steatotic liver disease plus manual acupuncture. Standard care, prescribed by a gastroenterology and hepatology specialist, includes at least 30 minutes of aerobic exercise on 5 days per week and dietary advice to reduce caloric intake and, when clinically indicated, carbohydrate and/or fat intake. Adherence, medication changes, treatments outside the protocol, and barriers to adherence will be assessed weekly during weeks 1 to 6. When non-adherence is identified, a standardized reminder will be provided and documented. Manual acupuncture will be administered at the Acupuncture Clinic of Imam Reza Hospital in 12 sessions over 6 weeks, comprising 2 sessions per week and 30 minutes per session. A total of 32 needles will be used in each session: the bilateral points BL-17, BL-18, BL-19, BL-20, LR-13, LR-14, LR-3, LI-11, SP-6, SP-9, SP-10, KI-3, PC-6, ST-36, and ST-40, and the midline points CV-6 and CV-12. Sterile, disposable stainless-steel needles measuring 0.25 × 40 mm will be used. After achieving De qi, manual tonification using gentle clockwise rotation and low-amplitude lifting and thrusting will be performed. Needle stimulation will be applied briefly at the beginning of the session and, if required, once more before needle removal. Electroacupuncture will not be used. Before each acupuncture session, the participant's general condition, dizziness or syncope, anticoagulant use, and the skin at the intended needling sites will be assessed. An intervention-specific two-part safety checklist will be completed at each of the 12 acupuncture sessions. It will include a closed question regarding common or uncommon needling-related adverse events and an open question regarding any new symptom or sign. Independently of adherence monitoring and session-specific safety assessment, from the start of week 1 through the end of week 18, participants in both groups will receive a structured weekly safety telephone call with the same script, duration, and two-part safety checklist. The closed question will assess adverse or unwanted events and changes in health status since the preceding contact, and the open question will assess any new symptom or sign. Calls will be conducted by a safety monitor blinded to group allocation using a coded participant list without group labels. These calls are not a continuation of protocol-defined standard care. Week 18 is a follow-up and outcome-assessment timepoint only. Routine medications are permitted and will be recorded. Acupuncture, moxibustion, or cupping outside the study protocol will not be permitted during the study.

Category

Treatment - Other

2

Description

Control group: During weeks 1 to 6, participants in the control group will receive standard conventional care alone for non-alcoholic fatty liver disease/metabolic dysfunction-associated steatotic liver disease, according to the recommendations of a gastroenterology and hepatology specialist. Standard care includes at least 30 minutes of aerobic exercise, such as brisk walking, on 5 days per week and dietary recommendations to reduce caloric intake and, according to each participant's clinical condition, carbohydrate and/or fat intake. Adherence, medication changes, treatments outside the protocol, and barriers to adherence will be assessed and documented weekly during weeks 1 to 6. When non-adherence is identified, a standardized reminder will be provided and documented. Participants in this group will not receive acupuncture as part of the study. Independently of adherence monitoring, from the start of week 1 through the end of week 18, participants in the control group will receive the same structured weekly safety telephone calls as the intervention group, with the same script, duration, timing, and two-part safety checklist. The closed question will assess adverse or unwanted events and changes in health status since the preceding contact, and the open question will assess any new symptom or sign. Calls will be conducted by a safety monitor blinded to group allocation using a coded participant list without group labels. These calls are not a continuation of protocol-defined standard care. Week 18 is a follow-up and outcome-assessment timepoint only. Routine medications and any treatment changes will be recorded. Acupuncture, moxibustion, or cupping outside the study protocol will not be permitted during the study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

PERSIAN Cohort Research Center, Imam Reza Hospital

Full name of responsible person

Seyyed Kazem Farahmand

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PERSIAN Cohort Research Center, Imam Reza Hospital, Ebne Sina Street, Imam Reza Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

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Web page address
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Seyyed Kazem Farahmand

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
Traditional Medicine

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Full name of responsible person
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Position
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Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Person responsible for updating data

Contact

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Seyyed Kazem Farahmand

Position
Assistant Professor

Latest degree
Ph.D.

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Traditional Medicine

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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
There is currently no plan to make deidentified individual participant data publicly available because public data sharing is not included in the approved informed consent process and participant confidentiality must be protected. Scientifically justified requests may be considered after completion of the study, subject to approval by the principal investigator and the research ethics committee and in accordance with Mashhad University of Medical Sciences regulations.
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