

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The effects of dietary interventions on cardiovascular indexes among individuals with cold and hot temperament based on Persian medicine

Protocol summary

Study aim

Investigating the functioning of the autonomic nervous system in different moods and diets

Design

A non-randomized clinical trial in the population of healthy people who are divided into two hot and cold temperament groups by completing a questionnaire and determining temperament.

Settings and conduct

It will be done in the Chamran Heart Center of Isfahan, and people will be subjected to Holter monitoring first, and the variables of heart rate variability index, blood pressure and body temperature will be measured. People receive a diet according to their temperament for three days, and then the above-measured indices are again given, after which they receive a normal diet for 3 days. And finally, for three days, they will receive a diet against their temperament.

Participants/Inclusion and exclusion criteria

Having physical and mental health based on history and initial examinations

Intervention groups

The intervention of this diet plan is cold and hot in nature.

Main outcome variables

Heart Rate Variability (HRV); Mean Body Temperature; Heart Rate; Systolic and Diastolic Blood Pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200428047232N2**

Registration date: **2023-07-29, 1402/05/07**

Registration timing: **prospective**

Last update: **2023-07-29, 1402/05/07**

Update count: **0**

Registration date

2023-07-29, 1402/05/07

Registrant information

Name

Samane Pourajam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3332 2986

Email address

s_pourajam@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of dietary interventions on cardiovascular indexes among individuals with cold and hot temperament based on Persian medicine

Public title

Evaluation of autonomic function in individuals with hot and cold temperaments receiving food recommendations based on Persian medicine viewpoints

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Having physical and mental health based on history and initial examinations 18/5-25: BMI Not having cardiovascular disease, high blood pressure, neurological diseases, liver and kidney disease, diabetes, thyroid disease, alcohol consumption, rheumatological diseases, autoimmune, immunodeficiency, malignancy, amyloidosis. Not consuming any special diet Not taking any medicine or supplement during the last month Women on the 17th to 27th day of the menstrual cycle

Exclusion criteria:

Travel A very stressful event Reluctance to cooperate Non-compliance with the diet Illness or death during the implementation of the plan

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Ethical Committee of Isfahan University of Medical Sciences

Street address

Isfahan, Daneshgah Blvd , Hezar Jarib Ave, No. 18

City

Isfahan

Province

Isfahan

Postal code

۸۱۳۷۸۶۶۵۱۵

Approval date

2019-11-02, 1398/08/11

Ethics committee reference number

IR.MUI.MED.REC.1398.402

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

Healthy people with hot and cold temperament

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Heart rate variability index, Blood pressure , heart rate, body temperature

Timepoint

The first day, the third day, the ninth day

Method of measurement

Holter Monitorig

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: Healthy people with hot temperament receive a diet compatible with the temperament for 3 days. After three days of normal diet (rest), they receive a diet against the temperament for 3 days. These diets include cold/hot foods that will be prescribed by an Iranian medical specialist.

Category

Lifestyle

2**Description**

Intervention group 2: Healthy people with cold temperament receive a diet compatible with the temperament for 3 days. After three days of normal diet (rest), they receive a diet against the temperament for 3 days. These diets include cold/hot foods that will be prescribed by an Iranian medical specialist.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Chamran Hospital

Full name of responsible person

Samaneh Pourajam

Street address

Amin hospital, Isfahan, Iran

City
Isfahan
Province
Isfahan
Postal code
8148653141
Phone
+98 31 3112 2020
Email
spourajam@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Street address
Hazar Jarib St., Isfahan University of Medical Sciences
and Health Care Services, Building No. 4, Research
and Technology Vice-Chancellor
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 8138
Email
askari@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

50

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
Esfahan University of Medical Sciences
Full name of responsible person
Hossein Mozafarvandi
Position
Medical student

Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Hezar Jerib street, Isfahan, Iran
City
Esfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 918 139 1373
Email
Hossein.mozafarvandi@live.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Samane Pourajam
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
amin hospital,Isfahan,Iran
City
Esfahan
Province
Isfahan
Postal code
8148653141
Phone
+98 31 3112 2020
Fax
Email
s_pourajam@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Samane Pourajam
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
amin hospital,Isfahan,Iran
City
Esfahan

Province

Isfahan

Postal code

8148653141

Phone

+98 31 3112 2020

Fax**Email**

s_pourajam@med.mui.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

questionnaire: Mizaj-e-Damagh (temperament of brain) identification in Persian medicine

When the data will become available and for how long

6 months

To whom data/document is available

All researchers in the field of Iranian health and medicine

Under which criteria data/document could be used

Use in the field of healthcare is allowed

From where data/document is obtainable

Send an email to the main organizer of the project.

What processes are involved for a request to access data/document

After checking the received e-mail and evaluation by the moderator, she will take possession of the files at the discretion of the moderators

Comments