Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Samane Pourajam
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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 scienece
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

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Isfehan

Postal code
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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 tempreture

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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
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Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Building No. 4, Research and Technology Vice-Chancellor
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8174673461
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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
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Person responsible for updating data

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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