

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the Effectiveness of Interventions Based on the Eastern Mind-Body Approach on Cardiovascular Responses and Stress Reduction in prehypertensive Subjects.

Protocol summary

Study aim

Reduces high blood pressure and stress in prehypertensive people

Design

The study samples consisted of 120 prehypertensive males and females selected by purposive sampling according to inclusion and exclusion criteria and were randomly assigned into 8 parallel groups of 15 individuals.

Settings and conduct

The study population included all prehypertensive males and females in Tabriz city in 2020. At first, cardiovascular responses will measure by digital wrist sphygmomanometer. Next, subjects will assigne into 4 experimental and control groups. Then, Mental Pressure Inventory will completed and cardiovascular responses recorded as a pre-test. In the next step, Tai Chi Chuan, yoga, and meditation will be performed for one 30-minute session per week, for a total of 10 weeks, and 24 hours after the end of the course, the dependent variables will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- systolic blood pressure 120 to 139 mmHg, and diastolic blood pressure 80 to 89mmHg 2- Age between 25 to 54 years 3- Adequate literacy for reading and writing 4- Ability to attend the sessions. Exclusion criteria: 1- Sensory-motor disabilities 2- Use of anxiolytic drugs 3- Participation in other treatment sessions simultaneously.

Intervention groups

Tai Chi Chuan: A set of slow, rhythmic, and stretching movements of different parts of the body with deep breathing to achieve physical health and balance of mind and body. Yoga: Ancient Indian practice aimed at balancing the mind and body. Meditation: Repetitive cycles transfer attention from active levels to abstract and subtle levels and reach a state of relaxation, and

return to active levels of thinking. Control group: It do not receive any of the above interventions.

Main outcome variables

systolic blood pressure; diastolic blood pressure; heart rate; stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200607047679N1**

Registration date: **2020-06-16, 1399/03/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-16, 1399/03/27**

Update count: **0**

Registration date

2020-06-16, 1399/03/27

Registrant information

Name

Davoud Ezzati

Name of organization / entity

University of Tabriz

Country

Iran (Islamic Republic of)

Phone

+98 41 3545 3463

Email address

ezzati_d@tabrizu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-14, 1399/03/25

Expected recruitment end date

2020-07-15, 1399/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Interventions Based on the Eastern Mind-Body Approach on Cardiovascular Responses and Stress Reduction in prehypertensive Subjects.

Public title
Comparison of the effectiveness of Eastern mind-body approach on cardiovascular responses and stress in prehypertensive subjects

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Systolic Blood Pressure 120-139mmHg, and/or Diastolic Blood Pressure 80-89mmHg aged=25-55 Adequate literacy for reading and writing Ability to attend the sessions
Exclusion criteria:
Sensory-motor disabilities Use of anxiolytic drugs Participation in other treatment sessions simultaneously

Age
From **25 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

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

Ethics committee of Tabriz University of Medical

Sciences

Street address
No. 66, Mirzaie Alley, Enghelab ave, Maralan street

City
Tabriz

Province
East Azarbaijan

Postal code
5164954933

Approval date
2019-07-29, 1398/05/07

Ethics committee reference number
Ethics ID: IR.TBZMED.REC. 1398.539

Health conditions studied

1

Description of health condition studied

prehypertension

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood pressure between 120/80 to 140/90 mm Hg

Timepoint

Blood pressure measurement before the start of the intervention and 10 weeks after the start of the intervention

Method of measurement

digital wrist sphygmomanometer (EmsiG, Model: BW 62)

2

Description

Timepoint

Method of measurement

3

Description

Blood pressure between 120/80 to 140/90 mm Hg

Timepoint

Blood pressure measurement before the start of the intervention and 10 weeks after the start of the intervention

Method of measurement

digital wrist sphygmomanometer (EmsiG, Model: BW 62)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tai chi Chuan
Category
Lifestyle

2

Description
Intervention group: Yoga
Category
Lifestyle

3

Description
Intervention group: Meditation
Category
Lifestyle

4

Description
Control group: No intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz City
Full name of responsible person
Davoud Ezzati
Street address
Maralan Street
City
Tabriz
Province
East Azarbaijan
Postal code
5164954933
Phone
+98 41 3545 3463
Email
ezzati@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Tabriz
Full name of responsible person
Touraj Hashemi Nosrat abad
Street address
Maralan Street
City
Tabriz
Province
East Azarbaijan

Postal code
5164954933
Phone
+98 41 3545 3463
Email
ezzati@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Tabriz
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
University of Tabriz
Full name of responsible person
Davoud Ezzati
Position
ph.D Candidate
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Maralan street
City
Tabriz
Province
East Azarbaijan
Postal code
5164954933
Phone
+98 41 3545 3463
Email
ezzati@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Tabriz
Full name of responsible person
Davoud Ezzati
Position
ph.D candidate
Latest degree

Master
Other areas of specialty/work
Psychology
Street address
Maralan Street
City
Tabriz
Province
East Azarbaijan
Postal code
5164954933
Phone
+98 41 3545 3463
Email
ezzattid@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
University of Tabriz
Full name of responsible person
Davoud Ezzati
Position
ph.D Candidate
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Maralan Street
City
Tabriz
Province
East Azarbaijan
Postal code
5164954933
Phone
+98 41 3545 3463

Email
ezzattid@yahoo.com

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

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

Title and more details about the data/document

All data will be presented on average, as our research is a group study.

When the data will become available and for how long

about 2 years

To whom data/document is available

People who work in health areas

Under which criteria data/document could be used

For research, prevention and treatment

From where data/document is obtainable

Davoud Ezzati- University of tabriz- E-mail:
ezzattid@yahoo.com

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

Once the applicant has explained how to use the data in this study along with sufficient documentation, I will deliver the data to him or her within approximately one month.

Comments