Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 parellel 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; heat 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

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Maralan Street

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5164954933

Phone
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Email
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Tabriz

Full name of responsible person
Touraj Hashemi Nosrat abad

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5164954933

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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
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

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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
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: ezzatid@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