

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

ezzatid@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**

ezzatid@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**

ezzatid@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

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East Azarbaijan

**Postal code**

5164954933

**Phone**

+98 41 3545 3463

**Email**

ezzatid@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

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**Postal code**

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**Phone**

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**Email**

ezzatid@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: 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**