

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of oral capsule of curcumin and vitamin E on the hot flush and anxiety in postmenopausal women: a triple blind randomised controlled trial

#### Protocol summary

##### Study aim

To determine the effect of oral curcumin and vitamin E capsules on hot flush and anxiety in postmenopausal Women

##### Design

Randomized controlled clinical trial with three parallel arms.

##### Settings and conduct

This study will be performed on 93 menopausal women in Ahar city. The researcher will go to the health centers and will provide a list of women around menopausal age along with their phone number, then will call them and they will be invited to participate in the study. In face to face session, eligibility criteria will be assessed and the Green Scale, the Spielberger State-Trait Anxiety Inventory and Female Sexual Function Index will be completed through interview with eligible participants. Participants will be randomly assigned into three groups (two intervention groups and one control group) through block randomization.

##### Participants/Inclusion and exclusion criteria

Participants will be menopausal women with hot flush at least twice a week.

##### Intervention groups

The first intervention group will receive oral curcumin capsule, the second intervention group will receive the oral vitamin E capsule and the control group will receive the placebo.

##### Main outcome variables

The main outcome variables include hot flash and anxiety, which will be assessed by the Green scale and the Spielberger State-Trait Anxiety Inventory, respectively.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120718010324N44**

Registration date: **2018-06-23, 1397/04/02**

Registration timing: **prospective**

Last update: **2018-06-23, 1397/04/02**

Update count: **0**

##### Registration date

2018-06-23, 1397/04/02

##### Registrant information

##### Name

Mojgan Mirghafourvand

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6969

##### Email address

mirghafourvandm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-04, 1397/04/13

##### Expected recruitment end date

2018-10-05, 1397/07/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of oral capsule of curcumin and vitamin E on the hot flush and anxiety in postmenopausal women: a triple blind randomised controlled trial

#### Public title

The effect of curcumin and vitamin E on hot flush and anxiety in postmenopausal women

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Willingness to participate in the study Having sufficient literacy to complete the questionnaire or the presence of a literate person in the family Normal menopause Being married Women who have been under 6 years old since their menopause. Having at least 40 years and a maximum of 60 Having hot flush at least twice a week

##### Exclusion criteria:

Use of tobacco and alcoholic beverages and herbal medicines Stressful factors such as the death of relatives in the first six months of the past and loss of occupation Known psychiatric or systemic problems including cardiovascular, digestive, liver, endocrine, etc. Use of any effective medicines for hot flashes (Clonidine, Methyl dopa, Gabapentin, Selective Serotonin Reuptake Inhibitors (SSRIs), Norepinephrine inhibitors (SNRI), and Soy isoflavone Factors that cause vasomotor disorder, such as thyroid disease, according to the person expression Use of any effective medication to treat a person's sexual response (Antihypertensive, Thiazide diuretics, Antidepressant drugs such as Serotonin and Noradrenaline and Reuptake, Antihistamines, Barbiturates, Narcotics, Diazepam, Amphetamines, Cocaine History of allergy to turmeric or other drugs, food and color Taking anticoagulant drugs (Heparin, Warfarin, Enoxaparin)

#### Age

From **40 years** old to **60 years** old

#### Gender

Female

#### Phase

2

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **93**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Participants will be assigned by block randomization method with a 1: 1: 1 assignment ratio to three groups (two intervention groups and one control group).

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

Participants, researcher and analyst will be completely blind in this study. The drug and the placebo will be the

same in appearance (shape, color and odor), and the packaging of drugs will be done by someone who is not involved in the research

#### Placebo

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

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138947977

#### Approval date

2018-05-27, 1397/03/06

#### Ethics committee reference number

IR.TBZMED.REC.1397.208

## Health conditions studied

### 1

#### Description of health condition studied

hot flush

#### ICD-10 code

N95.1

#### ICD-10 code description

Menopausal and female climacteric states

### 2

#### Description of health condition studied

anxiety

#### ICD-10 code

F41.9

#### ICD-10 code description

Anxiety disorder, unspecified

## Primary outcomes

### 1

#### Description

hot flush

### **Timepoint**

Before the intervention, 4 and 8 weeks after the intervention

### **Method of measurement**

Hot flush checklist

## **2**

### **Description**

Anxiety

### **Timepoint**

Before the intervention, 4 and 8 weeks after the intervention

### **Method of measurement**

State- Trait Anxiety Inventory

## **Secondary outcomes**

## **1**

### **Description**

Sexual function

### **Timepoint**

Before the intervention, 4 and 8 weeks after the intervention

### **Method of measurement**

FSFI= Female Sexual Function Inventory

## **Intervention groups**

## **1**

### **Description**

The first Intervention group will receive oral capsules of curcumin twice a day at a dose of 500 milligrams for eight weeks

### **Category**

Treatment - Drugs

## **2**

### **Description**

The second intervention group will receive oral Capsule Vitamin E 200 IU twice a day for eight weeks.

### **Category**

Treatment - Drugs

## **3**

### **Description**

The control group will receive placebo capsules twice a day for 8 weeks

### **Category**

Placebo

## **Recruitment centers**

## **1**

### **Recruitment center**

#### **Name of recruitment center**

Health Centers in Ahar city

### **Full name of responsible person**

Khatereh Ataei

### **Street address**

Ahar city, East Azarbaijan county, Iran

### **City**

Ahar

### **Province**

East Azarbaijan

### **Postal code**

5143814998

### **Phone**

+98 41 4438 8341

### **Email**

iro@tbzmed.ac.ir

### **Web page address**

<http://tabriz-phc.tbzmed.ac.ir>

## **Sponsors / Funding sources**

## **1**

### **Sponsor**

#### **Name of organization / entity**

Tabriz University of Medical Sciences

#### **Full name of responsible person**

Abolghasem Jouyban

#### **Street address**

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

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#### **Email**

iro@tbzmed.ac.ir

#### **Web page address**

<http://researchvice.tbzmed.ac.ir>

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Tabriz University of Medical Sciences

### **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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Khatereh Ataei

**Position**

MSc Student of Midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Faculty of Nursing Midwifery, South Shariati Street

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**Phone**

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khaterehatayi@gmail.com

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mojgan Mirgharvand

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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**Web page address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mojgan Mirghorvand

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

Faculty of Nursing Midwifery, South Shariati Street

**City**

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<http://nursing.tbzmed.ac.ir>

## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The results of the clinical study will be published as a paper.

**When the data will become available and for how long**

Immediately after publishing the results.

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

Scientific using with citation to article.

**From where data/document is obtainable**

mirghafourvandm@tbzmed.ac.ir

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

Maximum one week after the communication by email.

**Comments**

## Person responsible for updating data

### Contact