

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the Effect of Topical use of Chamomile oil and Dill oil on Abdominal Obesity and Comparison with Placebo Group\_ A Randomized Clinical Trial

#### Protocol summary

##### Study aim

Determining the effect of topical application of chamomile and dill oil on abdominal obesity

##### Design

Randomized clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients, rand function of Excel software was used for randomization.

##### Settings and conduct

This study is conducted in the form of a double-blind randomized clinical trial among those who refer to Iranian medical treatment centers.

##### Participants/Inclusion and exclusion criteria

Main Inclusion Criteria: Women between the ages of 25 and 55 years with a waist circumference of  $\geq 80$  cm who have the necessary cooperation in taking the medicine and are not pregnant. Main Exclusion Criteria: Not using another topical drug that interferes with the effect of the studied drug Use other weight loss methods

##### Intervention groups

Intervention group: 6 weeks of the combination of chamomile oil and dill oil once a day in the amount of 2 cc per square meter (in such a way that the entire abdominal area except for the radius of 2 cm around the navel (10 cm square) is completely lubricated and with a thin layer of oil should be covered) without massaging the area. After using the oil, cover the area with a plastic cover and have 30 minutes of aerobic activity and the plastic cover is removed from the abdomen after the aerobic activity. Control group: topical use of placebo oil (sesame oil) according to the instructions of the intervention group

##### Main outcome variables

1- Abdominal circumference size 2- Abdominal subcutaneous fat thickness in three areas

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230902059321N1**

Registration date: **2023-10-18, 1402/07/26**

Registration timing: **retrospective**

Last update: **2023-10-18, 1402/07/26**

Update count: **0**

##### Registration date

2023-10-18, 1402/07/26

##### Registrant information

##### Name

Maryam Bashiri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8609 5791

##### Email address

maryambashiri18@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-22, 1401/03/01

##### Expected recruitment end date

2022-12-22, 1401/10/01

##### Actual recruitment start date

2022-05-22, 1401/03/01

##### Actual recruitment end date

2022-11-06, 1401/08/15

##### Trial completion date

empty

## Scientific title

Evaluation of the Effect of Topical use of Chamomile oil and Dill oil on Abdominal Obesity and Comparison with Placebo Group\_ A Randomized Clinical Trial

## Public title

Effect of Topical use of Chamomile oil and Dill oil on Abdominal Obesity

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Women between 25 and 55 years Necessary cooperation in taking medicine Women suffering from abdominal obesity Waist circumference greater than 80 cm The possibility of following up patients Fill out a consent form by patients Not pregnant

### Exclusion criteria:

Not using another topical drug that interferes with the effect of the studied drug Use other weight loss methods Medical condition that prohibits aerobic exercise Patients who do professional sports activities Patients on a weight loss diet History of allergic reaction to topical use of Chamomile oil and Dill oil The presence of an active skin lesion in the study area Women who intend to become pregnant during the treatment period Pregnant women Patient dissatisfaction Hypothyroidism and uncontrolled diabetes mellitus History of using steroid drugs in the last three months

## Age

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

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **60**

Actual sample size reached: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients are divided into case and control groups by random allocation method. block randomization method and table of random numbers are used to prepare the random list. It is taken in the way that we design a random block with 6 rows and 10 columns and write down the number of 30 letters A and 30 letters B randomly in its houses. With the first patient's visit, the first cell from row 1 of column 1 is selected and assigned to the intervention or control group based on the letter in the patient's cell, and then we draw a line on the corresponding letter with the selected meaning. We do the same for the rest of the patients to finally reach the determined sample size. We made 60 cards and write letter A on 30 for intervention and on the other 30 letter B for the control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly

will be selected and open it, based on selected letter (A or B) patients will be assigned to intervention or control group.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The intervention group will receive a can of chamomile and dill oil, and the placebo group will receive a can of sesame oil. The medicine of both groups is ready to be delivered in similar packaging and in a can with dull color. The lid of the placebo oil can is smeared with chamomile and dill essential oil.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences., Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2022-05-10, 1401/02/20

#### Ethics committee reference number

IR.IUMS.REC.1401.133

## Health conditions studied

### 1

#### Description of health condition studied

Obesity

#### ICD-10 code

E65-E68

#### ICD-10 code description

Obesity and other hyperalimentation

## Primary outcomes

### 1

#### Description

Abdominal circumference size

#### Timepoint

At the beginning of the intervention, then every three weeks until the end of the intervention

#### **Method of measurement**

Tape measure

### 2

#### **Description**

Abdominal subcutaneous fat thickness in three areas: the thickness of the horizontal skin fold at 3 cm from the navel and 1 cm below it on the right side, the thickness of the skin fold above the navel at the midpoint of the line between the breast and navel junction, the thickness of the left supra iliac skin fold above the iliac crest. In the left midaxillary line

#### **Timepoint**

At the beginning of the intervention, then every three weeks until the end of the intervention

#### **Method of measurement**

Skinfold Caliper

## **Secondary outcomes**

### 1

#### **Description**

Body weight

#### **Timepoint**

At the beginning of the study and then every three weeks until the end of the study

#### **Method of measurement**

Digital weight scale

### 2

#### **Description**

Body Mass Index

#### **Timepoint**

At the beginning of the study and then every three weeks until the end of the study

#### **Method of measurement**

Dividing people's weight (in kilograms) by the square of height (height times height in meters)

## **Intervention groups**

### 1

#### **Description**

Intervention group: In the intervention group for 6 weeks, a combination of chamomile oil and dill oil once a day in the amount of 2 cc per square meter (in such a way that the entire abdominal area except for the radius of 2 centimeters around the navel (10 square centimeters) is completely lubricated and covered with a thin layer of oil) without massaging the area. After using the oil, cover the area with a plastic cover and have 30 minutes of aerobic activity (fast walking in such a way that the heart rate and breathing rate increase and sweating occurs) and the plastic cover is removed from the abdomen after the aerobic activity.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: The control group received placebo oil for 6 weeks once a day in the amount of 2 cc per square meter (in such a way that the entire abdominal area except for the radius of 2 centimeters around the navel (10 square centimeters) was completely greased and covered with a thin layer of oil. be) used without massaging the area. After using the oil, cover the area with a plastic cover and have 30 minutes of aerobic activity (fast walking in such a way that the heart rate and breathing rate increase and sweating occurs) and the plastic cover is removed from the abdomen after the aerobic activity.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Behesht Iranian traditional medicine healthcare centre

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

Maryam Bashiri

##### **Street address**

No. 847, Behesht St., South Side City Park, Vahdat Eslami St., Hassan Abad Square,

##### **City**

Tehran

##### **Province**

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##### **Postal code**

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##### **Phone**

+98 21 5558 0388

##### **Email**

stm@iums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Research Institute for Islamic and Complementary Medicine (RICM)

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

Dr Amir Hossein Jamshidi

##### **Street address**

9, Pirnia Allay, Lalezar Street, Jomhuri Street

##### **City**

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##### **Province**

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##### **Postal code**

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imhicmr@iums.ac.ir

**Web page address**

https://oldricm.iums.ac.ir/

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Institute for Islamic and Complementary Medicine (RICM)

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Maryam Bashiri

**Position**

Traditional Iranian medicine Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

School of Traditional Medicine, No 847, Behesht St. South Side of Shahr Park, Vahdat-e-Islami St., Hasan Abad Sq., Tehran, Iran.

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Somayye Mahroozade

**Position**

Traditional Medicine Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No 847, Behesht St. South Side of Shahr Park, Vahdat-e-Islami St., Hasan Abad Sq., Tehran, Iran

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MaryamBashiri18@yahoo.com

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

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

make this available

**Data Dictionary**

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