

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of The Effect of Dark Chocolate 78% on Depression among Menopausal Women: A Randomized Controlled Trial

Protocol summary

Study aim

Determining the effect of 78% dark chocolate on depression (primary outcome) and sleep quality and anthropometric indicators among postmenopausal women (secondary outcomes).

Design

A double-blind randomized controlled clinical trial, 60 postmenopausal women will be assigned to one of the intervention and control groups with a ratio of 1:1, using a computerized random number table and through blocks of six.

Settings and conduct

People will be selected from the health centers of Tabriz, Al-Zahra and Taleghani hospitals. The list of people will be extracted from the Sib system first. The chocolates of both groups will be presented in the same shape and size and similar packages. Due to the difference in the taste of dark and milk chocolate, the outcome evaluation will be blind and a person who was not involved in the sampling will be asked. to check the results at the end of the intervention.

Participants/Inclusion and exclusion criteria

Entry requirements: age 45-65, menopause, having depression, desire to consume chocolate and not allergic to cocoa and any of the components of chocolate. Conditions of non-entry: cardiovascular, digestive, liver or kidney diseases, diabetes mellitus, high blood pressure under treatment, fibrocystic breast problems, dyslipidemia, neurological or neuropsychological diseases, depression under treatment, hormone therapy, habit of daily consumption of cocoa or coffee products. Habitual use of invigorating teas.

Intervention groups

Participants in the intervention group will receive 12 grams of 78% dark chocolate and participants in the control group will receive 12 grams of milk chocolate daily for 8 weeks. The cocoa content of milk chocolates will be less than 2%.

Main outcome variables

Comparison of the average score of depression in the two groups receiving dark chocolate and the control group after the end of the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220926056046N1**

Registration date: **2022-12-10, 1401/09/19**

Registration timing: **prospective**

Last update: **2022-12-10, 1401/09/19**

Update count: **0**

Registration date

2022-12-10, 1401/09/19

Registrant information

Name

Solmaz Ghanbari Homaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3524 5181

Email address

homayisolmaz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-15, 1401/09/24

Expected recruitment end date

2023-08-20, 1402/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Assessment of The Effect of Dark Chocolate 78% on Depression among Menopausal Women: A Randomized Controlled Trial

Public title
Effect of dark chocolate on depression in menopausal women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 45-65 Being menopausal Desire to consume dark chocolate No allergy to cocoa or any of the chocolate components Having mild or moderate depression based on the Beck Depression Questionnaire and the diagnosis of a clinical psychologist
Exclusion criteria:
 Cardiovascular disease diabetes mellitus Under treatment high blood pressure Digestive diseases Liver diseases Kidney Diseases Fibrocystic breast problems Under treatment dyslipidemia Under treatment neurological or neuropsychological diseases Under treatment depression Hormone therapy Habit of daily consumption of cocoa or coffee products Habitual use of invigorating drinks Severe depression based on the Beck's questionnaire

Age
From **45 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Study participants will be assigned to one of the intervention and control groups with a 1:1 allocation ratio using the random block method with a block size of six using the website www.random.org. In order to hide the allocation (Allocation Concealment), the sequence of allocation will be specified by a person not involved in the study using a randomizer, and dark and milk chocolate will be placed inside the foil and in the same packages that are numbered consecutively.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants, the researcher, the collector and the evaluator of the results will be blinded. The chocolates of

both groups will be in the same shape and size and same packaging. a person who was not involved in the sampling will be asked to check the outcomes at the end of the intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz university of medical science, Azadi avenue

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2022-12-04, 1401/09/13

Ethics committee reference number

IR.TBZMED.REC.1401.807

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

2

Description of health condition studied

Sleep quality

ICD-10 code

F51

ICD-10 code description

Sleep disorders not due to a substance or known physiological condition

3

Description of health condition studied

Anthropometric indicators

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Depression score

Timepoint

The end of the 8th week after starting to consume chocolate

Method of measurement

Beck Depression Questionnaire

Secondary outcomes

1

Description

Score of sleep quality

Timepoint

The end of the 8th week after starting to consume chocolate

Method of measurement

Pittsburgh Sleep Quality Index

2

Description

Anthropometric indices

Timepoint

The end of the 8th week after starting to consume chocolate

Method of measurement

Seca height gauge and scale and tape measure

Intervention groups

1

Description

Intervention group: Participants in the intervention group will receive 12 grams of 78% dark chocolate daily for eight weeks. The nutritional content of dark chocolate per 6 grams will be: energy: 32 kcal, carbohydrates: 3.2 grams, fat: 2.03 grams, salt: 0.025 grams, trans fatty acids: 0 grams. The product will be prepared from Chichak Company in Tabriz.

Category

Treatment - Other

2

Description

Control group: 12 grams of milk chocolate daily for eight weeks. The nutritional content of control group chocolate per 6 grams will be: energy: 32 kcal, carbohydrates: 3.2 grams, fat: 2.03 grams, salt: 0.025 grams, trans fatty acids: 0 grams. The cocoa content of milk chocolates will be less than 2%. The product will be prepared from Iran Chocolate (Chichak) Company in Tabriz.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Elham Abdoli

Street address

School of Nursing and Midwifery, Shariati street

City

Tabriz

Province

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5138947977

Phone

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2

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Elham Abdoli

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3

Recruitment center

Name of recruitment center

Health care centers

Full name of responsible person

Elham Abdoli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Parviz Shahabi

Street address
Research department, third floor, central construction
number 2, Tabriz university of medical sciences,
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dabir Khanecent@tbzmed.ac.ir

Grant name

Grant code / Reference number
70312

**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
Elham Abdoli

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Solmaz Ghanbari Homaie

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Solmaz Ghanbari Homayi

Position
Assestant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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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

Participant data is confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available