

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparative investigation between the effectiveness of Salvia officinalis extract and Cognitive remediation therapy on cognitive function in menopausal women

Protocol summary

Study aim

Determining and comparing the effect of sage extract and cognitive restorative treatment on cognitive function of postmenopausal women referring to health centers in Kerman in 1400

Design

A controlled clinical trial, with parallel, randomized groups, on 90 postmenopausal women. Individuals will be divided into three groups for randomization using online software to generate random sequences and by block random allocation method with six blocks.

Settings and conduct

First, after obtaining the code of ethics from the ethics committee of Kerman University of Medical Sciences and obtaining the code of clinical trial and presenting it to Kerman University of Medical Sciences, the researcher with a letter of introduction, refers to clinics affiliated to Kerman University of Medical Sciences. It will be obtained from postmenopausal women through the apple system and they will be included in the study randomly and if they have inclusion criteria and conscious satisfaction.

Participants/Inclusion and exclusion criteria

Iranian women 45 to 65 years old, Cutting menstruation for at least one year, Minimum literacy reading and writing, Lack of sensitivity to herbal medicines, No addiction or smoking, Lack of any known physical illnesses, Lack of any significant psychiatric disorders, Do not use any drugs that affect memory and cognitive function and do not take phytoestrogens from three months ago, Absence of severe cognitive disorders

Intervention groups

Sage extract group, sage extract pills will be given in variable doses that follow the estrogen pattern of the menstrual cycle. The counseling group will receive 8 sessions of 90 minutes (one session per week) as a group of cognitive remediation therapy. The control

group does not receive any treatment.

Main outcome variables

Cognitive function in menopausal women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201027049164N3**

Registration date: **2021-10-07, 1400/07/15**

Registration timing: **prospective**

Last update: **2021-10-07, 1400/07/15**

Update count: **0**

Registration date

2021-10-07, 1400/07/15

Registrant information

Name

Masumeh Ghazanfarpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative investigation between the effectiveness of Salvia officinalis extract and Cognitive remediation therapy on cognitive function in menopausal women

Public title

Comparative investigation between the effectiveness of Salvia officinalis extract and Cognitive remediation therapy on cognitive function in menopausal women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian women 45 to 65 years old Cutting menstruation for at least one year Minimum literacy reading and writing Lack of sensitivity to herbal medicines No addiction or smoking Lack of any known physical illnesses such as epilepsy and vascular and renal and liver diseases Lack of any significant psychiatric disorders of anxiety and depression and significant psychiatric neurological symptoms Do not use any drugs that affect memory and cognitive function Having a personal desire and conscious satisfaction to participate in the study Do not take any phytoestrogen herbal medicine for three months before the intervention No infection or no history of breast or vaginal cancer Absence of severe cognitive disorders (Alzheimer's and dementia)

Exclusion criteria:

Symptoms of drug allergy Taking any medication while conducting research Existence of severe stress during treatment Absence of more than two sessions in counseling sessions Has taken less than 85% of the drug Acute and chronic diseases infection during the study

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the selection, numbers from 1 to 90 will be allocated to the participants, respectively, then using the random block allocation method with six blocks, individuals will be divided into three groups of 30. How to place people in each of the counseling groups and sage extract and control will be random, which will be done using online software to generate random sequences (www.randomizer.org/). In order to hide the process of random allocation and prevent bias, the selection of this action will be done after the final list is

prepared by a person other than the main researcher and the researcher will be obliged to act exactly accordingly.

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 Kerman University of Medical Sciences

Street address

Deputy of Research and Technology; ebne-e-Sina St., Jahad Blvd., Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2021-09-29, 1400/07/07

Ethics committee reference number

IR.KMU.REC.1400.366

Health conditions studied**1****Description of health condition studied**

cognitive function impairment

ICD-10 code

G31.84

ICD-10 code description

Mild cognitive impairment, so stated

Primary outcomes**1****Description**

cognitive function

Timepoint

Beginning of the study (before the start of the intervention) and end of the intervention

Method of measurement

Montreal Cognitive Assessment Questionnaire (MOCA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The counseling group will receive 8 sessions of 90 minutes, one session per week as a group of cognitive rehabilitation counseling.

Category

Treatment - Other

2

Description

Intervention group 2 : Sage extract tablets will be given in variable doses that follow the estrogen pattern of the menstrual cycle. Thus, at the beginning of the menstrual cycle, estrogen is low, and then, as the menstrual cycle gradually increases, the dose of sage tablets increases. The maximum dose of the pill is given on the fourteenth day according to the peak of estrogen in the normal cycle, then, as in the normal cycle, when the amount of estrogen decreases, the dose of sage pill also decreases. That is, we will start the dose of the drug from 70 mg twice a day, and until the fourteenth day, we will add 10 mg every day, and on the fourteenth day, we will have the highest dose, ie 200 mg, and again we will have a 14-day reduction process.

Category

Treatment - Drugs

3

Description

Control group: They will only receive routine clinic interventions and will not receive any other intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

درمانگاه های وابسته به دانشگاه علوم پزشکی کرمان

Full name of responsible person

Mohadese Yazdani

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Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mohadese Yazdani

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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