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

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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
Street address
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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Person responsible for scientific inquiries

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Assistant professor

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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