Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of mental health and lifestyle educational intervention on health promoting behaviors in elderly women under the care of a family doctor

Protocol summary

Study aim

Determining the effect of mental health and lifestyle educational intervention on health promoting behaviors in elderly women under the care of a family doctor.

Design

This study is a randomized controlled educational trial with a control group with parallel groups with a pre-test-post-test design. Based on the prepared list of elderly women eligible to enter the study in 2 clinics, the elderly women will be randomly placed in the intervention and control groups.

Settings and conduct

The intervention group will be trained in 7 training sessions, but the control group will not receive training during this period. The location of the study is family doctor's offices in Pasargad city.

Participants/Inclusion and exclusion criteria

Conditions for entering the study 1. Be covered by a family doctor and registered in the electronic health system (Sib). 2. Age over 60 years 3. Absence of mental health disorders in the Sib system 4. The ability to communicate (not suffering from severe vision and hearing defects that cannot be corrected with glasses and hearing aids) 5. Willingness to participate in the study and complete the informed consent form. Exclusion condition 1. Unwillingness to continue cooperation 2. Absence in more than 1 training session 3. Death or migration of the elderly 4. Failure to complete the questionnaire post test

Intervention groups

For the intervention group, 7 educational sessions will be held weekly for 90 minutes in the form of short lectures, group discussions, questions and answers in 3 groups of 23 elderly women. The control group will not receive training during this period.

Main outcome variables

Improving the mental health and lifestyle of elderly women Promoting health-promoting behaviors of elderly women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111017007816N20**
Registration date: **2023-06-07, 1402/03/17**
Registration timing: **retrospective**

Last update: **2023-06-07, 1402/03/17**
Update count: **0**

Registration date

2023-06-07, 1402/03/17

Registrant information

Name

Mahin Nazari

Name of organization / entity

School of health

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

manazari@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-01, 1402/02/11

Expected recruitment end date

2023-06-01, 1402/03/11

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of mental health and lifestyle educational intervention on health promoting behaviors in elderly women under the care of a family doctor

Public title
The effect of mental health and lifestyle educational intervention on health promoting behaviors
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Be covered by a family doctor and registered in the electronic health system (Sib). Age over 60 years old Not suffering from mental health disorders in the Sib system Ability to communicate (not suffering from severe vision and hearing defects that Glasses and hearing aids cannot be modified) Willingness to participate in the study and complete the informed consent form.
Exclusion criteria:
Unwillingness to continue cooperation Absence in more than 1 training session Death or migration of the elderly Failure to complete the questionnaire post test
Age
From **60 years** old to **80 years** old
Gender
Female

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Pasargad health center has 5 family doctor's offices under its coverage. 2 family doctor's offices that will be selected randomly, which will be randomly assigned using the table of random numbers in EXCL software. One family doctor's office will be assigned to the control group and another family doctor's office will be assigned to the intervention group.
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
Shiraz University Of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand St.
City
Shiraz
Province
Fars
Postal code
7153675541
Approval date
2023-04-30, 1402/02/10
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1402.012

Health conditions studied

1

Description of health condition studied
mental disorders
ICD-10 code
F06
ICD-10 code description
Other mental disorders due to known physiological condition

Primary outcomes

1

Description
mental health
Timepoint
Before and one month after the intervention
Method of measurement
Golderg's General Health Questionnaire

2

Description
Health promoting lifestyle
Timepoint
Before and one month after the intervention
Method of measurement
Health-promoting Lifestyle Profile Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, for educational

intervention, for elderly women in the intervention group, an educational program will be held in the form of short lectures, discussion groups, questions and answers, and using educational aids such as (pamphlets and PowerPoint). Elderly women will be divided into groups of 23 people and will be trained in 7 90-minute training sessions. The control group will not receive training during this period.

Category

N/A

2

Description

Control group: The control group will not receive training during this period.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Family doctor's office number 1

Full name of responsible person

Behbood Zarei

Street address

Imam Khomeini street

City

Pasargad

Province

Fars

Postal code

7374189154

Phone

+98 917 351 1486

Email

pasargad1@imo.org.ir

2

Recruitment center

Name of recruitment center

Family doctor's office number 2

Full name of responsible person

Mohammad Shiravani

Street address

Imam Khomeini street

City

Pasargad

Province

Fars

Postal code

7374189167

Phone

+98 917 649 5183

Fax

Email

pasargad2@imo.org.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahin Nazari

Street address

Razi St. 10 - Razi Boulevard - Zahra Alley - School of Health - Shiraz University of Medical Sciences

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7153675541

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manazari@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Raziyeh Asadi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Public Health

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mahin Nazari
Position
Associate
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Raziyeh Asadi
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The total potential data can be shared after unidentifiable people
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
The total number of people referring to the magazine in which the article was published
Under which criteria data/document could be used
Supervisor
From where data/document is obtainable
Dr. Mahin Nazari Email manazari@sums.ac.ir
What processes are involved for a request to access data/document
The coordinators author takes about 1 week to 1 month
Comments