Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jul 2026

The Effect of the Training Program for Health Volunteers to the Ageing on Ageing Abuse: A Parallel Randomized Clinical Trial

Protocol summary

Study aim

Determining the impact of the training program of health volunteers to the ageing on ageing abuse

Design

A clinical trial study with a control group, with parallel groups, without blinding, randomized, on 80 ageing people, will use statistical consultant with SPSS software for randomization.

Settings and conduct

Education related to ageing abuse is first given by a researcher and nurse trained in this field to health volunteers in health community centers related to their field of activity, and then to health volunteers in comprehensive health centers related to the ageing themselves who have a history of elder abuse. They provide training in groups in two face-to-face sessions for one hour

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 60 years and older, understanding and speaking persian language, history or being subjected to elder abuse based on the score of the questionnaire (Vulnerability to Abuse Screening Scale (VASS-21), obtaining the score of cognitive ability based on the test Mental Status Assessment of Older Adults (Mini - Cog), obtaining individual independence score in the test (Activities of Daily Living (ADL). Conditions of non-entry: Having a background of depression based on the test Geriatric Depression Scale (GDS-15

Intervention groups

The intervention group includes elderly people who have a history of elder abuse, who receive the intervention of health liaison training on Ageing abuse. The control group includes Ageing people who have a history of elder abuse who only receive routine training from community health centers and health liaisons.

Main outcome variables

Ageing Abuse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045524N4**
Registration date: **2023-09-15, 1402/06/24**
Registration timing: **prospective**

Last update: **2023-09-15, 1402/06/24**
Update count: **0**

Registration date

2023-09-15, 1402/06/24

Registrant information

Name

Amirheidar Bakhshiarab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3222 4816

Email address

bakhshiarab@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of the Training Program for Health Volunteers to the Ageing on Ageing Abuse: A Parallel Randomized Clinical Trial

Public title
The Effect of Training Health Volunteers on Ageing Abuse
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age 60 years and older understanding and speaking Persian language history of or being abused by the elderly based on the Vulnerability to Abuse Screening Scale (VASS-21) questionnaire score obtaining a cognitive ability score based on the Mental Status Assessment of Older Adults (Mini-Cog) test obtaining an individual independence score on the Activities of Daily Living (ADL) test
Exclusion criteria:
Having a background of depression based on the Geriatric Depression Scale (GDS-15) test
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation sequence is obtained by the methodology consultant with the software. Eligible patients are registered by two people trained by the researcher. Allocation of participants to interventions is done by a trained nurse. In order to hide the random allocation, the names of the groups will be placed in a sealed envelope in the sequence of random allocation. Envelopes are numbered. People get a code in the order of their entry into the study, and an envelope is opened for each person and assigned to the desired group. It will be determined by SPSS software to create a random allocation sequence from the block method to quadruple volume. Patients will be selected based on the researcher's desired criteria and will be randomly placed in two groups A (test) and B (control group) based on the order determined by Spss software. The order of randomization will be done secretly; It means that there are 80 envelopes in the package, each of which contains code A and B. After obtaining informed consent and determining that the desired person participates in the study, the person trained by the researcher takes the desired envelope in the specified order and acts according to the group registered in the envelope.
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 in Research of Shahroud University of Medical Sciences
Street address
7th Square, Research and Technology, Shahroud University of Medical Science, Shahroud Town
City
Shahroud
Province
Semnan
Postal code
3614773955
Approval date
2023-09-04, 1402/06/13
Ethics committee reference number
IR.SHMU.REC.1402.080

Health conditions studied

1

Description of health condition studied
Ageing Abuse
ICD-10 code
Y07.9
ICD-10 code description
Unspecified perpetrator of maltreatment and neglect

Primary outcomes

1

Description
Investigation of Ageing Abuse with Vulnerability to Abuse Screening Scale (VASS-21) questionnaire
Timepoint
At the beginning of the study (before the intervention) and 4 weeks after the intervention
Method of measurement
The VASS-21Ageing Abuse Questionnaire and the cut point score of 3 and above indicates the potential risk of elder abuse.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first, related training such as the definition of ageing abuse, its recognition, its types, and prevention and notification strategies are given to the health volunteers by the researcher and a nurse trained by the researcher during a session, and then with the coordination of the health volunteers with During two face-to-face and group sessions for one hour, the elderly provide training on the issue of ageing abuse and its dimensions, as well as ways to prevent and report it. At the end of the second session, people will be given an educational pamphlet about ageing abuse. After selecting the people of the test group based on the entry criteria and obtaining informed consent, the trainings are conducted in the same comprehensive health service centers. Health volunteers in comprehensive health centers will talk to the ageing on a weekly basis through phone calls to investigate and answer their questions. After 4 weeks, the people of the test and control groups are again asked to be evaluated by a questionnaire related to ageing abuse.

Category

Other

2

Description

Control group: Ageing people who refer to community health centers receive care and routine training of the center.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive health centers
Full name of responsible person
Amirheidar Bakhshiarab
Street address
7th Square, Research and Technology, Shahroud University of Medical Science, Shahroud Town
City
Shahroud
Province
Semnan
Postal code
3614773955
Phone
+98 23 3222 4816
Email
amirheidari770@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mohammad Hassan Emamian
Street address
7th Square, Research and Technology, Shahroud University Medical Science, Shahroud Town
City
Shahroud
Province
Semnan
Postal code
3614773955
Phone
+98 23 3222 4816
Email
amirheidari770@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Amirheidar Bakhshiarab
Position
Faculty of Shahroud University of Medical Sciences
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
7th Square, Research and Technology, Shahroud University Medical Science, Shahroud Town
City
Shahroud
Province
Semnan
Postal code

3614773955

Phone
+98 23 3222 4816

Email
amirheidari770@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Amirheidar Bakhshiarab

Position
Faculty of Shahroud University of Medical Sciences

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
7th Square, Research and Technology, Shahroud University Medical Science, Shahroud Town

City
Shahroud

Province
Semnan

Postal code
3614773955

Phone
+98 23 3222 4816

Email
amirheidari770@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Amirheidar Bakhshiarab

Position
Faculty of Shahroud University of Medical Sciences

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
7th Square, Research and Technology, Shahroud University Medical Science, Shahroud Town

City
Shahroud

Province
Semnan

Postal code
3614773955

Phone
+98 23 3222 4816

Email
amirheidari770@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
Part of the patient's demographic information is shared after people have not been identified. All information related to measuring worry and blood pressure in patients can be shared after people have not been identified.

When the data will become available and for how long
Access starts 6 months after results are published

To whom data/document is available
Researchers and students of academic and scientific institutions

Under which criteria data/document could be used
Raw data for correlation studies

From where data/document is obtainable
amirheidari770@gmail.com

What processes are involved for a request to access data/document
Clear explanation of the reason for the need to access data and provide data after two weeks

Comments