

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-21 Ageing 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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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