Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Designing, Implementing And Evaluating An Intervention Program To Improve The Behavior Of Using Rehabilitation Tools And Assistive Technologies And Functional Independence In The Elderly

Protocol summary

Study aim
Determining the effect of an intervention program to improve the behavior of using rehabilitation tools and assistive technologies and functional independence in the elderly.

Design
The clinical trial is a randomized controlled trial and was divided into two control groups and an intervention group, the randomization is based on the table of random numbers and the sample size in this study is 90 elderly people. Blinding was not done in this study.

Settings and conduct
The elderly referring to comprehensive health service centers in Hamedan city will receive the appropriate educational program in two groups of 45 people in a simple random manner.

Participants/Inclusion and exclusion criteria
inclusion criteria 1- elderly 60 years and older who have absolute or relative functional dependence in the descriptive-analytical stage 2- In case of non-communicable diseases, their disease should be under control 3- obtaining informed consent and willingness to cooperate in order to participate in the study 4- elderly whose information is registered in Sib system 5- Having at least basic literacy to answer the questions 6- Cognitive abilities (getting a score of 6 or higher in the Persian version of the short test of the cognitive status of the elderly) exclusion criteria Lack of cognitive abilities Suffering from uncontrolled non-communicable diseases Independent elderly

Intervention groups
This study includes an educational intervention program in the intervention group and this intervention program was designed to improve the behaviors of using rehabilitation tools and assistive technologies and functional independence in the elderly. In the control group, there is no educational intervention program and this group only receives their routine training.

Main outcome variables
Improving the behavior of using rehabilitation tools and technologies

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220727055568N1**
Registration date: **2022-10-16, 1401/07/24**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-16, 1401/07/24**
Update count: **0**

Registration date
2022-10-16, 1401/07/24

Registrant information

Name
fataneh goodarzi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing, Implementing And Evaluating An Intervention Program To Improve The Behavior Of Using Rehabilitation Tools And Assistive Technologies And Functional Independence In The Elderly

Public title

The Behavior Of Using Rehabilitation Tools And Assistive Technologies

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly 60 Year-Old Dependent And Semi-Dependent In Case Of Non-Communicable Diseases, Their Disease Should Be Under Control Obtaining Informed Consent And Willingness To Cooperate In Order To Participate In The Study Elderly Whose Information Is Registered In Sib System Having At Least Basic Literacy To Answer The Questions Cognitive Abilities

Exclusion criteria:

Lack Of Cognitive Abilities Suffering From Uncontrolled Non-Communicable Diseases Independent Elderly

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

More than 1 sample in each individual

Number of samples in each individual: **45**

-

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible elderly who had moderate and severe level of functional status will assign to the intervention (n=45) and control (n=45) groups using a permuted block randomization with block sizes of 6. The block randomization list of the trial will generate using following website; https://www.sealedenvelope.com/simple-randomiser/v1/lists

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 Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences School

City

Hamadan

Province

Hamadan

Postal code

6517838687

Approval date

2022-07-06, 1401/04/15

Ethics committee reference number

IR.UMSHA.REC.1401.527

Health conditions studied

1

Description of health condition studied

Maintaining and promoting functional independence in the elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improving the behavior of using technologies and services for rehabilitation

Timepoint

The outcome of interest would be evaluated in the baseline and 3 months after the intervention

Method of measurement

The questionnaires for evaluating behavior and use of technologies for rehabilitation will be completed by trained researchers in both groups before and 3 months after completion of the intervention.

Secondary outcomes

1

Description

Functional Independence

Timepoint

Before The Intervention And After The Intervention

Method of measurement

Functional Independence Questionnaire

Intervention groups

1

Description
Teaching the elderly about the acceptance and behavior of using rehabilitation assistive technologies will be based on the final structures of the model and on the basis of changes in the structures of the model. The educational content includes the introduction of assistive technologies and the advantages of using them (improving performance, reducing personal assistance, knowing the types of assistive technologies, improving the quality of life, reducing disability, overcoming injuries, promoting functional independence), providing an introduction to technology. rehabilitation aids and provide training on how to choose the appropriate rehabilitation assistive technologies. Then, in the follow-up phase, after the completion of the educational intervention, in order to remind the training given during the intervention period, a suitable educational message will be sent to the intervention group daily for one month through the formation of a group on social networks. The other intervention is in the form of a home visit, so that at this stage, the participants of the intervention group, in terms of the need to use rehabilitation assistive technologies, once before the intervention and once after the intervention through a home visit by the researcher, based on the checklist. Home visits (environmental checklist) are evaluated. Then the necessary training is given on encouraging the use of rehabilitation assistive technologies with an emphasis on cheap environmental modifications that suit the needs of the elderly.

Category
Behavior

2

Description
The controls will receive only usual care and not educational Intervention

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive health service centers

Full name of responsible person
Majid Barati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

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?
Yes

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Majid Barati

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

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Person responsible for scientific inquiries

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Full name of responsible person
Majid Barati
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
SPSS file data can be shared
When the data will become available and for how long
After printing the article
To whom data/document is available
The data will be available to researchers
Under which criteria data/document could be used
It can be used for secondary studies
From where data/document is obtainable
Correspond with fataneh.goodarzi@gmail.com
What processes are involved for a request to access data/document
It will be sent after receiving the email
Comments