Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Comparison of the impact of self-care education through mobile learning and lecture method on loneliness and social isolation among community-dwelling older adults.

Protocol summary

Study aim
Determining and comparing the impact of self-care education through mobile learning and lecture method on loneliness and social isolation among community-dwelling older adults.

Design
Clinical trial of three groups of pre-test and post-test type on 144 elderly people. For randomization, the six-block random allocation method is used.

Settings and conduct
The research population is the elderly covered by comprehensive health service centers in South Tehran. A center with the largest covered elderly population is selected and Then the number of 141 samples will be continuously studied and they will be randomly placed in one of 3 groups by blocking, which includes the control group (without intervention), intervention 1 (self-care training through mobile phone application) and intervention 2 (training self-care in the traditional way). Each group will have 47 people and blinding will not be done.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. 60-70 years old based on WHO criteria, 2. Having a smart mobile phone with the Android operating system, 3. The ability to use educational software, 4. The absence of hearing, vision, touch and speech disorders. Exclusion criteria: 1. Non-participation of research samples for at least two sessions, 2. Suffering from a severe illness or disability.

Intervention groups
mobile learning group intervention: self-care training content through an offline application that will be provided by the researcher. The Intervention for the lecture group: this training will be conducted in the form of lectures with the help of educational aids such as markers, blackboards and PowerPoint in small groups of 8 to 10 people, in 6 training sessions and 2 sessions per week. There is no intervention in the control group.

Main outcome variables
The feeling of loneliness and social isolation of the elderly.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221024056283N1**
Registration date: **2022-11-09, 1401/08/18**
Registration timing: **prospective**

Last update: **2022-11-09, 1401/08/18**
Update count: **0**

Registration date
2022-11-09, 1401/08/18

Registrant information

Name
Mehrnoosh Partovirad

Name of organization / entity

Country
Iran (Islamic Republic of)

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partovirad76@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-06, 1401/09/15

Expected recruitment end date
2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the impact of self-care education through mobile learning and lecture method on loneliness and social isolation among community-dwelling older adults.

Public title

the impact of self-care education on loneliness and social isolation among older adults.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1. 60-70 years old based on WHO criteria, 2.The ability to perform Activities of Daily Living and not having the history of Psychological disorders based on self-report and the elderly medical file, 3. Being literate, 4. Having a smart mobile phone with the Android operating system, 5. The ability to use a mobile phone and educational software, 6. Not participating in similar training courses, 7. The absence of hearing, vision, touch and speech disorders.

Exclusion criteria:

1. Non-participation of research samples for at least two sessions, 2. Suffering from a severe illness or disability.

Age

From **60 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

For the random allocation of samples in three groups, the method of block random assignment from www.randomizer.org will be used. The size of the blocks will be 6. Concealment of the random allocation of samples in three groups will be done by dark-colored envelopes according to the number of samples.

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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences Girls' Dormitory ,in front of Al-Nabi Mosque,The end of North Kargar, North Kargar

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Province

Tehran

Postal code

1439957181

Approval date

2022-09-28, 1401/07/06

Ethics committee reference number

IR.TUMS.FNM.REC.1401.077

Health conditions studied

1

Description of health condition studied

loneliness

ICD-10 code

Z60

ICD-10 code description

Problems related to social environment

2

Description of health condition studied

social isolation

ICD-10 code

Z60.4

ICD-10 code description

Social exclusion and rejection

Primary outcomes

1

Description

Loneliness score in the elderly, which is measured by the loneliness inventory for older adults.

Timepoint

The measurement of loneliness in the elderly will be at the beginning of the study (before the start of the intervention) and after the end of the intervention and then 3 months after the end of the intervention.

Method of measurement

The way to measure the feeling of loneliness in the elderly is the self-report tool of the loneliness inventory for older adults made by Bandari (2021) in Iran.

2

Description

The score of social isolation in the elderly, which is measured by the Lubben Social Network Scale (LSNS).

Timepoint

The measurement of social isolation in the elderly will be at the beginning of the study (before the start of the intervention) and after the end of the intervention and then 3 months after the end of the intervention.

Method of measurement

The way to measure the social isolation in the elderly is the self-report tool of the Lubben Social Network Scale for older adults made by Lubben (2006) in Switzerland..

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The intervention of the mobile learning group: The educational content of the mobile learning group, based on Mobile Health, is provided through the designed software. The application is designed and implemented by the researcher with Java programming language by Android Studio. This application is an offline educational software that can be installed on the Android operating system. The application environment will be designed according to the specific needs of the elderly, so that changes such as reduced muscle strength and limitations in performing precise tasks, reduced visual acuity, reduced color perception and greater sensitivity to staring at the screen, will be customized and adjusted in such a way that To make the elderly benefit from the educational content to the maximum, and in addition to being easy to use, it is possible to use a suitable and adjustable font and color contrast. With the aim of increasing the attention, efficiency and use of different senses of the elderly, the educational content will be in the form of multimedia (text message and/or educational video and/or audio message) and in the form of 8 training sessions and two sessions per week for The time will be about 30 minutes for each session, which will include different dimensions of self-care (including physical self-care, psycho-emotional self-care, social self-care and spiritual self-care). The first meeting will be conducted face-to-face to state the objectives of the research, explain the educational program (educational chart), how to access the researcher for questions and clear possible doubts, how to install and use the software. After installing the software, the access code for the people of this group will be entered by the researcher. so that other people under study do not have access to educational content; The login code to the software will not be shared with the mobile learning group. The second to seventh educational sessions will be provided to the elderly of the mobile learning group by mobile phone application. The order of loading the content in the application will be done according to the educational chart presented in the first session, and until the content of the previous session is not studied, the next session will not be visible to the elderly. At the end of each week, follow-up will be done to ensure that the educational content is read by the mobile learning group, through a phone call or text message. Also, during the intervention, the researcher will be available to the people of this group by phone or via text message if they have questions or need additional explanations. The last meeting will be held in person with the purpose of summarizing the contents, questions and answering the post-test.

Category

Lifestyle

2

Description

Intervention group 2: The intervention of the training group in the way of lectures: Physical self-care, psycho-emotional self-care, social self-care, and spiritual self-care training will be held in the form of group lectures, using educational aids such as marker, blackboard, and PowerPoint in small groups of 8 to 10 people. Training will be provided in 6 sessions and 2 sessions each week for a duration of approximately 45 to 60 minutes for each session. These trainings will be conducted at the selected comprehensive health service center. At the end of each session, a group discussion will be held with the participation of the members of this group.

Category

Lifestyle

3

Description

Control group: There is no intervention for the control group; But at the end of the research, the content of self-care training will be given to the people of this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers south of Tehran

Full name of responsible person

Mehrnoosh Partovirad

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Tehran University of Medical Sciences Girls' Dormitory ,in front of Al-Nabi Mosque,The end of North Kargar, North Kargar

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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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1417653761

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mehrnoosh Partovirad

Position
Master Student Of Geriatric Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Position
Master Student Of Geriatric Nursing

Latest degree
Bachelor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
"There is no further information".
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
Undecided - It is not yet known if there will be 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