

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of education based on Health Literacy INDEX on self-care ability in elderly people

Protocol summary

Study aim

Determining the effect of education based on health literacy index on self-care ability in the elderly

Design

In this study, 68 elderly people are selected according to the Inclusion criteria that are coming to the neighborhood of the 6th district of Tehran. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct

The research area is located in District 6 of Tehran Municipality.

Participants/Inclusion and exclusion criteria

inclusion criteria: Being aged 60 to 70 years; Having reading and writing skills ;Not having vision, hearing and cognitive impairments with self-declaration ;Not having physical and motor limitation ;Not a member of the health team;The inadequacy of the health literacy level is lower than the 50th by adult health literacy questionnaire HELIA exclusion criteria: Do not want to continue studying ;Absence in two consecutive sessions;Acute physical and psychological problems

Intervention groups

First, the control group and then the intervention on separate days were invited to participate in the briefing. The intervention group received 6 one-hour training sessions with content of self-care ability based on the health literacy index published on the basis of the latest sources. The instruments used in this study were Adult Functional Health Literacy Questionnaire (TOFHLA) and researcher-made Self-care Questionnaire, completed by the subjects before and 8 weeks after completion of the intervention. The control group received routine trainings for neighborhood students.

Main outcome variables

Self-care status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170912036150N1**

Registration date: **2018-05-23, 1397/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-23, 1397/03/02**

Update count: **0**

Registration date

2018-05-23, 1397/03/02

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 436 5110

Email address

rashkih@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-25, 1397/02/05

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on Health Literacy INDEX

on self-care ability in elderly people

Public title

The effect of education on self-care of the elderly

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being aged 60 to 70 years Having reading and writing skills Not having vision, hearing and cognitive impairments with self-declaration Not having Physical and motor limitation Not a member of the health team The inadequacy of the health literacy level is lower than the 50th by adult health literacy questionnaire HELIA

Exclusion criteria:

Do not want to continue studying Absence in two consecutive sessions Acute physical and psychological problems

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample size of this study is 68, and according to inclusion and exclusion criteria they are divided to two groups: control (34) and intervention (34). The sampling method is Randomized block design. In this design, the samples are selected by random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, only participants were unaware of the allocation of study groups, as the coupled days were allocated to the intervention group and the individual days for the control group.

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

Nosrat St, District 6, Tehran, Tehran Province,

City

Tehran

Province

Tehran

Postal code

کد پستی : 1419733171

Approval date

2017-09-06, 1396/06/15

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3392

Health conditions studied

1

Description of health condition studied

self care

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

self care

Timepoint

At the beginning of the study and 8 weeks after the end of the intervention

Method of measurement

Self-care questionnaire in the elderly

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For intervention group six self-care educational sessions based on health literacy index will be held in the Mahalleh houses for 4 weeks. Each session will be last one hour

Category

Lifestyle

2

Description

Control group: Traditional education in neighborhood

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Neighborhoods HOUSE in Tehran Municipality 6th District

Full name of responsible person

Hossein Rashki Ghaleh No

Street address

Nosrat St, District 6, Tehran, Tehran Province,

City

Tehran

Province

Tehran

Postal code

1419733171 صندوق پستی

Phone

+98 21 6692 6355

Email

rashkih@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mrs. Cardan

Street address

Nosrat St, District 6, Tehran, Tehran Province,

City

Tehran

Province

Tehran

Postal code

1419733171 : کد پستی

Phone

+98 21 6692 6355

Email

rashkih@razi.tums.ac.ir

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

Hossein Rashki Ghaleh No

Position

Masters student Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery Tehran University of Medical Sciences Nosrat St., Tohid Sq., 1419733171 Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4208

Email

rashkih@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shahzad Pashaeypoor

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nosrat St, District 6, Tehran, Tehran Province,

City

Tehran

Province

Tehran

Postal code

1419733171 : کد پستی

Phone

+98 21 6105 4208

Email

pashaeypoor.sh@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hossein Rashki Ghaleh No

Position

Masters student Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery Tehran University of
Medical Sciences Nosrat St., Tohid Sq., 1419733171
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4208

Email

rashkih@razi.tums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available