

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of the family-centered self-care education on functional independence and life satisfaction among community- dwelling elderly adults

Protocol summary

Study aim

Determine the effect of the family-centered self-care education on functional independence and life satisfaction among community- dwelling elderly adults

Design

Randomized clinical trial,with parallel group with 126 patients,blinded,sealed boxes for concealment

Settings and conduct

The community of study is all the elderly who refer to Tehran health care home.After getting the permission from Tehran University of Medical Science dignity committee,the expert will introduce yourself.Afterwards, 126 of older adults who are eligible will be chosen.

Participants/Inclusion and exclusion criteria

The older adults who live with their wives or children, Not participating in same educational classes,The possibility of participating of family members in classes,The ability to speak farsi. Exclusion criteria: Participating in same educational classes.

Intervention groups

Intervention group:self care education in all domains based on family-centered empowerment theory.This intervention will be held in defined educational classes which making speech and discussion will be adopted. Control group:In the end,in one educational session,they will be educated and a booklet will be provided.

Main outcome variables

Functional independence,Life satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200824048499N1**

Registration date: **2020-09-14, 1399/06/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-14, 1399/06/24**

Update count: **0**

Registration date

2020-09-14, 1399/06/24

Registrant information

Name

Tannaz MehrabMohseni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 0951

Email address

sh-pashaeipour@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-10, 1399/06/20

Expected recruitment end date

2020-10-11, 1399/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the family-centered self-care education on functional independence and life satisfaction among community- dwelling elderly adults

Public title

The effect of the family-centered self care education on independence and life satisfaction

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
The older adults who live with wives or children
The possibility of participating of family members in classes

Exclusion criteria:
Participating in same educational classes

Age
From **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples should be allocated to intervention and control groups.(Each group contain 63 samples). The randomized allocation is like this;researcher assumes intervention group as A and parallel group as B. The elderly will be grouped in four blocks that each of them are paired (AA is defined intervention group and BB is defined for parallel group). Then,will be divided in 6 forms;1-AABB,2-ABAB,3-ABBA,4-BABA,5-BBAA,6-ABBA. If the number 4 is appeared on the dice,it will be recorded as BABA,or if the number 5 is shown,it will be written as BBAA. This action will be repeated till this sample will be completed.In order to conceal the allocation,sealed and vague boxes which have numbers,will be used.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study,the participants are aware of the participation,drawbacks and benefits of this study.After filling informed consent form, The participants and their families will be blind toward randomized allocation.Moreover, the researcher and the one who collects and analyzes the data will be blind too.

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
No 1,Poursina St,Qods St,Enghelab St

City
Tehran

Province
Tehran

Postal code
1415665881

Approval date
2020-08-24, 1399/06/03

Ethics committee reference number
IR.TUMS.FNM.REC.1399.091

Health conditions studied

1
Description of health condition studied
Functional independence,Life satisfaction

ICD-10 code

ICD-10 code description

Primary outcomes

1
Description
Functional independence

Timepoint
Before intervention and 8 weeks after intervention

Method of measurement
Katz questionnaire

2
Description
Life satisfaction

Timepoint
Before intervention and 8 weeks after intervention

Method of measurement
Life satisfaction Index-z Questionnaire

Secondary outcomes

empty

Intervention groups

1
Description
Intervention group: The intervention contains self care education in all domains,(physical,mental,social and spiritual) which focus on healthy and active life style ,(appropriate physical exercise,diet,the total hours of sleep and the balance between sleep and rest,positive self imagination,overcome the ineffectiveness and hopelessness and taking apart in social activities.) This study is based on family centered method.The classes

will be held once a week six times for 1.5 hours based on making a speech, question and answer and discussion in small groups with an emphasis on active family participation (Role model and sharing opinions and experiences).

Category

Lifestyle

2**Description**

Control group: This group will not be deprived of any health care of center. In the end, in one educational session, they will be educated about self care and a booklet will be provided.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

South Tehran Health Centre

Full name of responsible person

Dr. Mohamadreza Salmani

Street address

No 1178, Jeyhoon Ave, Emam Khomeini St

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Province

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1419733171

Phone

+98 21 6687 7803

Email

fnm@tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohamadali Sahraian

Street address

6th Floor, Central Building, Qods St, Keshavarz Blvd

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1419733171

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vcr@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

Tannaz MehrabMohseni

Position

Master degree student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Tannaz MehrabMohseni

Position

Master degree student

Latest degree

Master

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Person responsible for updating data

Contact

Name of organization / entity
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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 more 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

Yes - There is 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

Title and more details about the data/document

The letter of consent and the detail can be shared.

When the data will become available and for how long

This will be available 3 months after release.

To whom data/document is available

Nurses and Medical science experts.

Under which criteria data/document could be used

There is no specific occasion for observing the data.

From where data/document is obtainable

The best way to contact will be sending e-mail to address below: tanaz.mohseni95@gmail.com

What processes are involved for a request to access data/document

Whenever the e-mail has been seen,the request will be defined and the response will be sent as soon as possible.

Comments