Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+98 21 8897 0951

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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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1419733171

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+98 21 6687 7803

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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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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