Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Sep 2026

Designing and assessing the effectiveness of a community-based social marketing campaign on the social support, self-efficacy and physical activity of the elderly

Protocol summary

Study aim
The purpose of this research is to promote health-related behaviors, improve social support, self-efficacy and physical activity of the elderly.

Design
Random allocation of centers to the intervention and control groups using the balanced block randomization method - 500 people - community-based survey intervention

Settings and conduct
Samples: 65 to 75-year-olds in Rasht city - design and implementation of a community-based survey intervention with the participation of the elderly - the control group only receives routine geriatric care - blinding is not possible.

Participants/Inclusion and exclusion criteria
Elderly people of Rasht city, 65 to 75 years old/- Having the desire and consent to participate in the research Inclusion criteria: -Age 65 to 75 years old (based on information registered in Sib system) - Absence of cognitive problems such as dementia and Alzheimer's (based on information recorded in the Sib system) - Absence of diagnosed severe osteoporosis (based on the information recorded in the apple system and asking the person) - Having minimum reading and writing literacy to complete the questionnaire Exit criteria: - Unwillingness to continue participating in the study - Elderly people with mobility problems related to wheelchairs -Migration - death

Intervention groups
Forming a community-oriented campaign committee, holding an educational-advisory meeting, campaign implementation, interpersonal intervention in the direction of social support, intervention in the direction of improving the self-efficacy of holding the festival, free training courses, discount plans, etc. The control group will only take care of will receive the aging routine.

Main outcome variables
Social support, Self-efficacy, Physical activity

General information

Reason for update
Sampling has not been done so far due to lack of funding. I have a request to change the sampling date from July to November this year for one month.

Acronym
SMC

IRCT registration information
IRCT registration number: **IRCT20240429061582N1**
Registration date: **2024-05-22, 1403/03/02**
Registration timing: **prospective**

Last update: **2024-07-15, 1403/04/25**
Update count: **1**

Registration date
2024-05-22, 1403/03/02

Registrant information

Name
Roghayeh Safavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 3332 5075

Email address
roghayehsafavi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-10, 1403/08/20

Expected recruitment end date

2024-12-10, 1403/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and assessing the effectiveness of a community-based social marketing campaign on the social support, self-efficacy and physical activity of the elderly

Public title

Effects of community-based social marketing campaign on social support, self-efficacy and physical activity of the elderly

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having the desire and consent to participate in the research Age 65 to 75 years (based on the information registered in the Sib system) Absence of cognitive problems such as dementia and Alzheimer's (based on the information registered in the Sib system) Absence of diagnosed severe osteoporosis (based on the information recorded in the Sib system and asking the individual) having minimum reading and writing literacy to complete the questionnaire

Exclusion criteria:

Unwillingness to continue participating in the study Elderly people with mobility problems related to wheelchairs Migration death

Age

From **65 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **500**

More than 1 sample in each individual

Number of samples in each individual: **1**

An elderly person 65 to 75 years old living in Rasht city

Randomization (investigator's opinion)

Randomized

Randomization description

Using the block randomization table, centers are randomly assigned to intervention and control. Out of 16 centers, 8 will be intervention centers and 8 will be control centers. The number of participants in the group will be the same. Centers A will be the intervention and B will be the control.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

A community-based campaign

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Working group of Ethics Committee in Research Faculty of Health and Paramedicine-Tehran University

Street address

Enghelab St., Quds St., Porsina St., Faculty of Health

City

Tehran

Province

Guilan

Postal code

1417613151

Approval date

2024-04-28, 1403/02/09

Ethics committee reference number

IR.TUMS.SPH.REC.1403.017

Health conditions studied

1

Description of health condition studied

Inactivity in the elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Social support

Timepoint

3 Month

Method of measurement

Questionnaire of social support for physical activity by Sallis et al.

2

Description

Self-Efficacy

Timepoint

3 months

Method of measurement

Physical Activity Self-Efficacy Questionnaire for the Elderly, Shamsalinia et al.

Secondary outcomes

1

Description
Physical activity
Timepoint
6 months
Method of measurement
Short Form Physical Activity Questionnaire, Lee et al

Intervention groups

1

Description
Intervention group: 65 to 75-year-olds are residents of Rasht city, and based on the decisions of the campaign committee, interventions such as educational sessions, festivals, public walks, group discussion sessions, etc. are carried out for them. The elderly group in this committee includes 10 people are neighborhood health liaisons and elderly health ambassadors, each of whom will be responsible for 25 elderly people. The survey will be carried out in a period of 3 months with the method (3 messages, 3 times, 3 methods per month). The contents will be prepared in printed and electronic form from the source of physical activity guide in the old age of the Ministry of Health and Medical Education.
Category
Behavior

2

Description
Control group: will only receive the routine elderly care of the Ministry of Health.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive urban health service centers of Rasht
Full name of responsible person
Seyyed Mahmoud Rizvani
Street address
Health Deputy, Farhang Square, Azadegan Gilan Province, Rasht
City
Rasht
Province
Guilan
Postal code
41886-14975
Phone
+98 13 3334 6593
Fax
+98 13 3332 2057
Email
Roghayehsafavi@yahoo.com
Web page address
https://health.gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Roya Sadeghi
Street address
Enghelab St., Qods St., Porsina St., Faculty of Health
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 3333
Fax
+98 21 4293 3261
Email
sph@tums.ac.ir
Web page address
Http://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
Seyyed Roghayeh Safavi
Position
PhD
Latest degree
Master
Other areas of specialty/work
Health Promotion

Street address
Enghelab St., Qods St., Porsina St., Faculty of Health
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 3261
Fax
+98 21 4293 3261
Email
Roghayehsafavi@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Roya Sadeghi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Enghelab St., Qods St., Porsina St., Faculty of Health
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 3333
Fax
+98 21 4293 3261
Email
Sadeghir@tums.ac.ir
Web page address
Http://tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ensieh Jamshidi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Enghelab St., Qods St., Porsina St., Faculty of Health
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 3333
Fax
+98 21 4293 3261
Email
ensieyh_jamshidi@yahoo.com
Web page address
Http://tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The entire data can potentially be shared after de-identifying people or, for example, only part of the data, such as information related to the main outcome or the like, can be shared.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
The data/document will be available for researchers working in academic and scientific institutions and policymakers in the field of aging.
Under which criteria data/document could be used
It will be possible for the planners in the field of aging of the Ministry of Health to use the data with the consent of the researcher.
From where data/document is obtainable
Seyyed Roghayeh Safavi. PhD Candidate of Tehran University of Medical Sciences. Email: Roghayehsafavi@yahoo.com. Contact number: 09114560649. Address: Rasht, Farhang Square, Azadegan Street. Gilan Province Health Deputy
What processes are involved for a request to access data/document
Documents and files will be sent by e-mail within 5 working days.
Comments