

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Roya Sadeghi

Street address

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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

Seyyed Roghayeh Safavi

Position

PhD

Latest degree

Master

Other areas of specialty/work

Health Promotion

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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

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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

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