

# 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

##### 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

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##### Postal code

41886-14975

##### Phone

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#### 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

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##### Province

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##### 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

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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**