

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison the effect of spiritual care and routine care on the level of happiness in elderly inhabitant in retirement home

#### Protocol summary

##### Study aim

Determining the effect of spiritual care package on the level of happiness of elderly residents of Sabzevar Madar home in 2018

##### Design

A double-blind, randomized clinical trial with community-based control group and parallel group design. In this study 40 elderly people randomly assigned into intervention group (spiritual care) and control (routine care).

##### Settings and conduct

The research environment is Madar's elderly retirement home in Sabzevar. A total of 40 eligible people are selected. And they randomly divided into two intervention (receiving spiritual care) and control (routine care) groups. Before and after the intervention, the Happiness Questionnaire will be filled for two groups. Participants and statistical adviser will be unaware of the involvement of the elderly in the intervention or control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 60 years old; Ability to speak in Persian; at least one month stay in the nursing home; No concurrent participation in similar researches (related to research topic). Non- Inclusion criteria: not believing in Islam; Visual or auditory impairment that causes performance impairment; Mental disorders; Experiencing an stressful event in the last three months (such as losing the spouse or other close relatives).

##### Intervention groups

Intervention group: Receiving spiritual care including active listening and instilling hope on a daily basis, from one person to the elderly, listening to seniors' speeches and concerns, arranging facilities for worship, using supportive systems (attendance of the clergy, attendants, charities). Control group: in this group, elders receive no extra intervention. In other word, they receive routine daily care provided in the nursing home.

##### Main outcome variables

Happiness score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181101041522N1**

Registration date: **2018-12-08, 1397/09/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-08, 1397/09/17**

Update count: **0**

##### Registration date

2018-12-08, 1397/09/17

##### Registrant information

##### Name

toktam ayyari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4464 7278

##### Email address

ayyaari.t@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-21, 1397/08/30

##### Expected recruitment end date

2018-12-21, 1397/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison the effect of spiritual care and routine care on the level of happiness in elderly inhabitant in retirement home

### Public title

The effect of spiritual care on the level of elderly happiness

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Inclination to participate in the study aged over 60 ability to speak persian minimum one month stay at a nursing home lack of co-operation in research related to research topic

#### Exclusion criteria:

Not believing in Islam Visual impairment to the extent that causes performance impairment Hearing impairment to the extent that impairs performance impairment Mental disorders with regard to the elderly medical records Experience of stressful events in the last three months (such as losing the spouse or other close relatives)

### Age

From **60 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

- Participant
- Data analyser

### Sample size

Target sample size: **40**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this study, four permuted blocks consisted of the English letters A,B,C,D. The letters B, and A would be denoted the intervention group, and C, and D would be denoted the control group. The blocks are selected randomly and blindfolded. Each block is then deleted, and the next random block is selected. With each block, the entrance order to the intervention group or the control group is determined. Assumingly; block D, A, C, and B would be meant that the second, and fourth subjects are entered in the intervention group and the first, and third subjects are entered in the control group. The patients were divided into two equal groups, with 20 patients in the intervention group and 20 patients in the control group.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Participants in research and data analyst are unaware of the allocation of individuals to the control or intervention groups.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

##### Street address

No.1, Farhangian 15, Farhangian Street

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9611761311

#### Approval date

2018-10-29, 1397/08/07

#### Ethics committee reference number

IR.MEDSAB.REC.1397.051

## Health conditions studied

### 1

#### Description of health condition studied

Happiness of the elderly

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Happiness score in the Oxford Happiness Questionnaire

#### Timepoint

At the beginning of the study (before the intervention) and after the intervention and two weeks after the end of the intervention

#### Method of measurement

Oxford Happiness Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: delivering spiritual care daily from 9

o'clock to 12 o'clock for 4 weeks including: active listening and protectionist presence (daily presence beside the elderly and listening to his or her talk and concerns), supporting religious ceremonies (providing facilities and helping the elderly to practice worship) and using Supportive systems (clergy presence, visitors and charities), Instilling hope (encouraging the elderly to recount and record strengths and pleasant memories of life related to the positive and successful events of their life).

**Category**

N/A

**2**

**Description**

Control group: In this study, the control group does not receive any intervention.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Sabzevar Madar elderly home

**Full name of responsible person**

Mahdi Zabihollahi

**Street address**

22 Bahman Street, Kashfi Street

**City**

Sabzevar

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**Postal code**

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**Phone**

+98 51 4421 3817

**Email**

ayyaari.t@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Fereshte Ghorat

**Street address**

Deputy of Research and Technology; Sabzevar University of Medical Sciences; after Anonymous Martyrs tomb; Shohadaye Hastei Blvd.

**City**

Sabzevar

**Province**

Razavi Khorasan

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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**

Sabzevar 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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Toktam Ayyari

**Position**

nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No.1, Farhangian15, Farhangian street

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Toktam Ayyari

**Position**

Nurse

**Latest degree**

Bachelor

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Sabzevar University of Medical Sciences  
**Full name of responsible person**  
Toktam Ayyari  
**Position**  
Nurse  
**Latest degree**  
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**Other areas of specialty/work**  
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**Email**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be 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