

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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Razavi Khorasan

Postal code

9611761311

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

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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

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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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