

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Investigating the Impact of designed Leisure time Intervention on Loneliness and General Health in Widows Elderly

Protocol summary

Study aim

Determining the effect of designed Leisure time intervention on loneliness and general health in widows elderly

Design

This study is a clinical trial. The population of this study included 64 elderly widows over 60 years old who were referred to health centers of Jiroft. Individuals were selected according to inclusion criteria and then randomly divided into two intervention and control groups.

Settings and conduct

In this study, 64 women were selected from among widows elderly referred to health centers of Jiroft and then randomly divided into two intervention and control groups. Intervention consisted of 8 sessions of Leisure time program during 4 weeks which were held for the intervention group in kasra welfare complex of jiroft. Loneliness and general health were measured in both groups before and two weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being widow; Age over 60; Home inhabitant; Non-alcohol and drug addiction; Absence of stressful events in the last 6 months; Ability to communicate verbally; No acute underlying disease and severe pain; No participation in Same programs; Ability to do daily activities; The desire to participate in the study

Intervention groups

People were divided into two intervention and control groups by plain randomized method. First, a Pretest was done in both groups, Then the designed leisure time intervention in the intervention group was done for four weeks, two times a week, each time two hours. Sessions was done according to a schedule set. The control group received no intervention. The post test was done two weeks after intervention in both groups.

Main outcome variables

Loneliness; General Health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180513039627N1**

Registration date: **2018-07-14, 1397/04/23**

Registration timing: **retrospective**

Last update: **2018-07-14, 1397/04/23**

Update count: **0**

Registration date

2018-07-14, 1397/04/23

Registrant information

Name

Rehimeh Izadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-06, 1396/05/15

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Impact of designed Leisure time Intervention on Loneliness and General Health in Widows Elderly

Public title

The Impact of designed Leisure time Intervention on Loneliness and General Health in Widows Elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being widow Age over 60 Home inhabitant Non-alcohol and drug addiction Absence of stressful events in the last 6 months Ability to communicate verbally No acute underlying disease and severe pain No participation in Same programs Ability to do daily activities The desire to participate in the study

Exclusion criteria:

Age

From **60 years** old to **90 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The peoples were divided into two intervention and control groups with simple randomization method (lottery).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Rafsanjan University of Medical Sciences, Imam Ali Boulevard, Rafsanjan

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Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2017-07-31, 1396/05/09

Ethics committee reference number

IR.RUMS.REC.1396.82

Health conditions studied

1

Description of health condition studied

Loneliness

ICD-10 code

ICD-10 code description

2

Description of health condition studied

General Health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Loneliness

Timepoint

Before intervention and two weeks after the end of intervention

Method of measurement

Loneliness Questionnaire (UCLA)

2

Description

General Health

Timepoint

Before intervention and two weeks after the end of intervention

Method of measurement

General Health Questionnaire (GHQ-28)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention included 8 sessions of designed leisure time program during 4 weeks, two times a week, each session was for two hours. The intervention group became divided to two groups of 16 members. Sessions was done according to a schedule set. This program was consisted of activities like: sports activities(walking), artistic(handcraft), religious(Prayer), educational(nutrition, health, aging mobility exercises,

social connections), reminiscence, expression of life experiences, expression of emotions and feelings, control blood sugar and blood pressure and Weight.

Category

Lifestyle

2**Description**

Control group: No intervention was done in this group.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health care centers in Jiroft city

Full name of responsible person

Dr Majid Kazemi

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Faculty of Nursing and Midwifery, Jomhori Blvd,
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Rafsanjan 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**

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Majid Kazemi

Position

Phd

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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