

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of life review intervention on relationship quality and quality of life in rural elderly widows in Bojnourd city, North Khorasan province

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The effect of life review intervention on relationship quality and quality of life in rural elderly widows in Bojnourd city, North Khorasan province

Last update: **2020-10-29, 1399/08/08**

Update count: **0**

Registration date

2020-10-29, 1399/08/08

Design

This trial has two control and intervention groups, with parallel groups, no blinding, randomized, will be performed on 132 elderly rural widows. Excel software rand function will be used for randomization.

Registrant information

Name

Mahin Nazari

Name of organization / entity

School of health

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Iran (Islamic Republic of)

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Settings and conduct

From these centers, two centers will be selected due to the similarity of dialect and culture and the distance of the villages from the city of Bojnourd, which have relatively similar conditions. And one of the centers is designated as the intervention group and the other as the control.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

1- Age over 60 years old 2- At least one year has passed since the time of widowhood.3- A maximum of 20 years have passed since their widowhood.4- Willingness to participate in study (reminiscence sessions). 5 - The ability to communicate

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group: life review, which will be performed during 6 sessions for 6 weeks. During the sessions, photos, music and old equipment will be used to stimulate memory. Control group: No intervention (after the study, the training of the intervention group will be provided briefly for them in two sessions).

Main outcome variables

Quality of life - quality of relationships

Scientific title

The effect of life review intervention on relationship quality and quality of life in rural elderly widows in Bojnourd city, North Khorasan province

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111017007816N18**

Registration date: **2020-10-29, 1399/08/08**

Public title

The effect of life review intervention on relationship

quality and quality of life in rural elderly widows in Bojnourd city, North Khorasan province

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Older women over 60 At least one year has passed since my widowhood A maximum of 20 years have passed since they became widows Willingness to participate in study (reminiscence sessions) Ability to communicate Covered by comprehensive health databases and registered in the Apple system.
Exclusion criteria:
Reluctance to participate in the study

Age
From **60 years** old to **80 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **132**

Randomization (investigator's opinion)
Randomized

Randomization description
To start the study, the selected rural health centers will be referred and the information of widows over 60 years of age will be examined. Then, according to the inclusion criteria, if the number of people is approximately equal to the sample size, the census will be used. But if the number of people is higher than the desired sample size, the random allocation method will be used to select the subjects. In this way, we will write down the national code of the people who have the conditions to enter the study in separate sheets and put them in a container and ask one of the uninformed people present in the health center to select 66 sheets randomly. In the same way, control group will be selected.

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

Shiraz University Of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Province

Fars

Postal code

7153675541

Approval date

2020-05-13, 1399/02/24

Ethics committee reference number

IR.SUMS.REC.1399.196

Health conditions studied

1

Description of health condition studied

-

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Quality of life scores

Timepoint

Before and two months after the intervention

Method of measurement

Lipad Questionnaire

2

Description

quality of relationships

Timepoint

Before and two months after the intervention

Method of measurement

Relationship Quality

Secondary outcomes

empty

Intervention groups

1

Description

For the intervention group, life review training classes will be held in 6 sessions for 6 weeks. During these sessions, reviewing the late stages of widowhood, reviewing the moments of death of a spouse and how to deal with his or her absence, reviewing ways to deal with the challenges of livelihood, reviewing the training learned to deal with the challenges of widowhood, reviewing current challenges. Due to the prevalence of coronary heart disease, three training sessions will be conducted in person in accordance with health protocols, the other three sessions will be conducted through

educational media and the production of educational clips and memorable image clips, as well as telephone interviews.

Category

Behavior

2

Description

No intervention or training was provided for the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Rural health centers

Full name of responsible person

Dr Bazkhanei

Street address

Hor Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahin Nazari

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Nasim Pirzadeh

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Public Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mahin Nazari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

Contact

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Position

Masters student

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

The total number of people referring to the magazine in which the article was published

Under which criteria data/document could be used

Supervisor

From where data/document is obtainable

Dr. Mahin Nazari Email manazari@sums.ac.ir

What processes are involved for a request to access data/document

The coordinators author takes about 1 week to 1 month

Comments