

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1725 1001

###### Email address

manazari@sums.ac.ir

##### 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

**City**

Bojnoord

**Province**

North Khorasan

**Postal code**

74586647

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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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School of public Health, Shiraz University of Medical Sciences

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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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**Full name of responsible person**

Nasim Pirzadeh

**Position**

Masters student

**Latest degree**

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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**