

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jul 2026

### The Effectiveness of Structured Group Reminiscence Therapy on Depression and Anxiety of Elderly Women Smoking Hookah Referred to Larestan Community Health Centers, 2020

#### Protocol summary

##### Study aim

Determining the effectiveness of Structured Group Reminiscence Therapy on Depression and Anxiety of Elderly Women Smoking Hookah Referred to Larestan Community Health Centers, 2020

##### Design

Randomized clinical trial with control group, parallel groups without blindness, On 24 elderly women consuming hookah, followed for one month.

##### Settings and conduct

The present study will be performed on elderly women who smoke hookah and refer to health centers in Larestan city.

##### Participants/Inclusion and exclusion criteria

Samples tend to be voluntary to participate in research and before the intervention, the candidates obtained a score of 5 to 11 from the Elderly Depression Questionnaire, a score of 32 to 64 from the state Anxiety Test, and a score of 32 to 62 from the trait Anxiety Test.

##### Intervention groups

In this study, a Structured Group Reminiscence protocol will be used for the intervention group. In this program, twelve topics are discussed in 12 sessions (one to one and a half hours). 1. identification data. 2. Family photos, childhood playthings 3. Kids' chalkboard, chalk, school bag 4. Work tools and gadgets 5. Urban open space such as a park or community garden 6. Marriage 7. Home, garden and favorite animals 8. Next generation, infancy, and childhood period 9. Foods, cooking 10. Vacation, journeys 11. Celebration 12. Summarizing of sessions

##### Main outcome variables

After the intervention (for a month), The Elderly Depression , Spiel Berger Anxiety, and the MMSE Questionnaires are re-completed by participants.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090304001742N5**

Registration date: **2020-08-10, 1399/05/20**

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

Last update: **2020-08-10, 1399/05/20**

Update count: **0**

##### Registration date

2020-08-10, 1399/05/20

##### Registrant information

##### Name

mohammadrafi bazrafshan

##### Name of organization / entity

shiraz university medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 917 382 1959

##### Email address

mrbazr@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

##### Expected recruitment end date

2020-10-06, 1399/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

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| <b>Scientific title</b><br>The Effectiveness of Structured Group Reminiscence Therapy on Depression and Anxiety of Elderly Women Smoking Hookah Referred to Larestan Community Health Centers, 2020                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Public title</b><br>The Effectiveness of Structured Group Reminiscence Therapy on Depression and Anxiety of Elderly Women Smoking Hookah                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Purpose</b><br>Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Inclusion/Exclusion criteria</b><br><b>Inclusion criteria:</b><br>Samples tend to be voluntary to participate in research. Candidates must be at least 60 years old. Candidates have acceptable listening and speaking skills. Candidates with acute psychosis do not have chronic and debilitating diseases and cognitive disorders such as dementia. Depression and anxiety are not the result of physical problems such as hypothyroidism. Candidates do not have a history of using psychiatric medications due to psychological problems. Candidates did not receive treatment that impaired mental ability, memory, or thinking. Candidates should be familiar with Persian language. Before the intervention, the candidates obtained a score of 5 to 11 from the Elderly Depression Questionnaire, a score of 32 to 64 from the state Anxiety Test, and a score of 32 to 62 from the trait Anxiety Test. Candidates should have a moderate level of cognitive status (obtaining a minimum score of 21 in the Mini-Mental State Examination test). Candidates should not be in other treatment groups. Candidates have a history of hookah use for at least 1 year.<br><b>Exclusion criteria:</b><br>Occurrence of any severe social, familial crisis during the study (such as the grief of family members in the last 6 months) Hospitalization or acute and chronic illness that interferes with research. Cognitive disorders and physical disabilities that seriously hinder participation in group therapy sessions. Taking psychiatric pills due to psychological problems during the study Symptoms and signs of crisis at the time of expression and review of life events during the study Absence from meetings more than once Alcohol or drug abuse Lack of willingness of samples to continue participating in research | <b>Blinding (investigator's opinion)</b><br>Not blinded<br><b>Blinding description</b><br><b>Placebo</b><br>Not used<br><b>Assignment</b><br>Parallel<br><b>Other design features</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| <b>Age</b><br>From <b>60 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Gender</b><br>Female                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Phase</b><br>N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Groups that have been masked</b><br>No information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Sample size</b><br>Target sample size: <b>24</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Randomization (investigator's opinion)</b><br>Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Randomization description</b><br>Due to the fact that the final sample size is 24 people,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Health conditions studied</b><br><b>1</b><br><b>Description of health condition studied</b><br>Elderly women consuming hookah<br><b>ICD-10 code</b><br>Z72.0<br><b>ICD-10 code description</b><br>Tobacco use                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

## Primary outcomes

### 1

#### Description

A score of 5 to 8 indicates mild depression, 9 to 11 indicates moderate depression, and 12 to 15 indicates severe depression.

#### Timepoint

Before the intervention, immediately and one month after the intervention

#### Method of measurement

Elderly Depression Questionnaire

### 2

#### Description

The scores on either of the trait and state anxiety scales can range from 20 to 80. state Anxiety: Rating 20 - 31 Mild Anxiety, Score 32 - 42 Medium to Low Anxiety, Rating 43 - 53 Medium to High Anxiety, Rating 54 - 64 Relatively Severe, Rating 65 - 75 Severe and Rating 76 and Up indicate High Anxiety It is severe. For trait Anxiety: Rating 20 - 31 Mild Anxiety, Rating 32 - 42 Medium to Low Anxiety, Rating 43 - 52 Medium to High Anxiety, Rating 53 - 62 Relatively Severe Anxiety, Rating 63 - 72 Severe Anxiety, Rating 73 and Up Very Anxiety Shows extreme.

#### Timepoint

Before the intervention, immediately and one month after the intervention

#### Method of measurement

Spiel Berger Anxiety Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Receiving 8 sessions of structured group reminiscence therapy. In this program, twelve topics are discussed in 12 sessions (one to one and a half hours). In each of these sessions, stimuli are used to recall memories related to the topic of the session, which, depending on the topic of the session, may include photos, work tools, childhood toys, and so on. The protocol in this study will be implemented by the researchers themselves. In the present study, some sessions will be merged and the protocol will be reduced to 8 sessions (integration of sessions 1 and 2, 4 and 5, 9 and 10, 11 and 12). In order to record the course of changes in grades, participants will be asked to complete the questionnaires one month after the intervention in the pre-test stage, immediately after the intervention.

#### Category

Treatment - Other

### 2

#### Description

Control group: They do not receive any intervention.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Larestan Health Center

##### Full name of responsible person

Mohammad-Rafi Bazrafshan

##### Street address

Dr. Dadman Highway

##### City

Larestan

##### Province

Fars

##### Postal code

7431895639

##### Phone

+98 71 5224 7110

##### Fax

+98 71 5224 7111

##### Email

mrbazr@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Larestan University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Hossein Karimi

##### Street address

New City, North Ghadir Blvd., Karmandan St., Behind Larestan Grand Bazaar, Sina Building (Larestan University of Medical Sciences)

##### City

Larestan

##### Province

Fars

##### Postal code

7431889629

##### Phone

+98 71 5225 5512

##### Email

mrbazr@sums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Larestan 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**

Larestan University of Medical Sciences

**Full name of responsible person**

Mohammad-Rafi Bazrafshan

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

New City, North Ghadir Blvd., Karmandan St., Behind  
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**Email**

mrbazr@sums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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7431889629

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+98 71 5225 5512

**Email**

mrbazr@sums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Larestan University of Medical Sciences

**Full name of responsible person**

Mohammad-Rafi Bazrafshan

**Position**

Associate professor

**Latest degree**

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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**

Undecided - It is not yet known if there will be 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**

It can be shared by unidentifiable participants

**When the data will become available and for how long**

Access begins a year after the publication of results

**To whom data/document is available**

People who are working in the academic and scientific  
institutions

**Under which criteria data/document could be used**

It needs the agreement of Larestan University of Medical  
Sciences

**From where data/document is obtainable**

Dr. Mohammad Rafi Bazrafshan, Associate Professor,  
Larestan University of Medical Sciences, e-mail address:  
mrbazr@sums.ac.ir, Contact Phone: 07152247110,  
Mobile Number: 09173821959

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

Written and formal request to the vice chancellor for  
research of Larestan University of Medical Sciences

**Comments**