

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

empty	the randomized blocks method will be used to allocate people equally to the intervention and control groups. Assisting the researcher By referring to the health centers of the selected community, at first, individuals enter the study through available sampling and according to the inclusion and exclusion criteria. The researcher will design 4 blocks of 6 (with 6 cells) according to the final sample size, which is 24 people. Then, people are referred in order and using random block method, they are placed in each of the block cells. It will pre-mark each cell with the letters A and B, and according to the pre-arranged contract, the people in house A will receive the intervention and the people in house B will become members of the control group. Finally, 12 people in the intervention group and 12 people in the control group will be randomly assigned.
Scientific title The Effectiveness of Structured Group Reminiscence Therapy on Depression and Anxiety of Elderly Women Smoking Hookah Referred to Larestan Community Health Centers, 2020	
Public title The Effectiveness of Structured Group Reminiscence Therapy on Depression and Anxiety of Elderly Women Smoking Hookah	
Purpose Treatment	
Inclusion/Exclusion criteria Inclusion criteria: 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. Exclusion criteria: 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	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 Larestan University of Medical Sciences Street address Fars, Larestan, 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 Approval date 2020-04-27, 1399/02/08 Ethics committee reference number IR.LARUMS.REC.1399.003
Age From 60 years old	
Gender Female	
Phase N/A	
Groups that have been masked No information	
Sample size Target sample size: 24	
Randomization (investigator's opinion) Randomized	
Randomization description Due to the fact that the final sample size is 24 people,	Health conditions studied 1 Description of health condition studied Elderly women consuming hookah ICD-10 code Z72.0 ICD-10 code description 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

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Fars

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7431895639

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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

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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

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
Larestan Grand Bazaar, Sina Building (Larestan
University of Medical Sciences)

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Person responsible for scientific 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

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Person responsible for updating data

Contact

Name of organization / entity

Larestan University of Medical Sciences

Full name of responsible person

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Associate professor

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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