

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect groups reminiscence therapy on loneliness and spiritual well- being among elderly men with Multiple sclerosis

Protocol summary

Study aim

Comparing the effect of group reminiscence therapy on loneliness and spiritual well-being of elderly men with MS

Design

Clinical trials with control group (assigning groups to intervention and control in a simple random method)

Settings and conduct

This study will be conducted in Kahrizak nursing homes in Tehran, group- reminiscence therapy based will be held in groups of 6-5 people for 3 weeks and 2 times each week.

Participants/Inclusion and exclusion criteria

Inclusion criteria At least 6 months staying at the nursing home; Persian language; Multiple Sclerosis diseases
exclusion criteria Comorbidities of severe mental illness according to records; Experience of stressful events in the last 3 months (the loss of a spouse or other loved ones); History of attend to reminiscence therapy sessions previous or at the same; Severe hearing loss; Serious communication barrier

Intervention groups

6 sessions of group reminiscence therapy according to the Watts-Kpleys protocol are performed as follows, First session: the crises event of life Second session :family history Third session: job or major activity in life and personal interest Fourth session : stressful life experiences Fifth session : Review of love and hate in life Sixth session: The meaning and the purpose of life
Control group: Daily life activities.

Main outcome variables

The state of spiritual health and loneliness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170411033378N5**

Registration date: **2018-11-24, 1397/09/03**

Registration timing: **retrospective**

Last update: **2018-11-24, 1397/09/03**

Update count: **0**

Registration date

2018-11-24, 1397/09/03

Registrant information

Name

Efat Sadeghian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

sadeghian_e@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect groups reminiscence therapy on loneliness and spiritual well- being among elderly men with Multiple sclerosis

Public title

Comparing the effect of groups reminiscence therapy on

loneliness and spiritual well-being of elderly men

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Men aged 65 to 89 years At least 6 months staying at the nursing home, Persian language Multiple Sclerosis diseases
Exclusion criteria:
Comorbidities of severe mental illness according to records Experience of stressful events in the last 3 months (the loss of a spouse or other loved ones) History of attend to reminiscence therapy sessions previous or at the same Severe hearing loss Serious communication barrier

Age
From **60 years** old

Gender
Male

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization in this study is simple random.Tools used in randomization is table of random numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical

Street address

In front of Mardom Park, Hamedan University of Medical Sciences,

City

hamadan

Province

Hamadan

Postal code

38698 -65178

Approval date

2018-06-09, 1397/03/19

Ethics committee reference number

IR.UMSHA.REC.1397.139

Health conditions studied

1

Description of health condition studied

multiple scloresis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

loneliness

Timepoint

before and after of intervention

Method of measurement

Russell's loneliness questionnaire

Secondary outcomes

1

Description

spiritual well- being

Timepoint

before and after of intervention

Method of measurement

spiritual well-being questionnaire Palutzin and Waalson

Intervention groups

1

Description

6 sessions of group reminiscence therapy according to the Watts-Kpleys protocol are performed as follows, First session: the crises event of life Second session :family history Third session: job or major activity in life and personal interest Fourth session : stressful life experiences Fifth session : Review of love and hate in life Sixth session: The meaning and the purpose of life.

Category

Rehabilitation

2

Description

Control group: Daily life activities

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Kahrizak nursing home

Full name of responsible person

Efat Sadeghian

Street address

Shahid Fahmide boultar, park mardom street

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Research and Technology Vice-Chancellor

Street address

In front of Mardom Park, Hamedan 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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Efat Sadeghian

Position

Assistant Professor

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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Position

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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

Name of organization / entity

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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 whole data will be published after the unidentifiable
individuals are shared, which will be published as the
final report and article

When the data will become available and for how long

Starting available 6 months after the publication of
results

To whom data/document is available

Researchers working in academia and those working in
the industry can apply for them.

Under which criteria data/document could be used

Anyone who wishes to use the articles to be retrieved is
possible with email.

From where data/document is obtainable

by Email address

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

by Email address

Comments