

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effects of recreational therapy on the quality of life of elderly war victims: a two-group randomized controlled trial

Protocol summary

Study aim

assess the effects of recreational therapy on quality of life among Iranian elderly war victims

Design

Parallel group randomized clinical trial was conducted in 2018 in a war victim's home in Tehran, Iran. With a power of 0.90 and a confidence level of 0.95, sample size was estimated to be 32 for each group. Participants were conveniently selected and randomly assigned to control and intervention groups via the block randomization method.

Settings and conduct

This parallel group randomized clinical trial was conducted in a war victim's home in Tehran, Iran. Data were collected via a demographic questionnaire and the Short Form (36) Health Survey (SF-36). SF-36 was completed by each participant thrice, i.e. before, immediately after, and two weeks after the intervention

Participants/Inclusion and exclusion criteria

age of sixty or more, the ability to communicate verbally, no acute physical pain, no participation in similar recreation therapy programs, willingness to participate in the study, and no serious health problem which could prevent participation in recreational activities. Participants were excluded if they developed severe physical or mental problem during the study

Intervention groups

The intervention group ten ninety-minute sculpturing sessions, ten sixty-minute sessions for listening to a favorite music, ten thirty-minute relaxation sessions, ten 45-minute physical exercise sessions, and two daily trips and routine care were performed. These sessions were held in ten successive weeks. The control group just received routine care.

Main outcome variables

Improving the quality of life, preventing the progression of the disease and reaching the stage of disability, improving the capabilities of veterans, preventing the occurrence and occurrence of chronic diseases,

maintaining independence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201006048946N1**

Registration date: **2020-10-25, 1399/08/04**

Registration timing: **retrospective**

Last update: **2020-10-25, 1399/08/04**

Update count: **0**

Registration date

2020-10-25, 1399/08/04

Registrant information

Name

Maryam Pakseresht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3333 2068

Email address

pakseresht-m@medilam.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

2020-06-21, 1399/04/01

Actual recruitment end date

2020-09-22, 1399/07/01

Trial completion date

2020-10-06, 1399/07/15

Scientific title

The effects of recreational therapy on the quality of life of elderly war victims: a two-group randomized controlled trial

Public title

The effects of recreational therapy on the quality of life of elderly war victims

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age of sixty or more
The ability to communicate verbally
No participation in similar recreation therapy programs
Willingness to participate in the study
No acute physical pain, No serious health problem which could prevent participation in recreational activities

Exclusion criteria:

severe physical or mental problem

Age

From 60 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 64

Actual sample size reached: 63

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were conveniently selected and randomly assigned to control and intervention groups via the block randomization method

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 Baqiyatallah University of Medical Sciences

Street address

Arsham Complex 2. Third floor, Azadegan St., Chamran St., Khorramrudi Boulevard

City

Ilam

Province

Ilam

Postal code

paksereshtmaryam@yahoo

Approval date

2016-04-26, 1395/02/07

Ethics committee reference number

lr.bmsu.rec.1395.207

Health conditions studied

1

Description of health condition studied

War victim, Elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

War victim quality of life

Timepoint

Short Form (36) Health Survey (SF-36) was completed by each participant thrice, i.e. before, immediately after, and two weeks after the intervention

Method of measurement

Data were collected via a demographic questionnaire and the Short Form (36) Health Survey (SF-36). The items of the demographic questionnaire were age, gender, educational status, and previous history of hospitalization. Short Form (36) Health Survey (SF-36) is a self-administered survey with 36 items in the following eight dimensions: physical functioning (ten items), role limitations due to physical health problems (four items), bodily pain (two items), general health (five items), energy/fatigue (four items), social functioning (two items), role limitation due to emotional problems (three items), emotional well-being (five items), and a non-categorized single item. Items are scored from 0 to 100. Higher scores represent higher QOL. SF-36 can be completed in 5-10 minutes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in the intervention group were provided with both recreational therapy and routine care services of the study setting. recreational therapy consisted of ten ninety-minute sculpturing sessions, ten sixty-minute sessions for listening to a favorite music, ten thirty-minute relaxation sessions, ten 45-minute

physical exercise sessions, and two daily trips.

Category

Lifestyle

2

Description

Control group: Participants in the control group just received routine care services of the study setting

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Sarallah war victim's home

Full name of responsible person

Maryam Pakseresht

Street address

3rd floor,.Arsham apartment 2., Azadegan St.,Chamran St.,Khorramrudi Boulevard

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6931433894

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Email

paksereshtmaryam@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Salman Barasteh

Street address

No. 485,. Jomhory St., South Eskandari St., dead end of haft dastgah

City

Tehran

Province

Tehran

Postal code

1319846951

Phone

+98 21 6686 4257

Email

s.barasteh@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Ilam University of Medical Sciences

Full name of responsible person

Maryam Pakseresht

Position

Nursing Instructor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Maryam Pakseresht

Position

Nursing Instructor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person
Maryam Pakseresht
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available