

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect of humor therapy on chronic pain and its related disability of Mashhad city nursing homes residents

Protocol summary

Summary

1- Objectives: To determine the impact of humor therapy on the severity, quality of pain and disability caused by chronic pain in the elderly living in two separate nursing homes in Mashhad. 2- Design: Randomized Clinical Trial; two-group; in two separate degree in nursing homes in the city of Mashhad; Double-blind. 3- Setting and Conduct: Two Nursing Homes That are in a Same Rank of Well-being and Facilities selected and will be divided randomly into intervention and control groups. The Elderly in Nursing Homes Available for Sampling to 32 Patients in each Group are Selected. Humor therapy for 6 weeks, one Session per Week on an Ongoing basis in the Intervention Group was done, while the Control Group does not Perform Certain Actions. 4- Participants including major eligibility criteria: Participants in this study included two separate groups of 32 people in two separate nursing homes; that are a total sample size of 64 older adult. Inclusion criteria: have a desire to participate in the study; over 60 years old and have less than 85; Have at least able to read and write; Have lived in a nursing home for at least three months; Having chronic non-cancer pain for at least 3 months; No history of taking antidepressants or exhilarating; The lack of visual impairment to the extent that it is able at a distance of 6 meters, see fingers; No hearing impaired to the extent that it is able at a distance of 1 meter, hear whispers; No problem in Language to the extent that the Executive be able to answer questions; Lack of drug addiction and drug. Exclusion criteria: refusal to continue participating in the study and collaboration with researcher; absence of more than two sessions, subjects die; leave the nursing home forever, Access physical or mental disorders in the elderly from participating in the meetings during the study. 5- Interventions: Humor therapy for 6 weeks, each week a session of 60 minutes was done, with methods including: Humorous Videos; Humorous Games; Comic stories; Humorous music; Jokes. In the control group, does not take certain actions.

Questionnaire required (using a pain intensity and pain quality and disability due to pain) in both groups immediately before the first session, immediately in the third session and after the sixth session will be completed by the researcher and research assistant. 6- Main outcome measures variable: We expected, after treatment for 6 weeks in the experimental group, pain intensity and disability due to pain have reduced and quality of pain in the elderly have changed. In addition, this method as safe and uncomplicated and inexpensive with pharmacological pain relief methods should be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041027317N1**

Registration date: **2016-10-08, 1395/07/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-08, 1395/07/17

Registrant information

Name

Shohre Behrouz

Name of organization / entity

Department of Nursing, Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3726 4608

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behrouzsh2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-05-11, 1395/02/22

Expected recruitment end date

2016-06-15, 1395/03/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of humor therapy on chronic pain and its related disability of Mashhad city nursing homes residents

Public title

The effect of humor therapy on chronic pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Have a desire to participate in the study; Over 60 years old and have less than 85; Have at least able to read and write; Have lived in a nursing home for at least three months; Having chronic non-cancer pain for at least 3 months; No history of taking antidepressants or exhilarating; The lack of visual impairment to the extent that it is able at a distance of 6 meters, see fingers; No hearing impaired to the extent that it is able at a distance of 1 meter, hear whispers; No problem in Language to the extent that the Executive be able to answer questions; Failure to develop scenarios that you may have a problem laughing (hernia, advanced hemorrhoids, surgery over the past three months, drooping uterus, glaucoma, epilepsy; Lack of drug addiction and drug use; scores 15-item Geriatric depression scale is less than 8; lack of cognitive impairment, the Montreal cognitive test (MOCA) and earn a higher score of 26. Exclusion criteria: Refusal to continue participating in the study and collaboration with researcher; Absence of more than two sessions, Subjects die; Leave the nursing home forever, Access physical or mental disorders in the elderly from participating in the meetings during the study; Having any acute pain, such as toothache, cramps caused by colds, hit a limb.

Age

From **60 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences, School of Nursing and Midwifery

Street address

School of Nursing and Midwifery, St. IbneSina, Doktora intersection, University Avenue, Mashhad

City

Mashhad

Postal code

9137913199

Approval date

2016-05-07, 1395/02/18

Ethics committee reference number

IR.MUMS.REC.1395.66

Health conditions studied**1****Description of health condition studied**

Chronic pain , Pain disability

ICD-10 code

Z73.6, R52

ICD-10 code description

Limitation of activities due to disability, Other chronic pain

Primary outcomes**1****Description**

Quality of Pain

Timepoint

Immediately before the first session, 24 h after the third session, 24 h after the sixth session (last session)

Method of measurement

The short-form McGill Pain Questionnaire

2

Description

Disability related to pain

Timepoint

Immediately before the first session, 24 h after the third session, 24 h after the sixth session (last session)

Method of measurement

Modified German Version of the Brief Pain Inventory

3

Description

Pain Intensity

Timepoint

Immediately before and after each session

Method of measurement

Modified German Version of the Brief Pain Inventory

Secondary outcomes

1

Description

Social Support

Timepoint

Immediately Before the first session

Method of measurement

Duke Social Support

2

Description

Sense of Humor

Timepoint

Immediately before the first session

Method of measurement

Sense of Humor Questionnaire

Intervention groups

1

Description

In the intervention group: Humor therapy for 6 continuous weeks, each week and each session 60 minutes a day was done. Therapeutic humor program includes video clips with fun themes (humorous videos), games with themes joke (humor games), humor and funny stories (Comic stories) and music with themed joke (humorous music) and tell a jokes (jokes); That Performed by professional colleagues and researcher. In all of the Humor therapy protocols, have been used of experts opinion in this field related to this profession and is adjusted according to the culture elderly.

Category

Other

2

Description

In the control group: no plans or specific interventions was done and only the elderly in control group, will be monitored during 6 weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Salamati Nursing Home

Full name of responsible person

Mr Daghagh

Street address

Salamati nursing home, between Vakil Abad 62 and 64, Vakil Abad Street, Mashhad

City

Mashhad

2

Recruitment center

Name of recruitment center

Baran nursing home

Full name of responsible person

Mrs Esmaelinezhad

Street address

Hamed Jonoubi Street, Sajad Street, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research; Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, Vice chancellor for research, university street, near the cinema Hoveize, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research; Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Person responsible for general inquiries

Contact

Name of organization / entity
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty