Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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

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Country

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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
Immediatly Before the first sessain
Method of measurement
Duke Social Support

2

Description
Sense of Humor
Timepoint
Immediatly 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

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad Nursing School
Full name of responsible person
Shohre Behrouz
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Student of gerentology of nursing
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Person responsible for scientific inquiries

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Person responsible for updating data

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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