

# 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

###### Email address

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 Daghigh

#### **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*

Mashhad  
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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Mashhad Nursing School  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Assistant Professor; Department of Nursing; Faculty of  
Nursing and Midwifery; Mashhad University of  
**Full name of responsible person**  
Hadi Kooshyar  
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## Person responsible for updating data

### Contact

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Sciences  
**Full name of responsible person**  
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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*