

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Effect of dry Cupping therapy on chronic knee pain and Activity of daily living (ADL) among female older adults.

Protocol summary

Study aim

Determining the effect of balloon therapy on chronic knee pain and daily life activities of elderly women referred to day care centers in Qazvin.

Design

The clinical trial has a test and control group with random distribution by random number table method, phase 2 on 50 elderly women.

Settings and conduct

The research environment is Qazvin day care centers for the elderly. Available sampling will be done based on entry and exit criteria. Samples have chronic knee pain for at least the past three months. The cognitive ability of the samples will be determined based on the abbreviated cognitive test tool. Individuals will be divided into intervention and control groups by random allocation using the random number table method. Using the visual scale of pain and daily life activity questionnaire, the severity of pain and daily life activity in both groups will be measured. Twice a week for four weeks and during eight sessions of the desired intervention using 3 balloons, for 5-10 minutes will be performed on points SP10, SP9, ST36. One week after the last intervention, the intensity of pain and daily life activity in both groups will be measured and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria include having chronic knee pain during the last trimester. The condition for not entering the study is less than 60 years old.

Intervention groups

In the intervention group, twice a week for four weeks and during eight sessions, the desired intervention will be performed using 3 balloons for 5-10 minutes on three points in the knee. No intervention is performed for the control group during the study.

Main outcome variables

The main consequences include chronic pain and daily life activities.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220211053996N1**

Registration date: **2022-03-10, 1400/12/19**

Registration timing: **prospective**

Last update: **2022-03-10, 1400/12/19**

Update count: **0**

Registration date

2022-03-10, 1400/12/19

Registrant information

Name

neda najafy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3332 2940

Email address

nedanajafy1996@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-30, 1401/01/10

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dry Cupping therapy on chronic knee pain and Activity of daily living (ADL) among female older adults.

Public title

Effect of dry Cupping therapy on chronic knee pain and Activity of daily living (ADL) among female older adults.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having chronic knee pain for the past three months.

Exclusion criteria:

Age less than 60 years

Age

From **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done by random number table method to be placed in two groups of control and intervention.

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 the University of Rehabilitation Sciences and Social Health

Street address

Unit 242 , East Sky Tower, Palestine Street

City

Qazvin

Province

Qazvin

Postal code

3415745187

Approval date

2022-02-16, 1400/11/27

Ethics committee reference number

IR.USWR.REC.1400.306

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

Chronic knee pain in the elderly

ICD-10 code

M25.56

ICD-10 code description

Pain in knee

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

Score of daily life activity in Bartel questionnaire

Timepoint

Before the intervention and one week after the last intervention

Method of measurement

Bartel Activity of Daily Living

2**Description**

Chronic pain

Timepoint

Before the intervention and one week after the last intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In this intervention, after passing a training course under the supervision of an acupuncturist, we hold a ball of 95% alcohol-soaked cotton with a pair of pliers and set it on fire. Any excess alcohol must be removed from the cotton before turning on. The balloon stays in the designated points (SP10, SP9, ST36) for about five minutes. To separate the cups, gently press the edge of the cup with your index finger and allow some air to enter. In general, for each affected knee (both elderly knees may be affected), the treatment period is twice a week for four weeks.

Category

Treatment - Other

2**Description**

Control group: This group does not receive any intervention during the study. At the end of the study, two sessions of balloon therapy will be performed for the

control group and the use of this method to possibly improve the daily activities of the elderly will be explained.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin day care centers

Full name of responsible person

Hesamedin alame

Street address

Elderly day care centers

City

Qazvin

Province

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Postal code

۱۱۳۶۵/۴۱۸۷

Phone

+98 28 3356 1060

Email

h.alame@behzisti.gov.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Massoud Fallahi

Street address

Koodkiar St , Velenjak St , University of Rehabilitation Sciences and Social Health

City

tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 2218 0083

Email

webmaster@uswr.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Neda Najafy

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

Data such as information about the main event or the like can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

People in all academic and scientific institutions can apply to receive them.

Under which criteria data/document could be used

The results are done using statistical analysis and these results can be used by everyone.

From where data/document is obtainable

The first author can be called Nadanajafi and the mailing number nedanajafy1996@gmail.com can be found and the first author is responsible.

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

After 6 months of intervention and 1 month of data analysis, the results will be published through the university.

Comments