Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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

Qazvin

Postal code

۱۱۳۶۵/۴۱۸۷

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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

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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