Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Effect of Swedish Massage and Hip Strengthening Exercises on Pain, Range of Motion and Daily Life Function in The Elderly with Knee Osteoarthritis

Protocol summary

Study aim

Determining the comparative effect of Swedish massage and hip strengthening exercises on pain, range of motion and daily life function in the elderly with knee osteoarthritis.

Design

75 eligible seniors will be divided into two intervention groups and one control group using a simple random division method using a random number table, and the type of intervention will be determined again by random division.

Settings and conduct

The intervention is carried out on elderly people with knee osteoarthritis who refer to the outpatient clinic of Rafsanjan city. Both interventions are done individually at home.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 60 to 70 years, mentally alert, suffering from knee osteoarthritis according to a rheumatologist's diagnosis, presence of pain along with at least 3 out of 6 clinical criteria of the American Rheumatology Association and suffering from this disease duration of at least 6 months and at most 5 years, having chronic pain, having a basic score of 40-70 for knee pain on the VAS scale, Absence of skin problems at the massage site, No history of other autoimmune diseases and chronic neuropathic diseases, no intra-articular injection in the past three months, no history of knee surgery and severe knee injury and Non-entry criteria: having health problems affecting exercise and massage and chronic use of knee braces, crutches and having a regular exercise program

Intervention groups

Both intervention groups participate in two training sessions with one of their family members, and the Swedish massage protocol and hip strengthening exercises are taught in each group by the researcher using a training booklet and pictures. Then both trained groups perform the interventions for 8 weeks and 3 sessions of 30 minutes per week at home.

Main outcome variables

Pain, range of motion and daily life function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150519022320N33**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

Tayebeh Mirzaei

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effect of Swedish Massage and Hip Strengthening Exercises on Pain, Range of Motion and Daily Life Function in The Elderly with Knee Osteoarthritis

Public title

Comparison of Effect of Swedish Massage and Hip Strengthening Exercises on Pain, Range of Motion and Daily Life Function in The Elderly with Knee Osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 60 to 70 years People who are mentally alert and able to answer the questions of the questionnaires Patients with osteoarthritis of the knee according to the diagnosis of a rheumatologist, the presence of pain along with at least 3 of the 6 clinical criteria of the American Rheumatology Association and suffering from this disease for a minimum of 6 months and a maximum of 5 years Having pain for more than three months (chronic pain) Have a basic score of 40-70 (out of 100) for knee pain on the VAS scale. Absence of local skin infections or open skin in massage areas No history of other autoimmune diseases such as lupus erythematosus, rheumatoid arthritis and chronic neuropathic diseases such as diabetes No intra-articular injection during the last three months No history of knee surgery and severe injury to the knee

Exclusion criteria:

Having health problems that affect Swedish massage and exercises, such as heart and brain disorders chronic use of knee braces, crutches, and walkers having a regular exercise program in the previous 6 months

Age

From **60 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

After determining the samples, the data will be divided into 3 groups A, B, and C according to age and sex, in such a way that the first data in one of the 3 groups will be divided by a simple random method and using the "Random allocation software" are selected and and in the next 2 groups, the data is allocated in the same way based on the software. After allocating the data equally to 3 groups, treatment methods were written on 3 separate sheets and a method will be assigned to each group by lottery, and the intervention groups of Swedish massage and Hip Strengthening Exercises and the Control group will be determined.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Rafsanjan University of Medical Sciences

Street address

School of Nursing and Midwifery, Nurse avenue, Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2023-08-08, 1402/05/17

Ethics committee reference number

IR.RUMS.REC.1402.068

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

pain

Timepoint

All participants will complete the visual analog scale before the intervention and immediately after the end of the intervention.

Method of measurement

Visual Analogue Scale

2

Description
Range of motion
Timepoint
The range of motion of all participants will be measured by a goniometer before the intervention and immediately after the end of the intervention.
Method of measurement
goniometer

3

Description
daily life function
Timepoint
All participants will complete the sub-scale of daily life function from Knee Injuries and Osteoarthritis Outcome Questionnaire (KOOS) before the intervention and immediately after the end of the intervention.
Method of measurement
sub-scale of daily life function knee Injury and Osteoarthritis Outcome Score (KOOS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Swedish massage intervention group participates in two face-to-face educational sessions with one of their family members, and the massage protocol is taught by the researcher using a training booklet and pictures, and at the end of the sessions, all the elderly are taught one by one. They are evaluated in terms of performing the massage correctly around their knee joint. Then, for 8 weeks, 3 sessions a week and each session for 30 minutes at home, according to the training method, they apply Swedish massage on their knee joint. They are also provided with educational booklets and pictures. During the study, all participants are monitored through telephone follow-ups and can raise their questions and problems, and they are also reminded to perform massage in each session.
Category
Treatment - Other

2

Description
Intervention group: The intervention group of hip strengthening exercises together with one of their family members participates in two face-to-face training sessions and the protocol of doing the exercises is taught by the researcher using training booklets and pictures, and at the end of the sessions, all the elderly are taught one by one. They are evaluated in terms of doing the exercises correctly. Then, for 8 weeks, 3 sessions per week and each session for 30 minutes, they perform hip strengthening exercises at home according to the training method. They are also provided with educational booklets and pictures. During the study, all participants are monitored through telephone follow-ups and can raise their questions and problems, and are also reminded to do the exercises of each session.
Category
Treatment - Other

3

Description
Control group: The control group receives routine treatment, which includes conventional drugs and treatments under the supervision of a rheumatology specialist, and the researcher does not intervene on them.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Outpatient rheumatology clinic of Rafsanjan city
Full name of responsible person
Dr. Ali Ravari
Street address
Faculty of Nursing, Nurse Blvd., Jomhury street, Rafsanjan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Rafsanjan University of Medical 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Dr. Ali Ravari
Position
Associate Professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to

make this available	
Data Dictionary	Undecided - It is not yet known if there will be a plan to make this available