

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

The effect of Swedish massage on pain and sleep quality in patients with rheumatoid arthritis

Protocol summary

2019-09-22, 1398/06/31

Study aim

Determining the effect of Swedish massage on pain and sleep quality in patients with rheumatoid arthritis

Design

In this randomized clinical trial, patients were randomly divided into two groups of 30 samples. Sampling will take during 6 months.

Settings and conduct

Swedish massage will be performed in a room at Kashan Shahid Beheshti Hospital for 30 minutes for 8 weeks (first 4 weeks twice a week and second 4 weeks three times a week).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20 to 60 years, Patients with rheumatoid arthritis in hand joint, No history of hand surgery, Having the consent to participate in the study.

Exclusion criteria: Acute pain in the joints of the hand

Intervention groups

In the intervention group, Swedish massage will be performed for 30 minutes during 8 weeks (the first 4 weeks twice a week and the second 4 weeks three times a week). In the Control group, no intervention will not perform during 8 weeks

Main outcome variables

Pain and sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111210008348N41**

Registration date: **2019-09-22, 1398/06/31**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-22, 1398/06/31**

Update count: **0**

Registration date

Registrant information

Name

Neda Mirbagher

Name of organization / entity

Kashan University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Swedish massage on pain and sleep quality in patients with rheumatoid arthritis

Public title

The effect of massage in rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with rheumatoid arthritis in hand joints. The Visual Analog Scale > 4. The pittsburg sleep quality index > 5. No history of hand surgery. Age 18-65 years Having

the consent to participate in the study.

Exclusion criteria:

Acute pain in the joints of the hand.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method will be available (selection among patients with hand rheumatoid arthritis) and based on inclusion criteria. Random allocation in two groups of intervention and control will be simple randomization. Randomization is carried out by creating a random sequence of numbers using on an line randomizer tool (<https://www.randomizer.org>).

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

Ethics committee of Kashan University of Medical Sciences

Street address

Ravand Street, Kashan University of Medical Sciences.

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2019-07-23, 1398/05/01

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1398.029

Health conditions studied

1

Description of health condition studied

Swedish massage

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of Pain

Timepoint

Before, after and one month after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Quality of sleep

Timepoint

Before,after and one month After intervention

Method of measurement

Pittsburg sleep quality questionnaire

Intervention groups

1

Description

Intervention group:Swedish massage will receive for 8 weeks (first 4 weeks twice a week and second 4 weeks three times a week) for 30 minutes.

Category

Treatment - Other

2

Description

Control group: Routine care including joint physiotherapy, light exercise, non-steroidal anti-inflammatory drugs will be performed for patients by health personnel .

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Clinic of Kashan Shahid Beheshti Hospital

Full name of responsible person

Neda Mirbagher

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Sponsors / Funding sources

1

Sponsor

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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
Kashan 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
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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable