

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison the effect of foot reflexology massage and stretching exercises on pain and fatigue of patients with rheumatoid arthritis

Protocol summary

Summary

The objective of the following research is to determine and compare the effect of reflexology of metatarsus and stretching on the excessiveness of pain in patients afflicted by rheumatoid arthritis. The mentioned research is a clinical trial and the environment of the trial is the rheumatology clinic of Yasouj Medical Science University. As the public of interest is limited the eligible samples would be selected applying random sampling procedure and they would be divided into 3 groups randomly. The number of the samples is 25 for each group and 75 in total. The criteria for entering the trial include patient's tendency for participating in the trial, being older than 18, definite diagnosis of rheumatoid arthritis by the specialist, owning pain degree of (4-7), pain measurement and total fatigue degree 50 and above 50 based on the questionnaire, lack of experience in participating at any regular exercise program in the last six months and being allowed to participate at exercise program according to the specialist. Criteria for existing from the trial include: lack of tendency to continue cooperation after the trial. On one group of the trial, reflexology and for the other, starching exercises would be performed for 12 30-minute sessions 3 times a week for a month. The trial would be performed based on the significance of reduction of pain and fatigue due to inflammation of the bones and joints and being informed about the fact that which one of these procedure is more effective in reducing symptoms in rheumatoid arthritis patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112931166N1**

Registration date: **2017-01-30, 1395/11/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-30, 1395/11/11

Registrant information

Name

Majid Sadeghi

Name of organization / entity

Yasuj University of Medical Sciences Kohgiluyeh and Boyerahmad

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Recruitment status

Recruitment complete

Funding source

Yasuj University of Medical Sciences

Expected recruitment start date

2016-12-15, 1395/09/25

Expected recruitment end date

2017-01-14, 1395/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of foot reflexology massage and stretching exercises on pain and fatigue of patients with rheumatoid arthritis

Public title

The effect of foot reflexology massage and stretching exercises in patients with rheumatoid arthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Criteria for entering trials include: patient's tendency for participating in the trial; being older than 18; definite diagnosis of rheumatoid arthritis by the specialist; at least a year must have passed from the diagnosis; owning pain degree of (4-7) and above average based on MFI-20 questionnaire; pain measurement and total fatigue degree 50 and above 50 based on numerical scale; lack of known psychological problems including depression; not being under medication with psychochemical drugs prior to the disease; not being afflicted by other chronic and hazardous diseases; not being afflicted by dermatological disease in feet and sensual disorders in feet; lack of experience of reflexology of metatarsus; lack of wound; fracture and dermatological and movement disorders in feet; passage of at least 4 hours from taking pain killers; not being addicted to drugs; lack of cardiovascular diseases in lower limbs; lack of experience in participating at any regular exercise program in the last six months and being allowed to participate at exercise programs with the specialist's confirmation. Criteria for existing from the trial include: lack of tendency to continue the cooperation after the trial starts; alteration in any requirements of entering the trial; not being able to perform exercise program due to any reason; taking a new medication during the trial; being absent 4 sessions of the 12 sessions of the trial.

Age

From **18 years** old to **75 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

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

Yasuj University of Medical Sciences

Street address

Yasuj, Motahari Boulevard, Yasuj University of Medical Sciences

City

Yasuj

Postal code

7591741417

Approval date

2016-10-29, 1395/08/08

Ethics committee reference number

IR.YUMS.REC.1395.151

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

Pain

Timepoint

Once the first day of the intervention and before intervention And again on the last day and within 10 minutes after intervention

Method of measurement

Numerical Pain Scale

Secondary outcomes

1

Description

Fatigue

Timepoint

Once the first day of the intervention and before intervention And again on the last day and within 10 minutes after intervention

Method of measurement

Multidimensional Fatigue Inventory

Intervention groups

1

Description

For trial group (1), reflexology of metatarsus would be performed in 3 levels including: preparation (5 minutes), warm up (10 minutes) and reflexology of metatarsus techniques (15 minutes) which last for a month, 3 30-minute sessions a week. The reflexive point starts from the end of the first knuckle of the finger and it ends in

the sole. Preparation and warm up include warming up the feet by hands by determined movements, holding the foot from back and front by two hands and forming bending backwards movements, bending the metatarsus, rotation toward outside and movements in the sole. For stimulating reflexive points, massage would be performed using the fingers moving back and forth and by exerting a pressure about 0/5 centimeters.

Category

Other

2

Description

The patients of the trial would only receive the routine treatment for a month and no intervention would happen during this period. Before proceeding to any intervention, the excessiveness of pain and fatigue would be assessed in every 3 groups utilizing visual-criterion scale and MFI-20 fatigue multi-dimensional questionnaire.

Category

Other

3

Description

In trial group (2), stretching exercises would be used for intervention. Stretching exercises include 10 minutes of warm up, 15 minutes stretching and 5 minutes cooling down. Stretching exercises include 33 movements and have been chosen according to Bob Anderson stretching exercises in a way that no particular physical preparation is needed other than a simple warm up.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Mofateh Medical and Teaching Clinic affiliated to Yasuj University of Medical Sciences

Full name of responsible person

Shokrollah Behrozi

Street address

Yasuj, Montazeri Street, Adjacent to the Beheshti hospital

City

Yasouj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Dr Mohammad Malek Zadeh

Street address

Yasuj, Motahhari Boulevard, Yasuj University of Medical Sciences

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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

Yasuj 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

Person responsible for general inquiries

Contact

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Shahla Najafi

Position

Faculty Member and Trainer

Other areas of specialty/work

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Yasuj

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