Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

: The combined effect of energy conservation strategies and Hatha Yoga on the severity of fatigue and psychological well-being of patients with rheumatoid arthritis

Protocol summary

Study aim
Determining the combined effect of energy storage and hatha yoga strategies on the severity of fatigue and psychological well-being in patients with arthritic rheumatism

Design
A clinical trial with three intervention and no control groups, with factorial, randomized groups, 75 people

Settings and conduct
Community, Patients with Rheumatism Referred to Yasuj Mofteh Clinic. Approved and endorsed by the Ethics Committee. In each of the three groups before the beginning of the pre-test study using the Fatigue and the Psychological Well-being. After intervention the Fatigue and psychological well-being was completed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Diagnosis of rheumatoid arthritis by a rheumatologist. 2. Minimum literacy. 3. Age range 30 to 55 years. 4. Having the physical and cognitive ability to participate in Hata Yoga exercises. 5. No movement restriction in the range of joints. 6. Personal and informed consent. 7. The patient should receive the same treatment. 8. Do not participate in other intervention studies at the same time. 9. Lack of other chronic diseases. 10. Lack of active phase of the disease and any disease that is prohibited to perform hatha yoga. Exclusion criteria: 1. Absent more than 2 sessions to participate in the exercises. 2. Migration, transfer or death of the patient. 3. Another disease during illness.

Intervention groups
The three intervention groups included energy saving strategies, hatha yoga, and a combination of energy saving strategies and hatha yoga. In the Energy Saving Strategies group, training will be provided for 8 weeks. In the Hata Yoga training group, there will be 2 sessions per week for 8 weeks and 45 minutes per week for each session. The combined group will present energy conservation strategies and hatha yoga in 8 weeks.

Main outcome variables
Severity of fatigue and psychological well-being

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200212046468N1**
Registration date: **2020-03-11, 1398/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-11, 1398/12/21**
Update count: **0**

Registration date
2020-03-11, 1398/12/21

Registrant information

Name
Marziyeh Gholami

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-20, 1398/12/01

Expected recruitment end date
2020-05-19, 1399/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
: The combined effect of energy conservation strategies and Hatha Yoga on the severity of fatigue and psychological well-being of patients with rheumatoid arthritis

Public title
The combined effect of energy storage and hatha yoga strategies on severity of fatigue and psychological well-being in patients with arthritic rheumatism
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of rheumatoid arthritis by a rheumatologist Minimum literacy 3. Age range 30 to 55 years. Having the physical and cognitive ability to participate in Hatha Yoga exercises. No range of motion in the range of joints. Personal and informed consent. The patient should receive the same treatment. Do not participate in other intervention studies at the same time
Exclusion criteria:
Other chronic diseases. Active phase of the disease and any disease that is prohibited to perform hatha Yoga
Age
From **30 years** old to **55 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
Study samples are randomly selected and available at random. After selection, participants will be randomly assigned to a block between the three groups. Since the estimated sample size was 75 people, so by comparing 20 random numbers generated by Sample Randomizer software, how to arrange 75 research samples and assigning each number from 1 to 75 to one of the specified control and control groups and the block random allocation list.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ehtics commitee of yasuj University of Medical Sciences
Street address
Yasuj- Shahid Motahari Boulevard- Yasuj University of Medical Sciences
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Approval date
2020-01-13, 1398/10/23
Ethics committee reference number
IR.YUMS.REC.1398.133

Health conditions studied

1

Description of health condition studied
Patients with rheumatoid arthritis
ICD-10 code
M05.9
ICD-10 code description
Rheumatoid arthritis with rheumatoid factor, unspecified

Primary outcomes

1

Description
Severity of fatigue
Timepoint
Fatigue severity at baseline (before intervention) and after baseline
Method of measurement
Multidimensional Fatigue Assessment Inventory (MFI)

2

Description
Psychological well-being
Timepoint
Psychological well-being at baseline (before intervention) and after baseline
Method of measurement
Ryff’s Psychological Well-being questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Hata Yoga: In this group, the intervention will perform selected Hata Yoga exercises for 8 weeks twice a week and each session 45 minutes under the supervision of a qualified trainer. In the initial sessions, the trainer first puts people in Shawasana or dead bodies for 10 minutes and teaches mind control techniques and then 30 minutes of light exercises including 4 sleeping movements, 4 sitting exercises. And there will be 4 movements in the standing posture, and the important point is that after each movement there will be mental attention to the limbs and breathing, in all three positions there will be physical exercises along with breathing and relaxation exercises. Subsequent sessions of training will progress from moderate to moderate and will include a modified training program for at least one or two hours. Eat after breakfast or a light lunch in a yoga mat or at least a quiet place with a soft carpet in a balanced (not cold or warm) atmosphere.

Category
Rehabilitation

2

Description
Second Intervention group: energy conservation: In this group, the necessary training will be done for 8 weeks. Session 1- Introduction, introduction, pre-test, session 2- Group training and according to the status of each patient and Prioritize implementation, session 3- Training Group and according to the status of each patient and implementation of the plan, Session 4- Training in group and according to the status of each patient and implementation of pace, Session 5- Training in group and according to the status of each patient and implementation of posture , Session 6- Repeat and Practice Sessions, Session 7- Repeat and Practice Sessions, Session 8- Summary and Taking the Post-Test

Category
Rehabilitation

3

Description
Third Intervention group: The combined of Hata Yoga and energy conservation: In this group, all the interventions mentioned in the previous two groups will be combined.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital

Full name of responsible person
Marziyeh Gholami

Street address
Shahid Beheshti Hospital, Shahid Mohammad Montazeri Street, Yasuj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Hossein Mari Oryad

Street address
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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
Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Marziyeh Gholami

Position

MSc Student of Internal Surgery Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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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