

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of walking on sexual function in women with rheumatoid arthritis

Protocol summary

Study aim

The aim of this study was to determine the effect of walking on sexual function of women with joint rheumatoid arthritis.

Design

In this research, 56 eligible patients who are referred to Shahid Mofatheh Clinic of Yasuj were chosen. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct

Shahid Mofatheh Clinic of Yasuj

Participants/Inclusion and exclusion criteria

Arrival conditions: Patient with Rheumatoid arthritis and diagnosis by rheumatologist: Age of Pre-menopause (20-50 years): There is no underlying disease: No participation in sports activities in the last three years: A score of less than 26/5 in the Rosen Gender Indicator Questionnaire: Not giving birth in the last six months and not getting pregnant: Confirmation of the patient by the physician to participate in the walking exercise: Passed at least one year from the diagnosis of joint rheumatoid arthritis by a doctor: No use of sex hormones supplements affecting sexual desire. Non-arrival conditions: The patient's unwillingness to continue attending this research: Lack of attendance for more than two sessions: Disturbance in cognitive status and patient's alertness and balance during intervention: Separating from his wife: Getting pregnant: Immigration or death: Patient's menopausal during the intervention: Other illness: Transfer to another Medical center

Intervention groups

After complete explanation and explanation of the research objectives for the samples and informed consent, the questionnaires will be completed at the outset. In the intervention group, the walking practice protocol will be for 30 sessions over a period of 8 consecutive weeks (First and second weeks five days a week, The third and fourth weeks, four days a week And last month three days a week). The time and content of

the planned walking program varies over the course of 8 weeks so that the training time in each session starts from 60 minutes in the first session, 30 minutes in the final session and the intensity of the exercises from 60% in the first sessions to 70% in the sessions The end will end. All walking program meetings include: initial control and warm-up process, the main walking practice, and the process of cooling and final control. The second group will receive the usual treatment. The women's sexual function scale before the intervention begins, after the last day of the intervention and again after 2-3 times the proximity. Data collected by statistical software is analyzed. Sexual function of women with variable rheumatoid arthritis is the subject of this study.

Main outcome variables

Sexual function of women with rheumatoid arthritis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171209037802N1**

Registration date: **2018-01-12, 1396/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-12, 1396/10/22**

Update count: **0**

Registration date

2018-01-12, 1396/10/22

Registrant information

Name

Sara Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4325 4584

Email address

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of walking on sexual function in women with rheumatoid arthritis

Public title

"The effect of walking on sexual function in women with rheumatoid arthritis" ; "Evaluation of sexual function in patients with joint rheumatoid arthritis "

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with Rheumatoid arthritis and diagnosis by rheumatologist. The patient will be treated and have a medical record. Age of Pre-menopause (20-50 years) There is no underlying disease; infectious diseases and and diseases of the genital apparatus No participation in sports activities in the last three years A score of less than 26/5 in the Rosen Gender Indicator Questionnaire Absence in the acute phase of the disease Not giving birth in the last six months and not getting pregnant Confirmation of the patient by the physician to participate in the walking exercise Passed at least one year from the diagnosis of joint rheumatoid arthritis by a doctor No use of sex hormones supplements affecting sexual desire

Exclusion criteria:

The patient's unwillingness to continue attending this research Lack of attendance for more than two sessions Disturbance in cognitive status and patient's alertness and balance during intervention Separating from his wife Getting pregnant Immigration or death Patient's menopausal during the intervention Other illness Transfer to another Medical center Re-enter the acute phase of the disease

Age

From 20 years old to 50 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 56

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected as non-probabilistic sampling and then assigned to two intervention and control groups by random allocation of blocks with double blocks.

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 Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd, Yasuj

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591994799

Approval date

2017-12-26, 1396/10/05

Ethics committee reference number

IR.YUMS.REC.1396.133

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

M05.9

ICD-10 code description

Rheumatoid arthritis with rheumatoid factor, unspecified

Primary outcomes

1

Description

Sexual function

Timepoint

Before the intervention, the end of the eighth week and performing two or three intercourse after the end of the intervention

Method of measurement

Women's Sexual Function Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In group 1 (intervention), the walking protocol will be conducted for 30 sessions within 8 consecutive weeks (First and second week five days a week, third and fourth week four days a week, and the last month three days a week). The time and content of the planned walking program varies over the course of 8 weeks, so that the training time in each session starts from 60 minutes in the first session and It will end in the final session to 30 minutes, The intensity of the exercises will end 60% in the first sessions to 70% in the final sessions.

Category

Behavior

2

Description

Control group: In group 2 (control), people will not receive any interventions.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofateh Medical Clinic of Yasuj

Full name of responsible person

Sima Mohammad Hosseini

Street address

Shahid Mohammad Montazeri Street, Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591714983

Phone

+98 71 4325 4584

Email

rezaeisara1390@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Sima Mohammad Hosseini

Street address

Research Management of Yasuj University of Medical Sciences, Research and Technology Deputy of Yasuj University of Medical Sciences, ShahidMotahary Blvd. Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591714983

Phone

+98 71 4325 4584

Email

rezaeisara1390@gmail.com

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

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

Yasuj University of Medical Sciences

Full name of responsible person

Sima Mohammad Hosseini

Position

Ph.D. student of Internal Nursing Surgery

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery College, Dr. Shahid Jalil St, Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591994799

Phone

+98 74 3323 4115

Email

hossini3270@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Sima MohammadHosseini

Position

Ph.D. Nursing student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery College, Dr. Shahid Jalil

St,Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591994799

Phone

+98 74 3323 4115

Email

hossini3270@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Sara Rezaei

Position

Master student of Medical-Surgical nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery College, Dr. Shahid Jalil

St,Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591994799

Phone

+98 71 4325 4584

Email

sara.rezaei@yums.ac.ir

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