Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 rheumatologis؛ 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

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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
Kohgilouyeh-va-Boyrahmad
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
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Shahid Mohammad Montazeri Street, Yasuj
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
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Research Management of Yasuj University of Medical Sciences, Research and Technology Deputy of Yasuj University of Medical Sciences, ShahidMotahary Blvd. Yasuj
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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
Sima Mohammad Hosseini
Position
Ph.D. student of Internal Nursing Surgery
Latest degree
Master
Other areas of specialty/work
Nursery
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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