Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of emotional self- disclosure on disease activity, health status and sexual function in women with rheumatoid arthritis in comparison with control group

Protocol summary

Study aim
Determining the effect of emotional self disclosure on disease activity, health status and sexual function in women with rheumatoid arthritis

Design
A clinical trial with a control group, randomized, on 72 patients, the selection of sample subjects in a continuous method and the allocation of the samples to the test group (A) or control (B) will be done using the double block method.

Settings and conduct
The research will be conducted in a selected rheumatology clinic in Tehran. After receiving oral and written explanations related to the intervention, the participants of the test group will reveal their emotions in writing in the notebook, and the control group will receive only routine care.

Participants/Inclusion and exclusion criteria
Entry condition: age 18-45, at least 6 months have passed since the diagnosis, able to read and write in Persian, living with a spouse, having sexual activity, husband being monogamous, living in Tehran; Non-entry criteria: chronic disease other than rheumatoid arthritis in the research units, pregnancy or breastfeeding and less than 6 months have passed since the last delivery, the occurrence of a stressful event from 3 months before the intervention according to the patient's statement, suffering from major medical diseases affecting sexual function, sexual disorders being treated in woman or husband.

Intervention groups
Test: The participants will reveal their feelings in writing at home and preferably in a private room, once a day and 4 times a week for 4 weeks, and in the notebook they will reveal their emotions in written form. control: After the pre-test they will receive only routine care.

Main outcome variables
Disease activity; Health status; Sexual function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110629006917N6**
Registration date: **2022-08-19, 1401/05/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-19, 1401/05/28**
Update count: **0**

Registration date
2022-08-19, 1401/05/28

Registrant information

Name
Leila Amini

Name of organization / entity
Tehran University of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 21 3316 6574

Email address
l-amini@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-30, 1401/05/08

Expected recruitment end date
2023-03-28, 1402/01/08

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of emotional self- disclosure on disease activity, health status and sexual function in women with rheumatoid arthritis in comparison with control group

Public title

The effect of emotional self- disclosure on disease activity, health status and sexual function in women with rheumatoid arthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-45 years At least 6 months have passed since the diagnosis of the disease Able to read and write in Farsi Living with a spouse at the time of the study Having sexual activity at least once in the last 4 weeks Monogamous husband Living in Tehran

Exclusion criteria:

Suffering from another chronic disease other than Rheumatoid arthritis in research units Current pregnancy or breastfeeding and less than 6 months have passed since the last delivery According to the patient, the occurrence of a stressful incident 3 months before the intervention Suffering from major medical diseases affecting sexual relations (Diabetes, history of psychiatric disorders such as severe Depression, Psychosis, Bipolar disorder, substance abuse) according to the patient' statement and the contents of his file Taking drugs affecting sexual performance Sexual disorders under treatment in women or husbands (desire phase disorder, arousal phase disorder, orgasm disorder, sexual pain disorders)

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The selection of sample people will be done in a continuous method and the allocation of the samples to the test group (a) or control (b) will be done by the double block method. In this way, a person outside the research team will write different states of two groups (4 states in total: 1-A, B, 2-B, A, 3-A, A, and 4-B, B) on 4 note cards and will put each one in a closed envelope so that the researcher doesn't know the order of placement of people in two groups before opening the envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Iran University of Medical Sciences

Street address

Iran Nursing and Midwifery School, Rashid Yasemi Ave., Vali-e-Asr Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1996713883

Approval date

2022-06-20, 1401/03/30

Ethics committee reference number

IR.IUMS.REC.1401.272

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description

Disease activity

Timepoint

In each of the two test and control groups before the start of the study and 8 weeks after the intervention

Method of measurement

In both groups, it will be measured by a rheumatology specialist using the 28-DAS tool.

2

Description

Health status

Timepoint

The measurement of this variable will be done before the

start of the study, immediately and 8 weeks after the end of the intervention.

Method of measurement

Completing the health status questionnaire (AIMS2-SF) by the participants

3

Description

Sexual function

Timepoint

The measurement of this variable in all 6 areas will be done before the start of the study, immediately and 8 weeks after the end of the intervention.

Method of measurement

Completion of the Female Sexual Function Index (FSFI) questionnaire by the participants

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the participants will complete questionnaires including demographic characteristic, clinical status of the disease, FSFI (Female Sexual Function Index) and AIMS2-SF (health status questionnaire). Also before the study, the disease activity of both groups will be measured using the DAS-28 tool by a rheumatologist. Then participants will receive a notebook to writing their feelings freely. In this study, the researcher will give complete oral explanations about the intervention implementation to participants in intervention group. Also, a written guide of the intervention implementation method will be given to them. The intervention group participants will express their feelings freely and voluntarily at home and preferably in a private room, once a day and 4 times a week for 4 weeks. Free writing of emotions will be regardless of spelling and compositional points. During the study period, the writing process of the patients will be followed up by the researcher at the end of each week via phone call. After the completion of the intervention, the study questionnaire will be sent via WhatSapp and email and participants will completed them again.

Category

Rehabilitation

2

Description

Control group: First, the participants will complete questionnaires of demographic information and clinical status of the disease, FSFI (Female Sexual Function Index) and AIMS2-SF (health status questionnaire) before studying the disease activity of both group using the DAS-28 will be measured. The control group will receive only routine care after the pre-test.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology subspecialty clinic in Tehran

Full name of responsible person

Dr. Anousheh Haghighi

Street address

Unit 6, Second floor, Kouh Noor doctors building, It has not reach Fajr Street, Motahari

City

Tehran

Province

Tehran

Postal code

1588645413

Phone

+98 21 8881 0475

Email

Haghighi.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Leila Amini

Street address

Iran University of Medical Sciences, Hemmat Highway, Next to Milad Tower, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Email

adminsite@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Elnaz Ashrafpour

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasemi Street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 8888 2886

Email

elnazashrafpour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Leila Amini

Position

Assistant professor of reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Rashid Yasemi Street, Vali-e-asr Ave

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 4365 1000

Email

Amini.l@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Elnaz Ashrafpour

Position

Master's student in counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasemi Street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 8888 2886

Email

elnazashrafpour@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available