Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the Effect of Self-care Training Based on Concept mapping on the Quality of Life of Rheumatoid Arthritis Patients

Protocol summary

Study aim
Determining the Effect of Self-care Training Based on a Conceptual map on the Quality of life of Patients with Rheumatoid arthritis

Design
A non-randomized clinical trial with an intervention and control group, not blinded, the number of samples in each of the intervention and control groups is 35 people.

Settings and conduct
Rheumatoid arthritis patients who refer to Imam Hospital in Tehran during the study will be included in the study if they are eligible. First, the sample units of the control group and then the intervention group will be selected as convenience and continuously. Self-care training is conducted in the hospital classroom in person and using CDs in two sessions. The training time is coordinated with the patient and is maximum in two weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria are the age of the patient between 18 and 60 years, being literate, informed consent, definitive diagnosis of rheumatoid arthritis by a rheumatologist and the ability to use a CD. Exclusion criteria are having chronic diseases and other mental illnesses.

Intervention groups
First, the control group will be pre-tested and a month later, the post-test will be taken. Then self-care educational content is given to research units using CD. After reaching the desired sample size of the research in the control group, sampling is done for the intervention group. In this way, a pre-test will be done for the research units in the intervention group. Then the educational content is taught to the research units face-to-face and using CD in two sessions. At the end of the training, the educational content is also given to the research units in the form of a CD. Then, one month after the last training session, the post-test will be conducted.

Main outcome variables
Quality of life in rheumatoid arthritis patients; Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230405057828N1**
Registration date: **2023-06-23, 1402/04/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-23, 1402/04/02**
Update count: **0**

Registration date
2023-06-23, 1402/04/02

Registrant information

Name
Navid Dadashi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3313 2054

Email address
ndadashi@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-30, 1402/03/09

Expected recruitment end date
2023-09-10, 1402/06/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the Effect of Self-care Training Based on Concept mapping on the Quality of Life of Rheumatoid Arthritis Patients

Public title
Investigation of self-care training on rheumatoid arthritis patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age Between 18 and 60 Years Being Literate in Reading and Writing Informed Consent Definitive Diagnosis of Rheumatoid Arthritis By a Rheumatologist Ability to Use CD
Exclusion criteria:
Suffering From Other Chronic Diseases Suffering From Mental Diseases
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Not 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
Ethics Committee in Research Faculty of Nursing and Midwifery and Faculty of Rehabilitation - Tehran
Street address
Room 604, Sixth floor, Central building of Tehran University of Medical Sciences, Intersection of Qods St, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1981656183

Approval date
2023-02-23, 1401/12/04
Ethics committee reference number
IR.TUMS.FNM.REC.1401.187

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
Quality of Life Score in the Quality of Life Questionnaire of Rheumatoid Arthritis Patients
Timepoint
Measuring the Quality of Life at the Beginning of the Study (Before the Start of the Intervention) and one Month After the Last Session of Self-care Training
Method of measurement
Questionnaire of Rheumatoid Arthritis Quality of Life

Secondary outcomes

1

Description
Pain Score of Rheumatoid Arthritis Patients
Timepoint
At the Beginning of the Study (Before the Start of the Intervention) and One Month After the Last Training Session
Method of measurement
Rheumatoid Arthritis Pain Scale Questionnaire

Intervention groups

1

Description
Control Group: First, a Pre-test will be Taken from the Control group, and a Post-test will be taken a month later, Then Self-care Educational content will be taught Face-to-face Using a CD. The training is done in two sessions, the time of training will be coordinated with the patient and it is maximum in two weeks. Educational content is about disease Recognition, complications, drugs and treatments, physical self-care, sports activities, pain management, performance self-care, health promotion methods, sleep and rest, diet and joint protection principles.
Category
Lifestyle

2

Description

Intervention group: A pre-test will be conducted for the research units in the intervention group, then self-care educational content will be taught face-to-face using CDs and laptops. The training is in the form of a concept map, which shows in the form of a visual diagram. The training is done in two sessions and in the classroom located in the hospital. The training time is coordinated with the patient and is maximum in two weeks. The time of each session is 45 minutes. The educational content is about disease recognition, complications, drugs and treatments, physical self-care, sports activities, pain management, performance self-care, health promotion methods, sleep and rest, diet and joint protection principles. Then, one month after the last training session, the post-test will be conducted. In this research, information will be collected using a three-part questionnaire including a demographic questionnaire, a quality of life questionnaire for rheumatoid arthritis patients, and a pain questionnaire for rheumatoid arthritis patients, which will take 10 minutes to fill out. The validity of the questionnaires will be checked by the relevant professors.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Navid Dadashi

Street address

Dr. Gharib Street, At the end of Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 936 741 6647

Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Fotuhi

Street address

Research and Technology Vice-Chancellor, 6th floor, Central Organization of the University, corner of Quds St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Navid Dadashi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Unit 1, No. 7, Mitsagh End, Kohistan Blvd, Kitab Square, Saadat Abad

City

Tehran

Province

Tehran

Postal code

1981656183

Phone

+98 936 741 6647

Email

Naviddadashi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Navid Dadashi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

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Naviddadashi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

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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