

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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

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Tehran

Postal code

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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

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1419733171

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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
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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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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