

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Assessing the applying orem self-care model on level of activity daily living and pain in arthritis rheumatoid patient.

Protocol summary

Summary

This research is a clinical trial study with two groups of experimental and control. The samples of 60 patients with moderate severity of rheumatoid arthritis in accordance with the American College of Rheumatology criteria which was confirmed by physician specialists and using the DAS28 for measuring the severity of rheumatoid arthritis. sampling method was convenience sampling and Assignment of samples in groups was random allocation. (30 patient in both intervention and control group). Information collecting tools were demographic information, pain, Performance and Satisfaction in activities of daily living scale. Method in this study hold 4 training sessions in two system of supportive educative and partly compensatory system according to questionnaire for need assessment based on Orem's Self-Care model, which was used in the test group, while the control group did not receive any intervention. Data from pain and activity daily living scale, were collected in three phases, first; before the intervention, second; one month after intervention and third; three months after intervention in test and control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052517840N1**

Registration date: **2015-05-24, 1394/03/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-24, 1394/03/03

Registrant information

Name

Elahe sadat Saeedifar

Name of organization / entity

Tarbiat modares

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tarbiat Modares university

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the applying orem self-care model on level of activity daily living and pain in arthritis rheumatoid patient.

Public title

Applying model on level of activity daily living and pain in arthritis rheumatoid patient.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 60 patients with moderate severity of rheumatoid arthritis in accordance with the American College of Rheumatology criteria which was confirmed by

physician specialists and using the DAS28 for measuring the severity of rheumatoid arthritis;the aged range between 20-60;At least Literacy Exclusion criteria:In medical history, a history of cognitive problems such as dementia, psychosis, mental retardation: underlying diseases and disorders that are organic noticeable impact on performance.

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

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 of Tarbiat Modares University

Street address

Faculty of Medical Sciences, Tarbiat Modares University, Jalal Ale Ahmad Highway, Nasr (Gisha) Bridge, Tehran, Iran

City

Tehran

Postal code

111-14115

Approval date

2013-10-27, 1392/08/05

Ethics committee reference number

52/46715

Health conditions studied**1****Description of health condition studied**

Rheumatoid arthritis

ICD-10 code

Mo6.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes**1****Description**

pain

Timepoint

before the intervention, second; one month after intervention and third; three months after intervention

Method of measurement

Numeric pain scale

2**Description**

Activities of daily living

Timepoint

before the intervention, second; one month after intervention and third; three months after intervention.

Method of measurement

performance and satisfaction of Activities of daily living scale in Arthritis rheumatoid patient

Secondary outcomes**1****Description**

Stress, anxiety and depression

Timepoint

before the intervention, second; one month after intervention and third; three months after intervention

Method of measurement

DASS-21 scale

2**Description**

Quality of life

Timepoint

before the intervention, second?; one month after intervention and third?; three months after intervention

Method of measurement

Quality of Life Questionnaire SF36

Intervention groups**1****Description**

Intervention group:Method in this study hold 4 training sessions in two system of supportive educative and partly compensatory system according to questionnaire for need assessment based on Orem's Self-Care model, which was used in the test group.

Category

Behavior

Description

Control group :This group did not receive any intervention and just act according to their doctor's orders. Data from pain and activity daily living scale, were collected in three phases, first; before the intervention, second; one month after intervention and third; three months after intervention in test and control group.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of rheumatology

Full name of responsible person

Dr.Mohsen Ahkyani

Street address

Doctors Building 110,Beheshti street,shohada square,karaj.

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Tarbiat Modares University

Full name of responsible person

Saeed Mousavian

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City

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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

Vice Chancellor for research of Tarbiat Modares University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tarbiat Modares university

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty