

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Sep 2026

Effectives of educational intervention based on temporal self- regulation theory in Adherence to medication in adults with Rheumatoid arthritis in Velayat hospital Qazvin

Protocol summary

Study aim

Determining the Effectives of educational intervention based on temporal self- regulation theory in Adherence to medication in adults with rheumatoid arthritis in velayat hospital Qazvin

Design

This research is a randomized controlled trial. 200 patients referred to the rheumatology clinic of Velayat hospital are included in this study. Patients were randomly divided into two groups of control and intervention. Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct

200 patients with arthritis rheumatoid who had been referred to the Rheumatology Clinic of Velayat Hospital for following their treatments are enrolled in this study. This study is conducted in Qazvin Velayat Hospital, and patients are randomly assigned to intervention and control groups. This research is two-blinded.

Participants/Inclusion and exclusion criteria

The definite diagnosis of rheumatoid arthritis confirmed by a specialist, the absence psychological problems before the onset of rheumatoid arthritis, the absence of other chronic , satisfaction to participate in the study, have a minimum level of education reading and writing

Intervention groups

In this study, the target group will be trained by the researcher for 3-5 minutes, group sessions for 50 minutes. In the control group, interventions are administered routinely by hospital doctors. These interventions are limited to educational intervention related to increased awareness and sensitivity to regular drug use.

Main outcome variables

The impact on Medication adherence

General information

Reason for update

update trial status

Acronym

IRCT registration information

IRCT registration number: **IRCT20180108038271N1**

Registration date: **2018-06-30, 1397/04/09**

Registration timing: **prospective**

Last update: **2023-06-12, 1402/03/22**

Update count: **1**

Registration date

2018-06-30, 1397/04/09

Registrant information

Name

Shahnaz Asgari ghoncheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3367 4283

Email address

sh.asgari63@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-03, 1396/11/14

Expected recruitment end date

2018-08-05, 1397/05/14

Actual recruitment start date

2018-07-02, 1397/04/11

Actual recruitment end date

2018-09-30, 1397/07/08

Trial completion date

Scientific title

Effectives of educational intervention based on temporal self- regulation theory in Adherence to medication in adults with Rheumatoid arthritis in Velayat hospital Qazvin

Public title

Effectives of Adherence to medication in Rheumatoid arthritis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diagnosis of rheumatoid arthritis with confirmation by a specialist No known psychological problems including depression Treated psychedelic drugs before having rheumatoid arthritis Lack of chronic and other dangerous diseases Have at least reading and writing skills

Exclusion criteria:

Cancellation Participate in other educational studies Inability to read and write Inability to take medication independently

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

Actual sample size reached: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done individually and its tool is Stata statistical software

Blinding (investigator's opinion)

Single blinded

Blinding description

After filling the consent sheet, the participants are randomly divided into two groups of intervention and control according to the stata software. The research assistants and the biostatistician will be blinded to patient allocation groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Blvd,Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2018-01-20, 1396/10/30

Ethics committee reference number

IR.QUMS.REC.1396.388

Health conditions studied

1

Description of health condition studied

Rheumatoid Arthritis

ICD-10 code

M05.611

ICD-10 code description

Rheumatoid arthritis of right shoulder with involvement of other organs and systems

Primary outcomes

1

Description

Medication of Adherence for rheumatoid arthritis

Timepoint

Before the intervention, 3 and 6 months after the intervention began

Method of measurement

Medication of Adherence questionnaire

Secondary outcomes

1

Description

Quality of life Index

Timepoint

Before the intervention, 3 and 6 months after the intervention began

Method of measurement

Quality of Life Questionnaire 12 questions

2

Description

Anxiety and depression Index
Timepoint
Before the intervention, 3 and 6 months after the intervention began
Method of measurement
Anxiety Inventory - Depression

3

Description
Disability Index
Timepoint
Before the intervention, 3 and 6 months after the intervention began
Method of measurement
Health Assessment Questionnaire-Disability Index

4

Description
Temporary self-regulatory Index
Timepoint
Before the intervention, 3 and 6 months after the intervention began
Method of measurement
Temporary self-regulatory questionnaire

Intervention groups

1

Description
"Intervention group": Patients referring to Rheumatology Clinic of Velayat Hospital. Interventions are provided as training sessions for treating patients with rheumatoid arthritis
Category
Behavior

2

Description
"Control group": Patients referring to Rheumatology Clinic of Velayat Hospital In the control group, brief training is given on the disease
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat Hospital
Full name of responsible person
Shahnaz Asgari Ghoncheh
Street address
Elahiyeh, 22 bahman blvd, Minodar, Qazvin
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2

Recruitment center
Name of recruitment center
Booali Sina Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Amir Pakpour Haji Agha
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pakpour_amir@yahoo.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Amir Pakpour Haji Agha
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Effectives of educational intervention based on temporal self-regulation theory in Adherence to medication in adults with Rheumatoid arthritis in Velayat hospital Qazvin. Participants data file and clinical report and report will be available to enthusiasts after the end of the work in general and after unidentified people.

When the data will become available and for how long

Start the access period 12 months after printing the results

To whom data/document is available

The data will only be available to scholars working in academic and scientific institutions

Under which criteria data/document could be used

Overall analysis and comparison and correct referral

From where data/document is obtainable

To the researcher, please refer to
sh.asgari63@yahoo.com

What processes are involved for a request to access data/document

First, give a request to the researcher and the researcher

will inform the supervisor and then the data will be available to the interested party.

Comments