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
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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

2019-05-31, 1398/03/10

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

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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

Street address

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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

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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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