# 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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**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**

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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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## 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**