Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the impact of a comprehensive remote empowerment program on the quality of life and medication adherence of patients with psoriasis

Protocol summary

Study aim
Determining the impact of a comprehensive remote empowerment program on the quality of life and medication adherence of patients with psoriasis

Design
The clinical trial has a control group, with parallel, randomized groups, on 52 patients and is used for block randomization.

Settings and conduct
Psoriasis patients referred to Razi Hospital are included Convenient sampling sampling and then randomized block method is used.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The individual's personal consent to participate in the program; Adults 18 to 65 years old; Medical diagnosis of psoriasis according to the patient's medical record; Being in a stable state of illness; Having minimum reading and writing literacy; Ability to communicate; Access and ability to use a smartphone and the Internet. Exclusion criteria: Diagnosed mental and cognitive disorders; Previous participation in similar empowerment programs; History of suicide

Intervention groups
during 7 weeks, the control group will receive the usual care (treatment and individual care methods that have been carried out so far will continue), while the intervention group patients will receive a comprehensive remote empowerment program in addition to the usual care.

Main outcome variables
Treatment adherence; quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230219057453N1**
Registration date: **2023-03-27, 1402/01/07**
Registration timing: **prospective**

Last update: **2023-03-27, 1402/01/07**
Update count: **0**

Registration date
2023-03-27, 1402/01/07

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-02, 1402/01/13

Expected recruitment end date
2023-08-22, 1402/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the impact of a comprehensive remote empowerment program on the quality of life and medication adherence of patients with psoriasis

Public title
Investigating the impact of the empowerment program on psoriasis patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Personal consent of the person to participate in the program Adults 18 to 65 years old Medical diagnosis of psoriasis according to the patient's medical record Being in a stable state of illness Having at least reading and writing literacy Ability to communicate Access and ability to use a smart phone and the Internet
Exclusion criteria:
Diagnosed mental and cognitive disorders Previous participation in similar empowerment programs History of suicide
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
during two stages; The first step is the convenience sampling. In the second stage, patients will be allocated in two intervention and control groups by random block allocation method. The samples are randomly assigned to quadruple blocks A, A, B, B in random groups. So that 16 blocks of 4 letters A and B are made up.Then a block is randomly selected. RAS random allocation software will be used to randomly select blocks. A indicates sample placement in intervention group and B indicates sample placement in control group. First, a block will be randomly identified by RAS software and then the first eligible sample will be entered into the intervention or control group according to the order of the letters A or B. Sampling will continue until all samples are selected.
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 Faculty of Nursing and Midwifery, Tehran University of Medical Sciences
Street address
Shahvarz Blvd., corner of Qods St., Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶-۱۴۵۳۵
Approval date
2023-02-17, 1401/11/28
Ethics committee reference number
IR.TUMS.FNM.REC.1401.179

Health conditions studied

1

Description of health condition studied
psoriasis
ICD-10 code
L40
ICD-10 code description
Psoriasis

Primary outcomes

1

Description
Treatment compliance
Timepoint
Before the intervention, 2 weeks and 4 weeks after the intervention
Method of measurement
Moriski medication adherence questionnaire

2

Description
Quality of life
Timepoint
Before the intervention, 2 weeks and 4 weeks after the intervention
Method of measurement
Questionnaire of quality of life of World Health Organization,

Secondary outcomes

1

Description
stigma
Timepoint
Before starting the intervention, 2 weeks and 4 weeks after the intervention
Method of measurement
Geisenberg et al.'s questionnaire

Intervention groups

1

Description

Intervention group: At the beginning of the study, the study questionnaires including demographic information questionnaire, perceived stigma, quality of life and medication adherence were completed by the patients of both control and intervention groups. This study will be conducted for 7 weeks and the control group will receive the usual care, while the patients of the intervention group will also receive the comprehensive empowerment program in addition to the usual care. In this way, the intervention group will be joined by the researcher in virtual groups of 10 to 15 people in the WhatsApp social network and will receive the comprehensive empowerment program. In this research, a 7-week empowerment program will be held online and on the platform of virtual networks according to the patients' conditions, and each week will address a specific topic to promote self-care. The content of each of the sessions will be provided to all patients of the intervention group in the same way as a combination of online and offline sessions (4 online sessions and 3 offline sessions) with an interval of one week for 7 weeks. Or the training video will be sent in the virtual network groups and in the online meetings, the Skyroom link will be placed in the virtual network group to hold online group meetings. Online group meetings with members of groups of 10 to 15 people will be held on the virtual network for 10 minutes and through the Skyroom platform. became.

Category

Other

2

Description

Control group: Control group: study questionnaires including demographic information questionnaire, perceived stigma, quality of life and drug treatment adherence are completed by patients of both control and intervention groups. This study will be conducted in 7 weeks and the control group will receive the usual care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr Arezoo Rasti

Street address

Tehran Vahdat Islami Square - Razi Dead End - Hospital...

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tehran University of Medical Sciences

Proportion provided by this source

50

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

sayede Sara Mirhosseini

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after de-identifying the participants
When the data will become available and for how long
Start access after receiving information and data forever
To whom data/document is available
All applicants working in academic and scientific institutions
Under which criteria data/document could be used
The use of data and documents in scientific research is unimpeded.
From where data/document is obtainable
ایمیل arasti@tums.ac.ir
What processes are involved for a request to access data/document
Apply by email and after receiving the email up to 2 months later
Comments