Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of acceptance and commitment therapy (ACT) on improving quality of life, reducing symptoms of anxiety and depression, and enhancing psychological flexibility in patients with psoriasis.

Protocol summary

Study aim

Investigating the effectiveness of Acceptance and Commitment Therapy (ACT) on improving quality of life, reducing anxiety and depression, and enhancing cognitive flexibility in patients with psoriasis.

Design

This study is designed as a pilot quasi-experimental trial with parallel groups (intervention and control) conducted on 60 patients (30 participants in each group). Participants will be selected through convenience sampling, and allocation into the two groups will be performed using simple randomization with SPSS software. This study is designed as a pilot trial (preliminary phase).

Settings and conduct

Study setting: Dermatology department of Imam Reza Hospital in Amol city; Study population: patients with psoriasis; Type of blinding: single-blind; Blinding method: the data analyst was unaware of the participants' group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 and 40 years; ability to read and write; providing informed consent to participate in the study. Exclusion criteria: Diagnosis of severe psychiatric disorders based on medical records or psychiatrist evaluation; receiving concurrent similar psychological interventions at the time of enrollment.

Intervention groups

In the intervention group, Acceptance and Commitment Therapy (ACT) was delivered in eight in-person group sessions, each lasting 60 minutes, including instruction on ACT principles, mindfulness exercises, and homework assignments. In the control group, no intervention was provided during the study period; however, after the completion of the experimental sessions, ACT training was offered to them remotely (online).

Main outcome variables

Quality of life score on the DLQI scale; Anxiety score on the HADS scale; Depression score on the HADS scale; Cognitive flexibility score on the CFI scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251008067556N1**
Registration date: **2026-06-08, 1405/03/18**
Registration timing: **prospective**

Last update: **2026-06-08, 1405/03/18**
Update count: **0**

Registration date

2026-06-08, 1405/03/18

Registrant information

Name

Mahta Abdoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4324 5936

Email address

mhta.abdoli98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-20, 1405/03/30

Expected recruitment end date

2026-08-21, 1405/05/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of acceptance and commitment therapy (ACT) on improving quality of life, reducing symptoms of anxiety and depression, and enhancing psychological flexibility in patients with psoriasis.

Public title
Evaluating the effectiveness of Acceptance and Commitment Therapy (ACT) in patients with psoriasis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of psoriasis skin disease according to a physician's diagnosis Age range between 20-40 years Reading and writing The willingness and consent of consciousness to enter the research project
Exclusion criteria:
Diagnosis of severe psychiatric disorders based on medical records or psychiatrist evaluation. Receiving concurrent similar psychological interventions at the time of enrollment. Unwillingness to participate in the study or failure to provide informed consent.
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, participants will be allocated into intervention and control groups using a simple randomization method based on a random numbers table in SPSS software. First, the list of eligible participants will be entered into SPSS software. Then, a random variable with uniform distribution will be generated using the following command: Compute Random = RV.UNIFORM(0,1) After generating the random variable, the data will be sorted from the smallest to the largest random number, and participants will be assigned to the intervention and control groups according to the resulting order.
Blinding (investigator's opinion)
Single blinded
Blinding description
Given the nature of the intervention (Acceptance and Commitment Therapy), complete blinding was not feasible, as both the therapist and participants were aware of the type of intervention. However, to minimize bias in the data analysis process, partial (single) blinding was implemented; that is, the individual responsible for data entry and statistical analysis was unaware of group assignments (experimental or control). Furthermore, participants were not informed about the exact research hypothesis or the expected outcomes to prevent the occurrence of the expectancy effect.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ayatollah Amoli University of Science and Research
Street address
No. 2, Parsa 2 Alley, Rahimi Alley, Emam Reza Street, Amol
City
Amol
Province
Mazandaran
Postal code
4613856348
Approval date
2025-09-13, 1404/06/22
Ethics committee reference number
IR.IAU.AMOL.REC.1404.137

Health conditions studied

1

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

Primary outcomes

1

Description
Quality of life in patients with psoriasis
Timepoint
Before the intervention and after completion of the treatment sessions
Method of measurement
Measured using the Dermatology Life Quality Index (DLQI)

2

Description
Anxiety level in patients with psoriasis
Timepoint
Before the intervention and after completion of the treatment sessions
Method of measurement
Measured using the Anxiety subscale of the Hospital Anxiety and Depression Scale (HADS-A)

3

Description
Depression level in patients with psoriasis
Timepoint
Before the intervention and after completion of the treatment sessions
Method of measurement
Measured using the Depression subscale of the Hospital Anxiety and Depression Scale (HADS-D)

4

Description
Cognitive flexibility in patients with psoriasis
Timepoint
Before the intervention and after completion of the treatment sessions
Method of measurement
Measured using the Cognitive Flexibility Inventory (CFI) by Dennis & Vander Wal

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group receives Acceptance and Commitment Therapy (ACT) in a face-to-face, group format. The intervention consists of eight 60-minute group sessions delivered over eight weeks (one session per week). Session content is based on the six core ACT processes and includes: theoretical education, acceptance exercises, cognitive defusion practices, mindfulness exercises for present-moment awareness, values clarification, values-based goal setting, and committed action planning with homework assignments. Educational materials include presentation slides, a homework booklet, and simple practice files. The sessions are delivered by a clinical psychologist trained in ACT. To ensure treatment fidelity, sessions are reviewed by a senior researcher or clinical supervisor using a fidelity checklist, and participants' homework assignments are documented and evaluated.
Category
Behavior

2

Description
Control group: The control group receives routine care and does not receive any additional psychological intervention. Routine care includes standard medical follow-up, general dermatological advice, and prescribed medications provided by the dermatologist. To maintain structural equivalence, the control group receives only minimal contact during the study period (limited to necessary follow-up calls for scheduling assessments), and no educational or therapeutic sessions are provided. After data collection is completed, participants in the control group are offered a brief educational package on stress management and self-care if they wish.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Mahta Abdoli
Street address
Imam Reza Hospital, Emam Reza Street
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Amol
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4614937597
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Esmaeil Fattahi
Street address
Ayatollah Amoli Branch, Islamic Azad University, before Komdereh Village, Kilometer 6, Old Amol-Babol Road, Amol
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4661616917
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name@amol.iau.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Babol University of Medical Sciences

Full name of responsible person

Alireza Azizi

Position

University Faculty Members

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahta Abdoli

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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City

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Phone

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Email

name@mhta.abdoli98

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahta Abdoli

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary	Undecided - It is not yet known if there will be a plan to make this available