Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Integrated Group Therapy Based on Mindfulness and Acceptance and Commitment Therapy (ACT) on Quality of Life and Reduction of Perceived Stress in Patients with Hidradenitis Suppurativa

Protocol summary

Study aim
Effects of Mindfulness- and ACT-Based Group Therapy on Quality of Life and Perceived Stress in Patients with Hidradenitis Suppurativa

Design
Open-label, controlled, parallel-group clinical trial (30 patients). Quality of life and perceived stress are assessed before and after the intervention

Settings and conduct
An open-label, controlled clinical trial in 30 patients with Hidradenitis Suppurativa assigned to intervention and control groups. Quality of life and perceived stress are assessed before and after the intervention.

Participants/Inclusion and exclusion criteria
Confirmed diagnosis of Hidradenitis Suppurativa, age 18–60 years, disease duration of at least one year, willingness to participate in the study, and no concurrent psychological intervention.

Intervention groups
Intervention group: 15 patients receiving Mindfulness- and Acceptance and Commitment Therapy (ACT)-based group therapy plus routine care. Control group: 15 patients receiving routine care only.

Main outcome variables
The independent variable is Mindfulness- and Acceptance and Commitment Therapy (ACT)-based group therapy. The dependent variables are quality of life and perceived stress, measured using the WHOQOL-BREF and PSS questionnaires. Age, confirmed diagnosis of Hidradenitis Suppurativa, and disease duration are also recorded.

General information

Reason for update

Acronym
MACT-HS

IRCT registration information
IRCT registration number: **IRCT20260704070062N1**
Registration date: **2026-07-20, 1405/04/29**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-20, 1405/04/29**
Update count: **0**

Registration date
2026-07-20, 1405/04/29

Registrant information
Name
Fatemeh Hosseini
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 5540 3541
Email address
f.hosseini@razi.tums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-03-01, 1404/12/10

Expected recruitment end date
2026-11-21, 1405/08/30

Actual recruitment start date
2026-05-22, 1405/03/01

Actual recruitment end date
2026-12-21, 1405/09/30

Trial completion date
2027-01-20, 1405/10/30

Scientific title
The Effectiveness of Integrated Group Therapy Based on Mindfulness and Acceptance and Commitment Therapy

(ACT) on Quality of Life and Reduction of Perceived Stress in Patients with Hidradenitis Suppurativa

Public title
Effect of Mindfulness- and Acceptance and Commitment-Based Group Therapy on Quality of Life and Stress in Patients with Hidradenitis Suppurativa

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
1. Confirmed diagnosis of **Hidradenitis Suppurativa** Disease duration of at least one year Willingness and written informed consent to participate in the Acceptance and Commitment Therapy (ACT)-based treatment sessions Not receiving any other form of psychotherapeutic intervention during the study period Age between 18 and 60 years.

Exclusion criteria:
Participation in any psychological intervention within at least 6 months prior to enrollment in the study. Absence from more than two treatment sessions. Inability or unwillingness to complete the study assessments due to fatigue. Withdrawal of consent or unwillingness to continue participation in the study. Incomplete questionnaire responses.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Central Campus, University of Tehran, Jalalieh, Keshavarz Boulevard, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1461884513

Approval date
2026-01-18, 1404/10/28

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1404.702

Health conditions studied

1

Description of health condition studied
Hidradenitis suppurativa

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Quality of life

Timepoint
Before the intervention and after completion of the intervention

Method of measurement
Measured using the World Health Organization Quality of Life Questionnaire (WHOQOL-BREF)

Secondary outcomes

1

Description
Perceived stress

Timepoint
Before the intervention and after completion of the intervention

Method of measurement
Measured using the Perceived Stress Scale (PSS)

Intervention groups

1

Description
Intervention group: Fifteen patients with Hidradenitis Suppurativa receiving Mindfulness- and Acceptance and Commitment Therapy (ACT)-based group therapy plus routine care.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital, Tehran University of Medical Sciences, Tehran, Iran

Full name of responsible person
Zeinab Aryanian

Street address
Islamic Unity Street, below Islamic Unity Square, District 12, Tehran, Tehran Province, Iran,

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1199663911

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Fax

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ramin Kordi

Street address
6th Floor, Vice Presidency of Research and Technology Central Administration Building, Tehran University Keshavarz Blvd., at the corner of Qods St. Tehran, Iran

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Province
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141765383761

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+98 21 8163 3698

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Fatemeh Hosseini

Position
PhD Candidate of Biostatistics

Latest degree
Master

Other areas of specialty/work
Biostatistics

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No. 12, Unit 2, Ferdows Alley, Mirjalili St., Qazvin St., South Karegar St., Tehran, Iran

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Individual Participant Data (IPD) will not be shared because it contains confidential patient information. To protect participants' privacy and maintain confidentiality, these data will not be made publicly 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
Undecided - It is not yet known if there will be 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
Not applicable

Data Dictionary
Not applicable