Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the Effects of Stress Management Combined with Pharmacotherapy versus Pharmacotherapy as Sole Treatment on Quality of Life in Patients with Chronic Urticaria

Protocol summary

Study aim

Evaluating the Effect of Combined Stress-Management Therapy and Pharmacotherapy Compared to Pharmacotherapy Alone on the Quality of Life of Patients with Chronic Urticaria.

Design

Patients who had been referred for treatment of chronic urticaria within a few weeks before the start of the study and who currently had active disease were invited to participate in the study. Patients were divided into two groups, case and control, based on personal preference. In addition to drug therapy, the case group received 8 weeks of psychotherapy. The chronic urticaria questionnaire was completed for both groups before and after the intervention. After that, statistical analysis was performed on the two groups..

Settings and conduct

Two non-blinded groups of 50 patients each, selected from recent visitors to Dr. Pourvali's clinic who had not responded clinically to previous pharmacotherapy. In the control group, only the treatment stage was escalated, while in the intervention group, in addition to the escalated treatment stage, eight weeks of psychotherapy were provided.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age over 12 years Absence of severe chronic physical or psychological illnesses Diagnosis of chronic spontaneous urticaria Willingness and consent to participate in the study Exclusion Criteria: Incomplete questionnaire data or failure to attend the scheduled sessions.

Intervention groups

Intervention: Patients with chronic urticaria who receive both psychotherapy and pharmacological treatment for chronic urticaria. Control: Patients with chronic urticaria who receive only pharmacological treatment for chronic urticaria

Main outcome variables

Quality of life of patients with chronic urticaria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250912067222N1**
Registration date: **2025-12-07, 1404/09/16**
Registration timing: **retrospective**

Last update: **2025-12-07, 1404/09/16**
Update count: **0**

Registration date

2025-12-07, 1404/09/16

Registrant information

Name

Saeed Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8869 6323

Email address

dr.saeed.sadeghi@iau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-06, 1404/04/15

Expected recruitment end date

2025-09-06, 1404/06/15

Actual recruitment start date

2025-07-06, 1404/04/15

Actual recruitment end date

2025-09-06, 1404/06/15

Trial completion date

2025-09-11, 1404/06/20

Scientific title

Comparison of the Effects of Stress Management Combined with Pharmacotherapy versus Pharmacotherapy as Sole Treatment on Quality of Life in Patients with Chronic Urticaria

Public title

Effectiveness of stress management on the quality of life of patients with chronic diseases

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of chronic spontaneous urticaria Age 12 years and older Absence of severe chronic physical or psychological illnesses Ability to read and write in Persian Willingness and informed consent to participate in the study

Exclusion criteria:

Failure to complete the questionnaires or absence from the scheduled sessions

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization at the individual level will be performed to assign participants into two groups: intervention and control. Since demographic characteristics are not expected to significantly affect the outcomes, stratification will not be applied. Assignment to the intervention group will be based on participants' willingness to receive psychotherapy; those who wish to participate in the study without undergoing psychotherapy will be assigned to the control group. This study will not implement allocation concealment.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Tehran North Branch

Street address

Shahrak-e Gharb, Darya Boulevard, North Motahari Street, Shaghayegh 2 Alley, No. 8, Unit 10

City

Tehran

Province

Tehran

Postal code

1998879359

Approval date

2025-07-02, 1404/04/11

Ethics committee reference number

IR.IAU.TNB.REC.1404.113

Health conditions studied

1

Description of health condition studied

chronic urticaria

ICD-10 code

L50.1

ICD-10 code description

Idiopathic urticaria

Primary outcomes

1

Description

Quality of Life in Patients with Chronic Urticaria

Timepoint

Before the intervention and 8 weeks after treatment

Method of measurement

Chronic Urticaria Quality of Life Questionnaire

Secondary outcomes

1

Description

Urticaria Severity

Timepoint

Before the intervention and 8 weeks after

Method of measurement

Urticaria Activity Score in 7 days

Intervention groups

1

Description

Intervention group: Stress management, including

mindfulness and relaxation exercises over 8 sessions, alongside standard treatment for chronic urticaria

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Allergy Clinic

Full name of responsible person
Ali Pourvali

Street address
Allergy Clinic, Saadat Abad

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Province
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1997998394

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Vice President for Research and Technology

Street address
Islamic Azad University, Chaman Ara Street, Hakimiyeh, Babayi Highway

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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
Islamic Azad University

Proportion provided by this source
1

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
Islamic Azad University

Full name of responsible person
Ali Pourvali

Position
consultant

Latest degree
Subspecialist

Other areas of specialty/work
Immunology

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Person responsible for updating data

Contact

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Latest degree
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Other areas of specialty/work
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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 that researchers may need after de-identifying individuals.
When the data will become available and for how long
Possibility of access after publication in the journal and use by other researchers
To whom data/document is available
Academic and scientific researchers
Under which criteria data/document could be used
Allowed for use for retrospective analyses or other purposes that contribute to the production of knowledge.
From where data/document is obtainable
Contact information: The email address of the corresponding author or the first author of the article.
What processes are involved for a request to access data/document
After the article is published, new researchers can send their application via their academic email, describing the research objectives and how the research will be conducted, and within 2 weeks after verification, the data will be sent via email.
Comments