

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Cognitive behavioral program as an adjuvant therapy in Acne excoriée

#### Protocol summary

##### Study aim

effect of group based CBT in patients with moderate to severe AE could be effective to accelerate healing time, decrease the urge for skin piking, as well as improve anxiety and depressive symptoms.

##### Design

64 patients were studied in a phase 2 clinical trial in study and control group (32 patients in each group). randomization were performed by closed envelope method. the study was single blinded, thus investigator and analyzer were blinded in the study.

##### Settings and conduct

the study was perfpmed in confrence hall of Imam Reza hospital. patients in study group underwent 8 sessions of 90 minutes CBT therapy during 8 weeks. acceleration of improvement was assessed by dermatologist. Changes in anxiety and depression as well as willing of skin picking were assessed by means of inventories. Dermatologist and analyzer were blinded in patients' groups.

##### Participants/Inclusion and exclusion criteria

Inclusion: 1) clinically diagnosed as moderate to severe AE by dermatologist 2) Motivation to undergo CBT with goal of reducing skin-picking. 3) None of the patients had received medication for their acne at the baseline of the study. 4) They had not sought any psychiatric help yet and none of them reported the use of any psychotropic medications within the previous 4 weeks. Exclusion: 1)chronic systemic diseases, confirmed psychological disorder, 2) disinclination to continue. 3)Those who had mild lesions according to the dermatologist opinion.

##### Intervention groups

in study group, all the patients underwent 8 weekly sessions of CBT beside classic pharmacological therapy. in control group patients only received classic pharmacological therapy same as study group for 2 months.

##### Main outcome variables

time of clinical improvement of lesions changes in patient willing to skin picking changes in anxiety and depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190312043038N1**

Registration date: **2020-01-05, 1398/10/15**

Registration timing: **retrospective**

Last update: **2020-01-05, 1398/10/15**

Update count: **0**

##### Registration date

2020-01-05, 1398/10/15

##### Registrant information

##### Name

emadodin darchini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3878 6692

##### Email address

emadoddin.darchini@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2018-06-22, 1397/04/01

##### Actual recruitment start date

2017-06-22, 1396/04/01

##### Actual recruitment end date

2018-09-23, 1397/07/01

##### Trial completion date

2018-10-23, 1397/08/01

##### Scientific title

Cognitive behavioral program as an adjuvant therapy in

Acne excoriée

## Public title

Effects of cognitive behavioral program in Acne excoriée

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

- clinically diagnosed as moderate to severe acne excoriee by dermatologist no medication for their acne at the baseline of the study none of them reported the use of any psychotropic medications within the previous 4 weeks.

### Exclusion criteria:

chronic systemic diseases confirmed psychological disorder in case of disinclination

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

- Care provider
- Investigator

## Sample size

Target sample size: **52**

Actual sample size reached: **32**

## Randomization (investigator's opinion)

Randomized

## Randomization description

simple randomization by means of closed envelopes method

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Although there was no way to blind the study groups due to obvious intervention, the dermatologist was not aware of the patients' group while judging healing process.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Psychology campus, Azad university of Torbatjam

##### Street address

torbat-jam, azad university

##### City

torbatjam

##### Province

Razavi Khorasan

## Postal code

9177744685

## Approval date

2017-07-02, 1396/04/11

## Ethics committee reference number

44586

## Health conditions studied

### 1

#### Description of health condition studied

acne excoriee,

#### ICD-10 code

L70.5

#### ICD-10 code description

L70.5

## Primary outcomes

### 1

#### Description

improvement in severity of skin lesions

#### Timepoint

8 weeks

#### Method of measurement

according to acne severity scale

### 2

#### Description

urge to skin picking by patient

#### Timepoint

8 weeks

#### Method of measurement

acne skin picking scale (SPS)

### 3

#### Description

improvement in depression score

#### Timepoint

8 weeks

#### Method of measurement

Beck depression inventory

### 4

#### Description

improvement in anxiety score

#### Timepoint

8 weeks

#### Method of measurement

Beck anxiety inventory

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: beside standard pharmacological therapy for moderate acne (oral and topical) they underwent 8 sessions of cognitive behavioral therapy during 8 weeks. Each session lasts 1 hour and the topics in each session were pre-designed.

#### Category

Behavior

### 2

#### Description

Control group: patients underwent standard moderate acne pharmacological treatment for 8 weeks including oral antibiotic and topical retinoid.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital, Mashhad

##### Full name of responsible person

Emadodin Darchini-Maragheh

##### Street address

Dermatology Clinic, Imam Reza Hospital, Daneshgah avenue, Mashhad, Iran

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177744685

##### Phone

+98 51 3858 3845

##### Email

SRC@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Torbate-Jam University of Medical Sciences

##### Full name of responsible person

hamed mohammadi

##### Street address

Torbat-e-jam medical university

##### City

torbat-e-jam

##### Province

Razavi Khorasan

##### Postal code

385944390

##### Phone

+98 51 5252 3224

##### Email

mohammadih2@trjums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Torbate-Jam 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Emadodin Darchini-Maragheh

##### Position

dermatology resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

##### Street address

dermatology department, Emam Reza Hospital, Mashhad, Iran

##### City

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##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Vahid Mashayekhi

##### Position

professor

##### Latest degree

Subspecialist

**Other areas of specialty/work**

Dermatology

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Emadodin Darchini-Maragheh

**Position**

resident of dermatology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address****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**

no more data

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available