

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 excoりée

Public title

Effects of cognitive behavioral program in Acne excoりée

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- clinically diagnosed as moderate to severe acne excoりee 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 excoりee,

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

Mashhad

Province

Razavi Khorasan

Postal code

9755544685

Phone

+98 51 3858 3845

Email

emadoddin.darchini@yahoo.com

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

Street address

Dermatology department, Emam Reza Hospital,
Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177744685

Phone

+98 51 3858 3845

Email

mashayekhiv@mums.ac.ir

dermatology department, Emam Reza Hospital,
Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177744685

Phone

+98 51 3858 3845

Email

emadoddin.darchini@yahoo.com

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

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