Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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 envelops 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
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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 standarد 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 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Position
dermatology resident
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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
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