Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of transdiagnostic group intervention versus anxiety-based cognitive behavioral group therapy in subclinical paranoia: a comparison study

Protocol summary

Study aim
Determine the efficacy of transdiagnostic intervention compared to anxiety-based cognitive behavioral therapy on reducing paranoid thinking

Design
A randomized clinical trial with a control group based on the student community, with parallel groups, one blinded

Settings and conduct
In psychotherapy private clinic, blinding was performed for participants, they do not know in which treatment group assigned.

Participants/Inclusion and exclusion criteria
The inclusion criteria: age between 18 to 35 years old; subclinical paranoia scoring>1 based on the SCL-90 questionnaire and scoring>40 in the paranoia scale; and being based in Mashhad at the time of group therapy. The main selection criteria, however, was suffering from subclinical paranoia and its consequent dysfunction. Exclusion criteria : substance dependence; a case note DSM-V diagnosis of schizophrenia and any psychotic disorder; already being in receipt of psychological therapy and organic impairments.

Intervention groups
The content of transdiagnostic intervention sessions were prepared based on the protocol of Barlow et al. (2011) included emothional awareness, prevention of emotional avoidance and focus to emotional exposure. bsed on freeman et al. cognitive model, emphasize on anxiety role in formation and maintenance paranoia, and anxiety-based CBT modeled by key and crask(2003) include psychoeducation, relaxation and cognitive restructuring

Main outcome variables
Paranoid ideation; general performance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150315021482N4**
Registration date: **2018-06-30, 1397/04/09**
Registration timing: **retrospective**

Last update: **2018-06-30, 1397/04/09**
Update count: **0**

Registration date
2018-06-30, 1397/04/09

Registrant information

Name
Nahid Mojaver

Name of organization / entity
Mashhad University of Medical Science

Country
Iran (Islamic Republic of)

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+98 51 3852 3300

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mojavern1@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-08, 1397/01/19

Expected recruitment end date
2018-06-19, 1397/03/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Efficacy of transdiagnostic group intervention versus anxiety-based cognitive behavioral group therapy in subclinical paranoia: a comparison study

Public title
Efficacy of transdiagnostic approach versus cognitive behavioral in paranoid

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Subclinical paranoia scoring>1 based on the SCL-90 questionnaire and scoring>40 in the paranoia scale Living in Mashhad city at the time of group therapy
Exclusion criteria:
Substance dependence A case note DSM-V diagnosis of schizophrenia and any psychotic disorder Already being in receipt of psychological therapy Organic impairments

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization sequence was generated in block and the randomization code was written onto sealed numbered envelopes, ensuring that the random assignment of the groups was observed.

Blinding (investigator's opinion)
Single blinded

Blinding description
Because of both control and examination group, received the treatment, so the participants did not know in which group they were.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Corner of Milad tower, Hemat highway, Tehran City
City
Tehran
Province
Tehran
Postal code
1449614535

Approval date
2015-12-11, 1394/09/20

Ethics committee reference number
IR.IUMS.FMD.REC.1394,9211521201

Health conditions studied

1

Description of health condition studied
Subclinical paranoia

ICD-10 code
F22

ICD-10 code description
Delusional disorders

Primary outcomes

1

Description
Paranoid ideation

Timepoint
pre-intervention, post intervention, 3 months after intervention

Method of measurement
In screening Based on score >1 in PAR; sub-scale in SCL90-R and score>40 in Paranoia scale. Totally, in pre-intervention, post- intervention and follow-up, Paranoia scale is used for measure paranoia.

2

Description
General performance

Timepoint
pre-intervention, post intervention, 3 months after intervention

Method of measurement
Work and Social Adjustment Scale

Secondary outcomes

1

Description
Depression

Timepoint
Pre and post intervention and 3 months follow up

Method of measurement
Beck depression inventory

2

Description
Anxiety
Timepoint
Pre and post intervention and 3 months follow up
Method of measurement
Beck anxiety inventory

Intervention groups

1

Description
Intervention group: In the first group, group Transdiagnostic Cognitive Behavioral Therapy (10 sessions) will hold.
Category
Treatment - Other

2

Description
Control group: In the second group, group Anxiety Based Cognitive Behavioral Therapy (10 sessions) will hold.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ferdowsi University; Mashhad Payame Nour University
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Reza Arezumandan
Street address
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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
Iran 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
Nahid Mojaver
Position
Bachelor of Science
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Bachelor
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Person responsible for updating data

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9176699199
Phone
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
It is possible to share completed questionnaires file (SPSS version) by the participants in the study.
When the data will become available and for how long
1 year after publish the paper
To whom data/document is available
All psychologists and psychiatrists (Clinicians) working in the paranoid field
Under which criteria data/document could be used
For meta-analysis and review articles
From where data/document is obtainable
linked via leila.amirpour@gmail.com
What processes are involved for a request to access data/document
After sending the official application along with the letter of approval of the research project and the applicant's authentication, the file will be sent within one month.
Comments