Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Compilation Of Effectiveness of Compassionate Mind-Based Cognitive Therapy and Transcranial Direct Electrical Stimulation on Brain-Behavioral Systems, Dark Personality Traits, and the Theory of mind Adolescents with high-risk behaviors.

Protocol summary

Study aim
Comparison of the effectiveness of cognitive therapy based on compassionate mind and direct transcranial electrical stimulation on brain-behavioral systems, dark personality traits and mind theory of adolescents with high-risk behaviors

Design
The present research method was a quasi-experimental and comparative experiment in which a pre-test/post-test design with two experimental groups and one control group was used.

Settings and conduct
This study was performed in Bozorgmehr Counseling Center.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having a high-risk behaviors; willingness to participate in the study; not suffering from other disorders. Non-inclusion criteria: Participate in other intervention programs at the same time.

Intervention groups
The first intervention group was exposed to direct ultrasonic electrical stimulation, and the second experimental group was exposed to Compassionate Mind-Based Cognitive Therapy. The control group did not receive any treatment.

Main outcome variables
Brain-Behavioral Systems, Dark Personality Traits, and the Theory of Mind

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200209046441N1**
Registration date: **2021-01-25, 1399/11/06**
Registration timing: **retrospective**

Last update: **2021-01-25, 1399/11/06**
Update count: **0**

Registration date
2021-01-25, 1399/11/06

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2020-12-30, 1399/10/10

Actual recruitment start date
2020-11-30, 1399/09/10

Actual recruitment end date
2021-01-16, 1399/10/27

Trial completion date
2021-01-17, 1399/10/28

Scientific title
Compilation Of Effectiveness of Compassionate Mind-Based Cognitive Therapy and Transcranial Direct Electrical Stimulation on Brain-Behavioral Systems, Dark Personality Traits, and the Theory of mind Adolescents

with high-risk behaviors.

Public title
Mind-Based Cognitive Therapy and Transcranial Direct Electrical Stimulation on Brain-Behavioral Systems, Dark Personality Traits, and the Theory of mind Adolescents with high-risk behaviors and self-harm behaviors.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having high-risk behaviors based on a screening questionnaire Willingness to participate in the study No other mental disorders
Exclusion criteria:
Participate in other intervention programs at the same time
Age
From **15 years** old to **17 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Actual sample size reached: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
36 students with high-risk behaviors were randomly selected and then completely randomly (based on lottery) were divided two groups of 15 experiments and one group controls. Allocation was done through drawing a code in which every student was given a code and we put the codes in a container. Then 15 people who were taken out first were replaced in the first experimental group, 15 people later in the second experimental group and 18 people later in the control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Basmanj Street. Medical School - Second Floor
City
Tabriz
Province
East Azarbaijan
Postal code
5351869012
Approval date
2020-12-30, 1399/10/10
Ethics committee reference number
IR.IAU.TABRIZ.REC.1399.146

Health conditions studied

1

Description of health condition studied
Specific learning disability
ICD-10 code
یادگیری
ICD-10 code description
F81.0

Primary outcomes

1

Description
Behavioral brain systems
Timepoint
Before and after the intervention
Method of measurement
questionnaire

2

Description
Dark personality traits
Timepoint
Before and after the intervention
Method of measurement
questionnaire

3

Description
قبل و بعد از مداخله
Timepoint
Before and after the intervention
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Transcranial Direct-Current Stimulation (tDCS) is a technique used to

modify and modify brain function, which is now used as a healthy and effective procedure to treat most neurological conditions and even in medicine. Electrical Stimulation Technique A neural modification method that transmits electric current to a specific point in the skull over a very specific period of time, including an anode electrode that stimulates the nervous system and a cathode electrode that inhibits the nervous system. To stimulate the centers of the prefrontal cortex, this is responsible for controlling the complex movements of the anode electrode on the prefrontal cortex and the cathode electrode on the opposite shoulder (according to the 10-20 EEG system). Participants sit in a comfortable chair in a quiet room with no other sensory stimuli. Electrical stimulation of the brain by tDCS (Canadian-made Mind-Alif brand device) was instilled in students in a steady stream with a constant current of between 1.5 and 2 mA (intensity appropriate for client tolerance). Every other day and for 10 days, using a pair of 5×5 cm rubber electrodes covered with artificial sponge soaked in a normal saline solution and placed in the desired areas.

Category

Treatment - Other

2

Description

Control group: They did not receive any treatment.

Category

Treatment - Other

3

Description

Intervention group: Cognitive therapy based on a compassionate mind: Compassionate mind training is one of the psychotherapy methods in which empathy, empathy, compassion, acceptance and tolerance, responsibility and a sense of worth are taught (Gilbert, 2009). This treatment is designed by the research activities of Gilbert (2005). In the present study, this treatment method will be held in 12 sessions, each session for 90 minutes and in groups once a week.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bozorgmehr Counseling Center

Full name of responsible person

Dr. Seyed Mahmoud Tabatabai

Street address

Bozorgmehr Counseling Center, in front of Education District 2, 17 Shahrivar Jadid St., Tabriz City.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Mazandaran

Full name of responsible person

Alireza Khasali

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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

University of Mazandaran

Proportion provided by this source

5

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

Mazandaran University of Medical Sciences

Full name of responsible person

Hamidreza Dehghan

Position

student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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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
There is no need to publish data.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The collected data were analyzed using SPSS-23 software.
When the data will become available and for how long

To whom data/document is available
Supervisors, consultants and referees
Under which criteria data/document could be used

From where data/document is obtainable
To the dissertation
What processes are involved for a request to access data/document
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Comments