Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Aug 2026

Effectiveness of transdiagnostic therapy based on the research domain criteria framework compared with treatment as usual and transcranial direct current stimulation for youth non-suicidal self-injury: A randomized controlled trial

Protocol summary

Study aim

Comparing the efficacy of a transdiagnostic therapy based on the research domain criteria framework (TTB-RDoC), with treatment as usual (TAU) and transcranial direct current stimulation (tDCS) in the treatment of youth nonsuicidal self-injury (NSSI)

Design

Clinical trial with control group, with parallel group, double-blind, randomized, phase 2 on 68 participants, SAS function rand software was used for randomization.

Settings and conduct

Place of study: Imam Hossein (AS), Ibn Sina Hospital, Waliasr (AS) Hospital, Mashhad; Study population: men between 18 and 30 years old with a diagnosis of non-suicidal self-harm; One-way blinding (participants were not aware of the design objectives)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primary DSM-5 diagnosis of NSSI; No usage of medication; Being at the age of 18-30 years old; Ability to participate in all assessment and treatment sessions. Exclusion criteria: Receiving a full course of pharmacotherapy or psychotherapy, within the past 5 years; Having psychiatric disorders and substance abuse within twelve months before screening; Current diagnosis of any mental disorder; Patient's opposition to collaboration

Intervention groups

Intervention group 1: Transdiagnostic therapy based on research domain criteria framework; Intervention group 2: transcranial direct current stimulation; Control group: treatment as usual (cognitive-behavioral therapy)

Main outcome variables

Compare the efficacies of (TTB-RDoC), with (TAU) and (tDCS) in the treatment of youth NSSI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171029037068N1**
Registration date: **2023-09-23, 1402/07/01**
Registration timing: **retrospective**

Last update: **2023-09-23, 1402/07/01**
Update count: **0**

Registration date

2023-09-23, 1402/07/01

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

farrokhi.hossein@mail.um.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-02, 1401/03/12

Expected recruitment end date

2022-08-05, 1401/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effectiveness of transdiagnostic therapy based on the research domain criteria framework compared with treatment as usual and transcranial direct current stimulation for youth non-suicidal self-injury: A randomized controlled trial

Public title
Transdiagnostic therapy based on the research domain criteria framework for non-suicidal self-injury

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Primary DSM-5 diagnosis of non-suicidal self-injury (NSSI) No usage of medication Being at the age of 18-30 years old Speaking Persian fluently Ability to participate in all assessment and treatment sessions

Exclusion criteria:
Need for immediate medical treatment or the need for concurrent therapeutic interventions that would interfere with the treatment program Receiving a full course of pharmacotherapy or psychotherapy, within the past 5 years Having psychiatric disorders and substance abuse (except tobacco users) within twelve months before screening Current diagnosis of any mental disorder A history of epilepsy Significant head injury or other neurological conditions, or brain surgery A history of adverse reaction to tDCS or having a sensitive scalp Patient's opposition to collaboration at any time of research Having serious thoughts about suicide

Age
From **18 years** old to **30 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
The simple randomization method was performed with the help of SAS software. In this way, each subject is registered in the software and a code is defined for each person. Then, by means of the software, they are randomly divided into three intervention groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants assumed that all participants would receive the intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Ferdowsi University of Mashhad

Street address
No. 10, Kalantari Blvd, Azadi Sq, Mashhad.

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Mashhad

Province
Razavi Khorasan

Postal code
09188355827

Approval date
2023-03-14, 1401/12/23

Ethics committee reference number
IR.UM.REC.1400.033

Health conditions studied

1

Description of health condition studied
Nonsuicidal self-injury

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Nonsuicidal self-injury

Timepoint
At baseline (pre-treatment), at 8th weeks (post-treatment), and after a 12-month post-treatment followup period.

Method of measurement
Inventory of statements about self-injury (ISAS), Structured clinical interview for DSM-5 disorders-clinician version

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: TTB-RDoC is a group intervention program for youth with NSSI (18–30-year-olds). It comprises 16 sessions (twice a week) of 45 min. This program consists of four modules. Module 1: Emotion

Regulation, Module 2: Cognitive Training, Module 3: Behavioral Activation and Module 4: Interpersonal Skills. Each module is held in 4 sessions.

Category

Behavior

2

Description

Intervention group 2: The tDCS will deliver using two 5×7 cm electrodes covered in saline-soaked sponges. Electrodes were placed with a bipolar-balanced montage with anode on the right DLPFC (F4) and cathode on the left DLPFC (F3) according to EEG 10-20 system. tDCS was administered in a daily session lasting 20 min for 5 working days/week for 4 consecutive weeks

Category

Treatment - Devices

3

Description

Control group: TAU protocol includes new techniques from 'third' wave CBT, Acceptance Commitment Therapy (ACT) and Dialectical Behavior Therapy (DBT). The manual is evidence based and focuses on a flexible and formulation driven model to direct treatment in 15 sessions of 45 minutes and 2 sessions a week for young people. Cognitive-behavioral methodological techniques were performed in 5 sessions, including correction of cognitive errors, emotional regulation, and behavioral activation. Treatment techniques of commitment and acceptance in 5 sessions and included cognitive breakdown, self as background, conscious mind, values and acceptance and commitment.Dialectical behavioral therapy techniques in 5 sessions and included mindfulness, distress tolerance, interpersonal effectiveness and emotion control.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Hossein Farrokhi

Street address

Vahid 3, Vahid Avenue, Tollab Blvd., Mashhad

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Recruitment center

Name of recruitment center

Ebn Sina Hospital

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Ferdowsi University of Mashhad

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
Ferdowsi University of Mashhad

Full name of responsible person
Imanollah Bigdeli

Position
Professor of Psychology Department

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All potential data can be shared after de-identifying individuals

When the data will become available and for how long
The data will become available 3 months after the results are published

To whom data/document is available
There is no specific limitation and it will be accessible to all researchers in this field

Under which criteria data/document could be used

Currently, there are no special conditions and restrictions

From where data/document is obtainable

We will respond to applicants via email

What processes are involved for a request to access data/document

The aims and objectives of the research should be clearly explained.

Comments