

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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

+98 51 3868 0738

##### 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.

##### City

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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**2**

**Recruitment center**

**Name of recruitment center**

Ebn Sina Hospital

**Full name of responsible person**

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No 18, Moosavi GHoochani Blvd., Horre Ameli Blvd., Mashhad

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**3**

**Recruitment center**

**Name of recruitment center**

Valiasr Medical Clinic

**Full name of responsible person**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ferdowsi University of Mashhad

**Full name of responsible person**

Mohammadreza Hosseindokht

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housain@um.ac.ir

**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 scientific inquiries

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**Position**

Phd student

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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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**