# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Oct 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)

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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

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**2**

**Recruitment center**

**Name of recruitment center**

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**Recruitment center**

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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**
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**
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**Position**
Professor of Psychology Department

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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**