

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effect of Cognitive-behavioral therapy and Emotion-focused therapy on reducing self-injury function in adolescents

Protocol summary

Study aim

Comparison of the effect of Cognitive behavioral therapy and Emotion-based therapy on reducing the reliance on self-injurious functions in adolescents with self-injurious behavior.

Design

The clinical trial has two treatment groups and a control group with parallel, unblinded, randomized groups on 45 patients and outcome assessment.

Settings and conduct

To carry out the research, it will be referred to the second secondary schools of Semnan city. The sample size in this research will include 45 people who will be randomly divided into three groups of 15 people. In the next stage, these 3 groups of 15 people will be randomly assigned as the Emotion-focused experimental group, the Cognitive-behavioral experimental group, and the control group. 11group (45-minute) intervention sessions (2 sessions per week) will be held for the emotional-focused testing group. Also, 15 group intervention sessions will be held for the Cognitive behavioral testing group. The research will be carried out at the Empathy Counseling Center of Azad University, Semnan.

Participants/Inclusion and exclusion criteria

Entry requirements: Teenagers between the ages of 14 and 18 who have harmed their body for 5 days or more in the past year. Injuring the body without suicidal intent. Conditions of non-entry: no other mental illness No drug addiction

Intervention groups

The sample size in this research will include 45 people who will be randomly divided into three groups of 15 people and will also be randomly assigned. A group of 15 people from Emotion-focused intervention, a group of 15 people from Cognitive behavioral intervention and a group of 15 people will be considered as the control group.

Main outcome variables

Independent variable: cognitive behavioral therapy and

emotional therapy Dependent variable: self-injury and self-injury functions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220705055377N1**

Registration date: **2022-08-13, 1401/05/22**

Registration timing: **retrospective**

Last update: **2022-08-13, 1401/05/22**

Update count: **0**

Registration date

2022-08-13, 1401/05/22

Registrant information

Name

kiana kheirkhah

Name of organization / entity

The azad university of semnan

Country

Iran (Islamic Republic of)

Phone

+98 21 3344 8679

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k.kheirkhah74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-25, 1401/05/03

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of Cognitive-behavioral therapy and Emotion-focused therapy on reducing self-injury function in adolescents

Public title
Comparison of the effect of Cognitive-behavioral therapy and Emotion-focused therapy on reducing self-injury function in adolescents

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Adolescents between the ages of 14 and 18 who have harmed their body in 5 days or more in the last year. Injuring the body without suicidal intent. This behavior has resulted in clinically significant distress in interpersonal and academic functioning and other important areas.
Exclusion criteria:
Not having any other mental illness other than non-suicidal self-harm. Not taking medicine during the research period No drug addiction Absence of acute and chronic diseases or events such as parental divorce in the previous year No death of loved ones in the last 6 months

Age
From **14 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomness is done by lottery method. In this method, a code or number is prepared for each member of the sample, then the numbers are written on pieces of paper. The pieces of paper are placed in a container and mixed well, then 15 people are selected for the first treatment, 15 people for the second treatment and 15 people for 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

Ethics Committee of Semnan Azad University

Street address

Islamic Azad University, University Town, Semnan, Iran

City

semnan

Province

Semnan

Postal code

۳۵۱۳۱۳۷۱۱۱

Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.IAU.SEMNAN.REC.1401.007

Health conditions studied

1

Description of health condition studied

Non-suicidal self-injury

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The percentage of people who have self-harmed at least 5 times in the past year.

Timepoint

Measuring self-injury at the beginning of the study and after receiving interventions at the end of the study

Method of measurement

Self-injury questionnaire of Sanson (SHI)

2

Description

The percentage of people who have self-harm functions

Timepoint

Measuring self-injury at the beginning of the study and after receiving interventions at the end of the study

Method of measurement

Klonsky and Glenn self-injury functions questionnaire

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group1: Intervention group 1: The program of cognitive behavioral therapy of self-injury is presented based on a flexible system and model. The treatment techniques of this treatment are effective on teenagers and young people who self-injure. This treatment has 13 sessions of 45 minutes and 51 pages of worksheets are considered for assignments (Tyler et al., 2015). First session :Educating teenagers about what self-injury is (first component: What is self-injury?) and providing the necessary information regarding the functions of self-injury and the timeline of self-injury behaviors (second component: the function of self-injury)second session:Identifying specific treatment problems and goals (third component: problems and goals). Introducing cognitive behavioral therapy and explaining how this therapy can be useful for self-harm (fourth component: What is cognitive behavioral therapy and how can it help my self-harm). Empowering teenagers to identify and understand their feelings (the fifth component: recognizing feelings).third session:Adolescents come to understand how self-harm has dominated their lives (sixth component: relationships and strengths). We prepare the teenager to be motivated to change (seventh component: Are you ready to change?). Second stage: treatment planThe second stage of treatment has two main parts. In the first part, the thoughts, feelings and behaviors of the patient are discussed, and in the second part, the focus of the treatment is on solutions.fourth Session:This meeting has two parts. First, a review of the emotional memories of the fifth component is done, then if the teenager is in a depressed mood, activity planning is done. If activity planning is not necessary because the teenager has engaged in healthy activities during the week or the lack of activity is not the cause of depression, then the ninth component, the help triangle, can be used.By examining the emotional memories, we deal with the adolescent's feelings and examine the intensity and frequency of the feeling and discuss it (Eighth Component). We identify and examine the relationship between lack of feeling of success and lack of activity, contempt and lack of pleasure. We want fun activities to be done by examining the lost feelings during the week (continuation of component 8).fifth meeting:Introducing the help triangle (ninth component). Introduction and identification of negative spontaneous thoughts like help (tenth component).The sixth session:To identify negative spontaneous thoughts, two-dimensional thinking (black and white) and cognitive petrification, we use challenging thoughts and finding evidence for and against thoughts (11th component).The seventh session:Identification of fundamental beliefs (the twelfth component).The eighth session:Through cognitive-behavioral formula, we make teenagers understand their

behavioral patterns. We use the collection of past and present experiences, fundamental beliefs and current maintaining factors for this purpose (the 13th component).The ninth session:A decision is made about what coping strategy is suitable for the teenager (fourteenth component). Introducing the concept of problem solving (15th component).Tenth session:Three techniques that help to manage tension and positive interaction are discussed (components 16, 17, and 18: self-expression training, anger management, and self-care).The eleventh session:Training to deal with fear and situation (19th component).The second meeting:Teaching emotions control (riding waves), self-awareness and self-acceptance and self-soothing to teenagers (components 20, 21 and 22).Thirteenth session:Considering coping alternatives for self-harm and summarizing the coping strategies that have been discussed during the previous sessions (component 23).

Category

Treatment - Other

2

Description

Intervention group2: Intervention group 2: In this research, emotion-oriented therapy means the number of nine intervention sessions (Greenberg, 2015). Intervention group 2: In this research, emotion-oriented therapy means the number of nine intervention sessions (Greenberg, 2015). The first session: introducing and presenting the concepts of emotion-oriented therapy. Making the clients aware of their emotions according to the physical sensations and the conceptualization of the case done by the therapist. The second session: the client welcomes and accepts his emotional experience. If necessary, emotion regulation is done by the therapist. The third session: description of feelings in the form of words by the client and presentation of emotional notebook assignment. The fourth session: discovery of primary and secondary emotions by the client with the help of the therapist. The second stage of treatment: quitting. They can trust the feeling they have reached as a good source of information or not, whether this feeling is useful or not, finally whether it is necessary to change this feeling or not (Greenberg, 2015). Fifth session: Evaluation Regarding whether the primary emotion is a healthy or unhealthy response. The sixth session: Helping the client to identify the negative voice associated with unhealthy emotion. Access to alternative healthy emotional responses Session 9: Creating a new narrative to challenge destructive beliefs and opinions about self becoming

Category

Treatment - Other

3

Description

Control group: Control group: A group of 15 people will be considered as a control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Education of Semnan City

Full name of responsible person

Kiana Kheirkhah

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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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Web page address**Grant name**

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Semnan Islamic Azad University

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**

Semnan Azad University

Full name of responsible person

kiana kheirkhah

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Islamic Azad University, University Town, Semnan,
Iran

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Person responsible for scientific inquiries

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Position

student

Latest degree

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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)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Part of the data, such as information on the main outcome, can be shared.

When the data will become available and for how long

The access period starts 6 months after the announcement of the results

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

-

From where data/document is obtainable

Kiana Khairkhah k.kheirkhah74@gmail.com
09124313825

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

A written letter from the educational and academic institution should be sent to the email with the university seal.

Comments