

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of acceptance and commitment therapy on the emotional regulation, psychological flexibility, irritability, and emotional numbness in children of people with post-traumatic stress disorder.

Protocol summary

Study aim

Determining the effect of acceptance and commitment therapy on the components of emotional regulation, psychological flexibility, irritability and emotional numbness in children of people with post-traumatic stress disorder.

Design

The study design consists of two groups ACT and control that the members of each group are identified after random allocation using statistical tables and enter the group. The method of simple random allocation is based on the list of individuals and the total sample size is 70 people.

Settings and conduct

Conducting research and sampling and contact with individuals is the office of the Martyr and Veterans Affairs Foundation of Yazd (Counseling and Psychological Services Office). Initially, after determining the control and experimental group, an introductory session will be held for each group, which will provide general explanations about informed satisfaction, research ethics, and the overall design process and Then, after performing the pre test, each group enters the meeting process according to a specific protocol. Finally, after the post test, we will have a 1-month follow-up for the experimental group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. People 15 to 20 years old 2. The father with PTSD is alive 3. Children up to the age of 20 have been in the family environment. 4. There is no history of mental illness and hospitalization 5. People in the pre test have a score higher than the cutoff.

Exclusion criteria: 1. Having a physical, mental illness or long hospital stay while conducting research 2. Changes in the structure of life such as marriage during research 3. Leaving treatment sessions 4. Lack of adherence to treatment tasks

Intervention groups

Acceptance and Commitment Therapy Group (ACT) and control group

Main outcome variables

Emotion regulation; Psychological flexibility; Irritability and emotional numbness.

General information

Reason for update

Corrected due to a typo in determining the sample size.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210708051815N1**

Registration date: **2021-08-07, 1400/05/16**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-09, 1400/05/18**

Update count: **1**

Registration date

2021-08-07, 1400/05/16

Registrant information

Name

Amir masoud Mirbagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3823 6421

Email address

goosheamm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2021-08-16, 1400/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acceptance and commitment therapy on the emotional regulation, psychological flexibility, irritability, and emotional numbness in children of people with post-traumatic stress disorder.

Public title

The effect of ACT treatment on the psychological components of children of people with PTSD.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

People aged 15 to 20 years. Also, the person with post-traumatic stress disorder (their fathers) in the family should still be alive. Children must have lived with a person with PTSD until the age of 20. Also, people should not have a history of mental illness or hospitalization due to mental health problems. In addition, in anticipation of the intervention, these people should have a higher score than the cut-off in the research tools, which indicates the presence of that sign in the person. The cut-off scores for each device are specified in the description of the tool.

Exclusion criteria:

Having a physical or mental illness during the investigation that leads to hospitalization and interruption of the ACT treatment process. Changes in the structure of life, such as marriage or divorce during research. Leave treatment sessions. Lack of adherence to treatment tasks.

Age

From **15 years** old to **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the intervention group was coded with the letter A and the control group with the letter B, and then using the website www.sealedenvelope.com/simple-randomiser/v1/lists randomization list was prepared by selecting a sample size of 70 (two groups of 35) and permuted block randomization method (block size=4). Then, through the obtained randomization list, the subjects included in the study will be assigned to one of the two groups A or B. For example, suppose that in the

first four blocks, the permutation method is ABBA, so the first and fourth samples will be assigned to group A and the second and third samples to group B and the same will continue until the last sample (70th person).

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Kashan, I.R. Iran

City

Kashan

Province

Isfahan

Postal code

8715973474

Approval date

2021-07-07, 1400/04/16

Ethics committee reference number

IR.KAUMS.REC.1400.018

Health conditions studied**1****Description of health condition studied**

Secondary injury in children of people with post-traumatic stress disorder.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Emotional regulation

Timepoint

Once before the intervention and again after the intervention and also for the third time, one month after the intervention.

Method of measurement

Using the Gretz and Roemer Emotion Difficulty Scale Questionnaire (DERS)

2

Description

Psychological flexibility

Timepoint

Once before the intervention and again after the intervention and also for the third time, one month after the intervention.

Method of measurement

Using Acceptance and Practice Questionnaire - Second Edition (AAQ-II)

3

Description

Irritability

Timepoint

Once before the intervention and again after the intervention and also for the third time, one month after the intervention.

Method of measurement

Using the irritability questionnaire of Crick et al

4

Description

Emotional numbness

Timepoint

Once before the intervention and again after the intervention and also for the third time, one month after the intervention.

Method of measurement

Using Post-Impact Disorder Index (PCL) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: for the experimental group Specific protocol of treatment based on acceptance and commitment that is done in 8 sessions of 60 to 90 minutes per week and in group sessions. This protocol is known as the Walster and Westerop protocols. Description of the intervention protocol: In this study, a treatment protocol based on acceptance and commitment was used for post-traumatic stress disorder Walster and Westerop, which is a brief description of 8 treatment sessions as follows. The first session of treatment: 1. Therapeutic contract. 2. Establish a therapeutic relationship. 3. Introducing people to the subject of research and treatment and answering questionnaires. The second session of treatment: 1. Start by practicing mindfulness. 2. Review the last session. 3. Discover and examine a person's personal methods and evaluate their impact (creating creative frustration). 4. Talking about the temporary and ineffectiveness of avoidance methods. 5. Identify the cost of efforts to change negative emotions and thoughts. 6. Using

metaphors and giving hope to relieve helplessness. 7. Receive feedback and assign homework, creative helplessness. Third session of treatment: 1. Begin by practicing mindfulness. 2. Review the last session. 3. Assisting clients in identifying ineffective control strategies and realizing their futility. 4. Accepting painful personal events without conflict with them. 5. Getting feedback and doing homework is self-control, not a solution. The fourth session of treatment: 1. Start by practicing mindfulness. 2. Review the last session. 3. Introduce desire as an alternative to control. 4. Talking about cognitive fusion and understanding the barriers to desire. 5. Receive feedback and assign homework, acceptance. Fifth session of treatment: 1. Start by practicing mindfulness. 2. Review the last session. 3. Introduce cognitive fusion and make changes in language rules. 4. Receive feedback and assign homework, cognitive inconsistency. Sixth session of treatment: 1. Start by practicing mindfulness. 2. Review the last session. 3. Explain the concepts of role and context, see yourself as context and make contact with yourself. 4. Receive feedback and assign homework, yourself as an observer. Seventh session of treatment: 1. Start by practicing mindfulness. 2. Review the last session. 3. Helping clients identify values and valuable lives, identify values and goals. 4. Receive feedback and assign homework, fill in the value form.

Category

Behavior

2

Description

Control group: Control group: For the control group, the same number of sessions were held, but they did not use the components of ACT treatment, and research was conducted using the 8-session protocol of life skills training for adolescents.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of the Martyr and Veterans Affairs Foundation of Yazd

Full name of responsible person

Amir Masoud Mirbagheri

Street address

Riazi Square - Niloufar Alley 10 - First door

City

Yazd

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Yazd

Postal code

8915887647

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Email

goosheamm@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Kashan University of Medical Sciences

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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

Kashan University of Medical Sciences

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

Kashan University of Medical Sciences

Full name of responsible person

Amir Masoud Mirbagheri

Position

Graduate student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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City

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Amir Masoud Mirbagheri

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Amir masoud Mirbagheri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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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

Due to legal restrictions in the Martyr Foundation

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available