Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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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
Isfehan
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
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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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Province
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Fax
Email
goosheamm@gmail.com
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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Person responsible for scientific inquiries

Contact
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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
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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