Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effectiveness of emotion-oriented cognitive behavioral therapy on emotional and behavioral problems of elementary school girl students with symptoms of emotional problems

Protocol summary

Study aim

Determining the effectiveness of (ECBT) therapy on emotional and behavioral problems of elementary school girl students with symptoms of emotional problems

Design

The clinical trial has control and experimental groups, with parallel groups, targeted selection, and with 30 statistical samples that were used to select the samples from the Toronto Children's Emotional Dysfunction Questionnaire.

Settings and conduct

This study was semi-experimental in terms of the nature of the study and the method of data collection in the school environment in zabol , and during 16 sessions of 60 minutes, the program testing group (ECBT) was trained.

Participants/Inclusion and exclusion criteria

Inclusion criteria of Female students who have the following: 1- Obtaining a score above 60 on the Toronto Children's Emotional Dysfunction Scale (AQC) 2-Being 7-12 years old Exclusion criteria:1- Lack of consent to continue participating in the meetings 2- The occurrence of unforeseen events

Intervention groups

In this plan, there is an experimental group and a control group, it is the independent variable (emotional cognitive behavioral therapy) and the dependent variable (emotional and behavioral problems).This intervention aims to investigate the effectiveness of emotion-oriented cognitive behavioral therapy or its side effects on emotional and behavioral problems. In this study, before starting the treatment, both research groups answer the Achenbach Children's Behavior Inventory. Then, the experimental group was trained in emotion-oriented cognitive behavioral therapy (ECBT) for 16 sessions of 60 minutes. In the control group, the independent variable is not applied.

Main outcome variables

This study shows that this treatment can be implemented individually and in groups in the school environment ; low mood; My symptoms are physical; Painful feelings are negative towards oneself and improve emotional control .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240922063112N1**
Registration date: **2024-10-06, 1403/07/15**
Registration timing: **retrospective**

Last update: **2024-10-06, 1403/07/15**
Update count: **0**

Registration date

2024-10-06, 1403/07/15

Registrant information

Name

Elham Sargolzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3223 5199

Email address

elhamsrg544@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-19, 1403/06/29

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

2024-09-19, 1403/06/29

Actual recruitment end date

2024-09-22, 1403/07/01

Trial completion date

empty

Scientific title

The effectiveness of emotion-oriented cognitive behavioral therapy on emotional and behavioral problems of elementary school girl students with symptoms of emotional problems

Public title

The effectiveness of emotion-oriented cognitive behavioral therapy on emotional and behavioral problems

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Score above 60 on the Toronto Children's Emotional Dysfunction Scale Having the age of 7 to 12 years Informed consent to participate in meetings

Exclusion criteria:

Dissatisfaction to continue participating in meetings Unforeseen events (hospitalization, illness, etc.) Failure to participate in more than three treatment sessions

Age

From **7 years** old to **12 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Islamic Azad University - Zahedan Branch (Research Ethics Committee)

Street address

Daneshgah Blvd., Zahedan town

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9861645337

Approval date

2024-09-14, 1403/06/24

Ethics committee reference number

IR.IAU.ZAH.REC.1403.048

Health conditions studied

1

Description of health condition studied

Anxiety; depression; seclusion; physical complaints; social problems; thinking problems; attention problems; breaking the law; Aggressive behaviors

ICD-10 code

F38

ICD-10 code description

Other mood [affective] disorders

Primary outcomes

1

Description

Score 8 factor of anxiety-depression, isolation-depression, physical complaints, physical problems, social problems, thinking problems, attention problems, ignoring rules, and aggressive behavior in the Achenbach test (CBCL).

Timepoint

1-2 and 3 months after starting treatment sessions

Method of measurement

Achenbach Child Behavior Inventory (CBCL)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: This treatment program consists of 16 sessions designed to treat children and adolescents with emotional disorders in children. The training program consists of two parts: the first 8 sessions of the training part and the second 8 sessions of the training part (confrontation). Also, meetings are scheduled between the therapist and the parent (or one or more of the child's significant others) between therapy sessions. In the first part of the treatment, different emotions are introduced to the child,

which starts with the awareness of emotional reactions and leads to the recognition of specific anxiety reactions. The second part of the treatment is dedicated to the use and practice of the new skills acquired in situations that have been increasingly anxiety-provoking or situations that arouse other emotions. Treatment of the child's orientation towards the treatment, introducing the emotion of "joy". The second session: a session to help identify the child's feeling of anxiety and start identifying physical responses, introducing the use of the workbook for introducing the emotion "discomfort and sadness". The third session: an overview of the feeling of anxiety and physical clues and identifying the response. The child's physical actions, introducing the emotion of "anger". Fourth session: meeting with parents to provide more information about treatment for parents and to encourage their participation. The fifth session: introducing relaxation training, introducing the emotion of "pride and pride". The sixth session: introducing the role of anxious self-talk, introducing the feeling of "guilt". Problem for managing anxiety, introduction of "jealousy". Eighth session: Introduction of self-evaluation and self-rewarding for success in managing anxiety, review of skills and their formation in the 4-step plan "Worry". Session 9: Session with Parents in order to provide more information on treatment for parents and encourage their cooperation. The 10th session: practicing the 4-step model of the worried plan in less anxiety-provoking situations (FEAR) including F (n): fear and worry E (g): waiting for unfortunate events or trouble A (r, a) behaviors and thoughts Contributor, R (n): results and consequences. 11th session: continuing to practice the 4-step model in less anxiety-provoking situations, practicing coping with other mildly exciting experiences. 12th session: applying coping skills in the situation Imaginary and real things that cause moderate anxiety. Thirteenth session: Continuation of actual practice of the 4-step model in situations that evoke moderate levels of anxiety and other emotions. Fourteenth session: Application of the 4-step model in imaginary situations that evoke high levels of anxiety. Fifteenth session: Practicing coping skills in real situations that provoke high levels of anxiety and other emotions. The 16th session: Continuation of practicing coping skills in situations with high anxiety, a summary review of the treatment plan, post-test and saying goodbye to the participants.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Yaganeh Girls' Primary School
Full name of responsible person
Elham sargolzaei
Street address
Taleghani St
City
Zabol
Province
Sistan-va-Balouchestan
Postal code
9861645337
Phone
+98 54 3223 5199
Email
elhamsrg544@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Shirin shahreki
Street address
Daneshgah Blvd
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9861645337
Phone
+98 54 3223 5199
Email
elhamsrg544@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Islamic Azad University
Full name of responsible person
Elham sargolzaei
Position
student
Latest degree
Bachelor
Other areas of specialty/work

Medical Education

Street address
NO2, Iraj afshar Ave, modares Blvd. Zabol

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9861645337

Phone
0985432235199

Email
elhamsrg544@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Elham sargolzaei

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Medical Education

Street address
NO2, Iraj afshae Ave, Modares Blvd

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
9861645337

Phone
+98 54 3223 5199

Email
elhamsrg544@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Elham Sargolzaei

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Medical Education

Street address
NO.2, Iraj afshar Ave, Modares Blvd

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
9861645337

Phone
+98 54 3223 5199

Email
elhamsrg544@gmail.com

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

Statistical Analysis Plan
Not applicable

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
Not applicable