Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of unified protocol for transdiagnostic treatment on improving psychopathological symptoms and quality of life in children with emotional disorders

Protocol summary

Study aim
Effectiveness of unified protocol for transdiagnostic treatment on improving psychopathological symptoms and quality of life in children with emotional disorders

Design
Clinical trial with control group, with parallel group, one-sided blind with randomized group

Settings and conduct
Treatment is individual or group and with the presence of one or both parents. Children are encouraged to learn the skills of this protocol, which are developed and organized around the identification of emotions and awareness of thoughts and emotions and the experience of emotions to solve the puzzle of their emotions. The place of study is the first and second elementary schools of Kermanshah city.

Participants/Inclusion and exclusion criteria
Include Criteria; Age group 8 to 13 years. Early diagnosis of anxiety disorders or depression. Consent of the child and the parent(s) Exclude Criteria:

Intervention groups
The intervention group receives 15 weekly sessions of individual 50-minute treatment, in schools and by a trained therapist. The presence of one or both parents in the treatment process is mandatory. Assessments will be performed before the intervention, after the intervention and 2 months after the intervention. The control group receives psychological training. Psychological training, relaxation techniques are provided to reduce the level of stress and stress. The control group will receive integrated meta-diagnostic therapy (UP_C) after the end of the study.

Main outcome variables
Revised Child Anxiety and Depression Scale(RCADS) Pediatric Quality of Life Inventory Achenbach Behavior Inventory Score (CBCL)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180421039369N5**
Registration date: **2021-01-11, 1399/10/22**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-11, 1399/10/22**
Update count: **0**

Registration date
2021-01-11, 1399/10/22

Registrant information

Name
Nasrin Jaberghaderi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3427 4622

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nasrin.jaberghaderi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-10, 1399/08/20

Expected recruitment end date
2021-01-19, 1399/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of unified protocol for transdiagnostic treatment on improving psychopathological symptoms and quality of life in children with emotional disorders

Public title
Effectiveness of unified protocol for transdiagnostic treatment on improving psychopathological symptoms and quality of life in children with emotional disorders
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Existence of primary diagnosis of anxiety disorders or depression Consent of the child and the parent(s) to participate in the treatment and research process Age 8 to 13 years Ability of parents and children to read, write and speak Persian
Exclusion criteria:
Recurrence of psychological sign and symptoms before the start of the treatment process and after sampling Simultaneous infection with another disease Therapy with medicine or ECT
Age
From **8 years** old to **13 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
After selecting the samples based on entry criteria, the random sample of the samples is sampled in a sealed envelope. Ultimately, people are assigned to the control and test group
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding will only happen for the statistical analyst and data collector. In this way, after the assessment and disease, the sample is entered into the study and for each assessment or evaluation by another person who is not in the process of treatment and study. Information and data also will be coded and given to the statistical analyst for any necessary measurements without any personal details.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences
Street address
In front of Taleghani Hospital, Naft square
City
Kermanshah
Province
Kermanshah
Postal code
56423-22222
Approval date
2020-11-04, 1399/08/14
Ethics committee reference number
IR.KUMS.REC.1399.814

Health conditions studied

1

Description of health condition studied
Emotional disorders in childeren
ICD-10 code
F93
ICD-10 code description
Emotional disorders with onset specific to childhood

Primary outcomes

1

Description
Children's Anxiety and Depression score
Timepoint
pre-test, post-test, follow-up
Method of measurement
Revised Children's Anxiety and Depression Scale

2

Description
children's quality of life score
Timepoint
pre-test, post-test, follow-up
Method of measurement
Children's Quality of Life Questionnaire

3

Description
Child Behavior Checklis -Akhenbakh
Timepoint
pre-test, post-test, follow-up
Method of measurement
Child Behavior Checklist of scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Experimental or intervention group, treatment plan will be done in 15 sessions of individual therapy (50 minutes per session) by the researcher and psychotherapist who has received the necessary training in the implementation of this treatment.The presence of one or both parents in the treatment process is mandatory.
Category
Rehabilitation

2

Description
Control group: The number of members of the control group is 15 people. Participants are trained during the treatment sessions of the experimental group. These trainings make children and their parents aware of the nature of the problems they are involved in, if necessary and in case of aggravation of symptoms, along with psychological trainings, relaxation techniques to reduce the level of stress and psychological stress. Members of the control group will receive integrated meta-diagnostic therapy (UP_C) after the end of the study.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Education of Kermanshah Province
Full name of responsible person
Nasrin JaberGhaderi
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Department of Education of Kermanshah province,Farhangian1 Blv, Shahid Mostafa Emami Avenu, Kermanshah, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Reza Khodarahmi
Street address
Kermanshah University of Medical Science, Sepah Square,Shahid Beheshti Blv, Kermanshah,Iran.
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Pardis Jamshid Mofid
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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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
Undecided - It is not yet known if there will be a plan to make this available

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

Analytic Code
Not applicable

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