

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Emotional Regulation Training Based on Grass's Model on anxiety of parents of children with cancer at the Pediatric Center of Qods in 2018

Protocol summary

Study aim

Effect of Emotional Regulation Training Based on Grass's Model on anxiety of parents of children with cancer at the Pediatric Center of Qods in 2018

Design

The parents will be divided into two groups of control and test by random assignment using the random allocation rule (allocation of paired or individual scores to selected cases and simple lottery). The sample size for each group is 23, and a total of 46 people will be included in the study. Personal information and Beck Anxiety Inventory will be used to analyze the data.

Settings and conduct

Based on various researches, emotional regulation, in addition to positive effects on mental well-being, improves physical health. This study is done at the Pediatric Center of Qods and on the parents of children referred in available. Blinding has not been done in this study.

Participants/Inclusion and exclusion criteria

Having literacy; Availability of parents; Ability to speak and understand Persian language; Not to receive other psychiatric interventions; No anti-anxiety drugs or other anxiety treatments. Unwillingness to continue cooperation; Absence in a training place at least 2 sessions; Participate in other training programs to control anxiety.

Intervention groups

At first, the Beck Anxiety Test will be taken of two groups of test and control (pre-test). Education Based on Grass Modeling will hold eight sessions for 75 minutes in person and group for the test group and the control will receive routine center actions. Finally, the level of anxiety will be measured by This test (post-test) monthly for six months and the effectiveness of the intervention method will be considered.

Main outcome variables

The effect of emotional Regulation Training Based on Grass's Model in the study group; Measure the anxiety in this groups after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190314043055N1**

Registration date: **2019-06-30, 1398/04/09**

Registration timing: **retrospective**

Last update: **2019-06-30, 1398/04/09**

Update count: **0**

Registration date

2019-06-30, 1398/04/09

Registrant information

Name

Sedigheh Bahrami Nasir Mahaleh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3257 3208

Email address

s.bahramin@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2018-12-21, 1397/09/30

Trial completion date

2019-06-21, 1398/03/31

Scientific title

Effect of Emotional Regulation Training Based on Grass's Model on anxiety of parents of children with cancer at the Pediatric Center of Qods in 2018

Public title

Effect of Emotional Regulation Training Based on Grass's Model on anxiety of parents of children with cancer at the Pediatric Center of Qods in 2018

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Complete written consent form Having reading and writing skills The availability of parents of children Ability to speak and understand Persian language Not to receive other psychiatric interventions No anti-anxiety drugs or other anxiety treatments

Exclusion criteria:

Unwillingness to continue cooperation Absence in a training place at least 2 sessions Participate in other training programs to control anxiety

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60**Actual sample size reached: **46****Randomization (investigator's opinion)**

Randomized

Randomization description

Parents will be divided into two groups by random assignment using the Random Allocation Rule (assigning couple or individual scores to selected files and then simple lottery) to the control and test groups.

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 Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2018-09-16, 1397/06/25

Ethics committee reference number

IR.QUMS.REC.1397.123

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

The effect of Emotional Regulation Training based on Grass's Model on anxiety of parents of children with cancer

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

Effect of Emotional Regulation Training Based on Grass's Model on anxiety of parents of children with cancer

Timepoint

Eight sessions. 75 minutes per session in person and group for the test group

Method of measurement

Beck Anxiety Inventory

Secondary outcomes**1****Description**

Measure of anxiety in parents of children with cancer after intervention

Timepoint

Monthly for 6 months

Method of measurement

Beck Anxiety Inventory

Intervention groups**1****Description**

Intervention group: Complete Beck Anxiety Test

Questionnaire (pre-test) by parents of children with cancer. Holding 8 training sessions based on the Grass model for 75-minute in each session in person and group. Measure anxiety of parents of children with cancer by Beck Anxiety Inventory questionnaire in monthly for 6 months (post-test)

Category

Behavior

2

Description

Control group: Complete Beck Anxiety Test Questionnaire by parents of children with cancer (Pre-test). Get routine center actions. Measure anxiety of parents of children with cancer by Beck Anxiety Inventory questionnaire in monthly for 6 months (post-test).

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods Hospital

Full name of responsible person

Sedigheh Bahrami Nasir Mahaleh

Street address

Qods Medical Center, Qods Square, The first of Felestin shargi, Shahid Beheshti Blvd.,

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3415914595

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Email

s.bahramin@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Peymani

Street address

Deputy of Research, Mavedat Subside, Shahid Beheshti Blvd.,

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1391134156

Phone

+98 28 3333 7006

Email

research.dpt@qums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Personal

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Sedigheh Bahrami Nasir Mahaleh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 27, Sarve 15, Distinct 5, Mohammadieh

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Sedigheh bahrami nasir mahaleh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery
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Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Sedigheh Bahrami Nasir Nahaleh
Position
Nurse
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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

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

Data Dictionary

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