

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of counseling with cognitive-behavioral approach on anxiety and stress and quality of life of mothers of girls with early onset of puberty symptoms: a quasi-experimental study

Protocol summary

Study aim

The effect of cognitive counseling on anxiety and stress and quality of life

Design

A randomized controlled clinical trial with two parallel arms

Settings and conduct

This study will be performed in Tabriz primary schools on 60 mothers who have daughters with early puberty symptoms. Mothers will be evaluated according to the eligible criteria and if they have the criteria and desire to participate in the study, informed written consent will be obtained and initial assessments will be made. Participants will be assigned to the intervention and control groups using a random blocking method with the size of 4 and 6 blocks with a 1: 1 allocation ratio.

Participants/Inclusion and exclusion criteria

conditions of entrance: 1. Mothers having daughters with the onset of puberty praecox symptoms by the score 35-65 of anxiety in the Spielberger Anxiety Questionnaire and a score aver 21.8 in the Perceived Stress Questionnaire, has been studied. 2. Mothers with at least guidance school literacy 3. Having a daughter under 10 year old. Criteria for non-entry to study: 1. Having a history of mental disease according to the version of person himself 2- Experience of a severe mental crisis during the last 3 months, such as the death of relatives according to the version of person himself 3- taking the neuroleptics drugs by mothers 4- Mothers having physically and mentally other problems. 5- Participation in other similar studies

Intervention groups

For the intervention group, group counseling with a cognitive-behavioral approach will be held in 8 sessions of 45 to 60 minutes, once a week. An educational booklet is provided for the control group.

Main outcome variables

Average score of anxiety and stress and quality of life

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20110826007418N6**

Registration date: **2021-10-11, 1400/07/19**

Registration timing: **prospective**

Last update: **2021-10-11, 1400/07/19**

Update count: **0**

Registration date

2021-10-11, 1400/07/19

Registrant information

Name

Parisa Yavarikia

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

yavarikiap@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-12, 1400/07/20

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling with cognitive-behavioral approach on anxiety and stress and quality of life of mothers of girls with early onset of puberty symptoms: a quasi-experimental study

Public title

The effect of counseling with cognitive-behavioral approach on anxiety and stress and quality of life of mothers of girls with early onset of puberty symptoms

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having daughter with the age under 10 year Mothers with at least guidance school literacy Having a daughter with onset of pubertats praecox symptoms

Exclusion criteria:

Having a history of mental disease according to the version of the person himself. Experience of a severe mental crisis during the last 3 months, such as the death of relatives, according to the version of the person himself. using the neuroleptics drugs by mothers. Mothers who have had physically and mentally other problems Participation in other similar studies

AgeFrom **7 years** old to **10 years** old**Gender**

Female

Phase

N/A

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

Randomized

Randomization description

Participants will be assigned to two intervention groups (receiving cognitive-behavioral counseling) and the control group by random blocking method with 4 and 6 block sizes and 1: 1 allocation ratio. To conceal the type of intervention, it will be written on a piece of paper and numbered in a series of opaque envelopes. The envelopes will be opened in the order in which the participants enter the study and the type of group will be determined. Random allocation and preparation of envelopes will be done by a person not involved in sampling and data collection.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

South Shariati St. - School of Nursing and Midwifery, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2021-06-09, 1400/03/19

Ethics committee reference number

IR.TBZMED.REC.1400.227

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

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

2**Description of health condition studied**

Stress

ICD-10 code

Z73.3

ICD-10 code description

Stress, not elsewhere classified

3**Description of health condition studied**

Quality of Life

ICD-10 code**ICD-10 code description**

Quality life

Primary outcomes**1****Description**

Stress

Timepoint

Before and after the intervention

Method of measurement

Perceived stress questionnaire

2**Description**

Anxiety

Timepoint

Before and after the intervention

Method of measurement

Spielberger Questionnaire

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

Quality of Life

Timepoint

Before and after the intervention

Method of measurement

SF36 questionnaire

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

Intervention group: 8 sessions of cognitive-behavioral counseling for 45-60 minutes once a week in a quiet environment and in groups (5 to 7 people in each group) will be held. The content of these sessions includes initial psychological assessment, rearrangement of concepts, use of clinical skills, strengthening of skills and how to use them, generalization and maintenance, follow-up and evaluation after the intervention.

Category

Behavior

2**Description**

Control group: The participants of the control group will receive an educational booklet on puberty and health issues during this period.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Schools of Tabriz

Full name of responsible person

Faranak Rahimi

Street address

South Shariati St., School of Nursing and Midwifery

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 45 3252 8957

Email

faranak.rahimi94@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

Street address

research deputy, third floor, central building No:2
tabriz university of medical sciences, Golgasht
avenue, azadi street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947979

Phone

+98 41 3479 6969

Email

iro@tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Faranak Rahimi

Position

Master student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

South Shariati St., School of Nursing and Midwifery

City

Tabriz

Province

East Azarbaijan

Postal code

5138947979

Phone

+98 41 3177 2048

Email

faranak.rahimi94@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parisa Yavarikia

Position

Masters

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

South Shariati St., School of Nursing and Midwifery

City

Tabriz

Province

East Azarbaijan

Postal code

5138947979

Phone

+98 41 1479 6770

Email

yavarikiap@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parisa Yavarikia

Position

Master

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

South Shariati St., School of Nursing and Midwifery

City

Tabriz

Province

East Azarbaijan

Postal code

5138947979

Phone

+98 41 1479 6770

Email

yavarikiap@tbzmed.ac.ir

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

Participant data is confidential

Study Protocol

No - There is not 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

Undecided - It is not yet known if there will be 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