

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Designing and evaluation of educational program on anxiety, depression and quality of life in adolescents with a parent with cancer

Protocol summary

Study aim

Designing of educational program on anxiety, depression and quality of life in adolescents with a parent with cancer

Design

This is a single-blind, randomized controlled clinical trial study and going to design an educational program on anxiety, depression and quality of life of adolescents with a parent with cancer. The according to the results, the educational content is provided and adolescents with a parent with cancer are divided into two groups of control and test. Intervention is performed in the test group. Finally, compare the results immediately after and three months following the intervention, and compared with the control group to determine the effect of the relevant educational intervention on anxiety and depression and quality of life in adolescents.

Settings and conduct

The Study population and the research sample is adolescents with a parent with cancer who referred to the health centers of Tehran and Shahid Beheshti University of Medical Sciences. The research environment includes medical centers affiliated to Tehran University of Medical Sciences and Shahid Beheshti. Adolescents who met inclusion criteria are selected through easy sampling. They will be randomized and divided into two intervention and control groups (25 n)

Participants/Inclusion and exclusion criteria

The inclusion criteria: Having a parent is known to have cancer. Know about their parents' illness and live with their parents. Willing to participate in the study. The exclusion criteria: Do not want to continue to participate in research

Intervention groups

According to the results of the pre-test, the educational content of the training will be designed in cooperation with the experts. The intervention group will receive five sessions of the educational program. The participants in

control group receive the routine educational program.

Main outcome variables

anxiety-depression-quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190219042759N1**

Registration date: **2019-02-27, 1397/12/08**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-27, 1397/12/08**

Update count: **0**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

sedigheh arefi

Name of organization / entity

Tarbiat modares university

Country

Iran (Islamic Republic of)

Phone

+98 21 5520 5463

Email address

s.arefi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and evaluation of educational program on anxiety, depression and quality of life in adolescents with a parent with cancer

Public title

Designing and evaluation of educational program on anxiety, depression and quality of life in adolescents with a parent with cancer

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

13-18 years of aged Having a parent (father or mother) is known to have cancer Know about their parents' illness and live with their parents Willing to participate in the study

Exclusion criteria:

Do not want to continue to participate in research

Age

From **13 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Adolescents who met inclusion criteria, after acquaint with the goals of the study and will sign a formal written informed consent. Then, they will divide into two intervention and control groups (25 people). To prevent any information exchange between the participants, randomly (Roll of a die), the first one hospital is assigned to the control group and the other hospital to the intervention group, and the samples will be selected through available sampling

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**

Tarbiat Modares University

Street address

Jalal Ale Ahmad Ave, Nasr Bridge

City

Tehran

Province

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Postal code

14115-111

Approval date

2018-12-05, 1397/09/14

Ethics committee reference number

IR.MODARES.REC.1397.147

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

adolescents with a parent with cancer

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

Anxiety

Timepoint

Before the study and three months after the study

Method of measurement

questionnaire

2**Description**

Depression

Timepoint

Before the study and three months after the study

Method of measurement

questionnaire

3**Description**

Quality of life

Timepoint

Before the study and three months after the study

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: According to the results of the pre -test, the educational content of the training will be designed and modified in cooperation with the experts. The intervention group will receive five sessions of the educational program. The educational program include self-management education, coping, stress reduction methods and decision making. At the end of the educational program, a booklet will be given to the participants for study.

Category

Lifestyle

2

Description

Control group: The control group received only the routine follow-up care how to adapt to their parents' illness. At the end of the intervention anxiety and depression and quality of life was measured. Then, the designed educational content will be provided to them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Sedigheh Arefi

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2

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Sedigheh Arefi

Street address

N karegar Ave,Jalal AleAhmad junc

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat modares University

Full name of responsible person

Yaghob Fatollahi

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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

Tarbiat modares University

Proportion provided by this source

50

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

Tarbiat Modares University

Full name of responsible person

Sedigheh Arefi

Position

Ph.D. Student

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

Contact

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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

Participants information is confidential

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study protocol and Clinical study report

When the data will become available and for how long

After the completion of the study

To whom data/document is available

Public

Under which criteria data/document could be used

After publishing in scientific journals

From where data/document is obtainable

Magazine site- Author

What processes are involved for a request to access data/document

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Comments