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 by randomization and divide 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
Tehran
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 Fatolahi

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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
Ṣedigheh 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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Person responsible for updating data

Contact
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Tarbiat Modares University
Full name of responsible person
Sedigheh Arefi
Position
Ph.D Student
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Ph.D.
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