Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of an educational- self-help program on the mothers anxiety` of children with cancer

Protocol summary

Study aim
Effect of an educational- self-help program on the mothers anxiety` of children with cancer in Omid hospital,in 2018

Design
This study is a clinical trial in which 44 mothers of the child with cancer were selected and assigned randomly into 22 mothers in intervention and control group.

Settings and conduct
This study was carried out in Omid haspital in Isfahan. Intervention group attended in a eight session educational-self help program. Mothers filled Hamilton questtioner before and after intervention.

Participants/Inclusion and exclusion criteria
Mothers of the child with cancer Mothers were not simultaneously participating in some classes reducing anxiety like Yugo Mothers who agreed to attend in 8 session of scheduled programme Every alternative problem can affect on the anxiety of mother

Intervention groups
In the first,44 mothers of children with cancer who have inclusion criteria attend in the study.Then, mothers were randomly selected and assigned equally to intervention and control group.

Main outcome variables
Mothers` anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190616043902N1**
Registration date: **2019-11-30, 1398/09/09**
Registration timing: **retrospective**

Last update: **2019-11-30, 1398/09/09**
Update count: **0**

Registration date
2019-11-30, 1398/09/09

Registrant information

Name
Akram Akram

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5748 8527

Email address
akram.gholamiyan@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2019-01-20, 1397/10/30

Actual recruitment start date
2018-08-23, 1397/06/01

Actual recruitment end date
2019-02-19, 1397/11/30

Trial completion date
2019-02-19, 1397/11/30

Scientific title
Effect of an educational- self-help program on the mothers anxiety` of children with cancer

Public title
Effect of an educational- self-help program on the mothers of anxiety

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Mothers who have achild with cancer Mothers were not simultaneously participating in some classes reducing

anxiety like Yugo Mothers who agreed to attend in 8 session of scheduled programme Every alternative problem can affect on the anxiety of mother,

Exclusion criteria:

Mothers with the 3 years old child or less

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistical population includes mothers of children with cancer who are under treatment in Omid Hospital in Isfahan. They are available through a sampling method of 40 individuals. They were randomly drawn and equally allocated to an intervention and a control group.

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 Isfahan University of Medical Sciences

Street address

Hezar Jerib

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2019-02-27, 1397/12/08

Ethics committee reference number

IR.MUI.REC.1398.009

Health conditions studied

1

Description of health condition studied

children with cancer

ICD-10 code

ICD-10 code description

cancer

Primary outcomes

1

Description

anxiety

Timepoint

Before and after intervention

Method of measurement

Hamilton questioner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Educational-self help group programme was done through 8 session for paticipants

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Mahboobeh Namnabati

Street address

shahied Motahari

City

Isfahan

Province

Isfehan

Postal code

00983137927507

Phone

+98 31 3792 7516

Email

namnabat@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person
Ziba Noroozi
Street address
hezar jerib
City
Isfahan
Province
Isfehan
Postal code
3137927516
Phone
+98 31 3792 7532
Email
reseach@nm.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Akram gholamian
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar jarib Street
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Person responsible for scientific inquiries

Contact

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Esfahan University of Medical Sciences
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Position
Associate Professor
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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
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Mahboobeh namnabati
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Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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 documentation will be published after the intervention.

When the data will become available and for how long

2020

To whom data/document is available

All undergraduate and postgraduate students

Under which criteria data/document could be used

Researcher-PhD,Ms.Bs Students

From where data/document is obtainable

Namnabat@nm.mui.ac.ir ءشاذخخذثا أشئدشذشفه

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

sending an email Namnabat@nm.mui.ac.ir

Comments