

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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 hospital in Isfahan. Intervention group attended in a eight session educational-self help program. Mothers filled Hamilton questioner 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

Isfahan

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 participants

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Mahboobeh Namnabati

Street address

shahied Motahari

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00983137927507

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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

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hezar jerib

City

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Province

Isfahan

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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mahboobeh Namnabati

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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 ءشاذخذئا أشئدشذشفه
What processes are involved for a request to access data/document
sending an email Namnabat@nm.mui.ac.ir
Comments