

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

the effect of family-centered are on the self-efficacy and hope of parents of children with cancer

Protocol summary

Study aim

بررسی تاثیرمراقبت خانواده محور بر خودکارامدی و امید والدین کودکان مبتلا به سرطان

Design

Family-oriented, in four stages of perceived threat, self-efficacy, educational participation and evaluation are performed in four sessions of 20 to 40 minutes for the intervention group; The control group receives only routine ward care

Settings and conduct

Research environment of Hazrat Ali Asghar Hospital

Participants/Inclusion and exclusion criteria

Self-declaration of non-parental mental illness
Knowledge of the type of child disease No stressful event other than the child's illness during the past year
Absence from attending similar training sessions and classes Hospitalization and presence of the child for at least 5 days in the ward Lack of care for another patient at home

Intervention groups

First, by obtaining the necessary permits, they are randomly selected into experimental and control groups. A total of 64 parents of children with cancer are selected. The control group receives routine care, and after completing the training, self-efficacy and hope questionnaires are distributed to the experimental and control groups and distributed one month later. Finally, the data obtained from the questionnaires are collected and analyzed

Main outcome variables

Self-efficacy and hope

General information

Reason for update

Acronym

سرطان

IRCT registration information

IRCT registration number: **IRCT20141216020344N3**

Registration date: **2021-03-07, 1399/12/17**

Registration timing: **prospective**

Last update: **2021-03-07, 1399/12/17**

Update count: **0**

Registration date

2021-03-07, 1399/12/17

Registrant information

Name

Hamidreza Khoshnezhad Ebrahimi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7787 2189

Email address

khoshnezhad.hr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of family-centered are on the self-efficacy and hope of parents of children with cancer

Public title

the effect of family-centered are on the self-efficacy and

hope of parents of children with cancer

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Parents of children 6 to 12 years old with cancer Self-declaration of non-parental mental illness Knowledge of the type of child disease No stressful event other than the child's illness during the past year Absence from attending similar training sessions and classes - hospitalization Hospitalization and presence of the child for at least 5 days in the ward Lack of care for another patient at home
Exclusion criteria:
 Lack of parental cooperation

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 Iran University of Medical Sciences

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran
University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.IUMS.REC.1399.994

Health conditions studied

1

Description of health condition studied

Cancer in children

ICD-10 code

C80.1

ICD-10 code description

Malignant (primary) neoplasm, unspecified

Primary outcomes

1

Description

self-efficacy

Timepoint

Before intervention and immediately after intervention
and one month after intervention

Method of measurement

Scherer General Self-Efficacy Questionnaire

2

Description

hope

Timepoint

Before intervention and immediately after intervention
and one month after intervention

Method of measurement

Schneider Life expectancy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The family-centered model is implemented in four stages of perceived threat, self-efficacy, educational participation and evaluation during four sessions of 20 to 40 minutes for the intervention group. Based on this model, the first step in the intervention stage is threat perception, which increases parental knowledge and awareness. This is done through education about the disease, its complications, ways of prevention, ways of transfer and consumption of drugs, morale and follow-up of tests and treatment. The second step is the problem-solving stage, which is done to increase self-esteem and self-control. At this stage, when parents' knowledge and attitudes about the disease should be increased, they should be included in care programs. The third step is educational participation. The fourth step is evaluation, which is measured in two stages, one at the end of the intervention and one month later. Complete the relevant questionnaire. Then four 40-minute sessions are performed in four consecutive weeks (one session per week, every day). Before each session with the parents,

the meeting time is set and the sessions are held for their convenience in the study class of the department. In the first session (40 minutes), the researcher uses face-to-face training with parents about childhood cancer, common signs and symptoms, and diagnostic techniques. And treatment plans, depending on the stage and condition of the child's illness; These parents are then given basic training in this area. It should be noted that this session is presented separately to all parents in the intervention group. The second session is 40 minutes long, they are asked to talk about ways of communication. And exchange views with the hospital treatment team. In this session, they share their experiences and information about treatment, evaluation and control of treatment side effects. Other topics discussed in this session include ways to prevent infection, control and relieve pain, side effects of medications, improve self-control in the face of sick children and their problems, as well as ways to support other family members. During this session, the researcher tries to indirectly lead the discussion and guide the group towards enriching self-efficacy. During the third session, and in order to implement the third phase of the empowerment model, each participant is asked to teach one of their family members, who is responsible for child care, about what they have learned in the previous two sessions. , And answer the researcher's questions under his / her indirect supervision. During this session, any possible problems, such as forgetting the material or passing on incorrect information by the trained parents, will be corrected immediately by the researcher. In the fourth session or the final evaluation session, the researcher evaluates all the questions of the participants in the intervention group by asking questions about the total content taught and the items that were discussed in the second and third sessions. It finally clears up the remaining ambiguities.

Category

N/A

2

Description

Control group: Control group: in the control group, routine care is performed and family-centered interventions are not performed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Hospital in Tehran

Full name of responsible person

Dr. Shabahang Jafarnejad

Street address

Tehran, Modares Highway, after Mirdamad Bridge, Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar

Children's Hospital

City

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Jafarnejad.sh@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Shabahang Jafarnejad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatric Emergency Medicine

Street address

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

Iran University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Khoshnezhad Ebrahimi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatric Emergency Medicine

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

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Full name of responsible person

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Position

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Other areas of specialty/work

Pediatric Emergency Medicine

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data is encrypted in order to make the identities of
individuals unidentifiable and confidential

When the data will become available and for how long

En From the end of sampling to 6 months after the
publication of the article

To whom data/document is available

University Ethics Committee, Project Arbitration
Committee, Article Arbitration Committee and other
researchers

Under which criteria data/document could be used

Perform systematic review or meta-analysis by
mentioning the document

From where data/document is obtainable

Dr. Hamidreza Khoshnezhad Ebrahimi

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

After submitting the application via academic email, we
will provide information files to individuals within a
maximum of one week

Comments