

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of mothers' empowerment training on prevention of chemotherapy complications in children with cancer

Protocol summary

Study aim

Determining the Effect of Maternal Empowerment Training on Prevention of Complications of Chemotherapy in Children With Cancer Referring to Selected Hospital Affiliated to Tehran University of Medical Sciences in 1396

Design

Non-randomized (non-probable) random sampling units were selected and randomly divided into two groups of control and test groups. Each group included 20 subjects.

Settings and conduct

In this research, a randomized clinical trial study, the control and control groups were selected and studied during 2 months. The data were collected during the following stages: The researcher was referred to an outpatient chemotherapy department. Subsequently, the mothers who had entered the study were selected by non-randomized sampling method (non-probable) and then divided randomly into two groups (control and test groups) In each group, 20 subjects were studied. The research objectives were explained to the research units and meetings were held to empower mothers in the outpatient chemotherapy hall. The intervention stage was performed only for the test group

Participants/Inclusion and exclusion criteria

"Entry requirements" A child under 12 years of age with a definite diagnosis of cancer; the child is undergoing chemotherapy (at least 1 course of chemotherapy and maximum 3 chemotherapy courses); the mother have a mental health; the mother does not have a disabling illness; do not complete a special educational course such as classes Chemotherapy education Health care personnel "Failure to enter" Mother has chronic illness

Intervention groups

The intervention group includes mothers who have empowerment training for them The control group includes mothers who do not receive empowerment training

Main outcome variables

Complications of chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180121038467N1**

Registration date: **2018-10-06, 1397/07/14**

Registration timing: **retrospective**

Last update: **2018-10-06, 1397/07/14**

Update count: **0**

Registration date

2018-10-06, 1397/07/14

Registrant information

Name

Leila lashgari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

2017-11-22, 1396/09/01

Actual recruitment end date

2018-01-20, 1396/10/30

Trial completion date

2018-01-20, 1396/10/30

Scientific title

The effect of mothers' empowerment training on prevention of chemotherapy complications in children with cancer

Public title

The effect of empowerment of mothers on the prevention of complications of chemotherapy in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

For a child, chemotherapy has begun Mother has mental health Mother has no debilitating illness Do not pass specific educational courses such as chemotherapy classes

Exclusion criteria:

Mothers with chronic diseases Children who, in addition to cancer, have another chronic illness

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **40**

20 people in both groups

Actual sample size reached: **40**

More than 1 sample in each individual

Actual sample size in each individual: **20**

Twenty in the case group and 20 in the control group were selected and included mothers who brought their children to outpatient chemotherapy at the Bahrami Children's Hospital

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomized case that uses a random number table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

58/5000 In this study, a 4-part empowerment model was used

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Research in Azad University, Tehran Medical Sciences Branch

Street address

8, Kiani Alley, Imam Hossein Square, Damavand St. Bahrami Hospital

City

Tehran

Province

Tehran

Postal code

3439123900

Approval date

2017-07-26, 1396/05/04

Ethics committee reference number

IR.IAU.TMU.REC.1396.64

Health conditions studied

1

Description of health condition studied

Prevention of chemotherapy complications in children under chemotherapy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Complications of chemotherapy

Timepoint

The second week, the fourth week, the eighth week

Method of measurement

check list

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: In the experimental group, training was conducted based on the steps of empowerment model in 5 one-hour sessions, the steps of which were as follows: Step One: This step was conducted by a researcher in two sessions of one hour by lecture and group discussion with the aim of increasing knowledge And understanding and then understanding the threat through awareness of the nature and complications of the disease, exacerbating factors and important points of control and prevention of

complications and effective factors in controlling the disease, and in particular infection control. PowerPoint, and pamphlet were used at this stage. Mothers were divided into four groups of five. Step two: This phase was conducted with group discussion during 3 sessions of one hour. At this stage, mothers were faced with a real problem. The experiences of each other were known to solve the problems of chemotherapy and its better control, and there were concrete examples of the situation of the child and what they did to improve the problem. The purpose of the meeting was to increase the self-esteem, self-esteem and self-control of mothers. The best solution for solving children's problems was choosing the appropriate nutrition style and infection control, preventing complications by lecture method. Step 3: At the end of each session, patients were asked to promote self esteem and self-esteem through the educational participation, the topics discussed in Educational sessions were shared with the exchange of information, and a number of questions were asked by the researcher of the mothers and a booklet was given to them and the mothers were asked to explain the information to other members of the family. Step Four: To evaluate before each session Ask questions about the topics discussed to ensure you learn the content SAT took place then gave moms an opportunity during this period By placing the phone, the researcher solved the questions posed by the mother in implementing the empowerment model.

Category

Prevention

2

Description

Control group: "There was no intervention for the control group and ethically, after the completion of the research, all educational issues were distributed as CDs and educational manuals and provided to the control group"

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Street Kiani Children's Hospital
Bahrami Tehran

Full name of responsible person

Shams al-Muluk Jalal Manesh

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Bahrami Children's Hospital, Imam Hossein Square,
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Sponsors / Funding sources

1

Sponsor

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Grant name

Azad University of Medical Sciences, Tehran University of
Medical Sciences, Faculty of Nursing and Midwifery

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

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Position

University faculty

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Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available