Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of family-based care training versus no training on the family function in accommodation with children with cancer: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of family-based care training versus no training on the family function in accommodation with children with cancer

Design
This is a randomized clinical trial, in which 90 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible children with cancer who will refer to Besat Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 2 to 18 years, Having cancer for at least one month, Literate parents Exclusion criteria: Affecting other chronic diseases

Intervention groups
Intervention group: Routine treatment as well as face-to-face family-based care training sessions including improving the cognitive status of parents and how to communicate with the child with cancer for 45 to 60 minutes once a week for 2 weeks Control group: Just routine treatment

Main outcome variables
Family function in accommodation with the child

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N303**
Registration date: **2019-09-28, 1398/07/06**
Registration timing: **retrospective**
Last update: **2019-09-28, 1398/07/06**
Update count: **0**

Registration date
2019-09-28, 1398/07/06

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-05, 1398/02/15

Expected recruitment end date
2019-08-06, 1398/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of family-based care training versus no training on the family function in accommodation with children with cancer: a randomized clinical trial

Public title
Effect of family-based care training versus no training on

the family function in accommodation with children with cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 2 to 18 years, Having cancer for at least one month, Literate parents

Exclusion criteria:

Affecting other chronic diseases

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-01-26, 1397/11/06

Ethics committee reference number

IR.UMSHA.REC.1397.788

Health conditions studied

1

Description of health condition studied

Children with cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Family function in accommodation with the child

Timepoint

Two weeks after the intervention

Method of measurement

By history taking and using Paediatric Quality of Life Questionnaire (PAQLQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment as well as face-to-face family-based care training sessions including improving the cognitive status of parents and how to communicate with the child with cancer for 45 to 60 minutes once a week for 2 weeks

Category

Other

2

Description

Control group: Just routine treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan City

Full name of responsible person

Danyal Shadi

Street address

Besat Hospital, Shahed Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan 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
Hamedan 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
Hamedan University of Medical Sciences
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Person responsible for updating data

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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