Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of family-oriented care versus no care on quality of life in children with cancer: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of family-oriented care versus no care on quality of life in children with cancer. Design: a randomized clinical trial. Setting and conduct: The eligible children with cancer who may hospitalized in Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: age of 2 to 15 years; having cancer; at least one month past from the diagnosis of the cancer; receiving at least two courses of chemotherapy. Exclusion criteria: Physical or mental disorder; absence from educational sessions more than one session. Intervention group: Routine treatment plus educational session of family-oriented care 40 minutes sessions daily for 4 days. Control group: Just routine treatment. Primary outcome: Assessing the quality of life before intervention and one month after that using standard questionnaire. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610039014N119**
Registration date: **2016-10-22, 1395/08/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-22, 1395/08/01

Registrant information

Name

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Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2016-09-17, 1395/06/27

Expected recruitment end date

2017-09-18, 1396/06/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-oriented care versus no care on quality of life in children with cancer: a randomized clinical trial

Public title

The effect of family-oriented care versus no care on quality of life in children with cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 2 to 15 years; having cancer; at least one month past from the diagnosis of the cancer; receiving at least two courses of chemotherapy.
Exclusion criteria: Physical or mental disorder; absence from educational sessions more than one session.

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

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 the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2006-09-18, 1385/06/27

Ethics committee reference number

IR.UMSHA.REC.1395.303

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

C80.9

ICD-10 code description

Malignant neoplasm, unspecified

Primary outcomes

1

Description

Assessing the quality of life

Timepoint

before intervention and one month after that

Method of measurement

using standard questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus educational session of family-oriented care 40 minutes sessions daily for 4 days.

Category

Treatment - Other

2

Description

Control group: Just routine treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Zari Ravandi

Street address

Besat Hospital, Shahed Square

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Hamadan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty