

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

A comparative study of the effect of the family-centered empowerment model based on mucositis management on the quality of life of parents and children with cancer undergoing chemotherapy

Protocol summary

Study aim

Comparison of the average quality of life scores of parents and children with cancer undergoing chemotherapy in two control and intervention groups (using family-centered empowerment according to Al-Hani model)

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients. The random allocation sequence was determined using Random Allocation Software.

Settings and conduct

A semi-experimental study was conducted on 60 parents of children with cancer undergoing chemotherapy who referred to Shahrekord Kashani Hospital in 2019-2020. The sampling method was available and then they were divided into two intervention and control groups by random allocation method. The data analyst was blinded to the allocation of the participants to the study groups. In the intervention group, the trainings were as much as possible face-to-face in eight sessions (one session per week must be face-to-face) and in the form of four topics (threat understanding, problem solving, participation and evaluation) according to the model Empowerment of Alhani's family took place three times a week for 20 minutes each time

Participants/Inclusion and exclusion criteria

Inclusion criteria Having the informed consent of the parents of children with cancer to participate in the study Having a child under the age of 18 Parents should be able to communicate verbally Exclusion criteria: withdrawal of the individual during the research The death of a child in research

Intervention groups

In the intervention group, the trainings were carried out as much as possible in person in eight sessions, the intervention was carried out according to Alhani's family-

centered empowerment model, three times a week for a month and each time for 20 minutes.

Main outcome variables

Parents' quality of life, mucositis, children's quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220724055542N1**

Registration date: **2022-09-26, 1401/07/04**

Registration timing: **retrospective**

Last update: **2022-09-26, 1401/07/04**

Update count: **0**

Registration date

2022-09-26, 1401/07/04

Registrant information

Name

nasim heidari farsani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3226 2103

Email address

nasimh2510@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-15, 1398/03/25

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effect of the family-centered empowerment model based on mucositis management on the quality of life of parents and children with cancer undergoing chemotherapy

Public title
The effect of family-centered empowerment model based on mucosal management on the quality of life of parents and children with cancer undergoing chemotherapy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Having the informed consent of the parents of children with cancer to participate in the study Having a child under the age of 18 with a definite diagnosis of cancer and undergoing chemotherapy Parents should be able to communicate (speech) . Parents not suffering from special diseases such as debilitating disease Lack of previous participation of parents in empowerment programs The absence of mucositis in the child at the time of entering the study At least one month has passed since the diagnosis of the disease Having a smartphone and virtual space9. Ability to use virtual space
Exclusion criteria:
 Withdrawal of the person during the research The death of a child in the research Occurrence of physical or mental problems for parents to the extent that the person is not able to continue cooperation Failure to participate in two face-to-face meetings and two online meetings Failure to answer the questionnaire questions completely

Age
From **1 day** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
They were selected from the convenient sampling method and then divided into two intervention and control groups by random allocation method. Random allocation sequence (20 blocks of 4) was determined using Random Allocation Software. For concealment, closed envelopes containing cards with red color (for the intervention group) and blue color (for the control group) were prepared according to the predetermined allocation

sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
The data analyst and reasercher were blinded to the allocation of participants to study groups to ensure that all analytical decisions were made unbiased

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

e.g. No. 7, Westrahmatieh

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8861638137

Approval date

2020-06-14, 1399/03/25

Ethics committee reference number

IR.SKUMS.REC.1399.092

Health conditions studied

1

Description of health condition studied

cancer

ICD-10 code

C81-C96

ICD-10 code description

Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue

Primary outcomes

1

Description

mucosit

Timepoint

Before, one. Three months after the intervention.

Method of measurement

who

Secondary outcomes

1

Description

Children's quality of life

Timepoint

Before, one. Three months after the intervention.

Method of measurement

Children's quality of life questionnaire from parents' point of view (ped quality of life)

2

Description

quality of life

Timepoint

Before, one. Three months after the intervention.

Method of measurement

sf36

Intervention groups

1

Description

Control group:did not receive any training

Category

Prevention

2

Description

Intervention group: The trainings are as much as possible face-to-face in eight sessions (one session per week must be face-to-face) and in the form of four topics (threat understanding, problem solving, participation and evaluation) according to Alhani's family-centered empowerment model, three times a week and every time It took place for 20 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar and Kashani Hospital

Full name of responsible person

nasim heidari

Street address

No. 7, West rahmatieh Ave

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nasimh2510@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Jafar Moghdisi

Street address

No. 7, West rahmatieh Ave

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Grant name

Grant code / Reference number

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

No

Title of funding source

Shahrekord Medical Sciences

Proportion provided by this source

50

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

The University OF SHAHREKORD

Full name of responsible person

Nasim Heydari Farsani

Position

NURSE

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
NASIM HEIDARI FARSANI
Position
NURSE
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Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
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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