Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
City
shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8861637138
Phone
+98 930 886 2435
Email
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
City
shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8861637138
Phone
+98 38 3222 3133
Email
shahriar@GMAIL.COM
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
Street address
No. 5, West DEHGHAN Ave
City
SHAHREKORD
Province
Chahar-Mahal-va-Bakhtiari

Postal code
8861638137
Phone
00933833222603
Email
NASIMH2510@GMAIL.COM

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
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
No. 5, West DEHGHAN Ave
City
SHAHREKORD
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8861638137
Phone
+98 38 3222 2603
Email
NASIMH2510@GMAIL.COM

Person responsible for updating data

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
nasim heidarifarsani
Position
nurse
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
No. 5, West dehghan Ave
City
shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8861637138
Phone
0098382262603
Email
nasimh2510@gmail.com

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