

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effect of using self-care application on the lifestyle and Quality of life of children with leukemia undergoing chemotherapy

Protocol summary

Study aim

Determining the effect of using a self-care application on the lifestyle and quality of life of children with leukemia undergoing chemotherapy

Design

The clinical trial has a control group, with parallel groups, without blinding, randomized and on 60 patients, the lottery method will be used for randomization.

Settings and conduct

After designing the software in the Android environment by the software engineering team, first, the lifestyle and quality of life questionnaire of cancer children will be completed and collected by both groups, which are children with leukemia undergoing chemotherapy at Dr. Sheikh Mashhad Hospital. The intervention group will be trained through the application by the researcher and the control group will receive the same educational content in the form of pamphlets and face-to-face training. After completing the questionnaires, 2 months from the end of the intervention, data analysis will be done. It is not possible to blind the research units due to installing the software and blinding the data collectors due to all the procedures being performed by the student.

Participants/Inclusion and exclusion criteria

The population of this research is children with acute leukemia. Inclusion: age range of 7-12 years, suffering from acute leukemia, history of chemotherapy for more than one month, access to a smart mobile phone and the ability to use it. Exclusion: using educational games related to the disease, suffering from a psychological disease

Intervention groups

The intervention group will be trained through the application by the researcher, and in the control group, the same educational content will be presented in the form of pamphlets and face-to-face training. The educational content of the application will be related to self-care of children with leukemia with video, text, audio

and image content.

Main outcome variables

Lifestyle, Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211007052692N2**

Registration date: **2022-12-17, 1401/09/26**

Registration timing: **prospective**

Last update: **2022-12-17, 1401/09/26**

Update count: **0**

Registration date

2022-12-17, 1401/09/26

Registrant information

Name

Fatemeh Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4429 5764

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karimif992@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of using self-care application on the lifestyle and Quality of life of children with leukemia undergoing chemotherapy

Public title
Using a self-care application in children with leukemia

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Age range 7 to 12 years Having acute lymphoblastic and myeloblastic leukemia A history of chemotherapy for more than one month Access to a smart mobile phone with Android operating system and the ability to use it
Exclusion criteria:
 Using educational games related to the disease Having a psychological illness

Age
From **7 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
 Allocation of samples is done in such a way that patients are entered into two groups of 30 people, intervention or control based on the balanced block method. Considering that completing the research tools and installing the application with relevant explanations will be done when the child is discharged from the ward and in a separate room, so the possibility of information leakage will be very minor or will not exist at all. Random allocation is also done in such a way that at first 6 blocks of 4 will be formed from different placement situations of the two groups and then a lottery will be done once to select the order of the blocks. the advantage of this method is that for every 4 blocks of the research unit, half of the people in the intervention group and half of them will be the control group.

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

Mashhad University of Medical Science

Street address

In front of University 18, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2022-07-05, 1401/04/14

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.050

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia

2

Description of health condition studied

Acute myeloblastic leukemia

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

Primary outcomes

1

Description

life style

Timepoint

Before and 2 months after the intervention

Method of measurement

Lifestyle questionnaire of children with leukemia

2

Description

Quality of Life

Timepoint

Before and 2 months after the intervention

Method of measurement

Quality of life questionnaire for children with cancer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After justification by the researcher and parents, this group will undergo self-care training using the application method. The designed application has educational items about self-care in children with leukemia in the use of diet and medicine, activity and rest and with video, text, audio and image, which will be available to the child in the specified time period.

Category

Lifestyle

2

Description

Control group: This group receives the same educational content related to self-care in children with leukemia undergoing chemotherapy in the form of pamphlets and face-to-face training.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Sheikh Mashhad Hospital

Full name of responsible person

Ali Ghasemi

Street address

Dr. Sheikh Children's Hospital, Dr. Sheikh Street,
Tawheed Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

Street address

Research and Technology Vice-Chancellor, Qurashi
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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Karimi

Position

Masters Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Hamidreza Behnam Vashani

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Latest degree

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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

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Karimi

Position

Masters Student

Latest degree

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Other areas of specialty/work

Nursery