Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Studying The Effect of Mobile Health Program on Adherence to Treatment in Adolescents with Leukemia

Protocol summary

Study aim
Determining the Effect of Mobile Health program on treatment adherence in adolescents with leukemia

Design
This research is a randomized clinical trial with an intervention and control group with a sample size of 70 people.

Settings and conduct
Sampling will be done based on the inclusion criteria after obtaining the relevant permits from relevant officials in hospitals.participants will be randomly assigned to the intervention and control groups.a written consent form will be obtained from candidate. For the intervention group, the researcher will install the App designed by the researcher and provide educational content and communicate with the teenagers through the app.In the control group, there will be no intervention.The research environment is chemotherapy clinics and oncology departments of Mofid, Shohada Tajrish, Ali Asghar Medical Centers.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:Being able to read and write in Persian.Access to a smart phone.Living in a family and with one's biological parents.Age group 10 to 21 years old Exclusion criteria:Not completing the questionnaire. Not using the application

Intervention groups
For the intervention group, it will be providing educational content and communicating with patients for eight weeks through the installation and implementation of an application designed by the researcher regarding the disease.The application was designed by a researcher and can be installed on teenagers' mobile phones. Through this application, teenagers can learn about the disease and adjust the time of taking their medicines, and the process of taking medicines is recorded in the application. Also, this application contains six chapters, the content of which will be appropriate and understandable for teenagers. Patients in the control group will have routine treatment and follow-up.

Main outcome variables
Adherence to drug treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161024030474N7**
Registration date: **2023-09-02, 1402/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-02, 1402/06/11**
Update count: **0**

Registration date
2023-09-02, 1402/06/11

Registrant information

Name
Azam Shirinabadi Farahani

Name of organization / entity
School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21886553668

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farahani1381@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2023-11-22, 1402/09/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying The Effect of Mobile Health Program on Adherence to Treatment in Adolescents with Leukemia

Public title
The Effect of Mobile Health Program on Adherence to Treatment in Adolescents with Leukemia
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being able to read and write in Persian Access to a smartphone Suffering from leukemia so that at least one year has passed since the diagnosis of the disease Living in the family and with one's biological parents Not having any other disease other than leukemia Not being at the end of life Age group 10-21 years Giving informed consent No history of participating in similar training classes
Exclusion criteria:
The occurrence of any incident that leads to the teenager becoming ill and being hospitalized, so that he is not able to continue cooperation The occurrence of any incident that leads to discharge from the hospital or its change Not completing the questionnaire Not using the application
Age
From **10 years** old to **21 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In the current study, sampling will be done based on the inclusion criteria, and then the random allocation of the samples will be done using the simple randomization method to intervention and control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Using the designed application is considered as the main intervention in this study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Faculty of Nursing and Midwifery, Niayesh Intersection, Valiasr St., Tehran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2023-06-20, 1402/03/30
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1402.043

Health conditions studied

1

Description of health condition studied
Treatment adherence, Mobile Health, leukemia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
treatment adherence
Timepoint
Before the intervention, after the intervention (eight weeks)
Method of measurement
Questionnaire of compliance with treatment Moriski et al

Secondary outcomes

empty

Intervention groups

1

Description
The purpose of the intervention is to use the application designed by the researcher for eight weeks. This application includes three parts of educational content, a warning system, and the ability to send messages, and its educational content are six chapters and will include: a definition of cancer and its cause, symptoms of cancer,

chemotherapy drugs, and their side effects, as well as the recommendations of the nursing staff and training on how to adjust the time of taking drugs. Regarding the warning system, the samples can communicate with the researcher through the section designed to send messages in the application. In addition, a page has been designed for uploading photos, through which the patient can clarify the results of the tests or any questions and ambiguities by sending photos.

Category
Other

2

Description
Control group: Control group:No intervention will take place and the patients will receive their routine treatment plan.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Children's Medical Center Hospital

Full name of responsible person
Mohammadreza Modaresi

Street address
No. 62, Dr. Mohammad Gharib St., end of Keshavarz Blvd., Tehran

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Tehran

Province
Tehran

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modaresipul@gmail.com

2

Recruitment center

Name of recruitment center
Mofid Children Hospital

Full name of responsible person
Masome Hosseinpour

Street address
Shariati St., above Hosseinieh Irshad, before Mirdamad St.

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1551415468

Phone
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3

Recruitment center

Name of recruitment center
Tajrish Shohadaye Hospital

Full name of responsible person
Dr. Farideh Mousavi

Street address
Tajrish Shohadaye Educational Medical Center., Shahadari St., Tajrish Square., Tehran.

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1989934148

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pr-shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Afshin Zarghi

Street address
School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Niyayesh Cross-Section, ValiAsr St.

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Tehran

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1985717443

Phone
+98 21 8865 5366

Email
sbnmf@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azam Shirinabadi Farahani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Behesht School of Nursing and Midwifery-near Niayesh crossroads - Valiasr St

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Email

farahani1381@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azam Shirinabadi Farahani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masome Hosseinpour

Position

MSc Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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City

Tehran

Province

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Postal code

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Phone

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Email

masomehosseinpour@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

There is no further information

When the data will become available and for how long

The access is possible 6 months after the results are published.

To whom data/document is available

Researchers, students, hospital staff

Under which criteria data/document could be used

For the purpose of study and research by referring to this study

From where data/document is obtainable

Contacting with: masomehosseinpour@gmail.com

What processes are involved for a request to access data/document

After sending an e-mail to the above-mentioned address, the maximum period of 1 month

Comments