

# 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)

##### Phone

+98 21886553668

##### Email address

farahani1381@sbfmu.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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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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**Province**

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1551415468

**Phone**

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**Email**

masomehosseinpour@gmail.com

**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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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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+98 21 8865 5366

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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  
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Shahid Behesht School of Nursing and Midwifery-near  
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## Person responsible for scientific inquiries

### Contact

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Shahid Beheshti University of Medical Sciences  
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farahani1381@sbm.ac.ir

## 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**  
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1985717443  
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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