

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of self-care education with smartphone application on complications of stemcell transplantation in leukemic patients

Protocol summary

Study aim

determin the effect of self-care education with smartphone application on complications of stemcell transplantation in leukemic patients

Design

Randomized clinical trial; with control group, parallel groups, without blinding

Settings and conduct

The statistical population of this study is leukemia patients undergoing stem cell transplantation. The research place is the transplant parts of Dr. Shariati Hospital of Tehran. when patient is admitted to the transplant part after obtaining informed consent, the self-care education application and how to use it, is given to patient. two weeks, one, two and three months after the intervention, the relevant questionnaires will be completed with patient cooperation.

Participants/Inclusion and exclusion criteria

"The inclusion criteria" at least reading and writing literacy, ages 15 to 60, having an android mobile phone by the patient or his carers (family), Patients with leukemia and candidates for stem cell transplantation, the absence of identified psychological disorders. "Exclusion criteria" patient does not participate as a research sample in Other research at the same time . The client is not from the medical staff and the client or his / her family has no history of bone marrow transplantation, and If the patient does not want to use the application will be excluded from the study.

Intervention groups

"Control group" receive routine care and training includes a pre-transplant group training session that is conducted as a lecture at the transplantation center. In "Intervention Group" in addition that a self-care education app developed by the researcher and approved by four specialists is installed on the patient's cellphone. The duration of the intervention is before transplant chemotherapy up to three months after the intervention.

Main outcome variables

nausea and vomiting , Mucositis, Infection , anxiety and depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100725004443N28**

Registration date: **2020-01-11, 1398/10/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-11, 1398/10/21**

Update count: **0**

Registration date

2020-01-11, 1398/10/21

Registrant information

Name

Masoumeh Zakerimoghadam

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care education with smartphone application on complications of stemcell transplantation in leukemic patients

Public title

The effect of self-care education with smartphone application on complications of stem cell transplantation

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Have at least reading and writing skills Age between 15 and 60 years Having an Android mobile phone by a patient or his family Lack of psychological disorders detected Patients with leukemia candidates for stem cell transplantation

Exclusion criteria:

The client is not simultaneously involved in another research as a research sample The client does not want to use the application If the client is from the medical staff The client or his/her family has a history of bone marrow transplantation

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected by continuous sampling and the patients will be placed in two groups of control and intervention by Block Balanced Randomization (BBR). By using the free web site <http://www.randomization.com/>, the assignment sequence will take place..

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**

Ethics committee of Tehran University of Medical Sciences

Street address

Office building of Tehran University of medical Sciences, Keshavarz St, Tehran.

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Tehran

Postal code

1417653761

Approval date

2019-06-19, 1398/03/29

Ethics committee reference number

IR.TUMS.FNM.REC.1398.039

Health conditions studied**1****Description of health condition studied**

complications of stemcell transplantation in leukemic patients

ICD-10 code

C95.9

ICD-10 code description

Leukemia, unspecified

Primary outcomes**1****Description**

anxiety and depression(A score above 11 based on the Hospital Anxiety and Depression Scale)

Timepoint

Two weeks, one and three months after the intervention

Method of measurement

Hospital Anxiety and Depression Scale

2**Description**

Nausea(Mild or Moderate or Severe by Scale)

Timepoint

Two weeks, one and three months after the intervention

Method of measurement

Visual analogue scale (VAS)

3**Description**

vomiting(Mild or Moderate or Severe by Scale)

Timepoint

Two weeks, one and three months after the intervention

Method of measurement

khavar oncology scale

4

Description

Mucositis(Grade 0 to Grade 4 by scale)

Timepoint

Two weeks, one and three months after the intervention

Method of measurement

Form of diagnosis and severity of mucositis

5

Description

infection(yes or no based on scale)

Timepoint

One and three months after the intervention

Method of measurement

Clinical and laboratory signs and symptoms of infection in patients undergoing stem cell transplantation

6

Description

Readmission

Timepoint

One and three months after the intervention

Method of measurement

Readmission Rate Form

Secondary outcomes

empty

Intervention groups

1

Description

Control group: For patients in the control group, routine care and routine training includes a pre-transplant group training session that is conducted through the lecture center at the transplantation center.

Category

Other

2

Description

Intervention group: In Intervention group, the researcher train the self-care education program with smart phone application in addition to the routine training of the transplantation center. this application was made by the researcher and confirmed by four experts. we give the smartphone application to the patient or his caregiver (in patients who need care) and train them how to use the application and practice with them and also their possible questions are answered. if there is a problem or the question to answer them the researcher's mobile phone number is given to them. also the patient's phone number will be taken by the researcher and will be contacted by the investigator weekly at least 10 minutes in the morning or evening, in order to encourage the use of the educational application and respond to the patient's likely questions. This smartphone application

includes: leukemia, treatment methods, familiarity with bone marrow transplantation and its stages of action, possible complications and self-care methods for these patients, training in appropriate post-transplant nutrition, training on how to control infection , Cleaning, bathing, hand washing, oral hygiene, the way and rate of meeting and communication with others and observing its principles, possible complications of the disease and methods for preventing complications and early diagnosis, relief of symptoms, control and prevention methods Nausea and vomiting, oral ulcers and mucositis, and anxiety control methods. this smartphone application are approved by four members of the faculty and transplantation department. During the intervention, which starts from the beginning of pre-transplant chemotherapy as a linkage regimen and continue for up to three months after the transplantation, the questionnaire for transplantation complication will be completed Selectively in both control and intervention groups after two weeks, one and three months.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital in Tehran

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Tehran 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
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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