Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of the Continuous Care Model Based on Mobile Application Compared with Usual Care on Resilience and Self-Compassion in Patients with Acute Leukemia

Protocol summary

Study aim
Determining the effect of the mobile application-based continuous care model on resilience and self-compassion in patients with acute leukemia

Design
A parallel two-arm randomized controlled trial. Random allocation will be performed using a randomized block design with sealed envelopes.

Settings and conduct
The trial will be conducted at educational therapeutic centers affiliated with Shahrekord University of Medical Sciences. After screening for eligibility and obtaining informed consent, participants will be randomly allocated to the two groups.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Informed consent; age ≥18 years; no history of other cancers or prior participation in the continuous care model; Persian literacy; smartphone ownership and ability to use the app; absence of cognitive, hearing, or visual impairments per medical record; and a minimum of 3 months since definitive diagnosis of acute leukemia by a specialist. Exclusion Criteria: Patient death; withdrawal of consent; incomplete questionnaires at any of the three assessments; or irregular app use (less than twice weekly) leading to program discontinuation.

Intervention groups
The control group receives usual hospital care (including periodic physician visits and access to common educational pamphlets). The intervention group, in addition to standard care, participates in an 8-week continuous care model. This model consists of four stages: orientation, sensitization, control, and evaluation. Users are required to use the application at least twice a week, which includes multimedia educational content on the disease, nutrition, symptom management, and specialized modules on resilience and self-compassion. They also receive weekly support via an in-app messaging system.

Main outcome variables
Mean resilience score; Mean self-compassion score.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260128068679N1**
Registration date: **2026-02-06, 1404/11/17**
Registration timing: **prospective**

Last update: **2026-02-06, 1404/11/17**
Update count: **0**

Registration date
2026-02-06, 1404/11/17

Registrant information

Name
Sogand Soleimaninejadian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3334 6015

Email address
st-soleimaninejadian.s@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-04-21, 1405/02/01

Expected recruitment end date
2026-07-23, 1405/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of the Continuous Care Model Based on Mobile Application Compared with Usual Care on Resilience and Self-Compassion in Patients with Acute Leukemia

Public title

Effect of the Continuous Care Model Based on Mobile Application in Patients with Acute Leukemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study and provision of written informed consent. Age of at least 18 years. No history of other malignancies. No prior participation in a continuous care model program. Ability to read and write in Persian. Ownership of a smartphone and ability to use the mobile application. No cognitive, hearing, or visual impairments based on the patient's medical records. Access to the internet and basic digital literacy required to use the mobile application. At least three months have elapsed since the definitive diagnosis of acute leukemia by a specialist physician.

Exclusion criteria:

Death of the participant. Participant's unwillingness to continue participation in the study. Failure to complete the questionnaires at any of the three assessment time points (before the intervention, immediately after the intervention, and two months after the intervention). Withdrawal from the care program during the study due to non-adherence to the intervention, defined as using the application fewer than two times per week.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be gradually enrolled using a convenience sampling method based on the eligibility criteria and will be randomly assigned to the intervention and control groups. Randomization will be performed using block randomization with variable block sizes. In this method, the letter "A" represents the control group and the letter "B" represents the intervention group. Various possible combinations of these two groups will be written on cards, each placed inside sealed, opaque envelopes. To ensure allocation concealment, blocks of different sizes—such as six-member blocks (e.g., ABBABA) and two-member blocks (e.g., AB, BA)—will be used. The envelopes will be kept in a box, and the researcher will remain unaware of the group assignments until a card is selected. Before enrolling each participant, a nurse blinded to the study aims and group assignments will randomly select an envelope from the box, determining the group to which the participant will be allocated.This process will continue until all cards have been used, after which the cards will be returned to the box and the random selection process will be repeated until the desired sample size is achieved.

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 Shahrekord University of Medical Sciences

Street address

Central Administration Building, Kashani Boulevard, Shahrekord,

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2026-01-27, 1404/11/07

Ethics committee reference number

IR.SKUMS.NUMHE.REC.1404.018

Health conditions studied

1

Description of health condition studied

Acute myeloblastic leukemia

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

2

Description of health condition studied

Acute lymphoblastic leukemia [ALL]

ICD-10 code
C91.0
ICD-10 code description
Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description
The mean total score of patients on the Connor-Davidson Resilience Scale (CD-RISC)
Timepoint
The questionnaire will be completed at three time points: at the beginning of the study (before the start of the intervention), at the end of the eighth week (immediately after the completion of the intervention period), and eight weeks after the end of the intervention.
Method of measurement
Connor-Davidson Resilience Scale - 25 Item

2

Description
The mean total score of patients on the Self-Compassion Scale – Short Form (SCS–SF)
Timepoint
The questionnaire will be completed at three time points: at the beginning of the study (before the start of the intervention), at the end of the eighth week (immediately after the completion of the intervention period), and eight weeks after the end of the intervention.
Method of measurement
Self-Compassion Scale – Short Form , 12-item version

Secondary outcomes

empty

Intervention groups

1

Description
Control group: The control group receives the hospital's usual care (including periodic physician visits and access to common educational pamphlets).
Category
Behavior

2

Description
Intervention group: In addition to standard care, patients participate in a follow-up care model for 8 weeks. This model consists of four stages:(1) Orientation: A 45-minute training session for installing and learning how to use the application.(2) Sensitization: Access to the application, which includes multimedia educational content about the disease, nutrition, symptom management, and specialized modules on resilience and self-compassion (including audio/video files and interactive exercises). Users are required to use the application at least twice a week and receive daily motivational messages.(3) Control: Weekly support through an in-app messaging system and phone calls when needed.(4) Evaluation: Continuous monitoring of app usage and a final assessment.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Kashani Hospital
Full name of responsible person
Sogand Soleimaninejadian
Street address
Parastar Street, Shahrekord
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Phone
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Email
Kashani@skums.ac.ir
Web page address
https://kashanihp.skums.ac.ir/

2

Recruitment center
Name of recruitment center
Hajar Hospital (S)
Full name of responsible person
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Hajar-Hospital@skums.ac.ir
Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Dr. Ali Hassanpour Dehkordi
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University Central Headquarters, Kashani Boulevard
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Email
info@skums.ac.ir
Web page address
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Sogand Soleimaninejadian
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Nursing
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Sogand Soleimaninejadian
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Others
Street address
No. 17, Alley 11, Moallem Blvd
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Postal code
8814855131
Phone
+98 38 3334 6015
Fax
Email
st-soleimaninejadian.s@skums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Sogand Soleimaninejadian
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Others
Street address
No. 17, Alley 11, Moallem Blvd
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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

Not applicable

Analytic Code

Yes - There is 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

Deidentified Individual Participant Data (IPD) set: This set includes all collected data after the removal of identifiers. The main components are: (1) baseline demographic data (e.g., age, gender, education level), and (2) complete baseline, immediately post-intervention, and two-month follow-up scores from the Connor-Davidson Resilience Scale and the Self-Compassion Scale.

When the data will become available and for how long

The deidentified individual participant data and related documents will be made accessible in a public data repository no later than 6 months after the online publication of the primary results in a peer-reviewed journal. The data and documents will remain available for a minimum of 5 years from the date of first sharing in the repository.

To whom data/document is available

Available to researchers affiliated with academic, healthcare, or non-profit research institutions worldwide, for the purpose of conducting scientific research. Access is not restricted based on geography or sector, but applicants must demonstrate an ethical approval for their proposed analysis.

Under which criteria data/document could be used

Data may be requested for reanalysis, secondary analysis, individual participant data meta-analysis, or methodological research. Requests for commercial use are not permitted. All proposed analyses must have ethics committee approval. A Data Use Agreement (DUA) outlining terms of use, privacy, and publication must be signed prior to access.

From where data/document is obtainable

All correspondence must be conducted in Persian or English. Primary Contact: Sogand Solaimaninezadian Affiliation: Shahrekord University of Medical Sciences Postal Address: Central Administration Building, Kashani Blvd, Shahrekord, Postal Code: 8815713471 Email: st-soleimaninejadian.s@skums.ac.ir

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

Initial Request: The applicant submits a formal email request to the Principal Investigator (see contact details above). The email must include: A brief research proposal (max. 2 pages) detailing the study objectives, methodology, and planned analyses. A valid ethics approval letter from the applicant's institutional review board (IRB) or ethics committee. A completed Data Request Form (the template will be provided upon initial inquiry). Administrative and Scientific Review: The request is first checked for completeness. It is then reviewed by a Data Access Committee (DAC) established for this study, consisting of the Principal Investigator and at least one independent senior faculty member from the Faculty of Nursing and Midwifery. The DAC evaluates the scientific merit, feasibility, and ethical compliance of the proposed project. Data Use Agreement (DUA): If approved, the applicant will be sent a Data Use Agreement (DUA) draft. This legally binding document outlines the terms of data use, confidentiality obligations, publication policies, and data destruction protocols. The finalized DUA must be signed by an authorized representative of the applicant's institution and returned. Data Preparation and Transfer: Upon receipt of the fully executed DUA, the deidentified data sets and supporting documents (e.g., data dictionary, analysis code) will be prepared and transferred to the applicant via a secure method (e.g., encrypted email or secure university file-sharing service). Overall Timeline: Applicants should expect the entire process, from submission of a complete application to data transfer, to take approximately 6 to 8 weeks, depending on the completeness of the initial submission and the speed of correspondence and contract execution.

Comments

This data sharing plan aligns with the principles of the ICMJE and the FAIR (Findable, Accessible, Interoperable, Reusable) guiding principles for scientific data management. We are committed to responsible data sharing to maximize the scientific value of the contributions made by our study participants.