Original Paper

Gamified Self-Care Mobile App for Lifestyle Support in Children With Leukemia: Development and Randomized Controlled Trial

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Abstract

Background: Children with leukemia undergoing chemotherapy may experience difficulties maintaining a healthy lifestyle and self-care behaviors. Mobile health interventions incorporating interactive and gamified educational features may provide an accessible complement to conventional education.

Objective: This study aimed to develop and preliminarily evaluate a gamified self-care mobile app and evaluate the effect of the resulting intervention package on lifestyle scores among children aged 7 to 12 years with leukemia undergoing chemotherapy.

Methods: This 2-phase study was conducted in Mashhad, Iran. In phase 1, the app was developed using evidence from pediatric oncology guidelines and literature and underwent multidisciplinary expert review, user-based quality assessment using the Mobile App Rating Scale, and technical testing. In phase 2, a total of 60 children undergoing chemotherapy were randomly allocated in a 1:1 ratio to an intervention or control group. Both groups received routine face-to-face education and a pamphlet; the intervention group additionally received the Lukemo app and weekly telephone follow-up for 8 weeks. The prespecified primary outcome was the total score of the Persian version of the Pediatric Quality of Life Inventory 4.0 (PedsQL 4.0), assessed at baseline and after 8 weeks.

Results: Thirty children were allocated to each group in phase 2, and 59 completed the study (intervention: n=29; control: n=30). At 8 weeks, mean lifestyle scores were 89.79 (SD 10.88) in the intervention group and 81.10 (SD 10.57) in the control group (P=.003). The mean change from baseline was 9.10 (SD 10.36) vs 1.00 (SD 2.39) in each group, respectively, yielding a between-group difference in change of 8.10 points (95% CI 4.08-12.12; P<.001). Within-group improvement was significant in the intervention group (P<.001) but not in the control group (P=.05).

Conclusions: The intervention package incorporating the Lukemo app and weekly telephone support was associated with greater improvement in lifestyle scores over 8 weeks among children with leukemia undergoing chemotherapy. The independent contributions of the app, gamification, and telephone support could not be determined. Longer-term and multicenter studies are needed to assess sustainability and generalizability.

Trial Registration: Iranian Registry of Clinical Trials IRCT20211007052692N2; https://en.irct.ir/trial/66986

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KEYWORDS

leukemia; child; mobile apps; gamification; randomized controlled trial

Introduction

Leukemia is the most common childhood malignancy and accounts for approximately one-third of pediatric cancers worldwide [1]. Although advances in chemotherapy have substantially improved survival rates, treatment-related complications frequently impair physical activity, nutrition, sleep, and psychosocial functioning, resulting in unhealthy lifestyle patterns and reduced quality of life [2,3]. Lifestyle behaviors, including adequate nutrition, physical activity, infection prevention, medication and treatment adherence, and symptom monitoring, are important components of supportive care for children undergoing chemotherapy [4]. However, children with leukemia face particular challenges in maintaining these behaviors because chemotherapy-related fatigue, nausea, pain, appetite changes, infection risk, and other treatment-related symptoms can interfere with daily self-care and participation in healthy activities [4,5]. Consequently, self-care education in this population needs to be understandable, age appropriate, engaging, and sufficiently accessible to support the repeated application of recommended behaviors in daily life. Although self-care education can mitigate treatment-related symptoms and promote better health outcomes in pediatric oncology populations [5], conventional approaches such as verbal instructions and printed pamphlets may provide limited opportunities for active participation, repetition, feedback, and reinforcement and may be difficult to sustain during prolonged treatment [6].

Mobile health technologies provide opportunities to overcome some of these limitations by providing children and their caregivers with continuous and accessible educational content, reminders, and opportunities for repeated learning. Smartphone-based interventions can also incorporate interactive elements that allow children to actively engage with educational material rather than receiving information passively. Gamification, defined as the incorporation of game elements into nongame contexts, may further increase engagement and motivation by providing age-appropriate challenges, immediate feedback, rewards, and a sense of progression [7,8]. These characteristics may be particularly relevant for children undergoing prolonged chemotherapy, for whom repeated exposure to self-care information and active engagement with recommended behaviors may be challenging. Previous studies in pediatric chronic diseases have reported beneficial effects of digital and game-based interventions on self-management, knowledge, and health-related behaviors [9,10]. Nevertheless, evidence regarding the development and effectiveness of gamified mobile interventions specifically targeting lifestyle and self-care among children with leukemia undergoing chemotherapy remains limited.

Therefore, this study aimed to develop and preliminarily evaluate a gamified self-care mobile app and evaluate the effect of the resulting intervention package on lifestyle scores among children aged 7 to 12 years with leukemia undergoing chemotherapy.

Methods

Study Design

This study was conducted in two sequential phases: (1) development and preliminary evaluation of a gamified self-care mobile app and (2) evaluation of its effectiveness through a parallel-group randomized controlled trial.

Phase 1: App Development and Preliminary Evaluation

Content Development

Educational content was developed by the research team through an extensive review of scientific literature, clinical guidelines, and authoritative educational resources related to self-care for children with leukemia.

A systematic search was conducted for the literature published between 2018 and 2023 using the PubMed, Scopus, Web of Science, and Google Scholar databases. UpToDate was also consulted as a clinical point-of-care resource. In addition, reputable cancer educational resources were reviewed to inform the educational content of the app, including the American Cancer Society, Leukemia & Lymphoma Society, American Childhood Cancer Organization, eCancer, and Cancer.Net [11-14]. These sources were used to identify relevant information on childhood leukemia, chemotherapy-related adverse effects, nutrition, infection prevention, oral care, physical activity, sleep, and psychosocial coping.

Because children aged 7 to 12 years require parental involvement in self-care, the app was designed to be family centered, allowing both children and parents to benefit from the educational materials.

On the basis of feedback from hospitalized children, parents, and oncology nurses, the research team decided to deliver the educational content in a game-based (gamified) format to enhance engagement, enjoyment, and learning.

App Design and Development

Following the development and initial expert review of the educational content, the content was transferred to a multidisciplinary software development team for integration into the mobile app.

The app was developed using the Unity game engine (Unity Technologies) and the Blender software (Blender Foundation) for 3D modeling and character design. The app, named Lukemo (derived from leukemia and chemotherapy), was designed around a child-friendly interactive environment.

The virtual setting consisted of 4 sequential locations reflecting daily life activities: living room, kitchen, playroom, and bedroom (Figure 1). A child character representing a boy aged 10 years with leukemia guided users through the game.

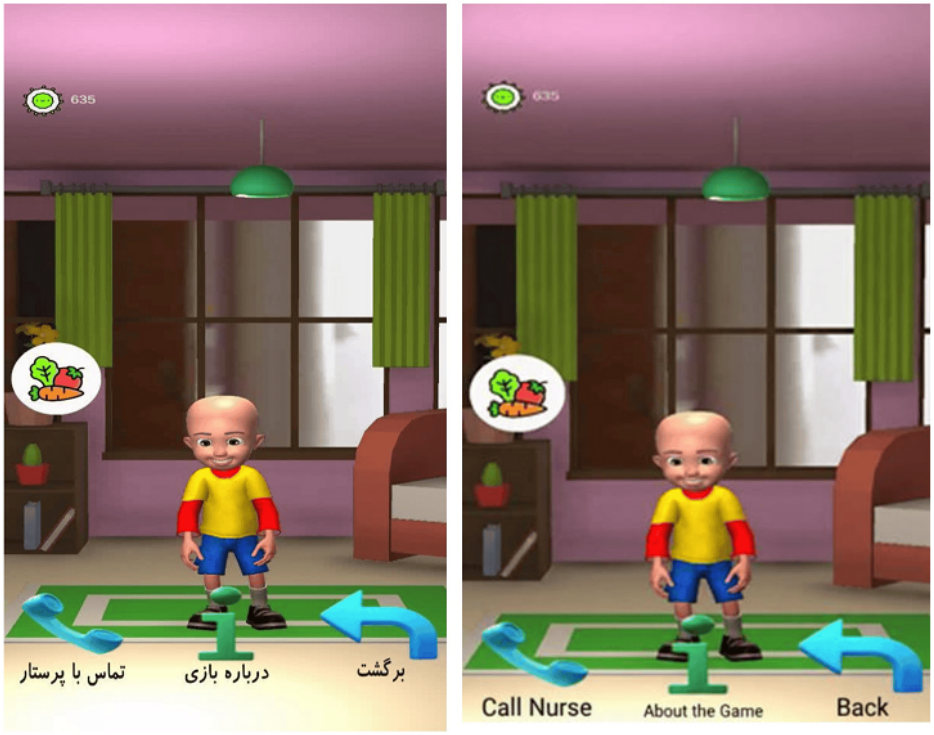
Each environment addressed specific self-care behaviors. The kitchen focused on nutrition management and appetite stimulation; the playroom addressed safe physical activity and

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entertainment; the bedroom addressed sleep hygiene, oral care, and relaxation techniques; and the living room provided navigation, nurse contact, and guidance menus.

Game elements included animations, sound effects, storytelling, quizzes, rewards, points, visual feedback, and virtual "white blood cell" rewards for healthy choices. These gamification strategies were incorporated to reinforce learning and promote behavior change.

Figure 1. Screenshot of the Lukemo home screen in Persian (A) and English (B).



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Expert Content Review

The educational content and its presentation within the app were reviewed by a multidisciplinary expert panel of 10 experts comprising 3 pediatric oncologists, 4 pediatric oncology nurses, and 3 software specialists. All experts held doctoral-level qualifications in their respective fields and had at least 10 years of relevant professional experience. Experts were purposively selected based on their professional expertise and experience relevant to pediatric oncology care, pediatric self-care education, and/or software and mobile app development.

The experts independently reviewed the educational content and its presentation within the app with respect to relevance, clarity, comprehensiveness, age appropriateness, and appropriateness of the presentation for the target population. The review was conducted qualitatively, and no formal quantitative content validity indexes, such as the content validity index or content validity ratio, were calculated.

Experts were invited to provide comments and suggestions regarding the content and presentation of the app. All comments were reviewed by the research team, and proposed revisions were discussed collectively. Content or presentation elements identified as unclear, incomplete, inappropriate, or insufficiently age appropriate were revised before user-based testing. Where differing opinions were expressed, the research team reviewed the comments and reached a consensus regarding the final revision.

User-Based Quality Assessment

Thirty child-parent dyads participated in the user-based assessment of the app. These participants were recruited separately from the participants subsequently enrolled in the phase 2 randomized controlled trial.

Perceived app quality was assessed using the original Mobile App Rating Scale (MARS). The MARS was selected because it provides a structured assessment of mobile app quality across dimensions relevant to the evaluation of an app, including engagement, functionality, aesthetics, and information quality.

Following exposure to the app, each child-parent dyad completed the MARS jointly. Responses were scored according to the standard MARS scoring procedure, with higher scores indicating more favorable perceived app quality [15].

The user-based assessment was conducted before the randomized controlled trial, and none of the 30 child-parent dyads included in phase 1 was subsequently enrolled in phase 2.

Technical Testing

Technical testing was conducted by the software development team before the app was introduced into the randomized controlled trial. Three complementary procedures were used: black-box testing, white-box testing, and Android compatibility testing.

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Black-box testing assessed the app's externally observable functions without examining the underlying source code. The main functions tested included app installation and launch; navigation between the 4 virtual environments; access to educational content, animations, and audio; quizzes; scoring; reward allocation; progress indicators; and completion of interactive activities. A function was considered to have passed the test when it operated according to its intended specification without crashes, incorrect outputs, inaccessible content, or other functional errors.

White-box testing was performed by the software development team to examine the internal logic and source code components underlying the app's core functions, including navigation, scoring, reward assignment, and data handling. The purpose was to identify programming errors, incorrect logical pathways, and failures that could affect app functionality.

Android compatibility testing was conducted across Android devices to assess installation, screen presentation, navigation, functionality, and stability under different device conditions. Compatibility was considered acceptable when the app could be installed and launched successfully and its core functions operated without critical display, navigation, functional, or stability problems.

Identified problems were documented and corrected by the software development team. The affected functions were subsequently retested to verify that the problems had been resolved before the app was used in phase 2.

Phase 2: Randomized Controlled Trial

Setting and Participant Recruitment

Participant recruitment for the randomized controlled trial was conducted from June 1, 2022, to September 30, 2022, at the chemotherapy ward of Dr. Sheikh Pediatric Hospital, Mashhad, Iran.

Potentially eligible children aged 7 to 12 years were identified among patients receiving chemotherapy in the chemotherapy ward during the study recruitment period. The researcher screened patients against the predefined eligibility criteria and approached eligible children and their parents or legal guardians in person during hospitalization.

The study objectives, procedures, potential benefits and risks, voluntary nature of participation, and follow-up requirements were explained to the child and parent or legal guardian. Children were enrolled after eligibility was confirmed and informed consent procedures had been completed.

Eligibility Criteria

Children were eligible to participate if they met all the following criteria: (1) a diagnosis of acute leukemia, including acute lymphoblastic leukemia or acute myeloid leukemia; (2) a history of receiving chemotherapy for more than 1 month; (3) age of 7 to 12 years; (4) no previous use of disease-related educational games; and (5) access to an Android smartphone and the ability to use the device.

Participants were withdrawn from the study if any of the following occurred: (1) the child or parent or guardian no longer consented to continued participation; (2) the child developed a psychological disorder during the study; (3) the child did not use the Lukemo app during at least 20% of the 8-week intervention period (ie, during fewer than 2 of the 8 intervention weeks), with app use defined as logging into the app and completing at least one educational module or game activity during a session as recorded by the app back end; or (4) the child died during the study period.

Sample Size

The sample size was calculated manually using the formula for comparing the means of 2 independent groups:

$$n = \frac{(Z(_{1-\alpha/2)} + Z_{1-\beta})^2 \times [(S_1^2 + S_2^2)]}{(X_1 - X_2)^2}$$

The parameters were obtained from a previous study by Naseri et al [16], in which the mean quality of life scores were 86.2 (SD 16.4) and 74.1 (SD 16.0). Assuming a 2-sided significance level of .05 ($Z_{1-\alpha}/2$=1.96) and 80% statistical power ($Z_{1-\beta}$=0.84), the required sample size was calculated as 28.11 participants per group. This was rounded to 28 participants per group (56 participants in total). To allow for potential participant loss during follow-up, 30 participants were recruited into each group, resulting in a total sample of 60 children.

Randomization and Allocation Concealment

After eligibility had been confirmed and the baseline assessment had been completed, participants were randomly allocated in a 1:1 ratio to the intervention or control group using block randomization with a fixed block size of 6. The random allocation sequence was generated using a random number table by a researcher who was not involved in participant recruitment or outcome assessment.

The allocation codes were placed in sequentially numbered, opaque, sealed envelopes to maintain allocation concealment. The envelopes were prepared and secured before participant enrollment. After a participant had met all eligibility criteria and completed the baseline assessment, the study coordinator opened the next envelope in numerical order and assigned the participant to the group indicated in the envelope. Thus, allocation was concealed until eligibility and baseline assessment had been completed.

Intervention and Control Conditions

Both groups received routine face-to-face ward education delivered by pediatric oncology nurses according to standard hospital practice, including verbal instructions and printed pamphlets regarding diet, rest, and general self-care during chemotherapy.

Intervention Group

Overview

Children in the intervention group received routine face-to-face education and the standard educational pamphlet provided at hospital discharge in addition to the Lukemo mobile app. Before discharge, the researcher conducted a brief face-to-face

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orientation session of approximately 15 to 20 minutes with the child and parent. The session included installation of the app on the child's or parent's personal Android smartphone, demonstration of the main features, and instructions on how to navigate and use the educational and game-based content.

The Lukemo app was provided free of charge and was available for home use for 8 weeks. No payment, subscription, or membership was required. Participants were instructed to use the app during the 8-week intervention period as part of their routine self-care learning at home. The intervention protocol did not prescribe a fixed daily or weekly minimum duration or number of sessions; therefore, the frequency and duration of actual app use were determined by the participants and their families. The app was primarily designed for offline use, and internet access was not required for its core educational and game-based functions.

The app combined educational, interactive, and game-based elements to support self-care learning. Core features included multimedia educational modules, animated storytelling, quizzes, reward-based tasks, points, visual feedback, and virtual incentives ("white blood cells") awarded for completing designated activities. Children could navigate 4 interactive virtual environments (kitchen, playroom, bedroom, and living room), which addressed self-care topics including nutrition management, physical activity, sleep hygiene, infection prevention, and psychological coping.

The content was developed by pediatric oncology nurses and researchers using clinical guidelines, peer-reviewed literature, and international cancer educational resources and was subsequently reviewed by a multidisciplinary expert panel.

The app was not developed according to a single formal theoretical framework. Rather, its design was informed by established principles of self-care education, behavior change, and gamification. Features such as goal-oriented tasks, performance feedback, reinforcement through rewards, repeated practice, and modeling were incorporated where applicable. Storytelling, points, challenges, rewards, and visual progress indicators were used to support engagement with self-care content. The family-centered design also facilitated parental involvement in their children's self-care.

The app provided immediate feedback through scores, rewards, and visual progress indicators. Educational content was presented in simple, age-appropriate language and supported by visual and animated elements. The interface was designed to be child-friendly, visually rich, and easy to navigate, with limited text and interactive elements appropriate for children aged 7 to 12 years.

Adherence Monitoring and Support

App use was operationally defined as actively logging into the Lukemo app and completing at least one educational module or game activity during a session. App use and engagement were monitored through the app back end throughout the 8-week intervention period. The back end recorded app access and activity data, including the occurrence of app use, frequency of use, and completion of educational modules or game activities. These data were used to characterize participants' engagement with the app during the intervention period.

In addition to app-based monitoring, participants in the intervention group received scheduled weekly telephone calls throughout the 8-week intervention period. The calls were conducted at fixed weekly intervals by the research team and were intended to remind children and parents to use the app, answer educational questions, address technical problems, and encourage continued engagement. The calls were not automatically triggered by app use data.

The weekly telephone calls were part of the intervention protocol and were provided only to participants in the intervention group. The control group received the same routine face-to-face education and educational pamphlet but did not receive scheduled weekly telephone calls. Thus, the intervention evaluated in this trial consisted of the Lukemo app together with structured weekly telephone support.

No automated push notifications, SMS text messages, or email reminders were used. The app was available for home use throughout the 8-week intervention period, and participants used their personal Android smartphones.

Access and Delivery Context

The app was installed by the researcher on the participants' or parents' personal Android smartphones during the hospital visit and was provided without charge. Participants used the app independently in their home environment without direct supervision. No real-time online communication was embedded within the app. Technical or educational support was provided through the scheduled weekly telephone calls.

For editorial and peer-review purposes, a demonstration version or temporary access to the app can be provided upon request to facilitate evaluation of its features and content.

Control Group

The control group received routine ward education only, consisting of face-to-face verbal instruction by nurses and printed pamphlets covering dietary and rest recommendations without digital or interactive components.

Outcome Measure

Lifestyle was assessed using the Persian version of the Pediatric Quality of Life Inventory 4.0 (PedsQL 4.0), a 23-item instrument developed and validated for assessing lifestyle among school-aged children [15]. The questionnaire comprises physical functioning, emotional functioning, social functioning, and school functioning and includes 27 items scored according to the instrument's prescribed response format. The total score ranges from 0 to 108, with higher scores indicating a healthier lifestyle.

The questionnaire was administered in person in paper-based format at baseline and after the 8-week intervention. It was completed by the child, while parents and/or the researcher provided assistance when necessary. Assistance was limited to clarifying the meaning of items and did not include suggesting or selecting responses on behalf of the child. The same

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administration procedure was used at both baseline and follow-up.

The Persian version was selected based on its previously reported validity and reliability in the target population [17]. In the present study, the internal consistency of the questionnaire was acceptable, with a Cronbach α of 0.81.

Blinding

Due to the nature of the intervention, participants (children and their parents) and care providers could not be blinded to group allocation. The primary outcome was assessed using the self-administered PedsQL 4.0, which was completed directly by the children and parents. Because participants were aware of their group allocation, participant-reported outcome assessment was not considered blinded. Data analysts were blinded to group allocation to minimize the potential for bias during data analysis.

Statistical Analysis

SPSS (version 26; IBM Corp) was used for statistical analysis. Between-group comparisons were performed using the independent-sample 2-tailed *t* test or Mann-Whitney *U* test as appropriate, and within-group comparisons were performed using the paired-sample *t* test or Wilcoxon signed-rank test as appropriate. Statistical significance was set at $P<.05$. All analyses were performed on participants who completed the study (complete-case analysis). One participant in the intervention group withdrew because of disease progression.

No interim analyses, data monitoring committee, or early stopping guidelines were prespecified or implemented as the intervention was educational, minimal risk, and of short duration. All outcomes were assessed after completion of the 8-week follow-up.

Ethical Considerations

Ethics approval for this clinical trial was obtained from the ethics committee of Mashhad University of Medical Sciences (IR.MUMS.NURSE.REC.1401.050). This study was registered with the Iranian Registry of Clinical Trials under registration number IRCT20211007052692N2.

Written informed consent was obtained from the parents or legal guardians, and written age-appropriate assent was obtained from all participating children before data collection. For illiterate parents or legal guardians, consent was obtained in accordance with the approved ethical procedures from a legally authorized representative. Participants were assured of the confidentiality and anonymity of their information, and participation was entirely voluntary, with the right to withdraw at any time without consequences.

Results

Phase 1: App Development and Preliminary Evaluation

Content Development

Educational content was extracted from current clinical guidelines, peer-reviewed literature, and international cancer educational resources. The final curriculum covered chemotherapy side effect management, nutrition, hydration, infection prevention, oral care, physical activity, fatigue management, sleep hygiene, and psychological coping.

Content was tailored to the developmental level of children aged 7 to 12 years and structured to enable parental involvement.

Expert Content Review

Ten experts, including pediatric oncology nurses, pediatricians, and software specialists, evaluated the relevance, clarity, and comprehensiveness of the content. Minor revisions were made based on their feedback. All items were judged to be appropriate and clinically accurate.

User-Based Quality Assessment

Thirty child-parent dyads, who were distinct from the participants enrolled in the phase 2 randomized controlled trial, evaluated the app using the original MARS. The overall app quality score, calculated as the mean of the 4 objective MARS domains, was 4.54 (SD 0.15) out of 5, indicating a high level of overall app quality. The domain scores were 4.62 (SD 0.22) for engagement, 4.63 (SD 0.28) for functionality, 4.57 (SD 0.27) for aesthetics, and 4.33 (SD 0.20) for information quality. The subjective quality domain was assessed separately and was not included in the overall MARS score. Overall, the app demonstrated favorable quality across the 4 objective domains, with particularly high ratings for engagement, functionality, and aesthetics, supporting its use in the subsequent randomized controlled trial.

Technical Testing

Black-box, white-box, and compatibility testing confirmed appropriate functionality, usability, and stability across different Android devices. No critical technical issues were detected before trial implementation.

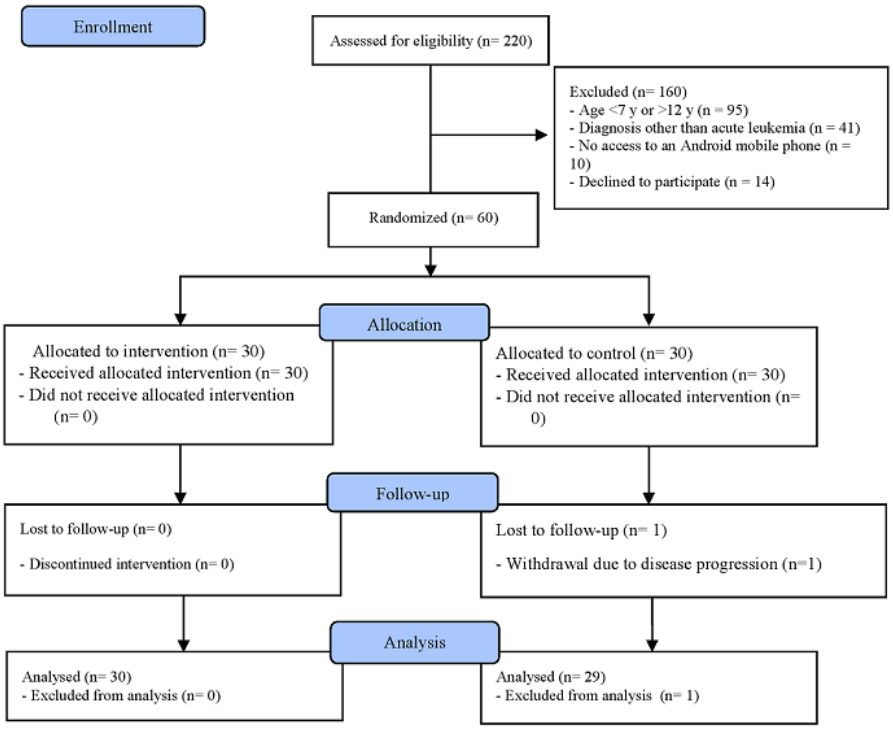
Phase 2: Randomized Controlled Trial

Participant Flow

Overall, 60 children were randomized into the intervention (n=30) and control (n=30) groups (Figure 2). One participant in the intervention group withdrew due to disease progression during follow-up. In total, 59 participants completed the study (intervention: n=29; control: n=30).

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Figure 2. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.



Baseline Characteristics

No statistically significant differences were observed between groups regarding sex, duration of illness, or other baseline and disease characteristics (*P*>.05 in all cases; Table 1).

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Table 1. Baseline demographic and clinical characteristics of the participants.

Characteristics	Intervention (n=29)	Control (n=30)	*P* value
Sex , n (%)			.28[a]
Male	23 (79.3)	20 (66.7)	
Female	6 (20.7)	10 (33.3)	
Educational level, n (%)			.49[b]
Preschool[c]	2 (6.9)	5 (16.7)	
Primary school	23 (79.3)	22 (73.3)	
Lower secondary school	4 (13.8)	3 (10)	
Disease type, n (%)			.65[d]
All	26 (89.7)	27 (90)	
AML[e]	3 (10.3)	3 (10)	
Number of hospitalizations, mean (SD)	4.34 (4.09)	5.97 (5.78)	.50[f]
Time since diagnosis (mo), mean (SD)	8.48 (10.71)	6.93 (7.88)	.91[f]
Duration of chemotherapy (mo), mean (SD)	8.31 (9.80)	7.27 (8.98)	.74[f]

[a]Chi-square test.

[b]Fisher exact test.

[c]The educational level distribution included a "preschool" category for some participants. Importantly, this category referred to the participants' educational status and did not indicate an age below the eligibility threshold. All randomized children were within the prespecified age range of 7 to 12 years at enrollment. The educational level categories and corresponding frequencies are shown in this table.

[d]Mann-Whitney *U* test.

[e]AML: acute myeloid leukemia.

[f]Mann-Whitney *U* test was used for the corresponding comparison.

App Use and Engagement

Of the 29 participants in the intervention group who completed the 8-week intervention, 29 (100%) used the Lukemo app at least once during the trial period. In total, 86.2% (25/29) of the participants used the app at least once per week throughout the 8-week intervention period, and 69.0% (n=20) completed all educational modules. App use was defined as logging into the app and completing at least one educational module or game activity during a session. These measures were derived from the app back end and were used to characterize engagement with the intervention.

Primary Outcome: Lifestyle Score

The total score of the Persian version of the PedsQL was the prespecified primary outcome. At baseline, the mean lifestyle score was comparable between the intervention and control groups (*P*=.81). After 8 weeks, the intervention group demonstrated significantly higher lifestyle scores than the control group (mean difference: 8.69 points; 95% CI 3.09-14.29; *P*=.003).

The mean change from baseline was 9.10 (SD 10.36) points in the intervention group and 1.00 (SD 2.39) point in the control group, corresponding to a between-group difference in change scores of 8.10 points (95% CI 4.08-12.12; *P*<.001). Within-group analysis showed a statistically significant improvement in lifestyle score in the intervention group (*P*<.001), whereas the change in the control group was not statistically significant (*P*=.05; Table 2).

Table 2. Means and SDs of lifestyle scores among participants before and after the intervention in the 2 groups.

	Intervention (n=29), mean (SD)[a]	Control (n=30), mean (SD)[b]	*P* value
Before the intervention (score range 30-120)	80.69 (9.21)	80.10 (10.10)	.81[c]
After the intervention (score range 30-120)	89.79 (10.88)	81.10 (10.57)	.003[c]
Score change (after minus before)	9.10 (10.36)	1.00 (2.39)	<.001[c]

[a]Within-group comparison (Wilcoxon signed-rank test): *P*<.001.

[b]Within-group comparison (Wilcoxon signed-rank test): *P*=.05.

[c]Mann-Whitney *U* test.

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Discussion

Principal Findings

This 2-phase study developed and preliminarily evaluated a gamified self-care mobile app for children with leukemia undergoing chemotherapy and subsequently evaluated the intervention package in a randomized controlled trial. In phase 1, the app underwent expert content review, user-based quality assessment, and technical testing. In phase 2, children allocated to the intervention group showed a greater improvement in total lifestyle score over 8 weeks than those receiving usual education and a pamphlet. The mean lifestyle score increased by 9.10 points in the intervention group compared with 1.00 point in the control group, resulting in a between-group difference in change scores of 8.10 points (95% CI 4.08-12.12; $P<.001$).

The magnitude of this change should be interpreted in relation to the PedsQL scoring range. Because the questionnaire total score ranges from 30 to 120, the observed 8.10-point between-group difference in change represents approximately 9.0% of the questionnaire's total possible range. This indicates a measurable difference in lifestyle scores over the 8-week study period. However, to our knowledge, an established minimal clinically important difference for the PedsQL specifically among children aged 7 to 12 years with leukemia undergoing chemotherapy has not been established. Therefore, the statistical significance and magnitude of the observed difference should not be interpreted as definitive evidence of clinical importance. Further studies establishing clinically meaningful thresholds for this instrument and population are warranted.

The findings are consistent with previous evidence suggesting that mobile health interventions can support health education and self-management behaviors [7,18]. Interactive and gamified features may facilitate children's engagement with educational content by providing repeated exposure, feedback, rewards, and age-appropriate interaction [8,19]. The favorable user-based quality assessment observed in phase 1, particularly in the engagement and functionality domains, supports the feasibility of using a mobile app as a component of the intervention in this population.

However, the present trial does not allow the independent contributions of gamification or the mobile app itself to be determined. Participants in the intervention group received access to the Lukemo app in addition to routine education and a pamphlet and also received scheduled weekly telephone contact for reminders, educational questions, technical support, and encouragement. Therefore, the observed between-group difference should be interpreted as the effect of the overall intervention package compared with usual education and a pamphlet rather than as an isolated effect of the app's gamification features. An important consideration is that the intervention evaluated in this trial was not limited to the Lukemo app. Participants in the intervention group received the app in addition to routine education and the educational pamphlet together with scheduled weekly telephone support throughout the 8-week intervention period. These calls were used to remind children and parents to use the app, answer educational questions, address technical problems, and encourage continued engagement. Although back-end data showed substantial app engagement, with 86.2% (25/29) of participants using the app at least once per week throughout the intervention period and 69.0% (n=20) completing all educational modules, the contribution of the weekly telephone support to engagement and the observed outcome cannot be separated from that of the app. Because this study did not include an attention-matched control condition, the independent effects of the mobile app, its gamified features, and the weekly telephone support cannot be determined. Accordingly, the observed between-group difference should be interpreted as the effect of the overall intervention package rather than as an isolated effect of the app or its gamified components. Future studies using factorial designs, attention-matched control conditions, or automated intervention delivery without scheduled human contact could help disentangle these effects.

Previous pediatric oncology studies have also suggested potential benefits of digital approaches for symptom management, health education, and self-management [20,21]. The present findings extend this literature by evaluating a gamified self-care app focused on multiple lifestyle-related behaviors during chemotherapy. Nevertheless, differences in intervention content, outcome measures, follow-up duration, and study populations should be considered when comparing these findings with those of previous research.

Traditional educational approaches, such as brief verbal instruction and printed materials, may provide important foundational information but may offer fewer opportunities for repeated interactive learning after discharge [22]. A mobile app can provide educational content at home and allow children and their families to revisit information when needed. In the present study, therefore, the app may have served as a complementary educational resource rather than a replacement for routine nursing education.

From a nursing perspective, digital educational tools may complement face-to-face education by extending access to age-appropriate self-care information beyond the hospital setting. Such tools may also facilitate family involvement in children's self-care. However, implementation should consider the additional support required for technical problems, digital literacy, and access to appropriate devices and connectivity.

Strengths and Limitations

A major strength of this study is its two-phase design, which combined structured app development and preliminary evaluation with a randomized controlled trial. The intervention was specifically designed to address the developmental and educational needs of children with leukemia undergoing chemotherapy and incorporated family involvement.

Several limitations should be considered when interpreting the findings. First, participants and those involved in intervention delivery could not be blinded because of the nature of the digital educational intervention, which may have introduced performance or response bias. Second, the primary outcome was assessed using a questionnaire-based measure rather than an objective behavioral measure; therefore, self-report and recall-related bias cannot be completely excluded. Third, the

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intervention group received scheduled weekly telephone contact in addition to access to the Lukemo app, whereas the control group did not receive equivalent attention-matched contact. These calls provided reminders, educational clarification, technical assistance, and encouragement and may have contributed to engagement or the observed outcome. Consequently, the independent contributions of the app, its gamified components, and the weekly telephone support cannot be separated, and the findings should be interpreted as the effect of the overall intervention package. Fourth, the follow-up period was limited to 8 weeks, preventing assessment of whether the observed improvement in lifestyle scores was sustained over the longer term. Fifth, the study was conducted at a single pediatric oncology center with a relatively small sample, which may limit the generalizability of the findings to other clinical settings and pediatric oncology populations. Finally, participation required access to an Android-compatible smartphone and sufficient ability to use the device. Although this requirement facilitated delivery of the intervention, it may have excluded children or families with limited access to appropriate devices, connectivity, or digital skills. Therefore, the findings may not be fully generalizable to populations with different levels of digital access or health and digital literacy.

Conclusions

The findings suggest that a gamified self-care mobile app delivered as part of a broader intervention package that included routine education and weekly telephone follow-up was associated with greater improvement in lifestyle scores among children with leukemia undergoing chemotherapy over an 8-week period. The findings support the potential role of interactive digital educational tools as a complement to routine pediatric oncology education. However, the independent contributions of the app and its gamified components cannot be determined from the present study, and the persistence of the observed improvement beyond the 8-week follow-up remains uncertain. Multicenter studies with longer follow-up and objective measures of engagement and health behavior are needed to evaluate the sustainability and broader applicability of these findings.

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Data Availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Generative AI Use

The authors used ChatGPT (GPT-6; OpenAI) to assist with language editing, improving readability, and refining the wording of the manuscript. All AI-assisted text was reviewed and revised by the authors, who take full responsibility for the accuracy, integrity, and final content of the manuscript. No artificial intelligence tools were used to conduct the statistical analyses or generate the study results.

Authors' Contributions

Conceptualization: HBV, NA, MR
Formal analysis: NA, MR
Methodology: HBV, NA, MR
Writing—original draft: TP
Writing—review and editing: FK, HBV, NA, MR, TP
All authors reviewed the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist.

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[PDF File (Adobe PDF File), 17872 KB-Multimedia Appendix 1]

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Abbreviations

CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
MARS: Mobile App Rating Scale
PedsQL 4.0: Pediatric Quality of Life Inventory 4.0

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