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Original Article

Effects of Child Life intervention on the symptom cluster of pain–anxiety–fatigue–sleep disturbance in children with acute leukemia undergoing chemotherapy

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ABSTRACT

Objective: This study aims to explore the application effect of Child Life intervention on pain, anxiety, fatigue, and sleep disturbance in children with acute leukemia.
Methods: In a single-blinded, parallel-group randomized controlled trial, 96 children with acute leukemia were randomized to either the intervention group, which received Child Life intervention twice a week for 8 weeks, or the control group, which received routine care. Outcomes were evaluated at baseline and day 3 postintervention.
Results: All of the participants completed the study. Compared with the control group, the intervention group showed a significant reduction in pain, anxiety, fatigue, and sleep disturbance ($P < 0.001$). However, no significant differences were observed in the disorders of excessive somnolence.
Conclusions: Child Life intervention can effectively improve pain, anxiety, fatigue, and sleep disturbance in children with acute leukemia undergoing chemotherapy. The results suggest that symptom cluster management intervention based on Child Life provided a promising approach for simultaneously treating multiple symptoms within a cluster.

Introduction

The incidence of childhood cancer has been gradually increasing. The overall incidence of childhood cancer worldwide ranges from 50 to 200 cases per million children.[1] Acute leukemia (AL) is the most common cancer in childhood.[2] Annually, more than 3000 new cases of acute lymphoblastic leukemia (ALL) in childhood were diagnosed in the United States.[3] Leukemia accounts for 40%–50% of the childhood cancer burden in India.[4] In China, the incidence rate of AL in children is 4/100,000.[5] Chemotherapy is the primary treatment method.[6] With the improvement of combination chemotherapy and medical technology, the 5-year disease-free survival rate of children with AL has reached nearly 80%.[7] Although the survival rate of the disease has gradually improved, a cancer diagnosis, lengthy hospital stays, various invasive treatments, and the side effects of chemotherapy, such as pain, nausea, fatigue, vomiting, and hair loss, can adversely impact affected children's physical, emotional, and psychosocial abilities.[8] Cancer is a traumatic event. Being diagnosed with a life-threatening disease, in particular, may lead to post-traumatic stress disorder (PTSD). Children and adolescents with cancer have a much higher prevalence of anxiety, depression, or PTSD than the general population due to long-term treatments and invasive operations that cause them to lose interest in everyday activities.[9]

Symptoms do not exist in isolation.[6] They often interact with each other and appear simultaneously in clusters, which increases the burden of symptoms and diminishes the quality of life.[10,11] Dodd et al[12] were the first to describe the concept of *symptom clusters*, saying that a *cluster* was composed of three or more interrelated but distinctive symptoms over a specific period. Interventions based on a single symptom in a symptom cluster can alleviate the problem of multiple symptoms. Children with AL have received considerable attention from researchers owing to their

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large population base. Several studies have found that children with AL have somatic, gastrointestinal, emotional, and self-image clusters.[13–15] More than 40% of children with AL will develop the pain, anxiety, fatigue, and sleep disorder symptom cluster (PAFS cluster) during chemotherapy, which accounts for about 75% of the children's lives.[16,17] A study by Cheng et al[18] demonstrated that the PAFS cluster was moderately correlated with functional status and quality of life. The more severe the cluster, the worse the patients' physical function and quality of life. Therefore, effective interventions based on the PAFS cluster in clinical nursing can better alleviate symptoms, enhance body function, and improve patients' quality of life.

With the intensifying of research on the PAFS cluster in patients with cancer, researchers are committed to applying various intervention strategies to improve their symptom cluster interference. However, their work has focused primarily on adult patients with cancer.[19,20] The intervention programs are primarily based on psychology and apply psychoeducation, cognitive-behavioral and mindfulness-based stress reduction therapies, and other methods to enhance the patient's understanding of the disease and improve symptom self-management, reduce the PAFS cluster's impact, and relieve symptom distress.[21,22] However, limited intervention strategies are available for children with AL due to their immature comprehension and cognitive abilities.

Play comes naturally to children, giving them unique ways of expression. It is an essential part of their lives, facilitating the development of sensory, motor, and cognitive processes.[23] Therefore, children with life-threatening illnesses also need to play, perhaps even more so than healthy children.[24] *Play therapy* combines play with therapy. The therapy allows children to relax in a free atmosphere of recreation. It encourages them to express their deepest feelings, revealing emotions naturally and easing their inner distress. Liu et al[25] carried out a pictographic game intervention to reduce the pain caused by intrathecal injection during chemotherapy for children with AL and effectively improve their compliance with intrathecal injection. Child Life has recently attracted increasing attention from scholars as a comprehensive nondrug intervention. The concept of Child Life was originated in the 1950s. The theory of children's stress and coping, cognitive development, family support systems, and games forms the basis for games to be used to carry out dynamic, continuous, and diversified psychological interventions to meet the social and healthy development needs of hospitalized children and their family members.[26]

Several studies have shown that Child Life has achieved good results in reducing pain, improving anxiety, depression, and other adverse emotions, and improving sleep disorders in children with cancer.[27–29] Scott et al[30] conducted a retrospective analysis of Child Life intervention in 425 children with cancer aged 2–12 who needed anesthesia. Their results showed that implementing Child Life interventions could reduce the absolute use of anesthetic drugs by more than 16%, which could not only effectively save medical costs but also reduce the adverse reactions of anesthetic drugs. Currently in China, healthcare providers actively implement the construction of Child Life teams and apply this model to carry out clinical interventions in managing chronic diseases in children. Child Life was found to have specific intervention effects on improving children's treatment compliance, reducing emotional distress, and enhancing family self-efficacy.[31,32] However, most intervention studies applying the Child Life concept and its model focus on a single symptom, and few intervention studies focus on symptom clusters.

We developed an intervention program based on Child Life for Chinese children with AL who were undergoing chemotherapy. This study aimed to explore the effects of Child Life intervention on the PAFS cluster in this population. We hypothesized that the intervention would improve pain, anxiety, fatigue, and sleep disturbance more effectively than the existing treatment.

Methods

Study design

A prospective, parallel, single-blinded pilot RCT was conducted from February 2020 to October 2021. This pilot study adhered to the CONSORT Statement.[33]

Participants and setting

Patients meeting the following inclusion criteria were invited to participate in this study: (1) aged between 8 and 14 years; (2) diagnosed with AL; (3) receiving chemotherapy; and (4) able to speak and understand Chinese. Patients were excluded if they (1) were associated with other malignant tumors, severe organic craniocerebral syndrome, or psychiatric diseases; (2) had critical or unstable conditions that required special care from caregivers; (3) were enrolled in other clinical trials; and (4) had intellectual disabilities or other conditions that prevented them from participating.

Based on an estimated effect size of $\alpha = 0.05$ (two-tailed as the direction was hypothesized) and $\beta = 0.20$ (one-tailed as the direction was hypothesized), we estimated that we would require 40 participants per group. Therefore, 48 participants per group were recruited in this study based on a 15% dropout rate.

Procedure

Fig. 1 shows the procedural flow of this study. Study subjects were recruited from the two hematology departments of the Children's Hospital of Soochow University. The hematology departments had patient characteristics, treatment protocols, and nursing care routines. The two wards were used as the intervention and the control groups, implementing the closed envelope method. A review of medical records and consultations with oncologists confirmed the eligibility criteria. The purpose of the study was explained to the children and their parents by a research assistant, and written informed consent was obtained. The control group received routine care, whereas the intervention group received routine care and Child Life intervention. Masking the identities of the participants and interveners was not feasible, but the outcome data collectors were naive concerning this information.

Control group

Children in the control group were provided routine care by bed nurses after admission, including examinations related to admission assessment, health assessment, diet, and life care. Before medical operations such as bone marrow puncture and central vein catheterization, the routine preoperative examination was improved, and the patient's condition was observed after surgery. In addition, special dietary care and activity guidance during chemotherapy were provided according to the doctor's advice.

Intervention group

Forming the Child Life intervention team

The Child Life intervention team was formed and led by the chief nurse. The team included the chief nurse, a hematology physician, two hematology nurses, three departmental medical game counselors, and two masters-level nursing students. The hematology physicians and nurses are all ranked intermediate-level or above and have worked in the specialty for over 10 years. The department medical game counselors have junior rank or above and have worked in hematology for 5–10 years. They have been trained and assessed by the hospital's Child Life department. The head nurse is the team leader and is primarily responsible for its organization and operation. The hematologist is responsible

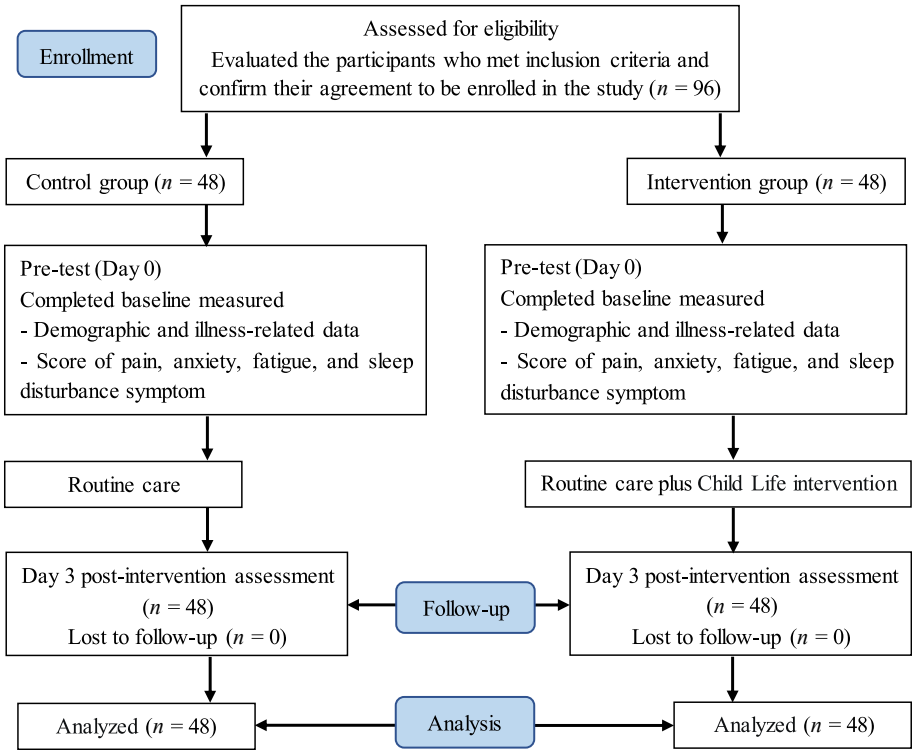

Fig. 1. Participant flow diagram.

for assessing and treating the child's condition and implementing the Child Life intervention. The hematology nurse is responsible for all treatment and care of the child and assists the team members in carrying out the Child Life intervention. The department's medical game counselor implements the Child Life intervention. Finally, the masters-level nursing students participate in constructing the Child Life intervention program.

Organize Child Life personnel training

Before formally implementing the intervention program, the Child Life team leader organized relevant training and assessment to ensure that the team members accurately mastered the Child Life intervention program and its specific operation methods. The 3-h training includes theoretical lectures and case study discussions, focusing on the organization and service scope of Child Life, development status, common skills, and implementation methods. Three actual clinical cases were presented. Their primary purpose was to enhance group members' understanding of Child Life and master the implementation skills. The simulated cases assess the group members' mastery of Child Life theoretical knowledge and implementation skills.

Implementing Child Life interventions

In addition to routine care, the intervention group received the Child Life intervention. The intervention period was 2 months, twice a week, and 30–40 min per session. The locations selected were the bedside, playroom, and peripherally inserted central venous catheter (PICC) clinic. The researchers established each participant's intervention program record sheet according to the intervention program process. They adjusted the intervention program rules in time according to the medical procedure plan. All program implementation rules were registered, and reasons for failure were explained in the remarks.

By referring to the game measures and concepts recommended by the International Child Life Professionals Association,[34] the research team used a literature review and group discussion to draw up the first draft of the Child Life intervention. The on-site consultation method invited nine experts to review the Child Life intervention. The nine specialists included two Child Life specialists, two psychologists, one nursing professor, two hematology head nurses, and two doctors from the Department of Hematology. The scheme was modified according to expert advice. Two children with AL were selected to try the scheme, and their feedback information was collected. Both participants indicated that the scheme was easy to understand and master. Table 1 shows the specific interventions for Child Life.

Measures

Demographic and clinical characteristics questionnaire

The general information questionnaire was designed by the researcher and included age, gender, education level, time of diagnosis, clinical classification, and chemotherapy stage.[15]

Chinese version of Pediatric PROMIS

The Pediatric Patient-Reported Outcomes Measurement Information System (Ped-PROMIS) uses symptoms, quality of life, and functional measures for children. The framework includes physical, psychological, and social dimensions to measure the feelings and experiences of children and adolescents ages 8–17 experiencing multiple chronic conditions (eg, cancer, kidney failure, asthma, obesity, rheumatoid arthritis, and other conditions).[35] In this study, the Chinese Version of Ped-PROMIS (C-Ped-PROMIS) Pain Interference (8 items), Anxiety (8 items), and Fatigue (10 items) short forms were used to evaluate the pain, anxiety, and fatigue symptoms of children with AL in the past week.[35] Each item uses a 5-point Likert response scale ranging from “never” to “almost always.” Each short-form test score is converted into a standard score with an average of 50 and a standard deviation of 10. This evaluation system is confirmed to measure the health status of children accurately with a minimum number of items. It is

Table 1
Themes and contents of the intervention.

Game stage	Themes	Outline
Developmental play phase	Establish a relationship (Day 1)	• Self-introduction and take the initiative to talk, understand the disease of children, medical treatment process • Give gifts, introduce the benefits and procedures of intervention studies • Understand the children's interests and hobbies, introduce the types and time of child life intervention
	Cognitive preparation (Day 1 before operation*)	• Play picture games to explain common causes of leukemia, successful cases, and related treatment plans for children • Models and audio animation are used to introduce common medical devices and adverse effects of chemotherapy to children
Medical simulation game stage	Program support (Day 1 before operation)	• Doll model is used to demonstrate the process of PICC and bone waist piercing for children • The investigator accompanies the child to perform medical procedures and played the child's selected audio • Physical contact with children during medical operations, such as: touch, pat, at the same time to give verbal comfort and encouragement, and agree on a small prize
	Role simulation (Week 2–3)	• Children role play "if I were a nurse," simulate oral care, venipuncture, and other medical operations
Supportive play phase	Active response (Week 2–3)	• Children practice relaxation techniques commonly used in medical operations, such as deep breathing, listening to music, conversation to divert attention
	Information support (Week 3–4)	• Children with "I want to know" to start the dialogue, for children to explain the current concerns • Learn measures to reduce the risk of infection through videos • Use age-appropriate language to explain immediate treatment options for the child
	Emotional support (Week 5–6)	• Listen to the voice of the child – a letter to "Me after discharge" • Praise cards are issued to convey the care and encouragement of medical staff • "Moving Moments" encourages children to express gratitude to family members
	Social support (Week 7–8)	• Introduce children of the same age, give play to peer advantages, and carry out peer help games • Establish an information exchange platform to promote mutual communication

Operation*: the routine invasive operations of the hematology department such as PICC catheterization and bone lumbar puncture. PICC, peripherally inserted central catheter.

widely used to assess the symptoms of chemotherapy in children. The higher the score on the brief table, the more serious the symptoms. The scale has demonstrated acceptable internal consistency (Cronbach's α = 0.835–0.910).[35]

Sleep disturbance scale for children (SDSC)

SDSC comprises 26 items, divided into six aspects to evaluate the sleep status of children aged 6–15, reflecting children's sleep and wake rhythm and sleep behavior. The child's caregiver will fill in the memory by combining the sleep conditions of the child over the past 7 days. Each item is scored on a 5-point Likert scale ranging from 1 to 5, with a total score of 26–130. The higher the score, the more severe the sleep disorder. The internal consistency range of the scale was 0.71–0.79, retest reliability was 0.71, and diagnostic accuracy was 0.91.[36]

Data collection

Trained surveyors issued the electronic questionnaires. If participants required help, the research assistant would assist them with its completion on the tablet and submit it immediately. In addition, the research assistant would assist those needing help to complete the survey independently. The parents completed the sociodemographic section of the general information questionnaire on the day informed consent was signed by the children and their parents. Disease data were obtained by a research assistant by consulting medical records. The child filled out the C-Ped-PROMIS, and the parents completed the SDSC. Three days after the implementation of the intervention, the same research assistant, who was naïve regarding the study conditions, issued and submitted the C-Ped-PROMIS and SDSC electronic questionnaires.

Data analysis

Data analysis was performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to analyze the demographic and clinical characteristics of the participants. Continuous variables are reported as means (standard deviations), and categorical variables are reported as frequencies (percentages). The chi-square, *t*-, and Mann–Whitney *U*-tests compared the intervention and control groups. A P value of < 0.05 was considered statistically significant.

Ethical considerations

The study was approved by the Research Ethics Committee of the Children's Hospital of Soochow University (IRB No. 2020KS022). Written informed consent was obtained from all participants and their parents before participating in the study. Furthermore, the participants and their parents were informed of confidentiality and their right to leave the study at will without penalty.

Results

General data of patients

The intervention group consisted of 48 children with a mean age of 11.00 years (SD: 2.67), including 21 (43.8%) boys and 27 (56.3%) girls. There were 48 children in the control group with a mean age of 10.29 years (SD: 1.95), including 28 (58.3%) boys and 20 (41.7%) girls. Table 2 presents the general information on the two groups. No statistically significant differences were observed between the two groups, indicating comparability.

Effect of Child Life intervention on the PDFS cluster

Table 3 presents the descriptive statistics for pain, anxiety, fatigue, and sleep disturbance in both groups before the intervention. No significant difference between the two groups existed at baseline. Table 4 shows the effects of the Child Life intervention on outcome measures compared to the control group. The intervention group showed a significant reduction in pain, anxiety, fatigue, and sleep disturbance ($P <$

Table 2
Comparison of the participants' characteristics between the intervention group and the control group.

Characteristics	Intervention group ($n = 48$), n (%)	Control group ($n = 48$), n (%)	Statistic value	P value
Age, years, mean ± SD	11.00 ± 2.67	10.29 ± 1.95	1.488	0.140[b]
Gender				
Boy	21 (43.8)	28 (58.3)	2.043	0.153[a]
Girl	27 (56.3)	20 (41.7)		
Residence				
City	19 (39.6)	24 (50.0)	2.344	0.310[a]
Town	19 (39.6)	12 (25.0)		
Rural	10 (20.8)	12 (25.0)		
Diagnosis				
Acute lymphoblastic leukemia	38 (79.2)	36 (75.0)	0.236	0.627[a]
Acute myelocytic leukemia	10 (20.8)	12 (25.0)		
Chemotherapy phase				
Pretreatment	13 (27.1)	16 (33.3)	0.910	0.634[a]
Induced relief	26 (54.2)	26 (54.2)		
Consolidation phase	9 (18.8)	6 (12.5)		

[a] Chi-square test.
[b] Independent t-test. SD: Standard deviation.

Table 3
Comparison of the PDFS cluster between the intervention and control groups before intervention.

Symptoms	Intervention group ($n = 48$), mean ± SD	Control group ($n = 48$), mean ± SD	Statistic value	P value
Pain	24.77 ± 5.00	24.15 ± 4.83	0.62	0.534[a]
Anxiety	25.52 ± 5.63	26.19 ± 5.86	0.57	0.571[a]
Fatigue	32.79 ± 6.66	32.13 ± 6.05	0.51	0.609[a]
Sleep disturbance, median (P25, P75)	60.5 (51.3, 69.6)	61.5 (54.5, 67.7)	−0.49	0.623[b]
Disorders initiating and maintaining sleep, median (P25, P75)	21.5 (20.0, 23.8)	22.0 (19.0, 24.0)	−0.02	0.985[b]
Sleep breathing disorders, median (P25, P75)	5.0 (3.0, 7.0)	5.0 (3.3, 7.0)	−0.82	0.403[b]
Disorders of arousal, median (P25, P75)	5.0 (5.0, 7.0)	6.0 (5.0, 8.0)	−1.23	0.218[b]
Sleep–wake transition disorders, median (P25, P75)	15.0 (11.0, 17.6)	13.0 (11.0, 17.0)	−0.42	0.672[b]
Disorders of excessive somnolence, median (P25, P75)	8.0 (7.0, 10.0)	9.0 (7.3, 12.0)	−1.36	0.175[b]
Sleep hyperhidrosis, median (P25, P75)	6.0 (5.0, 7.0)	6.0 (4.0, 6.0)	−1.13	0.260[b]

PDFS, pain, anxiety, fatigue, and sleep disorder; SD, Standard deviation.
[a] Chi-square test.
[b] Mann–Whitney U test.

Table 4
Comparison of the PDFS cluster between the intervention and control groups after intervention.

Symptoms	Intervention group ($n = 48$), mean ± SD	Control group ($n = 48$), mean ± SD	Statistic value	P value
Pain	10.83 ± 2.55	15.29 ± 2.81	−8.14	<0.001[a]
Anxiety	10.48 ± 2.67	17.98 ± 2.40	−14.46	<0.001[a]
Fatigue	14.33 ± 4.26	21.19 ± 4.10	−8.03	<0.001[a]
Sleep disturbance, median (P25, P75)	30.5 (28.0, 33.0)	35.0 (33.3, 36.8)	−6.09	<0.001[b]
Disorders initiating and maintaining sleep, median (P25, P75)	10.0 (8.0, 11.0)	13.0 (12.0, 15.0)	−6.57	<0.001[b]
Sleep breathing disorders, median (P25, P75)	3.0 (3.0, 4.0)	3.0 (3.0, 3.0)	−3.19	<0.001[b]
Disorders of arousal, median (P25, P75)	3.0 (3.0, 3.0)	3.0 (3.0, 3.0)	−2.33	0.042[b]
Sleep–wake transition disorders, median (P25, P75)	6.0 (6.0, 7.0)	7.0 (6.0, 8.0)	−2.33	0.020[b]
Disorders of excessive somnolence, median (P25, P75)	5.0 (5.0, 6.0)	5.0 (5.0, 6.0)	−1.06	0.289[b]
Sleep hyperhidrosis, median (P25, P75)	2.0 (2.0, 3.0)	3.0 (2.0, 4.0)	−3.56	<0.001[b]

PDFS, pain, anxiety, fatigue, and sleep disorder; SD, Standard deviation.
[a] Chi-square test.
[b] Mann–Whitney U test.

0.001). No significant differences were observed in the disorders of excessive somnolence.

Discussion

Symptom cluster management is critical for children with AL undergoing chemotherapy because the adverse effects of symptom clusters on patients are often multiplicative rather than additive. However, previous intervention studies have been limited to heterogeneous patients, with most studies focusing only on individual symptoms.[37,38] In this study, for the first time, we developed Child Life intervention for symptom clusters in children with AL receiving chemotherapy. The results showed that symptom cluster management interventions offer a promising approach for treating multiple symptoms simultaneously in a cluster. In this study design, the JBI score has been administered using 13 items, 11 of which were assessed as "yes" and two as "no," as shown in the Supplementary material.

Children with AL generally experience more pronounced pain, anxiety, fatigue, and sleep disturbances during chemotherapy. Fatigue symptoms score the highest, in line with the findings of Gedalyd et al.[39] More than 35%–50% of children experience fatigue during chemotherapy, resulting from the interaction of multiple symptoms and their exacerbating triggers. The physiological mechanisms of pain, anxiety, fatigue, and sleep disturbance symptoms are interconnected and interact.[40] This outcome may be particular to the special group of children with AL, whose average age was (10.29 ± 1.95) years and whose cognitive and behavioral abilities were limited. In addition, more than

80% of the children with AL were in induction remission, facing sudden interruption of everyday school life and repeated invasive operations such as bone marrow aspiration and blood sampling during hospitalization. These conditions made the children highly susceptible to strong psychological stress reactions. However, pain, anxiety, and fatigue scores in this study were lower than in a previous one.[13] On the one hand, it may be due to the different severity of symptoms reflected by different assessment tools, especially the different ages of children and the different understanding of the health concept measured, which may affect the consistency of measurement results to some extent. On the other hand, several studies have shown differences in the outcome of symptoms reported by children and parents, which may be related to parents' overestimation of pain, anxiety, fatigue, and other symptoms experienced by children.[41,42] At present, encouraging medical staff to listen to children's feelings during diagnosis and treatment and collecting relevant health information reported by children has become a new trend in children's symptom cluster management. Unified symptom assessment tools help improve the intervention programs' accuracy and scientific nature.

This study showed that Child Life intervention could improve the PAFS cluster in children with AL. The results showed that anxiety, pain, fatigue, and sleep disturbance were significantly lower in the intervention than in the control group. Controlling pain, anxiety, and other symptoms is consistent with previous studies' results.[43,44] Witt et al[45] conducted a weekly 20–40 min drama game for 15 children with leukemia aged 3–13 years from the date of diagnosis. After a 2-month intervention, the children benefited from the game. It alleviates the emotional distress accompanying the disease's diagnosis and treatment. In addition, Mohammadi et al[23] administered nine sessions of 30–45 min of play-based occupational therapy to two children with ALL. The treatment effectively reduced pain, anxiety, and fatigue in hospitalized children.

Indeed, providing children with play has unique benefits because illness, stress, and physical limitations prevent ordinary play and socialization. These elements are essential for children's optimal growth and development. Most importantly, engaging in play activities during hospitalization improves children's coping skills and relieves their stress, thereby improving their psychosocial adjustment to the illness and the fact of hospitalization. The effectiveness of the Child Life intervention in improving symptom clusters may be due to the core element of capturing the child's cognitive biases, conducting coping behavior training, and continuously enhancing it. For example, various symptoms are presented to the child in pictures. The child becomes familiar with the symptoms, why they occur, and specific coping strategies. Once the child has learned these symptom management methods, they can be used both in the hospital and alone at home, facilitating long-term self-management. Zhang et al[22] performed a cognitive-behavioral intervention on symptom clusters of patients undergoing chemotherapy for gastrointestinal cancer. They showed that patients' psychological and energy deficiency symptom clusters were effectively improved after the intervention. The Child Life intervention program includes games like role play, painting, dolls, clown therapy, and more. The intervention had a clear theme, including developmental games, medical simulation games, and support games. It simulates medical procedures and explains them in advance so children can understand and play. This strategy will help children and their parents to understand better the medical procedures' details and prepare coping strategies in advance. The Child Life intervention lowered postoperative stress and anxiety levels significantly compared to the control group. Furthermore, it reduced the patients' demands for intraoperative sedation and anesthesia drugs, reflecting better compliance with future medical procedures.[46,47]

Children are quickly bored when offered only a single form of play. Thus, the project included picture book games, music therapy, doll models, audio animations, group games, and other game types. Children can choose age-appropriate games, enhancing their self-confidence and sense of control. Children's health education is conducted with games as the media to discuss the concerns of children and family members. Timely information and emotional support are provided to children to reduce anxiety and other unpleasant emotions and promote a more positive experience.[48] However, this protocol did not significantly change the phenomenon of excessive somnolence. This result may be related to the fact that children with AL view somnolence as a "normal" requirement of the disease or its treatment process. Furthermore, the causes of somnolence are relatively complex and closely related to disease progression, making nondrug intervention effects subtle.[49] Therefore, further strengthening the assessment and management of symptoms in children with AL and improving symptom management programs is required to reduce the symptom burden in children with AL.

During the development and implementation of this study, we felt that establishing a good "partnership" with the child would significantly improve the intervention's acceptability. To be proactive, healthcare professionals should first ask the child about their psychological needs and establish a trusting patient–provider relationship. For children reluctant to express their emotions because of their fear of an uncertain future and limited survival time, dynamic assessment of their subjective experience of the treatment process is imperative. Choosing the child's preferred or even favored language, patiently and meticulously providing emotional guidance, and establishing a good counseling relationship are the prerequisites for smooth interventions in the future. At the same time, play is a regular activity for children of all ages. To meet the play needs of different children, the researcher adopted an intervention model that combined multiple types of play with animated videos, drawing and reading, and doll models. Most children accepted this strategy. They were interested in the intervention's content and could cooperate well in completing the program. Therefore, applying the Child Life intervention for children with AL requires excellent overall quality of the personnel implementing it. It requires interventionists to have medical knowledge related to AL diseases, specific child psychological care and educational theories, medical counseling games, and art, drawing, and communication skills. Thus, the research team should include professional psychotherapists, art workers, basic medical researchers, and other professionals in the future symptom management intervention work and perfect AL symptom management program.

Limitations

The limitations of this study should be noted. First, sample selection and intervention were conducted in a hospital, limiting the extensibility of intervention in other backward areas to a certain extent. Second, the research object only involved children aged 8 to 14 with AL. Previous studies on young children were limited. Finally, this protocol's applicability to other symptom clusters in children with AL was not discussed.

Conclusions

Child Life intervention can effectively improve the PAFS cluster of children with AL undergoing chemotherapy. In addition, the results suggested that symptom cluster management intervention based on Child Life provided a promising approach to treating multiple symptoms simultaneously within a cluster.

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CRediT author statement

Rongrong Li: Conceptualization, Methodology, Formal analysis, Writing – original draft. **Xinyi Shen**: Data curation, Writing – original draft. **Lin Zhang**: Visualization, Investigation. **Yuying Chan**: Resources,

Supervision. **Wenying Yao**: Validation, Supervision. **Guanxun Zhang**: Methodology, Writing – review and editing. **Huiling Li**: Conceptualization, Funding acquisition, Resources, Supervision. All authors had full access to all the data in the study, and the corresponding authors had final responsibility for the decision to submit for publication. The corresponding authors attest that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Declaration of competing interest

All authors have none to declare.

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Ethics statement

The study was approved by the Research Ethics Committee of the Children's Hospital of Soochow University (IRB No. 2020KS022). All participants provided written informed consent.

Data availability statement

The data that support the findings of this study are available from the corresponding author, Prof. Huiling Li, upon reasonable request.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.apjon.2023.100243.

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