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Original Research Article

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A psychoeducational sleep health intervention for children with acute lymphoblastic leukemia during maintenance therapy: a proof-of-concept pilot study

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Abstract

Objective: Although sleep disturbances are common and impairing side effects of treatment for pediatric acute lymphoblastic leukemia (ALL), no research has studied whether prevention programs are effective. The current study assessed feasibility and acceptability of a brief sleep health education program during maintenance chemotherapy for ALL.

Methods: Twenty-five caregivers of children with ALL aged 4–8 years old ($M = 5.6$ years, $SD = 1.3$) receiving maintenance chemotherapy enrolled. An oncology nurse navigator (ONN) met individually with caregivers (15–30 min) to introduce them to a psychoeducational website on sleep during ALL treatment and a sleep action plan. Questionnaires were collected at baseline and 1-month follow-up. Medical records were reviewed for the 3 months prior to and following the ONN meeting for appointments documenting sleep discussions.

Results: The program was feasible (of 27 caregivers approached, 25 [93%] enrolled; of 25 enrolled, 22 [88%] completed the follow-up assessment), and the majority of caregivers (77%) rated the intervention as acceptable. Approximately 40% of children experienced clinically meaningful improvements in sleep disturbance or impairment from baseline to follow-up. The average proportion of physician appointments per patient with documented sleep discussions was lower at follow-up (34%) than at baseline (41%), although this was not statistically significant ($p = .17$).

Conclusions: A brief sleep health education program is feasible and acceptable during maintenance therapy for pediatric ALL. Providing families with comprehensive information on sleep during ALL treatment may improve child sleep and reduce the need to discuss sleep with oncologists. Findings support evaluation of Sleep ALL Night in a statistically powered, randomized trial.

Keywords: health promotion and prevention, oncology, psychosocial intervention, sleep disturbances.

Children undergoing treatment for pediatric acute lymphoblastic leukemia (ALL) often experience disrupted sleep as a consequence of their cancer-directed therapy. Sleep disruptions can begin during the intensive induction or consolidation phases of treatment, and persist through maintenance therapy when commonly used medications (e.g., corticosteroids) dysregulate the child's sleep patterns (Daniel et al., 2016; Rosen et al., 2015). Poor sleep is associated with increased fatigue and neurocognitive impairment, ultimately diminishing the pediatric ALL patient's overall quality of life (Cheung et al., 2017; van Litsenburg et al., 2011; Vasquez et al., 2022). Without treatment, poor sleep has been shown to develop into insomnia disorder (characterized by persistent struggles with falling or staying asleep, leading to daytime sequelae), persisting well into survivorship (Russell et al., 2020; Zhou & Recklitis, 2014). Indeed, of the >90% of children with ALL who will be long-term survivors, approximately 30% may meet criteria for insomnia even after reaching adulthood (Zhou & Recklitis, 2014).

Given the significant impact of sleep disturbances on quality of life in survivorship, implementation of programs to prevent its development in at-risk individuals are indicated (Richter et al., 2016). Preventive interventions have demonstrated efficacy within pediatrics (e.g., school-based preventive interventions for obesity) and may improve patient care while ultimately reducing healthcare costs (Berwick et al., 2025; Piotrowski et al., 2009; Romanelli et al., 2020). The development and evaluation of preventive sleep programs is especially relevant for children with ALL, as the majority of cancer centers across the United States lack the specialists necessary to provide evidence-based sleep therapies (Chan et al., 2021; Zhou et al., 2017). Additionally, while behavioral interventions for common sleep disorders such as insomnia are effective, treatment involves multiple appointments spread out over the course of several months (Zhou & Owens, 2016). For families already overwhelmed with the demands of pediatric ALL treatment (Greenzang et al., 2023), the behavioral changes required to improve insomnia can be overwhelming for both the child and their family (Merz & Tomfohr-Madsen, 2018), further highlighting the considerable need to prevent development of the disorder.

Despite significant sleep disruptions during treatment for pediatric ALL, we are not aware of prior research investigating the potential of strategies to prevent their development. To begin addressing this gap, we developed a stakeholder-

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informed program (Sleep ALL Night) to provide families with information critical to understanding and improving their child's sleep during maintenance therapy (Zhou et al., 2023). Following the ORBIT model for refinement and evaluation of novel behavioral interventions (Czajkowski et al., 2015), we conducted a single-arm, proof-of-concept pilot study in children receiving maintenance therapy for ALL. Specifically, we aimed to determine whether the Sleep ALL Night program would be feasible and acceptable to families and to gather information on the impact of Sleep ALL Night on child sleep and discussions about child sleep between caregivers and healthcare providers.

Methods

Participants

Eligibility criteria required that participants be English- or Spanish-speaking caregivers of a child between 4 and 12 years of age, who were enrolled in a frontline clinical trial for *de novo* ALL [protocol] and had completed at least two cycles of maintenance therapy. This treatment included an identical 5-day pulse of dexamethasone at the start of every maintenance cycle (Days 1–5) for all children. Of note, the clinical trial included both National Cancer Institute standard and high-risk disease as well as T-cell immunophenotype. Caregivers were excluded if their child had critical illness or if the child's oncology team declined permission to recruit. Children did not have to present with symptoms of a sleep disorder for their caregiver to be eligible for the study.

Procedure

Potential participants were identified using the Dana-Farber Cancer Institute 16-001 study database and approached at the time of an in-person outpatient oncology clinic appointment. Study staff explained the purpose of the study and offered families an opportunity to enroll. Consistent with the ORBIT model, small sample sizes (e.g., 20–25 participants) are sufficient for proof-of-concept studies, as clinical rather than statistical benefit is being assessed (Czajkowski et al., 2015); recruitment was ceased after 25 participants were enrolled. Upon study enrollment, the caregiver was asked to complete a baseline study assessment and then met with an oncology nurse navigator (ONN) for the intervention. ONNs were experienced in providing support to children and their families during pediatric ALL treatment but were not required to have previous sleep-related training. All ONNs first reviewed the study materials, then met with the study investigators for 1 hr to review the key talking points for the intervention visit and website content. Approximately 1 month after the intervention visit, caregivers completed a follow-up study assessment. Study procedures were approved by the hospital's IRB and conducted in 2023 and 2024; the trial was registered on ClinicalTrials.gov (NCT05866887). We followed the Consolidated Standards of Reporting Trials (CONSORT) checklist, and the final checklist is available as Supplemental File S1.

Intervention

The overarching goals of the 15- to 30-min meeting with the ONN were to familiarize caregivers with the study materials/website and encourage engagement with this content to learn more about sleep during ALL treatment. Specifically, the ONN focused on several talking points: (1) normalize the experience of disrupted sleep during pediatric ALL treatment; (2) inform caregivers that sleep is important even though it is rarely discussed during oncology appointments; (3) encourage caregivers to be proactive in managing their child's sleep; (4) introduce caregivers to the sleep action plan; (5) introduce caregivers to the Sleep ALL Night psychoeducational website. The website (https://sleepallnightdfci.org/) was designed as a tool for families to learn more about navigating potential disruptors of a child's sleep during maintenance therapy (e.g., how to mitigate the effects of corticosteroids on sleep), common myths about how to help children sleep better, and evidence-based strategies to improve sleep (e.g., increase morning wake time consistency). Sleep ALL Night website content was developed following a qualitative study with families of pediatric ALL patients and involved input from both medical and psychosocial experts in pediatric oncology (Zhou et al., 2023). Caregivers were encouraged to review the website upon going home and then as needed in conjunction with a sleep action plan.

Consistent with action plans implemented for children with a range of chronic medical conditions (Kessler, 2011), the sleep action plan was designed to guide caregiver decision-making about when their child's sleep may require further attention (Supplemental File S2). It was divided into three zones based on diagnostic criteria for insomnia disorder (American Academy of Sleep Medicine, 2014). Specifically, a green zone outlined appropriate sleep (e.g., child falls asleep in <30 min) and recommended passive observation of the child's sleep. A yellow zone described worsening sleep (e.g., child wakes up tired 3+ days/week) and recommended the family visit the Sleep ALL Night website for information and begin monitoring the child's sleep patterns using a sleep diary. Of note, a sleep diary was available on the website as a tool for caregivers, but sleep diary data were not collected as part of this research study. A red zone indicated problematic sleep (e.g., being awake for ≥30 min in the middle of the night for 3+ months) and referred the family to the Sleep ALL Night website for concrete recommendations to address the sleep concerns as well as information on how to initiate further evaluation. These recommendations were based on evidence-based strategies for pediatric insomnia, including strategies studied in children with ALL (Daniel et al., 2024; Meltzer et al., 2021; Zhou & Owens, 2016).

Measures

Demographics: Information (i.e., child age, sex, race, ethnicity, cancer diagnosis, and years from diagnosis) was abstracted from patient electronic medical records.

Feasibility (assessed at follow-up): The study would be deemed feasible if ≥30% of eligible caregivers who were approached agreed to enroll in the study and if ≥80% of participants who enrolled in the study completed the follow-up assessment. Although individual caregiver visits to the website were not tracked, overall website access aggregate data were also collected to inform feasibility.

Acceptability (assessed at follow-up): The Acceptability of Intervention Scale (AIM) consisted of four items asking participants how much they agreed that the intervention website and sleep action plan met their approval and were appealing, liked, and welcomed; higher scores indicate stronger acceptability (Weiner et al., 2017). The Intervention Appropriateness Measure (IAM) consisted of four items asking participants how much they agreed that the sleep action plan and intervention

website seemed fitting, suitable, applicable, and a good match for caregivers of pediatric ALL patients; higher scores indicate stronger appropriateness (Weiner et al., 2017). The intervention would be deemed acceptable if the average score on the AIM and IAM was ≥4 (i.e., "agree" or "completely agree").

Sleep disruption (assessed at baseline and follow-up): The Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance scale consists of eight items to assess the child's sleep disturbance (e.g., difficulty falling asleep; Daniel et al., 2020). The PROMIS Sleep-Related Impairment scale consists of eight items designed to assess the extent that sleep impairs function (e.g., daytime sleepiness). Higher scores on both scales indicate worse outcomes, and a reduction of five points or more in the T-score (i.e., 0.5 *SD*s) is considered a clinically meaningful improvement over time (Terwee et al., 2021).

Healthcare provider discussion about sleep: Medical records were reviewed for documentation of any sleep-related discussions during each child's appointments with a medical provider (oncologist or nurse) for the 3 months prior to study enrollment and the 3 months following the Sleep ALL Night intervention meeting with the ONN. Any documentation of the study meeting with the ONN was excluded from these data. Of note, there is no standard sleep assessment in the clinic; discussions about sleep vary by provider and family.

Statistical analysis

Descriptive statistics were used to summarize key study variables, including the primary aims of enrollment and follow-up survey completion rates. Paired sample *t*-tests were employed to compare PROMIS sleep disturbance and impairment variables from baseline to follow-up. The proportion of patients achieving clinically meaningful improvements in sleep scores was calculated along with 95% confidence intervals. Wilcoxon rank sum tests were used to compare proportions of visits per patient where sleep discussions were documented for the 3 months prior to study enrollment compared to the 3 months following the Sleep ALL Night intervention. Statistical significance was defined at an alpha level of 0.05, and Cohen's *d* or Wilcoxon effect size *r* methods were utilized where appropriate. Analyses were conducted using R software (version 4.4.3) and SPSS Statistics (version 28.0).

Results

The cohort included 25 caregivers of children with ALL aged 4–8 years old ($M = 5.6$ years, $SD = 1.3$) who were 10–22 months post-diagnosis ($M = 15.7$ months, $SD = 3.7$). The majority of children were female (56.0%) and non-Hispanic (92.0%); children were American Indian/Alaska Native (4.0%), Black/African American (8.0%), White (76.0%), or another race (12.0%).

Feasibility: Of the 27 caregivers approached, 25 (92.6%) enrolled. Of the 25 caregivers enrolled, 22 (88.0%) completed the follow-up assessment (two caregivers could not be reached, and one caregiver withdrew due to other obligations). All of the following analyses were conducted with these 22 participants. Caregivers completed the follow-up assessment an average of 27 days after the baseline assessment ($SD = 11.2$, range = 19–63). During the study period, there were a total of 125 unique visits to the website (excluding when the ONN introduced participants to the website) and a total of 960 events (times that a user engaged with the website). Of note, the website link was not provided to anyone outside of the study, and the website code purposefully did not include search engine optimization keywords to attract search engines, making it unlikely that non-participants accessed the website.

Acceptability: The majority of caregivers either "agreed" or "completely agreed" with the intervention's acceptability (77.3%; AIM $M = 4.4$, $SD = 0.6$) and appropriateness (77.3%; IAM $M = 4.4$, $SD = 0.6$).

Sleep: PROMIS sleep disturbance decreased from baseline ($M = 60.0$, $SD = 8.6$) to follow-up ($M = 56.2$, $SD = 9.6$), although this difference did not reach statistical significance ($p = .051$, Cohen's $d = .44$). PROMIS sleep impairment significantly decreased from baseline ($M = 60.2$, $SD = 7.4$) to follow-up ($M = 56.7$, $SD = 9.6$, $p = .049$, Cohen's $d = .45$).

Clinically meaningful improvement (i.e., T-score reduction of ≥5 points) was seen in eight (36.4%, 95% CI [20.7, 63.6]) children for sleep disturbance (Figure 1) and eight (36.4%, 95% CI [17.2, 59.3]) children for sleep impairment (Figure 2); a total of five (22.7%, 95% CI [7.8, 45.4]) children demonstrated clinically meaningful reductions in both sleep disturbance and impairment.

Provider discussion about sleep: Accounting for differences in number of appointments per patient, the average proportion of physician appointments per patient where sleep discussions were documented was lower at follow-up (34%, 95% CI [19, 49]) than at baseline (41%, 95% CI [23, 58]), although this difference was not statistically significant ($p = .17$, Wilcoxon effect size $r = .28$). No nursing notes (145 total appointments at baseline and 139 total appointments at follow-up) explicitly documented a discussion about sleep.

Discussion

This proof-of-concept pilot study demonstrates that Sleep ALL Night, a program where an ONN briefly introduces caregivers to a psychoeducational sleep website and sleep action plan, is feasible and acceptable during maintenance therapy for pediatric ALL. Despite the brief nature of this program, findings demonstrate that Sleep ALL Night has the potential to improve child sleep, with approximately 40% of children demonstrating clinically meaningful reductions in parent-reported sleep disturbance or impairment. Additionally, after Sleep ALL Night, overall child sleep impairment and disturbance decreased with small to medium effect sizes, further supporting the potential clinical utility of this intervention. A randomized controlled trial is indicated to determine whether changes in child sleep are replicated in a larger sample and due to Sleep ALL Night rather than other factors (e.g., natural changes in sleep during ALL treatment).

While sleep problems were not required for study inclusion, sleep disturbance and impairment scores at baseline were consistent with a slightly older pediatric cancer sample (ages 5–17) and significantly higher than general population child samples (Daniel et al., 2020). Given that sleep problems often develop into insomnia if left untreated, the high rate of sleep problems in this sample highlights the importance of implementing prevention programs for this at-risk population. Unlike traditional behavioral sleep interventions for children, our intervention does not require highly trained sleep experts, significant financial investment (for the family or the hospital), or additional medical appointments for already taxed caregivers. Instead, a brief meeting (15–30 min)

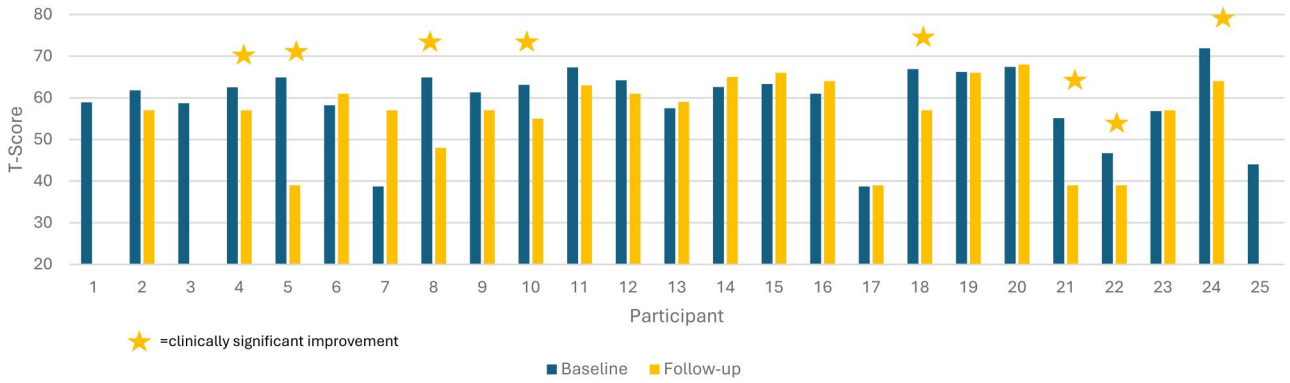

Figure 1. Change in sleep disturbance T-score from baseline to follow-up.

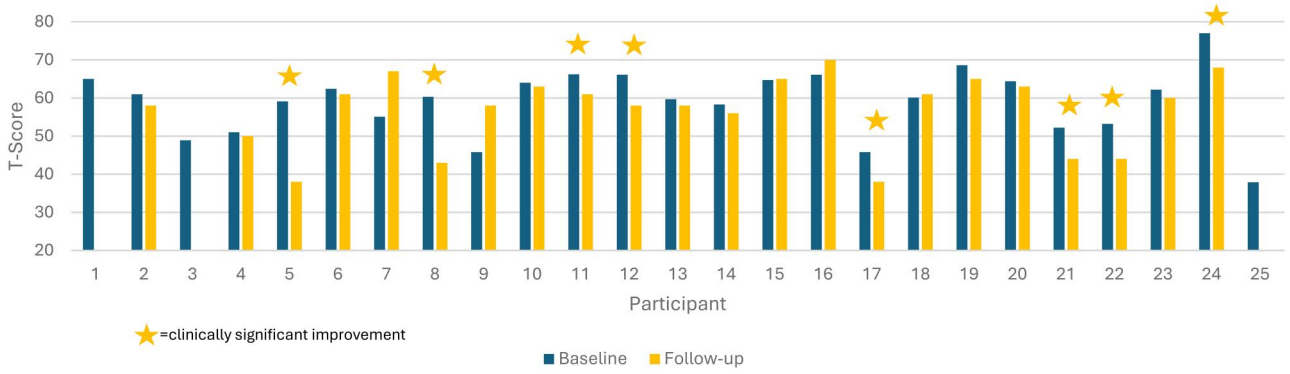

Figure 2. Change in sleep impairment T-score from baseline to follow-up.

with an ONN to orient to a scalable psychoeducational website and sleep action plan can be integrated into an existing visit, and caregivers can explore educational materials at their own convenience.

Interestingly, educating caregivers about their child's sleep may have secondary benefits for busy oncology clinicians. Our data suggest that sleep was documented less frequently in physician notes following the intervention. Although additional research is required to understand the cause, we hypothesize that caregivers felt more confident after Sleep ALL Night in recognizing when their child's sleep reached a clinical threshold for concern and thus did not feel the need to regularly discuss it with the child's oncologist.

Limitations

Although promising, findings should be considered in the context of study limitations. Most notably, the sample was small and largely White and non-Hispanic, which limits generalizability. Future research should target a more diverse sample and gather demographic information from caregivers, as characteristics (e.g., gender, socioeconomic status, education level, disability status) may impact engagement with the intervention. Second, individual feasibility data were not available (e.g., how often individual caregivers accessed the website), necessitating further exploration of these factors as well as potential mechanisms of action (e.g., change in caregivers' behaviors around child sleep). Similarly, as individual feasibility and cancer treatment data were not available, it is not possible to determine whether changes to sleep at the individual level were related to lack of engagement with the intervention, medical treatment, or other factors (e.g., hospitalization). Additional research is also required to understand the reasons for reduced documentation of sleep discussions in physician notes at follow-up and the lack of documentation of sleep discussions in all nursing notes pre- and post-intervention. Finally, Sleep ALL Night was designed to improve overall sleep health but does not provide specific treatments for all sleep disorders (e.g., parasomnias, sleep apnea). Future versions of this website will be designed to include guidance on how to seek proper evaluation for other sleep disorders.

Conclusion

Our study suggests that a brief psychoeducational web-based intervention, Sleep ALL Night, shows promise for improving sleep for pediatric ALL patients during maintenance therapy. Following the ORBIT model, future research should examine the effects of Sleep ALL Night in a statistically powered randomized trial to determine whether the intervention can prevent the development of sleep disturbances in this at-risk population. If supported in future research, Sleep ALL Night has the potential to be easily integrated into routine pediatric ALL care, as it requires only previously developed materials (e.g., psychoeducational website) and minimal contact time. As insomnia is highly prevalent and impairing for pediatric ALL survivors, preventing the development of sleep problems during treatment has the potential to meaningfully improve quality of life for patients and their families. More broadly, as pediatric cancer treatment is associated with a wide range of late effects (e.g., insomnia, sexual dysfunction, anxiety) that persist for years or even decades into survivorship

(Chevalier et al., 2023, 2024; Zhou & Recklitis, 2014), brief low-cost prevention interventions may be critical to improving long-term quality of life in this population.

Supplementary material

Supplementary material is available online at *Journal of Pediatric Psychology* (http://jpepsy.oxfordjournals.org/).

Data availability

The datasets generated by the current study are available from the corresponding author on reasonable request and with appropriate regulatory review and data privacy protections.

Author contributions

Lydia Chevalier (Formal analysis [equal], Visualization [equal], Writing—original draft [lead], Writing—review & editing [lead]), Morgan A. Paul (Formal analysis [equal], Writing—review & editing [supporting]), Lucille Lokko (Data curation [equal], Formal analysis [supporting], Project administration [equal], Writing—review & editing [supporting]), Kira Bona (Conceptualization [equal], Funding acquisition [equal], Investigation [equal], Methodology [equal], Project administration [equal], Resources [equal], Supervision [equal], Writing—original draft [equal], Writing—review & editing [equal]), and Eric S. Zhou (Conceptualization [equal], Funding acquisition [equal], Investigation [equal], Methodology [equal], Project administration [equal], Supervision [equal], Writing—original draft [equal], Writing—review & editing [equal])

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Conflicts of interest: The authors declare they have no conflicts of interest.

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Ethical approval

The study has been approved by the Dana-Farber Cancer Institute (IRB Protocol No. 22-677).

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