Sleep Disturbance in Hong Kong Children with Cancer: A Cross-Sectional Study Comparing Healthy Counterparts and Children with Other Chronic Diseases

RESEARCH PROTOCOL

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Table of Contents

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Abstract

Sleep disturbances are prevalent among children with chronic illnesses, yet the specific impact of cancer on sleep remains underexplored. This prospective and cross-sectional study aims to evaluate the prevalence, severity, and characteristics of sleep disturbances in Chinese children with cancer compared to healthy peers and children with other chronic diseases. By leveraging validated sleep assessment tools and parental reports, the goal is to identify unique challenges faced by children with cancer. Results might influence the design of personalized interventions aimed at enhancing the overall well-being of children with cancer.

1. Introduction

Sleep stands as a fundamental foundation for children's health as it supports physical state, emotional stability, and cognitive performance of children (Baddam & Nasser, 2021). Adequate sleep throughout childhood remains vital because it promotes physical development, strengthens immune functions, and facilitates memory consolidation (Paruthi et al., 2016). Chronic illness patients show a heightened risk of sleep disturbances, particularly cancer children, who experience these disturbances due to a combination of psychological and physiological and environmental factors (Lee et al., 2017).

1.1 Sleep Disturbances in Children with Cancer

Research data shows a high incidence of sleep disturbances affecting children treated for cancer since studies demonstrate a wide range from 40% to 80% (Ho et al., 2022; Kaushik et al., 2022; Sheikh et al., 2021). Sleep disruptions in children stem from various sources. Physiological side effects of cancer like pain along with nausea and fatigue emerge as vital factors that disrupt children during cancer treatment (Gedaly-Duff et al., 2006; Zupanec et al., 2017). The sleep issues get worse when cancer patients use corticosteroids and chemotherapy drugs since these medications disrupt the body's natural sleep-wake pattern (Hinds et al., 2007). External hospital factors amplify the existing sleep disturbances in pediatric cancer patients. Medical procedures frequently interrupt pediatric patients in hospital beds during nighttime hours, while ambient noise and bright lighting in the setting contribute to significant barriers to restful sleep (Perdikaris et al., 2009). The combination of internal factors and hospital environment elements prevents pediatric cancer patients from experiencing adequate sleep quality.

1.2 Comparison with Healthy Children and Other Chronic Illnesses

In contrast, healthy children generally experience more consistent and undisturbed sleep accentuates how chronic illnesses combined with hospitalization damage children's sleep quality. Children with other chronic illnesses also encounter sleep difficulties yet their reasons for these issues differ from those diagnosed with cancer. For instance, the condition of asthma triggers nighttime awakenings because of wheezing and coughing, while diabetic patients experience disrupted sleep due to fluctuating glucose levels (Adavadkar et al., 2022; Meltzer & Mindell, 2017). These conditions cause sleep interference but patients tend to experience less psychological and physical distress from cancer which leads to milder overall sleep issues.

2. Study Objectives

The objectives of this study are threefold:

1) To assess the prevalence and nature of sleep disturbances in children with cancer.
2) To compare sleep disturbances in children with cancer to those in healthy children and children with other chronic diseases.
3) To identify potential factors contributing to sleep disturbances in paediatric patients.

3. Study Significance

This study contributes to the comprehension of pediatric sleep disturbances by carefully evaluating sleep disruptions among three groups: children with cancer, children with other chronic illnesses, and healthy children. The data generated from this study provides vital information for developing targeted therapies specific to population groups with linked sleep disturbance factors. By pinpointing specific contributors, such as hospital environment, medication effects, or pain, the research will lay the groundwork for targeted interventions. These could include reducing nighttime disruptions, refining pain management, or designing sleep-friendly hospital settings. Furthermore, integrating tools like the Chinese version of PSQI into routine care could enable early detection and management of sleep issues, mitigating long-term risks like cognitive and emotional deficits

Beyond oncology, the study's comparison with children who have other chronic illnesses will reveal how different conditions uniquely disrupt sleep, guiding tailored strategies for diverse patient groups. The healthy control group will establish a benchmark for normal sleep, highlighting the extent of disruption caused by chronic illness and elevating sleep as a priority in pediatric care.

4. Methods

4.1 Study Design

A prospective and cross-sectional study will be conducted to examine and compare sleep problems in three groups of children: 1) healthy children, 2) children with various chronic illnesses and undergoing active treatment, and 3) children with cancer and undergoing active treatment. This research design allows for a one-time analysis of sleep characteristics and factors that contribute to disturbances in

three pediatric groups. The study aims to reveal distinct sleep disturbance characteristics of each examined group to determine how sleep changes relate to cancer and other medical conditions among individuals. Such research design allows effective assessment through simultaneous analysis to acquire an in-depth overview of sleep health dynamics among all groups.

4.2 Data Collection

This study will employ objective tools to comprehensively assess sleep disturbances and related outcomes across the three groups: children with cancer, children with other chronic illnesses, and healthy children.

4.2.1 The Chinese version of Pittsburgh Sleep Quality Index (PSQI)

The PSQI is a widely validated self-report questionnaire designed to evaluate sleep quality and disturbances (Mollayeva et al., 2016). Although originally developed for adults, it has been adapted and used effectively in pediatric populations with parental assistance for younger children (De La Vega et al., 2015; Tietze et al., 2014). The Chinese version of the PSQI, as validated for use in Hong Kong Chinese populations, including childhood cancer survivors, retains the same structure as the original PSQI (Ho et al., 2021). The PSQI consists of 19 self-rated questions and 5 questions rated by a bed partner or roommate. The 19 self-rated questions are grouped into 7 component scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. Each component is scored from 0 to 3, contributing to a global score ranging from 0 to 21. The Chinese version of the PSQI is completed by parents for younger children (e.g., aged 6-11) or by children aged 12-18 with parental assistance if needed. The PSQI's multidimensional approach will provide detailed insights into specific aspects of sleep disruption, such as prolonged sleep onset or frequent awakenings, particularly relevant to hospitalized children with cancer.

4.2.2 The Chinese version of Pediatric Quality of Life Inventory 4.0 (PedsQL 4.0)

The PedsQL is a well-established instrument for assessing health-related quality of life in children and adolescents aged 2-18 years (Varni et al., 2005). This study will use the Chinese version of PedsQL 4.0 Generic Core Scales, which include 23 items across four domains: physical functioning (8 items), emotional functioning (5 items), social functioning (5 items), and school functioning (5 items). Responses are scored on a 5-point Likert scale (0 = never a problem, 4 = almost always a problem), then transformed to a 0-100 scale, where higher scores reflect better health-related quality of life. The PedsQL yields a total scale score (average of all 23 items), a physical health summary score (average of the 8 physical functioning items), and a psychosocial health summary score (average of the 15 items across emotional, social, and school functioning domains). These scores provide a comprehensive assessment of overall quality of life and specific physical and psychosocial

health outcomes, enabling exploration of how sleep disturbances correlate with broader well-being in children with cancer, other chronic illnesses, and healthy controls. Parent-proxy reports for younger children and self-reports for older participants, mirroring the PSQI administration. The PedsQL 4.0 Generic Core Scale has undergone cross-cultural adaptation into Chinese and psychometric validation, rendering it suitable for application in clinical settings (Ji et al., 2011; Yeung et al., 2012). The Chinese version of PedsQL will serve as a secondary measure to explore how sleep disturbances correlate with broader quality-of-life outcomes, such as fatigue-related physical limitations or emotional distress, which are particularly pertinent to children with chronic illnesses like cancer.

4.3 Key Variables

4.3.1 Primary Outcome Variable

Sleep quality, measured by the global PSQI score, will be the primary endpoint. This encompasses the seven component scores (e.g., sleep duration, latency, efficiency), providing a holistic assessment of sleep health. A global score >5 will classify participants as having poor sleep quality, enabling prevalence comparisons across groups.

4.3.2 Secondary Outcome Variable

Health-related quality of life, assessed via the PedsQL total score and its domain-specific subscales (physical, emotional, social, school), as well as physical health summary score and psychosocial health summary score will examine the broader impact of sleep disturbances. This will help determine, for example, whether poor sleep in children with cancer correlates with reduced emotional or physical functioning compared to other groups.

4.3.3 Demographic Variables

To control for potential confounding effects on sleep patterns and access to healthcare resources, the following demographic and clinical variables will be collected: age (in years), gender, socioeconomic status (SES), disease type, disease status, and use of hypnotics (yes/no). SES will be assessed through parental education (categorized as primary or below, junior secondary, senior secondary, or university/college and above). For children with cancer, disease type (e.g., leukemia, lymphoma, brain tumor, bone tumor, or others) and disease status (e.g., stage 1-4, recurrence, years since diagnosis, treatment type such as chemotherapy, radiotherapy, surgery, immunotherapy, transplant, or combination) will be recorded. For children with other chronic illnesses, disease type (e.g., asthma, type 1 diabetes, chronic kidney disease) will be noted. These factors may influence sleep outcomes, e.g., older children may report greater daytime dysfunction, or lower parental education level may limit access to supportive care, necessitating adjustment in statistical analyses to isolate the effects of chronic illness on sleep quality.

4.4 Expected Outcomes

This study anticipates uncovering significant differences in sleep quality between children hospitalized with cancer, those with other chronic illnesses, and healthy children. The following outcomes are expected:

4.4.1 Children with Cancer

It is hypothesized that children with cancer will exhibit the most severe sleep disturbances among the three groups. Factors such as pain associated with the illness, side effects of chemotherapy, and frequent nighttime medical interventions are likely to result in reduced sleep duration, prolonged sleep latency, and increased sleep fragmentation. Reported data from the PSQI are also expected to place a majority of children with cancer above the clinical threshold for poor sleep.

4.4.2 Children with Other Chronic Illnesses

While children with other chronic illnesses are also expected to experience sleep disturbances, these disruptions are likely to be less severe than those observed in children with cancer. For example, conditions such as asthma or diabetes may cause episodic sleep interruptions (e.g., nocturnal coughing or nighttime glucose monitoring), but they are not typically compounded by the environmental and psychological stressors associated with hospitalization. A smaller percentage of this group is anticipated to exceed the clinical threshold for poor sleep on the PSQI.

4.4.3 Healthy Children

Healthy children are expected to demonstrate the highest sleep quality among the three groups, with results showing near-optimal sleep duration and efficiency. Reported data are anticipated to reflect low levels of sleep disturbances, with the majority of children scoring below the clinical threshold on the PSQI. These findings will provide a baseline for understanding how chronic illnesses and hospitalization affect sleep outcomes.

5. Study Population

This study will enroll Chinese children aged 6 to 18 years, divided into three distinct groups based on their health status: children with cancer, children with other chronic illnesses, and healthy children. A total sample size of 150 participants (50 per group) will be targeted to ensure adequate statistical power for comparative analyses. Recruitment will occur at Hong Kong Children's Hospital or the cancer and chronic illness groups, and healthy children will be recruited from healthy siblings of participants or the healthy children of hospital staff with specific inclusion and exclusion criteria applied to each group to maintain homogeneity and minimize confounding variables.

5.1 Children with Cancer (n=50)

Participants in this group will be children with a confirmed cancer diagnosis, such as leukemia, lymphoma, or solid tumors, who are currently hospitalized for treatment at the inpatient oncology wards of Hong Kong Children's Hospital. Eligible participants must be actively receiving cancer-directed therapy (e.g., chemotherapy, radiation) during their hospital stay. Inclusion criteria require that participants, or their parents or legal guardians as proxies, can provide accurate reports about sleep patterns, either through self-assessment or observation, ensuring reliable data collection. This group will capture the acute impact of cancer treatment and hospitalization on sleep, a critical focus of the study.

5.2 Children with Other Chronic Illnesses (n=50)

This group will comprise children diagnosed with chronic conditions other than cancer, such as asthma, type 1 diabetes, or chronic kidney disease, recruited from the cardiac, nephrology, and mixed wards of Hong Kong Children's Hospital. These illnesses are selected for their known potential to disrupt sleep—e.g., nocturnal asthma symptoms or glucose instability—while differing in pathophysiology from cancer. Participants must be under active management for their condition and currently hospitalized, but must not have a history of primary sleep disorders (e.g., narcolepsy, obstructive sleep apnea) unrelated to their chronic illness. This criterion ensures that observed sleep disturbances are attributable to the chronic condition rather than pre-existing sleep pathology.

5.3 Healthy Children (n=50)

The healthy control group will be of adequate sample size. These include siblings of pediatric patients (both oncology and non-oncology wards), and children of hospital staff (e.g., nurses, administrative personnel). Inclusion criteria require no history of chronic illness, psychiatric disorders, or known sleep conditions. Parental consent and child assent will be obtained for all participants.

5.4 Exclusion Criteria

Across all three groups, children will be excluded if they are not Chinese and are in intensive care units. Children who exhibit severe cognitive impairments that preclude accurate reporting of sleep experiences, either by themselves or their parents or legal guardians, will be excluded. Additionally, participants with neurological conditions known to independently affect sleep, such as epilepsy or cerebral palsy, will be excluded to avoid confounding the primary relationship between chronic illness and sleep disturbances. The use of sedative medications unrelated to the participant’s primary condition (e.g., for behavioral management rather than cancer treatment) will also disqualify participants, as these could artificially alter sleep patterns and obscure study outcomes. These exclusion criteria ensure that sleep disturbances observed are primarily linked to the participants’ health status rather than extraneous factors.

6. Procedure

Participants will be enrolled following informed parental consent and, for children under 18, age-appropriate assent, as detailed in the ethical approval section. Recruitment will occur at Hong Kong Children's Hospital for the cancer and chronic illness groups, while healthy controls will be recruited from siblings of sick children or children of hospital staff. Once enrolled, parents or legal guardians and participants will receive the demographics, the Chinese version of PSQI and PedsQL surveys in paper format, depending on preference, with instructions provided by trained research staff. Completing the questionnaires is estimated to take approximately 15-20 minutes. For hospitalized children (the cancer and chronic illness groups), surveys will be completed during their inpatient stay to capture real-time sleep experiences, and the study team will collect completed questionnaires on the same day. Healthy children can return their questionnaires via their parents/legal guardians, one extra visit may be required by the parents/legal guardians.

7. Statistical Analysis

Data will be analyzed using SPSS (version 29), a powerful statistical software package designed for clinical research. Descriptive statistics such as means, standard deviations, and frequencies, will summarize demographic characteristics (e.g., age, gender distribution), as well as PSQI global and component scores, and PedsQL total and subscale scores for each group. To compare sleep quality and health-related quality of life across the three groups, a one-way analysis of variance (ANOVA) will be used for continuous variables (e.g., PSQI global score, sleep duration, PedsQL physical functioning score). For secondary analyses, multiple linear regression will examine the relationships between sleep quality (PSQI score) and potential predictors (e.g., type of cancer treatment, pain levels) while adjusting for confounding factors such as age, gender, and socioeconomic status (SES). Pearson or Spearman correlations will be utilized to assess the relationships between PSQI and PedsQL scores, helping to evaluate the impact of sleep disturbances on health-related quality of life. A p-value of less than 0.05 will indicate statistical significance, and effect sizes (e.g., eta-squared) will be reported to quantify the magnitude of differences.

8. Parental Consent and Children's Assent

Ensuring the ethical participation of children in this study requires a dual approach, involving obtaining informed consent from parents or legal guardians and, where appropriate, obtaining assent from the children themselves.

8.1 Parental Consent

Informed consent will be obtained from the parents or legal guardians of all participants prior to enrollment. The consent process will involve a detailed explanation of the study's purpose – to evaluate sleep disturbances across children with cancer, healthy children, and those with other chronic diseases –along with its procedures, potential risks, and benefits. Parents or legal guardians will receive both verbal and written information in clear, non-technical language, including a description

of data collection methods, the voluntary nature of participation, and their right to withdraw their child at any time without affecting medical care or services received at Hong Kong Children's Hospital. The consent form will also outline confidentiality measures and the minimal risks involved, such as mild emotional distress from discussing sleep issues. Parents or legal guardians will have the opportunity to ask questions and will sign the consent form only after indicating full understanding and agreement.

8.2 Children's Assent

In addition to parental consent, age-appropriate assent will be sought from children aged 6 years and older, recognizing their capacity to understand and agree to participate in research. The assent process will be tailored to the child's developmental stage and health condition. For children with cancer or other chronic illnesses, who may be more familiar with medical contexts, the explanation will be sensitive to their experiences while remaining concise and engaging. Research staff will use simple, age-appropriate language to describe what participation involves, including answering questions about sleep through their parents/legal guardians or research staff. They will be reassured that there are no needles or painful procedures, that they can stop at any time, and that their decision will not impact their treatment or care. Assents will be documented via a signature or verbal confirmation, depending on the child's ability and preference, ensuring that their willingness to participate is respected. If a child expresses reluctance or distress, even with parental consent, their participation will be discontinued to prioritize their well-being.

9. Ethical Approval

This study will adhere to the highest ethical standards governing research involving human participants, particularly vulnerable populations such as children. Prior to commencing data collection, ethical approval will be sought from the Hospital Authority Central Institutional Review Board (IRB), ensuring that the study design, recruitment procedures, and data handling practices align with regulations and ethical guidelines. The IRB review will assess the study's potential risks and benefits, with a focus on minimizing any discomfort or burden to participants, especially given the involvement of children with serious illnesses like cancer. Informed consent will be obtained from parents or legal guardians of all participants, and age-appropriate assent will be sought from children aged 6 years and older, following best practices for pediatric research (Katz et al., 2016). Participants and their families will be fully informed about the study's purpose, procedures, voluntary nature, and their right to withdraw at any time without consequence to their medical care.

10. Data Handling and Record Keeping

Protecting the privacy and confidentiality of participants is a paramount concern in this study. To protect patient privacy, all research data would be handled in line with Hospital Authority/Hospital's policy in handling/storage/destruction of patients/ medical records. All data collected including demographic information, clinical records, the Chinese version of the PSQI, and the Chinese version of PedsOL 4.0,

will be de-identified using unique participant codes rather than names or other identifiable markers. These codes will be stored separately from the data in a password-protected electronic file accessible only to authorized research personnel. Physical records, such as consent forms, will be kept in a locked cabinet within a secure ward manager's office at Hong Kong Children's Hospital. Electronic data will be stored on an encrypted, institution-approved server compliant for safeguarding protected health information. Access to the data will be restricted to the principal investigator and trained research staff directly involved in the study, and no identifiable information will be disclosed in publications or presentations. Upon study completion, data will be retained for a minimum of five years, after which it will be securely destroyed. Paper records shredded, and electronic files permanently deleted to prevent unauthorized access. In the event of an incidental finding (e.g., severe untreated sleep apnea), the research team will notify the participant's parents/legal guardian and healthcare provider while maintaining confidentiality, ensuring appropriate follow-up care without breaching privacy protocols.

11. Ethical Considerations

The issue of confidentiality will be solved by recording the data in a manner that does not allow the participants to be identified (i.e. using a non-recognizable code for each patient). The study will be conducted in compliance with Declaration of Helsinki.

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