The Dreamcatchers Programme

A Nurse-led Multicomponent Interventional Protocol to Improve Sleep Quality in Paediatric Oncology Patients:

A Pilot Randomized Controlled Trial

Research Protocol
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Table of Contents

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1. Introduction

Sleep plays a crucial role in a child's development, contributing to cognitive functioning, emotional stability, recovery and overall wellness (Baddam & Nasser, 2021; Blackwell et al., 2020). Prolonged and intensive treatments received by paediatric oncology patients can lead to sleep disturbances that many carers and healthcare professionals overlook as transient side effects (Daniel et al., 2019). Sleep disturbances can be presented as a cluster of symptoms including difficulty initiating or maintaining sleep, reduced sleep duration, or perceived poor sleep quality (Richards & Pao, 2014). Recent studies showed that prevalence rates of sleep disturbance in leukemia survivors range from 13% to 50% (Russell et al., 2020), and up to 80% in children with central nervous system tumours (Rosen & Brand, 2020). Furthermore, a recent Hong Kong study by Ho et al. (2022) revealed that around 45% of pediatric oncology survivors struggle with ongoing sleep, which highlights the relevance of this issue globally as well as in local areas.

Sleep disturbances in this vulnerable population stem from factors such as pain and nausea from side effects of chemotherapies, and corticosteroids exacerbate these disturbances (Gedaly-Duff et al., 2006; Hinds et al., 2007; Lee et al., 2017). Not only would sleep disturbances cause immediate discomfort, but it would also significantly impact paediatric oncology patients' treatment adherence, daily activities, social engagement and quality of life (Cheung et al., 2017; Matricciani et al., 2019).

While pharmacological approach remains to be the go-to management for paediatric sleep disturbances, with about 60% of paediatric oncology patients being prescribed with sedatives (Walter et al., 2015), this approach carries extensive risks. Polypharmacy can lead dangerous drug interactions and development of drug dependency (Dhir et al., 2024; Owens et al., 2010). In contrast, non-pharmacological options allow patients and caregivers to manage their sleeping problems without increasing medication burden (Rogers et al., 2019), and also encourage patients and families to take a more proactive

role in managing patients' sleep health.

The Dreamcatchers Programme was developed as a nurse-led initiative in response to the pressing need of improving sleep quality in pediatric oncology patients. The programme supports relaxation and offers sustainable strategies for better sleep by introducing sleep hygiene, progressive muscle relaxation (PMR) and breathing control exercises to patients and carers. Evidence-based intervention supplies nurses with techniques built on holistic care, bridging gaps in nursing knowledge and skills.

This project proposal outlines a randomized controlled pilot study to evaluate the feasibility and preliminary effectiveness of the Dreamcatchers Programme, laying the foundation for a standardized sleep management protocol in pediatric oncology care. The following sections detail the literature base, service gaps, study design, and implementation strategies supporting this initiative.

2. Literature Review

A systematic review of non-pharmacological interventions for sleep in pediatric oncology was conducted from December 2023 to April 2024, with an extended search period through March 2025. The review analyzed the results of nine studies that implemented various strategies like music therapy, cognitive-behavioral interventions, physical activity and mindfulness (Hinds et al., 2007; Jacobs et al., 2016; Khoirunnisa et al., 2019; Liu et al., 2019; Rogers et al., 2019; Sriasih et al., 2019; Sulistyawati et al., 2021; Tanriverdi et al., 2022; Zupanec et al., 2017). Databases such as MEDLINE (Ovid), EMBASE (Ovid), PsycINFO, CINAHL and Cochrane Library were used in this review and the articles searched for non-pharmacological solutions to sleep problems. These interventions align with Spielman's behavioral model of insomnia, addressing the factors that contribute to, exacerbate, or maintain sleep disturbances (Spielman et al., 1987).

The systematic review identified interventions that promote relaxation through physiological and psychological mechanisms and summarized in Appendix I. The interventions included in the 9 studies induce relaxation by reducing hyperactivity, muscle tension, and anxiety, which typically affect sleep in pediatric oncology patients. Practicing breathing exercises like diaphragmatic breathing can stimulate the

parasympathetic system, leading to a reduction in heart rate, cortisol level, and feelings of arousal which supports sleep at night (Chen et al., 2016; Murphy, 2019). Doing gentle routines while focusing on muscles helps ease tension in the body, lessen discomfort caused by treatment and encourage relaxation for better sleep (Khoirunnisa et al., 2019; Sulistyawati et al., 2021). Sleep hygiene education is a central part of cognitive-behavioral approaches and supports establishing good sleep routines and a suitable sleep environment, which minimizes factors that can disrupt sleep (Rogers et al., 2019; Sriasih et al., 2019; Zupanec et al., 2017).

Mindfulness and education-based multicomponent approaches have been shown to reduce stress and help improve sleep quality (Liu et al., 2019; Sriasih et al., 2019). Zupanec et al. (2017) found that having a four-week relaxation and education program boosted sleep duration, underlining the efficacy of multicomponent approaches. Complementary therapies like massage showed subjective improvements in sleep and fatigue, yet quantitative outcomes were less robust (Jacobs et al., 2016). Physical activities including virtual reality-based exercises yielded mixed results, suggesting integration of physical activity with relaxation techniques would be more impactful (Tanriverdi et al., 2022). Nonetheless, the review demonstrated the feasibility of nurse-led delivery and highlighted the need for well-outlined steps.

2.1 Theoretical Framework

Spielman's model provides a framework for understanding how relaxation-based interventions address sleep disturbances by targeting predisposing, precipitating, and perpetuating factors (Spielman et al., 1987): Pediatric oncology patients are predisposed to insomnia due to baseline anxiety and stress from their diagnosis and treatments. Breathing and PMR exercises counter hyperarousal by engaging the parasympathetic nervous system, reducing cortisol levels and anxiety, enabling easier relaxation and sleep onset (Annisa et al., 2018; Chen et al., 2016). Regular practice mitigates cancer-related stress, addressing predisposing vulnerabilities (Sulistyawati et al., 2021).

Treatment-related pain, nausea, and emotional distress from hospitalization are categorized as precipitating factors that can trigger insomnia. Breathing and PMR exercises alleviate physical discomfort by releasing muscle tension and diverting

attention from pain, reducing the impact of precipitating factors (Khoirunnisa et al., 2019; Sulistyawati et al., 2021). These techniques are accessible and require minimal equipment, unlike music therapy, which may rely on trained professionals or resources (da Silva Santa et al., 2021; Ramanda et al., 2022).

Frequent naps or irregular sleeping times can decrease sleep drive which perpetuates to further sleep disturbances. Promoting regular routines and a suitable sleeping environment through education with caregivers can change these patterns (Rogers et al., 2019; Zupanec et al., 2017). Moreover, breathing exercises calm children and help them get back to sleep in case of nighttime awakenings (Murphy, 2019).

Breathing and PMR exercises offer distinct advantages over other interventions like music therapy or mindfulness. These techniques are simple, requiring no specialized equipment or extensive training, making them suitable for hospital or home settings (Chen et al., 2016). They can be adapted into playful activities (e.g. imagining squeezing lemons), engaging younger children who may struggle with mindfulness due to limited cognitive maturity (Burke, 2010; Burrows, 2022). Breathing and PMR exercises are cost-effective and scalable (da Silva Santa et al., 2021). They can alleviate physical discomforts to facilitate relaxation and enhance sleep as opposed to mindfulness that primarily targets mental and emotional dimensions (Sulistyawati et al., 2021).

2.2 Literature Gaps

Despite promising findings from the systematic review, standard procedures for managing sleep in children with cancer are found to be lacking in the published literature. Most of the measures taken were brief and there was no data available for long-term evaluation. The existing studies rarely review the sleep differences among children of various ages or the ways caregivers assist with sleep routines. Methodological limitations, including small sample sizes, reliance on self-report measures, and inconsistent reporting of intervention fidelity result in poor reproducibility.

3. Service Gaps

Sleep disturbances among paediatric oncology patients are often thought of as

temporary, instead of requiring more specific care (Daniel et al., 2019). Patients seldom report their sleep issues thus the problem is rarely being assessed. In current Hong Kong's clinical practice, there are no standardized protocols for addressing sleep disturbances, and bundled care approaches are often hindered by intensive treatments in minimizing patients' sleep disturbances. Zhou and Recklitis (2014) reported that nearly two-thirds of pediatric oncology patients did not get a routine check of their sleep-related issues during long-term follow-ups. This oversight results in a passive approach to addressing sleep complaints, only addressing them when they severely disrupt daily functioning. Consequently, cancer children experience sleep deprivation which can worsen their exhaustion, mood and performance.

While standardized non-pharmacological techniques are lacking, most sleep problems in children with cancer are managed with drugs, with over half of these patients prescribed with sedatives (Walter et al., 2015). Nevertheless, children who take multiple drugs and are given sedatives may face increased risks such as of addiction, mental fog and potential negative interactions between drugs (Dhir et al., 2024; Owens et al., in 2010), causing extra burden on caregivers, thus proving that new safe options are necessary.

Hong Kong nurses in paediatric oncology lack special training in sleep assessments and behavioral interventions. The integration of sleep care into holistic nursing practice relies on the development of guidelines and institutional support. Although there is evidence for non-pharmacological interventions, they face challenges due to lack of proper training for staff and practical logistical issues in hospitals.

4. Study Objectives

The Dreamcatchers Programme aims to close the gap by using a well-structured and evidence-based method developed by nurses for Hong Kong paediatric oncology patients. The pilot study seeks to evaluate the feasibility and preliminary efficacy of a nurse-led, non-pharmacological intervention designed to improve sleep quality in pediatric oncology patients. Grounded in behavioral approaches and integrated into routine clinical practice, the programme combines sleep hygiene education, PMR, and breathing control techniques. The specific objectives of this pilot study are as follow:

1. Primary Objective:

   To improve sleep quality (perceived restfulness), sleep latency, habitual sleep efficnecy, sleep disturbances and duration in pediatric oncology patients aged 6–12 years, as measured through Chinese version of the Pittsburgh Sleep Quality Index (PSQI).

2. Secondary Objective:

   To enhance the overall quality of life of participating children by promoting better sleep patterns during active cancer treatment and assess through Chinese version of Pediatrics Quality of Life Inventory (PedsQL) 3.0 Cancer Module.

3. Feasibility and Acceptability Objective:

   To assess the feasibility of the study, the recruitment, response, and retention rates will be documented. To assess the acceptability of the intervention by healthcare professionals and participants, a satisfaction survey and process evaluation will be conducted. The process evaluation is to assess whether the intervention is delivered as planned and to identify patients' perspectives on the intervention's strengths and limitations. The findings should help improve the effectiveness of the intervention and show if both healthcare workers and participants find the intervention usable and acceptable.

These objectives reflect a commitment to advancing holistic, evidence-informed strategies within pediatric oncology settings, with the long-term aim of strengthening nurses and ensuring better outcomes for patients, turning sleep management into a regular care plan for pediatric oncology.

5. Hypothesis

The Dreamcatchers Programme pilot study hypothesizes that:

1. Primary Hypothesis:

   The nurse-led multicomponent intervention will significantly improve sleep quality in pediatric oncology patients aged 6–12 compared to the waitlist control group, as measured by the Chinese PSQI, enhancing perceived restfulness, sleep latency, habitual sleep efficiency, sleep disturbances, and duration at T1 and T2.

2. Secondary Hypothesis:

   The intervention will enhance quality of life in patients undergoing active cancer treatment compared to the control group, as assessed by the Chinese PedsQL Cancer Module 3.0 at T1 and T2.

3. Feasibility and Acceptability Hypothesis:

   The intervention will be feasible (measured by recruitment, response, and retention rates) and acceptable to participants and healthcare professionals (evaluated via satisfaction surveys and semi-structured interviews), supporting integration into routine clinical practice.

6. Outcome Measures

The primary outcome focuses on improvements in sleep quality among pediatric oncology patients aged 6–12 years, as measured by the Chinese version of the Pittsburgh Sleep Quality Index (PSQI). Specifically, the study aims to assess:

- Perceived restfulness: Subjective sense of feeling rested after sleep.
- Sleep latency: Time taken to fall asleep.
- Habitual sleep efficiency: Ratio of total sleep time to time spent in bed.
- Sleep disturbances: Frequency and severity of disruptions during sleep.
- Sleep duration: Total amount of sleep obtained per night.

These components are captured through the PSQI global score, where a lower score indicates better sleep quality.

The secondary outcome focuses on enhancing the overall quality of life of participating children during active cancer treatment, as measured by the Chinese version of the Pediatric Quality of Life Inventory (PedsQL) Cancer Module 3.0. This includes:

- Health-related quality of life: Assessed through subscales addressing pain, fatigue, cognitive problems, and other treatment-related symptoms.

Higher PedsQL scores indicate better quality of life.

Additionally, the study evaluates feasibility and acceptability as secondary outcomes to determine the intervention's potential for integration into clinical practice:

- Feasibility: Measured by recruitment rates, response rates, and retention rates throughout the study.
- Acceptability: Assessed through a custom-designed satisfaction survey (with Likert-scale and open-ended questions) and semi-structured interviews conducted with the intervention group at T1.

These tools evaluate the clarity of educational materials, ease of performing exercises, perceived benefits, and overall satisfaction with the Dreamcatchers Programme.

7. Study Design

This study is structured as a pilot prospective and randomized controlled trial (RCT) with a 1:1 allocation to either the intervention group or waitlist control group. The intervention group will receive the Dreamcatchers Programme, including sleep hygiene education, PMR, and breathing control exercises, which will be delivered over 4 weeks with weekly in-person follow-ups. The waitlist control group will continue to receive routine hospital support and pediatric oncology health information (e.g., neutropenic diet tips) to maintain engagement without sleep-specific strategies. The trial will span 4 weeks, followed by a 3-month follow-up to assess the sustainability of outcomes.

7.1 Randomization and Allocation

The study will arrange participants in intervention and waitlist control groups at a 1:1 ratio through block randomization. A computer will be used to generate blocks for randomization to guarantee all the groups are of equal size and to minimize the risk of allocation bias. The randomization sequence is kept secret in sealed but opaque envelopes and will not be opened until enrollment, therefore lowering the chances of selection bias.

7.2 Blinding Procedures

Given the nature of the intervention, blinding participants and caregivers would not be feasible. However, outcome assessors, especially the nurses responsible for data collection, will remain unaware of group assignments. This single-blind design aims to reduce observer bias during data recording and interpretation.

7.3 Contamination Prevention

To prevent contamination, sessions for the intervention group will take place in a separate location (e.g., an educational room away from clinical areas) distinct from control group activities. Access to QR code videos will be password-protected for the intervention group, ensuring that control participants do not receive any intervention materials.

7.4 Duration

The intervention will last for 4 weeks, with data collection points at baseline (T0), immediately post-intervention (T1), and 3 months post-intervention (T2) to evaluate both short-term and sustained effects.

8. Sampling Method and Sample Size Planning

A simple random sampling method will be applied to recruit participants from the ambulatory chemotherapy day center of Hong Kong Children's Hospital (HKCH), where a list of all eligible attendees at the center is randomly generated by a computer. The decision to recruit day patients rather than hospitalized patients for the study of the Dreamcatchers Programme is grounded in practical, methodological, and generalizability considerations.

Pediatric oncology patients typically do not remain hospitalized indefinitely. Hospitalizations are often episodic, tied to specific treatment phases (e.g., chemotherapy cycles, management of complications), and vary in duration depending on the individual's condition and progress. In contrast, day patients regularly attend ambulatory chemotherapy day centers for scheduled treatments and are discharged afterwards, providing a more stable recruitment pool. The predictable attendance pattern allows consistent intervention delivery during their visits and facilitates adherence to the intervention schedule (weekly in-person follow-ups) and data collection at baseline (T0), post-intervention (T1), and 3-month follow-up (T2). By recruiting day patients, the study minimizes disruptions caused by fluctuating hospitalization status, ensuring feasibility for this pilot RCT.

Secondly, the Dreamcatchers Programme is designed as a non-pharmacological

intervention intended for use in both hospital and home settings. Recruiting day patients better aligns with the programme's adaptability, allowing the intervention to be tested in the setting where it is most likely to be applied long-term.

Despite hospitalized patients are accessible during their inpatient stay, they face unique environmental constraints (e.g. medical equipment, frequent nursing interruptions) that may limit the applicability of certain intervention components, such as creating a sleep-conducive environment. These hospital-specific barriers could confound results and obscure the intervention's true potential in home settings. Day patients, practicing the intervention at home, provide a more representative sample for evaluating its generalizability, as their sleep environment reflect those experienced by pediatric oncology patients post-treatment or during survivorship.

Furthermore, testing the intervention among day patients ensures that the protocol is feasible for children managing outpatient treatment schedules, enhancing the programme's external validity. By contrast, an inpatient-focused study might yield results less applicable to the broader pediatric oncology population, limiting the programme's scalability.

8.1 Eligibility Criteria

Principal investigator will approach those who are eligible, inform and ask for consent from caregivers and also assent from children when possible. The purpose of this approach is to avoid selection bias and improve the sample's relevance in the clinical environment.

Participants must meet the following **inclusion criteria**:

- Children who can read and communicate in Chinese
- Aged 6 to 12 years old (school-aged children).
- Diagnosed with cancer and currently undergoing active treatment.
- Identified as experiencing sleep disturbances, defined by a Chinese Pittsburgh Sleep Quality Index (PSQI) global score of ≥5.

The following **exclusion criteria** will apply:

- Diagnosed with hematological diseases unrelated to cancer (e.g., sickle cell anemia, thalassemia).
- Presence of severe cognitive impairment, which may hinder the ability to follow instructions or engage with intervention components.

These criteria are designed to select participants who are both clinically relevant and developmentally capable of participating in the intervention and completing required assessments.

8.2 Sample Size Planning

As this is a pilot feasibility study, the sample size is determined based on guidelines for evaluating preliminary interventions rather than hypothesis testing. According to Teresi et al. (2022), a minimum of 30 participants per group is generally sufficient for feasibility trials. To accommodate an estimated 10% attrition rate at the four-week post-intervention assessment, a total sample of 68 participants will be recruited, with 34 allocated to each group. An initial target of 10 participants (and their parents/legal guardians) from the intervention group will be invited for semi-structured interview for process evaluation. The analysis will continue until data saturation is achieved.

9. Description of the Evidence-Based Protocol

The Dreamcatchers Programme is a multi-component intervention, focusing on sleep hygiene education, PMR, and breathing exercises, is designed to address sleep disturbances in pediatric oncology patients through non-pharmacological approach. The programme is simple, feasible, and can be adapted to both hospital and home settings. It also involves a structured education, practice, and follow-up approach to make sure patients and caregivers are consistently able to put the intervention into play.

9.1. Sleep Hygiene Education

The first part of the intervention consists of a group education session on sleep hygiene for pediatric oncology patients and their caregivers. Each session will accommodate a maximum of 10 participants and will last approximately 45 minutes as informed by (2019), Sriasih et al. (2019), and Zupanec et al. (2017), facilitated by

a nurse using a PowerPoint presentation. The session will begin with highlighting how sleep contributes to recovery and general well-being. Next, strategies for creating an optimal sleep environment will be covered, including controlling lighting and noise that may disrupt sleep. The importance of establishing a consistent bedtime routine will be stressed, reminding them to maintain these practices at hospital or at home.

Suggestions of screen-free activities, along with alternative activities to engage children without interfering with their sleep will be discussed. Caregivers will learn techniques of diaphragmatic breathing and PMR to promote relaxation, further aiding sleep improvement.

Finally, patients and caregivers will learn how to complete the sleep diary so they can monitor children's sleep habits, how much they sleep, and whether they perform the recommended exercises. They will get the sleep diary as a booklet that covers the summary of what makes for positive sleep habits. The resource can assist caregivers and health professionals as a useful tool in seeing the progress made and helping improve sleep for young cancer patients. Patients and caregivers will be reminded to bring the sleep diary to follow-up appointments for review and data collection.

9.2. Progressive Muscle Relaxation (PMR)

Following the education session, practical demonstrations of PMR and breathing exercises will be conducted, allowing patients and caregivers to practice what they have learned. These exercises will be designed to be simple, age-appropriate, and easily integrated into daily routines.

Despite previous studies show that the effectiveness of PMR is not always high, the Dreamcatchers Programme includes PMR as it is seen as manageable for improving sleep time and quality (Khoirunnisa et al., 2019; Sulistyawati et al., 2021; Zupanec et al., 2017). PMR helps lower stress and anxiety by modulating the activities of the autonomic nervous system (Sari et al., 2024). The gentle movements in PMR make it possible for patients with less strength or mobility, as opposed to doing stretches, which might be difficult because of related issues like pain or weakness. PMR's simplicity ensures high adherence and ease of implementation in clinical or home

settings, aligning with the feasibility focus of a pilot study. Although stretching exercises are beneficial for physical health, there is insufficient evidence demonstrating stretching being able to improve sleep quality or address the psychological factors prevalent in this fragile population. The entire PMR routine will take approximately 10-15 minutes, consistent with the duration of relaxation exercises noted in earlier research.

9.3. Breathing Exercises

Breathing exercises will also be demonstrated and advised to be used before bedtime, aiming to reduce physiological arousal and promote relaxation through slowing down breathing rate, amplifying vagus nerve activity and normalizing stress responses (Chen et al., 2016; Chui et al., 2021). This intervention will specifically utilize diaphragmatic breathing control exercises, which are shown to enhance tidal volume and regulate breathing patterns (Zaccaro et al., 2018). The breathing routine, incorporating box breathing techniques, will last 5-10 minutes and is to be practiced as part of the children's wind-down routine before sleep (Murphy, 2019).

To support consistent practice, a video recording of the PMR and breathing exercises will be provided via QR code with reference to Student Health Service's (2016) materials, integrated into the sleep diaries for easy reference by patients and caregivers.

The participants will be supported after the first introductory session through weekly follow-up sessions for four weeks. These sessions are meant to repeat and practice the techniques learnt, solve any doubts, and monitor participants' sleep hygiene practices. Regular check-ups help to maintain contact and offer support to everyone involved in the treatment.

Nurses will play a key role in delivering sleep hygiene education, demonstrating exercises to patients and caregivers, and conducting follow-up sessions. The principal investigator will train nurses covering sleep hygiene principles, techniques of breathing and PMR exercises, instructions on charting the sleep diary. Trained nurses will conduct mock demonstrations of the group education session and individual exercise demonstrations with their peers. The entire training programme

will take around one week before the actual implementation of the intervention. Trained nursing staff then lead the group education session covering sleep hygiene principles, techniques of breathing and PMR exercises.

10. Data Collection Methods and Procedures

Data collection for this pilot RCT will occur at three time points: baseline (T0), immediate post-intervention (T1), and a 3-month follow-up (T2). A summary table of intervention and data collection methods and procedures is included in Appendix II.

10.1 Participant Recruitment

Participants will be recruited at ambulatory chemotherapy day centers at HKCH. Trained personnels will approach eligible families, provide study details, and obtain informed consent from parents/legal guardians as well as child assent when appropriate. After consent is obtained, participants will be randomly assigned to either the intervention group or the waitlist control group using a concealed block randomization method, managed by an independent researcher to minimize bias.

10.2 Baseline Assessment (T0)

At enrollment, all participants will complete the following assessments: demographic survey for data on age, gender, cancer type, and treatment phase, Chinese version of the PSQI for evaluating subjective sleep quality, Chinese PedsQL Cancer Module 3.0 for assessing quality of life, and sleep diary to track sleep patterns and exercise frequency (only for intervention group).

10.3 Post-intervention Assessment (T1)

Immediately following the four-week intervention period, all participants will undergo repeat assessments identical to those performed at T0, including Chinese PSQI, Chinese PedsQL Cancer Module 3.0, and sleep diary review.

In addition, participants in the intervention group will complete a satisfaction survey and semi-structured interview with both quantitative Likert-scale items and open-ended questions.

10.4 Three-month Follow-up (T2)

To assess the durability of the intervention effects, participants will complete a third round of assessments, including Chinese PSQI, Chinese PedsQL Cancer Module 3.0 and sleep diary review.

10.5 Data Integrity and Confidentiality

All research data will comply with Hospital Authority policies on the handling, storage, and destruction of medical records. Data collected, including demographic information and assessments (e.g., Chinese version of the PSQI and PedsQL Cancer Module 3.0), will be de-identified using unique participant codes instead of names. These codes will be stored separately in a password-protected electronic file accessible only to authorized personnel. Physical records, such as consent forms, will be securely locked in a ward manager's office at HKCH. Electronic data will be stored on an encrypted, institution-approved server to safeguard protected health information. Access will be restricted to the principal investigator and trained research staff, with no identifiable information disclosed in publications.

Data will be retained for five years post-study and then securely destroyed, with paper records shredded and electronic files permanently deleted. In the event of incidental findings, such as severe sleep disturbances, the research team will notify the participant's parents and medical team while keeping confidentiality.

11. Instruments

A combination of subjective instruments will be used in this study to capture a comprehensive understanding of the participants' sleep quality and overall well-being. The selected tools have been validated for use in pediatric populations and adapted for Chinese children. The authors of the Chinese versions of the PSQI and the PedsQL Cancer Module 3.0 have been contacted and have provided these instruments for use in this study.

The decision to utilize subjective measures rather than objective tools like wrist actigraphy, which focuses on what patients feel and experience, and offers more practical and suitable ways to meet the special requirements of this group. Objective

tools like wrist actigraphy, require wearing devices for a period that may cause discomfort or anxiety, especially for those with medical devices or skin sensitivities. Young children might remove these devices during sleep or play, leading to incomplete data. It is not necessary to spend significant resources on logistics and finances for actigraphy in a pilot study. Alternatively, sleep diaries and the PSQI provide insights into the pattern and quality of participant's sleep. The reliability, validity, and feasibility of each instrument have been carefully considered to minimize participant burden while maximizing data quality.

11.1 Chinese Version of the PSQI

The PSQI is used broadly to assess subjective sleep quality for the past month. There are seven components in the tool (including sleep latency, disturbances, and duration) that result in a global score of 0 to 21, with higher numbers reflecting worse sleep quality. The Chinese version has been validated for use among Chinese pediatric oncology populations, with Ho et al. (2021) reporting a Cronbach's alpha of 0.71, indicating acceptable internal consistency. The same study reported an intraclass correlation coefficient of 0.90, reflecting excellent test–retest reliability. There is strong agreement between the results from this tool and results from actigraphy.

11.2 Chinese Version of the PedsQL Cancer Module 3.0

The Chinese PedsQL Cancer Module 3.0 allows the measurement of quality of life in cancer children aged 2-18, examining issues such as pain, fatigue, and cognitive problems. Better health-related quality of life is indicated by a high score. Lau et.al. (2010) found that the overall score had high internal consistency with Cronbach's alpha of 0.87 among Chinese pediatric oncology patients. Study by Li et al. (2013) supported the construct validity of the Chinese version, as a strong positive link between children's self-esteem and quality of life ($r = 0.50$) and a strong negative correlation between treatment-related symptoms and quality of life ($r = -0.65$) was recorded.

11.3 Sleep Diary

Participants will be asked to complete the sleep diary throughout the study period. It tracks bedtime, wake time, perceived sleep quality, and specific for intervention

group – adherence to PMR and breathing exercises, while also including QR codes that link to instructional videos. While the sleep diary is not validated psychometrically, it helps capture real-life behaviors and participant's adherence to the programme.

11.4 Satisfaction Survey

The satisfaction survey is custom-designed that combines Likert-scale items and open-ended questions to assess the acceptability, usability, and perceived benefits of the Dreamcatchers Programme, only to intervention group at T1. The content includes items that evaluate the clarity of educational material, ease of performing exercises, and overall satisfaction with the programme. Quantitative responses will be analyzed descriptively, while qualitative responses will undergo thematic coding to identify common feedback patterns that can inform future refinements.

11.5 Semi-structured Interview

Supplementing the satisfaction survey, a semi-structured interview will be conducted with an interview guide provided for process evaluation. A total of 10 participants and their parents or legal guardians from the intervention will be invited for the interview. However, the final sample size will depend on the data saturation. An in-depth, one-on-one, audiotaped, semi-structured interview will be conducted with the 10 participants and their parents or legal guardians.

12. Data Analysis

The data analysis will evaluate the intervention's impact on sleep quality, duration, quality of life, as well as its feasibility and acceptability, comparing results against baseline measurements. For the Chinese PSQI, global and component scores will be compared between groups at T1 and T2 using independent t-tests, while repeated-measures ANOVA will assess group-by-time effects, specifically focusing on changes in subjective sleep quality from baseline to T1 and T2 to assess the intervention's impact over time.

Regarding the Chinese PedsQL Cancer Module 3.0, total and subscale scores will be compared to baseline and between groups at T1 and T2 using independent t-tests, with

repeated-measures ANOVA evaluating group-by-time effects for quality-of-life improvements. Descriptive statistics will summarize adherence rates, intervention practice frequency for the intervention group, confirming protocol fidelity.

For the satisfaction survey, quantitative analysis will involve calculating mean Likert scores per question, such as ease of understanding, usability, while qualitative analysis will use thematic coding of open-ended responses to identify common feedback themes, such as preferred components, for programme refinement.

This comprehensive analysis aims to assess acceptability, feasibility, and areas for programme refinement, using baseline comparisons to gauge intervention effectiveness. The qualitative data analysis process will begin immediately after each interview, following the thematic analysis framework introduced by Braun and Clarke (2006).

13. Parental Consent and Children's Assent

Consent from parents or legal guardians and assent from children should be sought in ensuring the ethical participation of children with cancer in this study.

Informed consent will be obtained from the parents or legal guardians of all participants prior to enrollment. Full information about the purpose of the study, along with the intervention procedures, expected duration, risks involved and possible benefits will be provided. Clarity about data collection, the voluntary aspect, and the right to withdraw their child is communicated both verbally and in writing. Participation in the study will not affect the medical treatment received at HKCH. Parents or legal guardians will be informed of confidentiality measures and mild risks, including slight emotional upsets from talking about sleep problems. They will maintain the right to ask questions and sign the consent form only after indicating full understanding and agreement.

Apart from parental consent, age-appropriate assent will be sought from children aged 6 years and older, recognizing their capability of understanding the research. The assent process will be adjusted to fit the child's age and health. Since children with cancer may be more familiar with medical contexts, the explanation will consider their experiences while remaining concise and engaging. Research staff will use simple, age-appropriate language to describe what process would be involved, including answering questions about sleep through their parents/legal guardians or research staff. Children will be

reassured that no invasive or painful procedures, that they can stop at any time, and their decision will not impact on their treatment or care. Depending on children's ability and preference, assent can be documented via signature or recorded verbally, ensuring their willingness is acknowledged. If a child expresses reluctance or distress, even with parents or level guardian's approval, their involvement will be discontinued to prioritize their well-being.

14. Ethical Approval and Considerations

Ethical approval from the Joint CUHK-NTEC Clinical Research Ethics Committee (CREC) and Hospital Authority Central Institutional Review Board (IRB) will be obtained before any data collection. The process helps guarantee that the research process, participant recruitment and data control follow ethical guidelines. The CREC and IRB will assess that there are more benefits to the study than risks, ensuring not to cause additional stress or pain to the participants. Parents or legal guardians should be provided with the details needed for informed consent and assent would be sought for children between the ages of 6 and 12 according to HKCH recommendations. All participants and their families will be fully informed about the study's purposes and be given the choice to withdraw from it without any changes to their care.

In order to ensure fairness, participants of the waitlist control group will be given access to the Dreamcatchers Programme once the final follow-up assessment is completed. As a result, all children attending the study are able to get the benefits, regardless of which group they were placed in.

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.

15. Significance of the Study

The Dreamcatchers Programme has significant implications for nursing practice and the care of pediatric oncology patients. This intervention aims to increase sleep duration by at least 30 minutes (Meltzer et al., 2012), reduce PSQI scores by 2 points or more (Ho et al., 2022), and raise PedsQL scores by 5 points or more (Ji et al., 2011). These improvements are expected to enhance not only the quality of sleep but also the overall

quality of life for young oncology patients.

The intervention programme allows healthcare professionals to opt for safer care practices, which is an important consideration for this vulnerable group. Furthermore, the programme helps nurses gain in-depth knowledge of sleep disturbances and increases their confidence when offering comprehensive care. As a result, nurses are better equipped to support cancer children with sleep disturbances and enhance their overall well-being.

The RCT serves as a foundational step toward in creating a consistent sleep management practice to address the absence of standardized practices in pediatric oncology care in Hong Kong. Positive results from this study will demonstrate the efficacy of the Dreamcatchers Programme in clinical settings, and encourage more extensive studies and wider usage.

The Dreamcatchers Programme seeks to achieve both better health outcomes for patients and to develop proactive, well-rounded sleep care by nurses in the long term. This achievement sets a standard for future improvements in pediatric oncology, so that sleep management will always be part of family-centered care. The programme could greatly benefit pediatric oncology patients, both at a local level and all over the world.

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Appendix I: Summary of Literature

Bibliographic Citation	Intervention	Duration	Category	Effect
Liu et al., 2019	Music therapy + Mindfulness	8 sessions (2.5 – 3 hours per session) for 8 weeks	Complementary + psychoeducational	Sleep quality improved post-intervention and between groups
Sriasih et al., 2019	Music therapy + Education	15 mins music playing before sleep for 3 days		Sleep quality improved post-intervention and between groups
Zupanec et al., 2017	Relaxation + Education	4 weeks	Psychoeducation + Cognitive behavioural	Increased sleep time for intervention group
Rogers et al., 2019	Relaxation + Education + Stimulus control	5 days (with 90 minutes protected sleep time for stimulus control)		Insignificant differences
Sulistyawati et al., 2021	Muscle relaxation	15 mins session twice per day for 7 days	Cognitive behavioural	Insignificant differences
Khoirunnisa et al., 2019	Muscle relaxation + Exercise	15 mins for 5 days	Cognitive behavioural + Physical	Sleep quality improved post-intervention and between groups
Tanriverdi et al., 2022	Virtual-reality based exercise	45 mins session 2 days per week for 12 weeks	Physical	Insignificant differences
Hinds et al., 2007	Exercise (pedaling bicycle)	30 mins twice daily for 2-4 days		Insignificant differences
Jacobs et al., 2016	Massage	20-30 mins for 2-3 nights	Complementary	Insignificant differences

Appendix II - Intervention and Data Collection Methods and Procedures

Stage	Description	Assessments/Activities	Participants	Notes
Recruitment and Consent	Recruitment occurs at ambulatory chemotherapy day centers at HKCH. Trained research nurses approach eligible families, provide study details, and obtain informed consent from caregivers and child assent when appropriate.	None	All eligible participants	Consent and assent obtained prior to randomization.
Randomization and Allocation	Participants are randomly assigned to intervention or waitlist control group using concealed block randomization managed by an independent researcher to minimize bias.	None	All participants	Ensures balanced group allocation; performed after consent.
Baseline Assessment (T0)	Conducted at enrollment to establish baseline measures. Assessments include: • Demographic survey (age, gender, cancer type, treatment phase) • Chinese PSQI (subjective sleep quality) • Chinese PedsQL Cancer Module 3.0 (quality of life)	Demographic survey, Chinese PSQI, Chinese PedsQL Cancer Module v3.0	All participants	Performed after randomization.
Intervention Group: Introductory Session	A total of 60 mins nurse-led group session at education room at HKCH introduces the intervention for up to 10 children and caregivers. includes: • 45 mins sleep hygiene education (role of sleep, optimizing sleep environment, addressing poor sleep habits) • Demonstration of box-breathing (4-4-4-4 cycle, 5–10 mins nightly) • Demonstration of PMR (tensing/relaxing muscle groups, 10–15 mins nightly)	Sleep diary distribution (intervention group)	Intervention group only	Child-friendly instructions (e.g., “squeeze a lemon” for PMR) ensure engagement.

	• Distribution of sleep diaries with QR code videos for home practice			
Weekly Follow-Ups (Weeks 1–3)	Weekly in-person sessions at the Integrated Rehabilitation Center reinforce intervention techniques. Nurses: • Re-demonstrate box-breathing and PMR • Review sleep diaries to check adherence to nightly practice • Address challenges and clarify techniques	Sleep diary review (intervention group)	Intervention group only	Ensures fidelity and supports adherence. Control group receives general health education to prevent contamination.
Immediate Post-Intervention Assessment (T1)	Conducted at the end of the 4-week intervention to evaluate short-term effects and adherence. Assessments include: • Chinese PSQI (sleep quality) • Chinese PedsQL (quality of life) • Sleep diary review (intervention group adherence) • Satisfaction survey, semi-structured interview (intervention group)	Chinese PSQI, Chinese PedsQL, review of sleep diary (intervention group), satisfaction survey and semi-structured interview (intervention group)	All participants (intervention and control)	Satisfaction survey and semi-structured interview includes Likert-scale and open-ended questions. Sleep diaries collected from intervention group to track exercises adherence.
Regular Follow-Ups (Post-Intervention to 3 Months)	Monthly follow-up sessions monitor sustained practice and address ongoing challenges for the intervention group. Nurses review sleep diaries and provide support for continued PMR and breathing exercise practice.	Sleep diary review (intervention group)	Intervention group only	Ensures continued engagement and adherence post-intervention.
Three-Month Follow-Up Assessment (T2)	Conducted 3 months post-intervention to assess durability of effects. Assessments include: • Chinese PSQI (sleep quality) • Chinese PedsQL (quality of life) • Sleep diary review (adherence, sleep patterns, intervention group)	Chinese PSQI, Chinese PedsQL, Sleep diary (intervention group)	All participants	Sleep diaries collected from intervention group to evaluate sustained adherence.