Introduction

Fatigue is a common and debilitating problem in children and adolescents with cancer; it is often underrecognized and undertreated. In this population, fatigue is frequently identified as one of the most troublesome symptoms experienced. The highest rates of cancer-related fatigue in children can be expected in patients receiving the most intensive chemotherapy, including those with acute myeloid leukemia, relapsed or refractory acute lymphoblastic leukemia, advanced-stage non-Hodgkin’s lymphoma, and recipients of autologous or allogeneic hematopoietic stem cell transplantation (HSCT). Guidelines from the National Comprehensive Cancer Network indicate that fatigue should be screened for routinely in children as young as 5 years of age. However, management strategies are limited and nonpharmacological approaches should be a priority.

Recent evidence suggests that exercise is an effective intervention to reduce cancer-related fatigue. However, many patients with cancer perceive physical (eg, discomfort, feeling sick) and psychosocial (eg, low mood, fatigue, body image concerns) barriers to exercise. In addition, the hospital environment is often not conducive to exercise because of space limitations, lack of privacy, strict infection control procedures, and equipment concerns. Safety in the hospital environment is a critical consideration in the design of an effective exercise intervention for children with cancer.
presence of accessed central venous lines is also a potential concern. An exercise program suitable for this population must be safe and suitable for medically fragile individuals, customizable to varying ability levels, and adaptable to different environments while maintaining a common structure that is amenable to evaluation.

Yoga is a mind-body practice with origins in ancient Indian philosophy. Various styles of yoga combine physical postures, breathing techniques, meditation, and relaxation. In the West, yoga is typically taught in a group-class format. However, therapeutically oriented yoga is often customized and individualized to the needs of specific individuals. Yoga is thought to be beneficial through improving physical strength and flexibility and, consequently, has benefits similar to other forms of exercise. While randomized controlled trials have identified that yoga has significant beneficial effects in adult cancer patients, far fewer studies have been conducted in pediatric oncology patients. As research and interest in the area of yoga for pediatric cancer patients grows, it is important to consider the development of a structured yoga program amenable to evaluation. In the context of clinical trials, it is also important to consider how safety of sessions can be assured and how monitoring and consistency may be accomplished across multiple institutions. Consequently, our objective was to describe the development of a yoga program and approach to monitoring sessions suitable for hospitalized children receiving intensive chemotherapy or HSCT.

Methods

The yoga program was developed with 2 goals: (1) to increase mobility in hospitalized children who are spending considerable time supine in bed and (2) to provide relaxation techniques that could be used across various environments. The intervention was targeted at children between the ages of 8 and 18 who were expected to be hospitalized for at least 3 consecutive weeks after initiation of intensive chemotherapy or autologous or allogeneic HSCT conditioning.

The program was designed by a team of clinicians and yoga teachers with experience working with this population. Yoga teachers were certified or had complementary training in yoga for children. Because of the challenges faced by our population of interest, 4 key tenets were identified early in the program development: (1) adaptability, (2) safety, (3) environmental flexibility, and (4) appeal to children. Procedures for evaluating compliance and safety of the yoga program were also developed, particularly to facilitate monitoring of a multisite clinical trial. The suitability of the program and approach to monitoring were evaluated during a pilot study completed with 11 children between January and October 2013.

| Table 1. Structure of the Yoga Program. |
|----------------------------------------|
| 1. Breathing (pranayama)               |
| 2. Warmup                              |
| 3. Poses (asanas)—low, moderate, or high intensity |
| 4. Balancing                           |
| 5. Cool down                           |
| 6. Final relaxation (savasana)         |

Results

Development of the Yoga Program

Adaptability. Given the rapidly changing clinical status of the population of interest, the program was designed to be easily tailored to individual children. One-on-one sessions conducted in each participant’s hospital room were selected as the mode of delivery, with an option for a parent or other family member to participate. A menu format with a set structure of breathing (pranayama), warmup exercises, hatha yoga poses (asanas) of different intensities, cool-down poses, and final relaxation (savasana) was used (see Table 1). Each yoga session would begin with pranayama and warmup exercises and end with cool-down poses and savasana; the duration of the session was targeted to vary between 15 and 45 minutes.

If children were too tired to complete some aspects of the practice such as balancing poses, these exercises were omitted from the session. To accommodate the high levels of fatigue and deconditioning anticipated, many poses were modified to be performed in bed or in a chair. This structure allowed for each session to be tailored to the ability, medical condition, and desires of enrolled participants.

Yoga sessions were offered on a daily basis Monday to Friday, with the goal of completing at least 3 sessions per week during 3 consecutive weeks. Table 2 shows an example of a low-intensity session, and Table 3 shows an example of a high-intensity session.

Safety. The population of interest is at high risk for treatment-related morbidity and mortality. Fever, infection, and sepsis are common, and admission to the intensive care unit may occur. In addition, all potential participants in the program have central venous lines that are typically accessed during hospitalization. Common hatha yoga poses were excluded from the design of the program if there were any safety concerns (eg, intense inversions, backbends), if poses required a high baseline level of conditioning to perform safely (eg, chaturanga), or if poses were not feasible in the setting of a hospital room. Poses were reviewed with clinical experts including physicians and physiotherapists to identify safety concerns and receive feedback on improving the program. Further emphasis on twists (eg, reclining twist) and balancing poses (eg, tree pose) was added based on this feedback.
Central venous lines were an area of particular concern in the development of the program. Any pose that had the potential to cause difficulty with central venous lines were removed from the program (eg, chest openers). Initially, we anticipated that children would need to have lines heparin-locked during sessions to facilitate movement. However, during our pilot study we found that children were able to comfortably perform yoga postures while lines were connected to an intravenous pole. Sessions were not conducted while cytotoxic agents were being administered. We encouraged yoga instructors to check in frequently with children about their lines. Other concerns taken into consideration are presented in Table 4.

### Environmental Flexibility

Our program aimed to provide yoga to children who were hospitalized and receiving high-intensity chemotherapy. It was anticipated that many of the participants in our program would be in protective isolation and unable to leave their hospital rooms. Therefore, the program was administered on a one-on-one basis by yoga instructors, in each participant’s hospital room. If necessary, hospital beds were moved to create sufficient space for yoga mats on the floor (see Figure 1). As previously mentioned, poses were modified to be performed in bed or in a chair. To comply with existing infection control policies, equipment brought in and out of hospital rooms was sterilized by yoga instructors. Each child and family member (if participating) were provided with a new yoga mat.

To allow participants privacy during sessions, our team worked collaboratively with nursing staff to conduct sessions at times when interruptions could be minimized. A sign placed on the outside of the door during yoga sessions reminded hospital staff to enter quietly when a session was in progress.

### Appeal to Children

Given the range of developmental abilities between participants, it was important that our program be appealing to children of different age groups. Participants
were actively involved in selecting which poses would be performed in each session, and family members were invited to participate in sessions. Strategies used for younger children included incentives such as sticker calendars to keep track of the number of sessions completed, and the addition of games, music, and accessories used during the sessions such as stones and feathers for breathing exercises and *sava-sana*. Participants were encouraged to collect all the accessories used during the sessions in a “yoga jar” given at the beginning of the program (see Figure 2). For older children and teenagers, strategies included emphasizing the child’s autonomy in selecting poses, the use of music, and the relation of yoga to activities of interest to the adolescent.

### Development and Evaluation of a System to Monitor Compliance of the Program and Safety of Sessions

The yoga program itself and adjudication of videotaped sessions were feasible. Specific results of the yoga performed have previously been described. To ensure consistency of implementation across sites, a detailed handbook has been created to train yoga instructors. This handbook includes detailed information on every pose in the program, instructions on how to perform each pose, language in which to explain each pose to children of different ages, and a comprehensive guide to safety.

We developed a system to monitor the fidelity of the program and safety of yoga sessions, particularly when sessions are conducted at other sites. Sessions were videotaped using an iPad, and the completed sessions were transferred to the reviewers via a secure file transfer protocol site. Each session was reviewed by 2 team members using a standardized 33-item checklist. Domains evaluated in the checklist included safety, overall quality, and adherence to the structure of the program. The checklist flags unsafe practice that requires immediate attention. A protocol to deal with unsafe practice in a multisite setting has also been developed.

### Discussion

We developed an individualized yoga program for hospitalized children receiving intensive chemotherapy. The program promotes a standard approach while allowing adaptability...
and emphasizing safety. The standardization of the program is important as it facilitates evaluation and dissemination. Adaptability of the program is important for a vulnerable patient population at risk for medical morbidity and mortality. Unique aspects of this program are the focus on safety (particularly around accessed central venous lines), tailoring of each session to accommodate the wide range of abilities and willingness to participate both within and between participants, focus on meeting the needs of children and adolescents, and ensuring the program can be conducted in a hospital setting.

This study is unique as, although there is great interest in yoga as an intervention for many medical conditions including cancer, few reports have carefully documented the rationale behind program development and described methods to preserve the fidelity and safety of the program. This approach will facilitate future clinical research of yoga by promoting transparency in methods and by potentially encouraging similar approaches to program development. We have previously demonstrated the feasibility of our program\textsuperscript{18}; qualitative comments collected during this evaluation revealed that the yoga intervention was well received by parents and children. As we described previously,\textsuperscript{20} children stated the following as examples: “It was good to move the muscles around when doing yoga on the mat”; “[Yoga] helps my elbows and knees be less stiff and feel good after the sessions”; and “Helps me feel a bit better, relaxed.” Likewise, parents indicated “Yoga should be an essential and daily program in the hospital”; “It gets the kids out of their minds and their illnesses”; and “Yoga helps them to keep moving.”

The strength of this study is the interdisciplinary group of individuals contributing to program development. Individuals with certification and expertise in yoga, pediatric oncology, pediatric HSCT, and physiotherapy all contributed to the design of this program. A weakness of the program is that although it was designed for multisite use, the program itself and monitoring of sessions have only been conducted at a single site to date. Execution of the study at multiple centers is likely to be associated with additional challenges. We have developed multiple strategies to address the anticipated challenges of extending our program at multiple sites, including a quality control and fidelity auditing procedure, standardized training with a reference handbook, scheduled support phone calls with instructors, and adverse event reporting protocols.

Future directions for research should include the adaptation of our program to different settings, including outpatient and inpatient settings, and to different populations of hospitalized children.

**Authors’ Note**

Caroline Diorio and Amanda Celis Ekstrand contributed equally to this work.

**Declaration of Conflicting Interests**

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