The adoption of healthy behaviours or how to « better survive » pediatric cancer: A program evaluation

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This thesis is dedicated to all childhood cancer survivors and their loved ones who experience challenges when adapting to their “new normal”.

“Because there is no moving on with cancer, only moving forward”

-Marel Tomeh, a young adult cancer survivor

“The hardest part of my cancer experience began once the cancer was gone”

-Suleika Jaouad, writer and cancer survivor

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ABSTRACT

Introduction. Survivors of pediatric cancer are known to experience long-term adverse effects that negatively impact their health and fulfillment in their various life roles. To address this issue, interventions aimed at reducing the adverse effects of the disease and treatments to improve the long-term quality of life of survivors of pediatric cancer must be put forward. However, there is little scientific evidence that supports the acceptability of integrating health promotion (HP) interventions in clinical care. Further, little is known about the potential effectiveness of this type of program to improve the functional outcomes (i.e., performance in activities of daily living) of children or adolescents affected by cancer. The overall aim of this doctoral project is therefore to contribute to the evaluation of a HP program in a pediatric oncology clinical context. It is structured around three main research questions: (1) what is the state of knowledge about complex HP interventions targeting physical activity and/or dietary behaviours in pediatric oncology, (2) what are the factors influencing participation in and implementation of the HP program, and (3) to what extent is the program acceptable and beneficial to improve the functional outcome of children and

adolescents affected by cancer? **Methods.** This study used a multiphase, mixed methods design. First, a scoping review on complex HP interventions in pediatric oncology was conducted. Then, were carried out qualitative studies to gather the perspectives of families affected by cancer and healthcare professionals on the HP program. Finally, we used a convergent mixed methods research design to evaluate the acceptability of the program and its impact on the functional outcomes of children and adolescents affected by cancer. **Results.** The scientific evidence and results of these studies demonstrate that, although not without challenges, implementing a HP program in a pediatric oncology setting is relevant and acceptable. The studies reviewed in Manuscript 1 showed that it is feasible to implement complex HP interventions in pediatric oncology and that they can potentially improve physical activity and dietary behaviours as well as patient outcomes such as physical and psychological health. This study also highlighted the lack of studies in the area of HP interventions or programs in pediatric oncology. In Manuscript 2, factors identified by families affected by cancer as influencing participation included tailoring the interventions to their specific needs and social support for the facilitators, and organizational barriers, health issues, and a lack of interest or need for the barriers. From the perspective of healthcare professionals, the need for HP interventions facilitated their implementation. However, a lack of embedment of HP interventions in clinical care and limited

involvement of clinicians negatively affected their implementation. Finally, in Manuscript 3, having participated in a HP in addition to the standard treatments did not result in improvements in terms of the functional performance in activities of daily living of children and adolescents affected by cancer. Yet, results support the acceptability of the program and families reported benefits in terms of their patient experience and health behaviours. **Clinical implications.** The results of this thesis support the integration of HP interventions to pediatric rehabilitation oncology services. This doctoral project also provides guidance for clinical practice by informing rehabilitation specialists on the most effective way to approach HP in the complexity that is everyday life of families affected by cancer.

ABRÉGÉ

Introduction. Il est reconnu que les survivants de cancer pédiatrique présentent des séquelles indésirables à long terme qui nuisent à la fois à leur santé ainsi qu'à leur accomplissement dans les différentes sphères de leur vie. Pour répondre à cette problématique, les interventions ayant pour but de diminuer les séquelles de la maladie et des traitements pour améliorer la qualité de vie à long terme des survivants de cancer pédiatrique doivent être mises de l'avant. Il y a toutefois peu de données sur l'efficacité de telles interventions pour améliorer le niveau fonctionnel des enfants et adolescents touchés par le cancer et sur leur acceptabilité dans un contexte réel de soins. L'objectif global de ce projet doctoral est donc de contribuer à l'évaluation d'un programme de promotion de la santé dans un contexte clinique en oncologie pédiatrique. Il s'articule autour de trois grandes questions de recherche : (1) quel est l'état des connaissances sur les interventions complexes de promotion de la santé visant l'activité physique et la nutrition en oncologie pédiatrique, (2) quels sont les facteurs influençant la participation et l'implantation du programme de promotion de la santé et (3) à quel point le programme est-il acceptable et bénéfique pour améliorer le niveau fonctionnel des enfants et adolescents affectés par le cancer ? **Méthodologie.**

Cette étude a utilisé un devis mixte, réalisé en phases multiples. Tout d'abord, un examen de la portée sur les interventions en promotion de la santé en oncologie pédiatrique a été réalisé. Ensuite, des études qualitatives ont été réalisées pour recueillir les points de vue des familles touchées par le cancer et des professionnels de la santé sur le programme. Enfin, nous avons utilisé un devis de recherche de type méthode mixte convergent pour évaluer l'acceptabilité du programme et son impact sur le portrait fonctionnel des enfants et adolescents touchés par le cancer. **Résultats.** Les données probantes et les résultats de cette étude démontrent que, bien que non sans défis, implanter un programme de promotion de la santé dans une clinique d'oncologie est pertinent et acceptable. Les études incluent dans l'examen de la portée du premier manuscript ont montré qu'il est faisable d'implanter des interventions complexes de promotion de la santé en oncologie pédiatrique et que ces interventions peuvent potentiellement améliorer le niveau d'activité physique et les habitudes alimentaires, en plus d'être bénéfiques pour la santé physique et psychologique. Dans le deuxième manuscript, les facteurs identifiés comme influençant la participation du point de vue des familles touchées par le cancer comprenaient l'adaptation des interventions à leurs besoins spécifiques et le soutien social comme facilitateurs ainsi que les obstacles organisationnels, les problèmes de santé et un manque d'intérêt ou de besoin comme barrières. Du point de vue des professionnels de la

santé, le besoin d'ajouter des interventions de promotion de la santé dans la clinique était le principal facilitateur. Cependant, le manque d'intégration des interventions en promotion de la santé dans les soins cliniques et l'implication limitée des cliniciens a eu une incidence négative sur leur implantation. Enfin, l'étude menée dans le troisième manuscript n'a pas démontré de bénéfices quant à la participation au programme de promotion de la santé en plus des soins standards sur le niveau de fonctionnement dans les activités de la vie quotidienne. Les résultats supportent toutefois l'acceptabilité du programme et les participants ont rapporté des bénéfices au niveau de leur expérience et de leurs habitudes de vie. **Retombées.** Les résultats appuient l'intégration des interventions de promotion de la santé aux services de réadaptation en oncologie pédiatrique. Ce projet doctoral guidera également la pratique clinique en informant les professionnels de la réadaptation sur la façon la plus efficace d'aborder la promotion de la santé auprès de cette population.

ACKNOWLEDGEMENTS

It is hard to believe that these few lines can be enough to express all my gratitude to those who have supported me during this long journey. During the last four years, I have experienced some periods of euphoria and rejoicing, but also of great discouragement. I want to thank those who have accompanied me by shining their light on my explorations and helping me in this journey. First and foremost, my supervisor, Isabelle Gélinas, for her constant support and guidance since we met at the beginning of my Master's degree many years ago, and for accompanying me in my projects even if they were not in her primary area of expertise. I also want to thank Johanne Higgins, for her insight and kindness; Kristopher Lamore, for his help navigating in this research project and finding my place, and Daniel Curnier for his expertise and for pushing me to see things differently. I had been told that the most valuable thing you have to look for in a supervisor-student relationship is trust – I feel very fortunate that I was able to trust and rely on all of them.

My appreciation also goes out to the many fellow students, professionals, and members of the research team who have gravitated around me and who have contributed, directly or indirectly, to my learning experience. From the *VIE* research

team, I particularly want to thank Claude Julie Bourque for her always thoughtful feedback on my projects and her passion for research which is truly inspiring, as well as Isabelle Bouchard for her collaborative work and friendship. Sharing my hardships and celebrating my successes with other students, who were already or became friends along the way, was also instrumental in finishing this thesis; I am thankful for Keven Lee, Annie Brochu, Jennifer Labonté, Émilie Bertrand, and Johanne Kerba for making the process more enjoyable. Keven may have followed me into grad school, I don't know if I would have found my way out without him.

Thanks as well to my family and friends, who have been an inexhaustible source of motivation. Having a tight circle of family members and friends who have the capacity to ground and anchor me is truly invaluable. I am especially grateful for my husband, Jean-Philippe, for his love, encouragement, and patience; I could have never done it without his unwavering support. I also want to thank my daughter Marguerite for reminding me to stay in the present moment and for inspiring me to become the best version of myself. I wish that, in turn, I am inspiring her to work hard to achieve her goals. My deepest appreciation also goes to the little one who will soon be joining our family for the resilience lesson and for encouraging me to submit this thesis before her arrival.

I would like to acknowledge the *Fondation des Gouverneurs de l'Espoir* for their financial support and dedication to improve children affected by cancer's quality of life. I have also received a Graduate Excellence Fellowship Award, the Margherita Rapagna Memorial Prize, and a Travel Grant from the School of Physical and Occupational Therapy.

Last but not least, the biggest thanks of all to the trusting parents, children, and healthcare professionals who allowed me to conduct this research project and their generosity when sharing their experiences with me.

Without the help of all of you, this thesis would not have been possible.

CONTRIBUTION TO ORIGINAL KNOWLEDGE

This thesis contains no materials that have been published elsewhere or written by someone else, except where specifically referenced. The research presented constitutes original material and contributes to the advancement of knowledge in the field of pediatric rehabilitation oncology.

This work will contribute knowledge towards evidence-based recommendations to guide the promotion of health interventions in the pediatric oncology population. More specifically, the novel contribution of this thesis to the knowledge base of pediatric oncology are a) to report on the extent of what is known on the use of complex behavioural interventions (CBI) or multimodal programs addressing physical activity and diet behaviour for children with cancer or childhood cancer survivors and their reported findings; b) to analyse the factors influencing the participation in the program from the perspectives of families affected by cancer and the implementation of the program from the perspective of healthcare professionals (HCPs), c) to assess the program's acceptability from the perspective of families affected by cancer and to determine to estimate the extent

to which interventions received through a HP program led to an improved functional outcome, compared to standard care.

The results from this study will also inform clinical practice on the acceptability, advantages, and limitations of conducting CBI through a HP program in a pediatric oncology clinical context. The studies in this thesis will provide useful information and strategies for clinicians who have an interest in the care of children and adolescents affected by cancer. By underscoring the importance of the use of efficient behavioural interventions and tertiary prevention initiatives in this field, we want to advocate for change, introduce innovations, and influence the way health care is delivered in this population. The ultimate goal is to support all children or adolescents affected by cancer to thrive and develop to their full potential. With this work, we also hope to expand opportunities for occupational therapists (OTs) and other rehabilitation specialists in the role-emerging area of practice of pediatric oncology rehabilitation and tertiary prevention, and to contribute to the growing body of evidence to move our professions forward.

All original data presented in this thesis was collected at CHU Ste-Justine (CHUSJ). The hospital is affiliated with the Université de Montréal. The Ethics Board of CHUSJ approved all studies involving research participants (consent

forms used can be found in Appendix I).

CONTRIBUTION OF AUTHORS

Prior to the completion of this manuscript-based thesis, several important steps were undertaken. First, the thesis protocol was prepared by Catherine Demers and approved by the thesis committee members, Daniel Curnier, PhD, and Kristopher Lamore, PhD, and by the thesis supervisors, Isabelle Gélinas, PhD, and Johanne Higgins, PhD.

Then, the research project was conducted and all the collected data was carefully examined and analysed by Catherine Demers with the help of collaborators. For Manuscript 1 (Chapter 4), Annie Brochu provided assistance with the screening of articles and manuscript preparation. For Manuscript 2, Keven Lee assisted with qualitative data analysis and Johanne Kerba with data collection and analysis. Expertise regarding study conception and research methodology was provided by Claude Julie Bourque and Kristopher Lamore. For Manuscript 3, Isabelle Bouchard provided assistance with the recruitment of participants, and Johanne Kerba with data analysis.

All these steps have been carried out by Catherine Demers under the supervision of Isabelle Gélinas and Johanne Higgins. Studies reported in Manuscripts 2 and 3 were part of a larger project, the *VIE project*, at CHUSJ; thus, the principal investigators and study coordinators, i.e. Daniel Sinett, Caroline Laverdière, Daniel Curnier, Serge Sultan, Valérie Marcil, Isabelle Bouchard, and Caroline Meloche, also oversaw study conception and design, data collection, analysis, and interpretation, and manuscript preparation. The thesis and three manuscripts contained in this thesis were written by Catherine Demers with editing and feedback from Isabelle Gélinas and Johanne Higgins.

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LIST OF ABBREVIATIONS

Abbreviation	Meaning
ADL	Activities of daily living
ALL	Acute lymphoblastic leukemia
AMPS	Assessment of motor and process skills
AYA	Adolescents and young adults
CAC	Children affected by cancer
CBI	Complex behavioural interventions
CCSS	Childhood Cancer Survivors Study
CFIR	Consolidated Framework for Implementation Research
CIPN	Chemotherapy induced peripheral neuropathy
CIPP	Context, Input, Process, and Product
HCPs	Healthcare professionals
HP	Health promotion
ICF	International Classification of Functioning, Disability and Health
ICP	Interprofessional collaboration
LAE	Late adverse effects
MABC-2	Movement ABC-2

OTs	Occupational therapists
ORBIT	Obesity-Related Behavioural Intervention Trials
PA	Physical activity
SCC	Survivors of childhood cancer
CHUSJ	Centre Hospitalier Universitaire Sainte-Justine
VIE	Valorization, Implication, Education

PREFACE

My interest in pediatric oncology rehabilitation was sparked early on during my clinical career as an Occupational Therapist (OT) at Centre hospitalier universitaire Sainte-Justine (CHUSJ). I came to quickly realize the sometimes devastating impact of cancer on the lives of children and adolescents affected by cancer, survivors, and their family members. Two years into my clinical practice, it became clear to me that the extent of knowledge I had and the evidence-based practice gaps did not allow me to provide optimal quality services to my patients; I was unsatisfied with the help I could provide to them in their recovery. Consequently, I made the decision to enrol in a Master's degree in Rehabilitation Science at McGill University. My goal was to gain further knowledge and skills that would enable me to create new evidence and translate existing evidence into practice. I had the opportunity to conduct my Master's research project at CHUSJ, my own work setting, with brain tumour survivors. More specifically, I investigated the performance in activities of daily living (ADL) of adolescents and young adults who had brain cancer during their childhood and explored the associations with their health-related quality of life. The results from this study highlighted the negative impact pediatric cancer, more specifically brain tumours, can have on the

functional outcome of survivors. Once heard in a conference from a cancer survivor, reflecting on her experience: '*There is no moving on with cancer, only moving forward' (Tomeh, 2019)*. Although survivorship should be celebrated, cure comes at a cost, and for many survivors, overcoming cancer is just the first of major hurdles to be surmounted following their diagnosis. This reflection of '*moving forward*' raises an ambiguity on what is yet to come.

When reviewing the literature during my M.Sc. studies, I unfortunately concluded that the evidence-based knowledge in the area of practice of pediatric rehabilitation oncology is very limited. As an emerging field of study, little research has been conducted to date, whereas the needs for rehabilitation of children or adolescents affected by cancer and survivors are tremendous. Moreover, having attended numerous conferences and symposiums on pediatric cancer, I can attest that the rehabilitation field is underrepresented. I enrolled into graduate studies to obtain answers; only to leave with more questions…

Acknowledging the gaps and the needs is an important first step, but it is crucial to take the next step and also to address them. Therefore, when I was offered the unique opportunity to join a highly experienced, multidisciplinary research team for an innovative project on health promotion in pediatric oncology, I jumped on the

occasion. Keeping the ultimate goal in mind to improve rehabilitation services and health outcomes for children affected by cancer, I am proud to present in the next pages the result of my PhD work.

Thesis organization and overview

This thesis is manuscript-based and is prepared in accordance with the regulations outlined by the Graduate and Postdoctoral Studies (GPS) Office. Following these guidelines, this thesis consists of a collection of three original manuscripts. One manuscript was published in a peer-reviewed journal and two are submitted. Each manuscript represents a step toward the overall aim of this project. Additional chapters have been included in this thesis; GPS requires that each thesis contains a literature review and conclusion that is separate from the manuscripts. Therefore, duplication of material and repetitions in this thesis is unavoidable.

The thesis is organized in 8 chapters.

Chapters 1 and 2 provide an introduction and a literature review on pediatric cancer, its adverse effects, and health behaviours in children affected by cancer and survivors.

Chapter 3 outlines the rationale, research objectives, and hypotheses of the thesis.

Chapter 4 introduces the methodology and the philosophical and theoretical foundations for the research project this thesis is built on.

Chapter 5 consists of a manuscript entitled *"Complex behavioural interventions targeting physical activity and dietary behaviours in pediatric oncology: A Scoping Review"*, published in the journal *Pediatric Blood & Cancer*. This review reports on the state of the evidence on the use and effects of complex behavioural interventions (CBI) targeting physical activity and/or dietary behaviours in pediatric oncology. Gaps in the literature and suggestions for studies in the field are discussed.

Chapter 6 consists of a Manuscript entitled *"Implementing health promotion interventions in a pediatric oncology setting: a qualitative study among families affected by cancer and healthcare professionals",* submitted to the journal *Health Promotion and Chronic Disease Prevention in Canada*. This study aims to determine the factors influencing the participation in a HP program from the perspectives of families affected by cancer and the implementation of the program from the perspective of healthcare professionals. The program, the *VIE project*,

consisted of CBI targeting physical activity and/or dietary behaviours across the cancer trajectory.

Chapter 7 consists of a manuscript entitled "*Acceptability and functional benefits of a health promotion program in pediatric oncology: A mixed methods study*", submitted to the *European Journal of Cancer Care*. This manuscript focuses on assessing the *VIE project*'s acceptability from the perspective of families affected by cancer and on estimating the extent to which interventions received through the program in addition to standard care led to an improved functional outcome, compared to standard care only.

Chapter 8 is a summary of the main findings and a general discussion integrating the main findings of the three manuscripts.

For the manuscripts, the tables, figures, and references are included at the end of each text. The references for all other chapters are presented at the end of the thesis.

CHAPTER 1: INTRODUCTION

Pediatric cancer survivorship is one of the great medical achievements of the last decades. However, while the success rate is impressive, there is still a lot of effort to make to improve the long-term health outcomes and quality of life of survivors. The literature documenting the various adverse effects of childhood cancer and its treatment is extensive [1-6]. A research team at the CHU Ste-Justine (CHUSJ) has contributed to the body of evidence in the field by developing and implementing the PETALE study [7]. This large study aimed to examine if genetic or biological factors can predict the development of known medical complications found in survivors of acute lymphoblastic leukemia (ALL), the most common cancer diagnosed in children. The findings from this study concluded that the medical and psychosocial drawbacks associated with ALL and its related treatments can be of major significance. For example, it was found that survivors were at higher risk of having a metabolic syndrome, dyslipidemia, hypertension, and high cholesterol [8]. These results indicate that, apart from genetic or biological factors, health behaviours such as practicing regular physical activity (PA) and adopting a healthy diet could also predict the development of adverse effects, which supports the need for early lifestyle intervention in this population. Consequently, the research

team concluded that the next logical step would be to move forward with an intervention study to address these modifiable factors.

This thesis's research project is embedded in the above-mentioned intervention study, called the *VIE project (*Valorization, Implication, Education) [9]. This innovative, health promotion (HP) program was developed at CHUSJ and implemented as a feasibility study. The goal of the program is to motivate children affected by cancer and their families to adopt and sustain health behaviour practices across the continuum of care to prevent adverse effects of cancer and its treatment, or at least reduce their incidence. The program consists of a 2-year, family-oriented multidisciplinary approach with three components: 1) the psychosocial component, which is designed to provide support and teach problem-solving skills to parents who have a child affected by cancer; 2) the nutrition component, which provides counselling by a registered dietician to support behavioural changes, and 3) the physical activity component, which consists of individual, supervised PA sessions for children and adolescents. Details of the program can be found in Appendices II and III.

There is evidence from the literature that supports the hypothesis that HP interventions such as the ones proposed by the *VIE project* are likely to influence behaviour change and reduce the severity of some cancer-related adverse effects

of cancer [10]. However, their effectiveness to improve health outcomes that are meaningful to clinical practice for rehabilitation professionals and relevant to the target population, such as how survivors function in their day-to-day life, has not been investigated. Furthermore, as it is an innovative program, the families affected by cancer and healthcare professionals' (HCPs) views and acceptance of a HP program delivered across the cancer continuum are not known. The ultimate goal is to implement the program in a sustainable way locally and to ultimately export it to other pediatric cancer centres. In this context, determining the feasibility and potential efficacy of the program within a real clinical context is needed for an optimal uptake of this program by children affected by cancer, their families, and pediatric cancer centres. The first step will be to synthesize research evidence that already exist in the field by conducting a scoping review. Then, to gather new data that can support these claims, a program evaluation of both processes and outcomes is required. When developed, a thorough evaluation of each *VIE project's* component had been planned. However, a more global program evaluation that also considers the perspective of families affected by cancer and HCPs has not been undertaken. Thus, the overall aim of this thesis is to contribute to the program evaluation of the *VIE project*. Before diving into the details of this program evaluation, background information will be presented to situate the study in its broader context. In the next chapter, the literature on pediatric cancer and its

treatment, adverse effects that can arise during or after pediatric cancer, health behaviours, and health promotion interventions in children affected by cancer and survivors of childhood cancer will be described.

CHAPTER 2: REVIEW OF THE LITERATURE

2.1 Pediatric cancer: An overview

Pediatric cancer is a rare disease that makes up for less than 1% of all cancers diagnosed each year in Canada; but it still ranks as the second-leading cause of death in children 1 to 14 years old after injury-related deaths [11]. There has been a steady increase in the incidence of pediatric cancer diagnoses in developed countries since the 1950s. This is probably due to environmental factors, and a concurrent decline in mortality [12-14], with the most recent Canadian data showing that the overall five-year survival rate for children 0 to 19 years old is now at 84% [15]. Consequently, a constantly increasing number of children, and families, are affected by and surviving cancer each year in Canada. The improvement in the survival rate can be attributed to a deeper understanding of pediatric cancer biology, improved cancer detection as well as the effectiveness of new treatments [16]. Nonetheless, efforts to better understand the causes of childhood cancer and to design more specific and selective treatment modalities are ongoing; researchers continue to pursue the goal of further improving cure and raising survival rates.

2.1.1 Types of pediatric cancer

Cancers diagnosed in children or adolescents differ from adult cancers with regards to incidence, prevalence, and etiology [17]. The most common cancers in children include acute lymphoblastic leukemia (ALL) and acute myelogenous leukemia, which comprise about 33% of all cancers in children [18]. They are characterized by an abnormal proliferation of leukocytes and a reduction of normal blood cells. Brain and spinal cord tumours are the second most common cancers in children, making up approximately 20% of pediatric cancers [18]. The third most common cancers in children are lymphomas, which start in the lymphocytes, lymph nodes, or other lump tissues such as the tonsils or thymus and can affect the bone marrow and other organs. Lymphomas account for 11% of cancers in children [18]; Non-Hodgkin's lymphomas are more likely to occur in younger children and Hodgkin's lymphomas are more common in adolescents.

Other types of cancers in children are rarer. Extracranial solid tumours include, but are not limited to, neuroblastomas, Wilms tumours, rhabdomyosarcomas, retinoblastomas and osteosarcomas. About 6% of pediatric cancers are neuroblastomas, which develop in infants and young children and are rarely found in children older than ten [18]. Wilms tumours account for about 5% of pediatric

cancers and start in one or, rarely, both kidneys [18]. Rhabdomyosarcomas are an aggressive and highly malignant form of cancer which develops from skeletal muscle cells that have failed to fully differentiate. This type of cancer can start nearly anywhere in the body, including the head and neck, groin, abdomen, pelvis or in the appendages. They are the most common type of soft tissue sarcoma in children and make up about 3% of pediatric cancers [18]. Retinoblastomas are a type of cancer that develops from immature cells of the retina and accounts for about 2% of pediatric cancers [18]. They usually occur in children approximately two years old and are seldom found in children older than six. Osseous cancers, including osteosarcomas and Ewing sarcomas, account for another 3% of pediatric cancers [18].

2.1.2 Associated treatments

Treatments for pediatric cancer are chosen based on the type of cancer, the stage of development and the age of the child. They include surgery, chemotherapy, radiation, hormone therapy, stem cell transplantation and new, innovative treatments such as targeted drug therapy or immunotherapy. Often, the combination of multiple treatments is indicated. Chemotherapy includes alkylating agents, antimetabolites, anthracyclines, plant alkaloids, anti-tumour antibiotics, taxanes and monoclonal antibodies. Pediatric cancers usually respond well to high-dose chemotherapy because of rapid cell turnover in children; this

effectiveness explains the difference in survival rates compared to adults [17]. The duration of treatment varies from a few months (e.g., lymphomas) to a two-year protocol (e.g., leukemia) and can last for many additional months or years because of complications and relapses. However, as treatments are designed to suppress cell growth and to eliminate malignancies, they have the potential to damage or interfere with function in essential organs. As such, these treatments often lead to short- and long-term adverse effects, which will be described in the next section.

2.1.3 Adverse effects

Although childhood cancers are more responsive to treatment than adult cancers, cancer therapies can be harsh and may have disabling effects on growing bodies. Indeed, despite the advances in research and technology, children experience a huge number of negative physical, cognitive, and psychosocial adverse effects that can start as early as the treatment phase or later on and often last into adulthood [19]. These negative effects are now well described in a growing body of literature on this subject. Therefore, concurrent with the success of cancer survivorship rate comes an increased appreciation of the adverse effects resulting from the disease and its treatment [4-6].

The International Classification of Functioning, Disability and Health (ICF) developed by the World Health Organization [20] will be used to classify the adverse effects and related disabilities associated with pediatric cancers and their treatments. See Figure 2.1[1] for the ICF framework applied to childhood and adolescent cancer. It is based on a literature review by Tanner [21] regarding functional impairments in children, adolescents, and young adults with cancer. The ICF provides a multi-dimensional framework that classifies health and health-related domains and describes changes in body function and structure, the level of capacity and the level or performance, while considering the environmental and personal factors. In the next section, impairments on body structure and function secondary to cancer and its treatments in children affected by cancer (CAC) and survivors of childhood cancer (SCC) will be described.

[1] Reprinted from Tanner et al., 2020. *Cancer Rehabilitation in the Pediatric and Adolescent/Young Adult Population.* Seminars in Oncology Nursing. 36(1), p.3, with permission from Elsevier

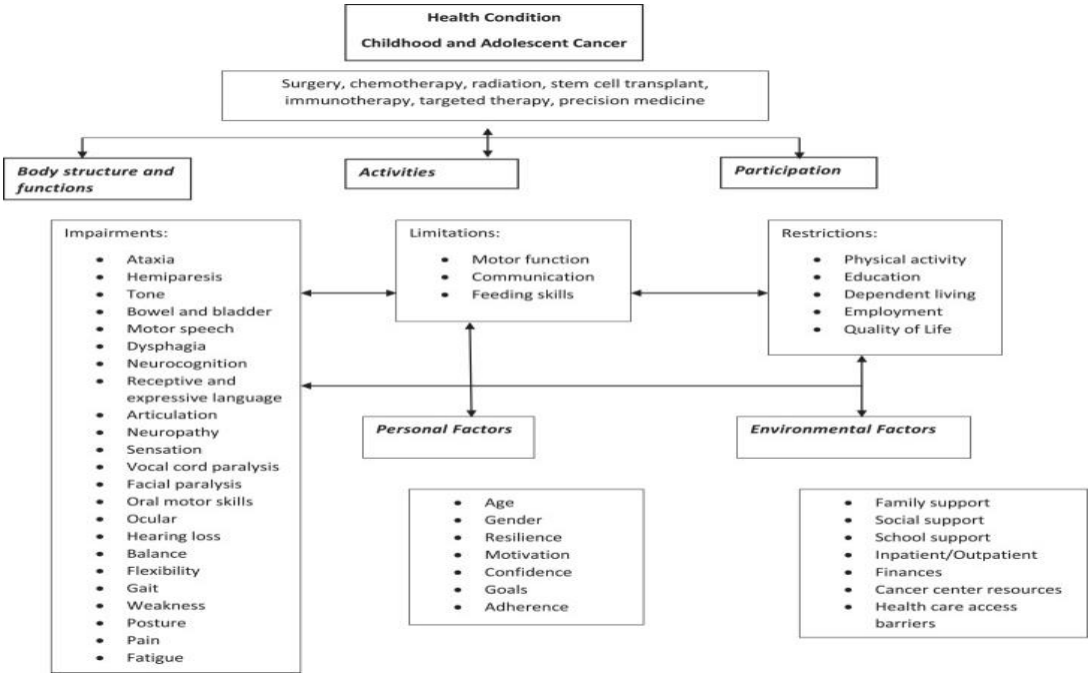

Figure 2.1 ICF model for childhood cancer rehabilitation (ICF-CC), adapted from the ICF model

Body structure and function – acute adverse effects

Acute toxicities that develop during cancer therapy are related to the immediate effects of cancer and treatments on rapidly dividing cells. Most children recover from these acute problems [22, 23].

Nausea is the most common symptom experienced by children (0-14 years old) [24] and adolescents or young adults (AYA) (15-39 years old) [25] receiving cancer treatments. Nausea and vomiting can have a negative effect on their emotional well-being (e.g., symptom distress, anticipatory anxiety, etc.), hinder treatment

compliance, lead to health complications and interfere with daily activities [26,27]. Fatigue is also common and can be defined as a distressing, pervasive symptom characterized by a lack of energy with physical (e.g., needing to sleep or rest more, lack of strenght) and psychosocial (e.g., sadness, guilt and annoyance) components [28]. Fatigue is experienced differently depending on developmental level, with school age children emphasizing the physical sensation, such as difficulties to move or feeling weak, while adolescents tend to focus more on mental and emotional tiredness, such as having a heard time concentrating and feeling socially isolated, along with the physical sensation of fatigue [29].

Chemotherapy treatments are also known to cause neutropenia and peripheral nervous system injury and dysfunction, termed chemotherapy induced peripheral neuropathy (CIPN). Neutropenia is defined as a significant reduction in white blood cells, which are needed to fight infections. Thus, children who receive treatment for cancer are extremely vulnerable to life-threatening infections, which are a major cause of morbidity and mortality. CIPN affects the sensory, motor and/or autonomic components of the peripheral nervous system [30]. Neurophysiological changes occur early during treatments with conventional nerve conduction studies demonstrating a motor or sensorimotor axonal neuropathy in ≥90% of patients by

the end of 4-5 weeks with weekly administration of vincristine, a type of chemotherapy known to cause CIPN [31].

According to a survey of expert in the field of pediatric oncology, other distressing symptoms frequently experienced by children in clinical trials are pain, anxiety, depression, sadness, disrupted sleep, nutrition problems, constipation, and alopecia [32]. Some symptoms are reported distinctively for CNS tumors, including headaches and problems with cognitive functioning [32].

Body structure and function – late adverse effects

In medicine, a late adverse effect (LAE) is a condition that appears after the acute phase of an earlier condition, and that can be caused either directly by the condition, indirectly by the treatment, or both. The wide array of potential LAE includes complications, disabilities, adverse outcomes, and second malignancies [33, 34]. The emergence of these LAE is largely variable; some of them can be clinically silent for a long period of time and only occur decades later, and the risk often does not plateau with aging [35]. More than 95% of SCC will have a significant health-related issue by the time they are 45 years old [36]. In general, the more frequently recognized risk factors for LAE include patient age at treatment, cumulative treatment dose and the treatment regimen [37, 38]. While

some LAE can be treated and cured, a major concern is that chronic LAE may increase in frequency and severity over time. They can also interact adversely with the normal ageing process, causing the development of conditions or impairments that normally occur in persons aged 65 years and older (e.g., frailty, poor physical performance, and changes in body composition) [39] and increasing the risk of premature major illness or early mortality [40, 41].

The long-term deficits the survivors are experiencing affect the whole person; they include, but are not limited to, physical, neurosensory, cardiometabolic, and endocrine complications [42]. Common musculoskeletal defects include deficits in bone mineral density, various skeletal deformities, osteonecrosis, muscle weakness [43] and amputation [44]. Survivors of childhood cancer are also at increased risk for neurosensory impairment including ocular degeneration, hearing loss [45] and CIPN. Neuromotor deficits include motor deficits such as ataxia, dysphagia or paralysis. Adult survivors of childhood cancer may also suffer from cardiometabolic conditions such as cardiomyopathy, heart valve and conduction disorders [46], increased cardiovascular risk factors including hypertension and dyslipidemia [47], and obesity [48]. Endocrine abnormalities are among the most frequently reported complications in SCC, growth hormone deficiency being the most common problem and resulting in impaired growth and changes in body

composition. They are particularly prevalent in children who receive radiation to the hypothalamic axis but affect between 20 and 50% of all individuals who survive into adulthood [49]. Adolescent and adult survivors, regardless of their cancer diagnosis, also report more chronic fatigue than their siblings [50].

A growing body of evidence shows that both traditional treatments and emerging therapies cause neurocognitive impairments in pediatric cancer survivors and that those impairments can progress over time [51]. For example, cancer-related cognitive dysfunction affects one third or more of the SCC in the United States [52-60]. Deficits in full-scale intelligence, verbal intelligence, visual-spatial skills, attention and concentration as well as nonverbal memory have all been observed among SCC [61]. Cognitive deficits are more common in survivors of childhood brain tumours, leukemia or other cancers who received cranial radiation, especially if received at a young age. However, impairments in attention, processing speed and executive functions have also been found in survivors of leukemia treated with chemotherapy only [62].

The late adverse effects are not limited to physical or cognitive health problems. Diagnosis, treatment and physical health conditions may also affect the psychosocial trajectory of SCC throughout their lifetime [63]. Symptoms of clinical

depression or anxiety are significantly higher in adolescents [64] and young adults [65] who are SCC compared to a group of healthy siblings. Studies have also found that suicidal ideation [66] and post-traumatic stress [67] were more present in adults who were SCC compared to healthy siblings. Many factors can explain the psychological distress in the SCC population, including the negative impact of late adverse effects in their life, a low self-esteem as well as medical-related anxiety [68]. In addition to psychiatric morbidity being overrepresented in this population [63], SCC are at increased risk of death related to risky behaviours, such as risk of dying of alcohol poisoning and suicide [69]. The main risk factors for mental health problems are unemployment, lower educational achievement, late effects of treatment, experiencing pain, and female sex [70]. In contrast to the adverse effects, there can be positive consequences of experiencing cancer during childhood [71]. For example, survivors have also reported having a more positive view of life [72], of self [71,72], and relationship with others (e.g., pro-social and less aggressive) [73,74]. This apparent contradiction can be explained by the posttraumatic growth that can happen as a result of their cancer experience [75]. Numerous factors are associated with a higher level of posttraumatic growth, such as a higher level of warmth in parenting, female gender, and older age at assessment [76].

2.1.4 Impact of adverse effects

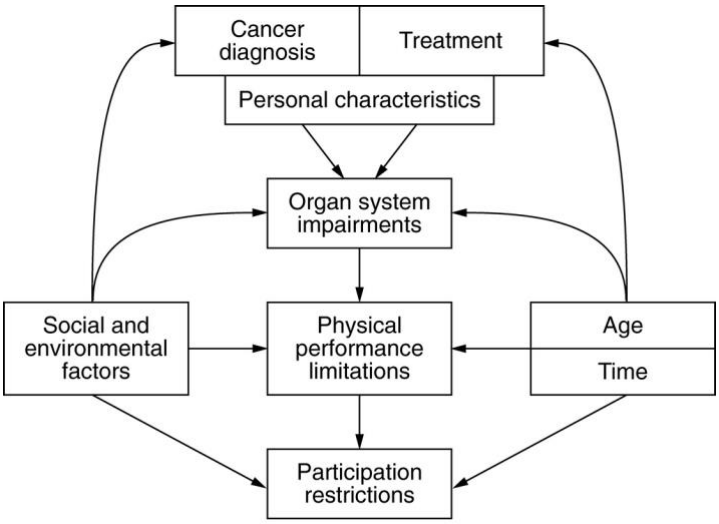

Figure 2.2 Conceptual model of disability among cancer survivors

Due to the various adverse effects, there is growing evidence from the literature that suggest that the global burden of childhood cancer is substantial and growing [77]. The childhood cancer population experiences activity limitations and participation restrictions, which negatively impact their quality of life. Ness and Gurney [78] developed a conceptual framework to illustrate the complex association between cancer, cancer treatment, adverse effects, functional limitations and potential disabilities, as shown in Figure 2.2[2]. The framework represents the relationships between pathology, impairment, activity (or physical performance) limitation and participation restriction. It should be noted that, when two or more symptoms or adverse effects are interacting with each other, they have a cumulative effect, and their impact is stronger than the sum of their individual effects.

[2] Reprinted from Ness, K. K. & Gurney, J.G. 2007. *Adverse late effects of childhood cancer and its treatment on health and performance.* Annual Reviews in Public Health, 28, p.280, with permission from Annual reviews

Activity limitations

The range and severity of adverse effects compromise the function and limit the activities of CAC and SCC. The current literature presents increasing evidence that CAC are challenged by physical performance shortly after diagnosis [79-81] and during acute treatment [82], such as reduced functional mobility [83,84] and manual dexterity [85]. Other common activity limitations in CAC can occur in communication, such as an affected caregiver-child interaction, and feeding, such as decreased or temporary cessation of oral intake [21]. Study results also show that motor performance remains impaired after completion of treatment [86] and that reduced physical performance persists throughout survivorship [78, 87-89]. SCC can struggle with a host of issues that have a cumulative effect and can leave them disabled or only able to function at a level that is not optimal. A report from the Childhood Cancer Survivors Study (CCSS) in the United States showed physical performance limitations in 20% of SCC [90]. Furthermore, survivors with chronic health conditions reported a 3.25-fold increased odds of functional impairments and 3.2-fold increased odds of activity limitations [91].

Participation restriction

At diagnosis and during acute treatment, most children cannot attend regular school [92] or participate in sports [93] due to their intense therapy regimens and

their associated side effects. Furthermore, less than optimal function in the physical and/or cognitive domains may influence activities of daily living and greatly affect CAC's ability to participate fully in expected roles at home, school, and work [94]. In a study with 41 children and adolescents diagnosed with leukemia or lymphoma, all participants reported ADL functional limitations shortly after diagnosis [81]. The CCSS has estimated that 8% of long-term survivors still experienced participation restrictions [84]. For example, compared to siblings, adult survivors are 23% more likely to use special education services, 4 times more likely to be unemployed, 20% less likely to marry, and more than twice as likely to live dependently [95, 96]. Another study showed that physical performance limitations are linked to an increased incidence of unemployment and low income in adult survivors of childhood cancer [97]. In a cohort of adult survivors of childhood cancer from Switzerland, survivors reported significantly more limitation in sporting activities and daily activities than siblings [98]. Regarding the psychosocial impact, a review showed that positive and negative consequences of childhood cancer coexist, including difficulties with friendships and other relationships, as well as challenges in SCC's sexuality and parenthood [99].

Quality of life

As illustrated by the Revised Wilson and Cleary Model of Health-related quality of life (Figure 2.3)[3] [100], adapted from Wilson and Cleary [101], it is expected that adverse effects of cancer and its treatment will ultimately have an impact on the quality of life of CAC and SCC. It has been shown among adult SCC that, in addition to the cancer diagnosis, the quantity and severity of chronic conditions particularly contribute to diminished health-related quality of life [102]. Furthermore, according to studies in the field, quality of life can be predicted by disabilities [80,97,103] and functional status [104].

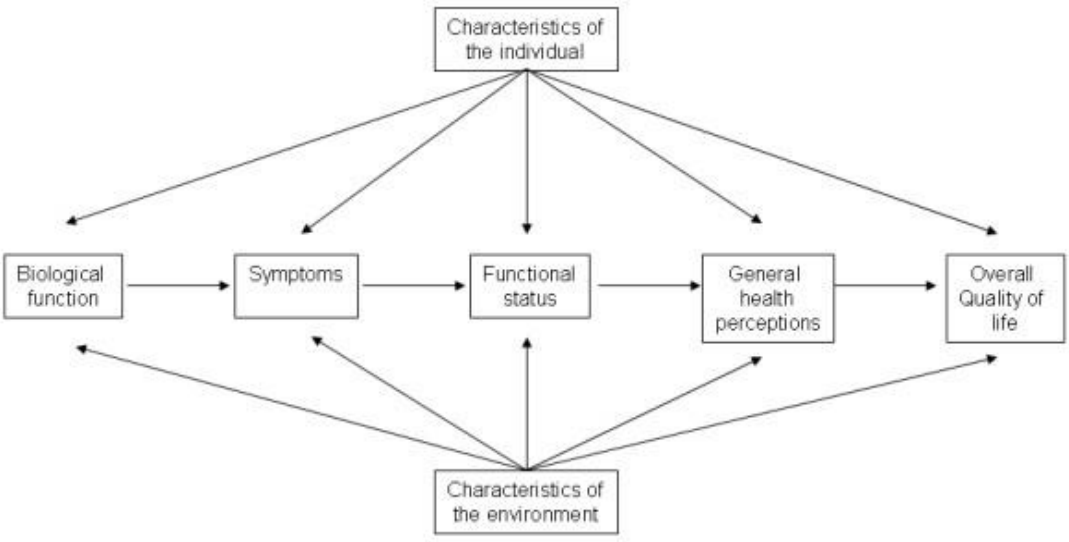

Figure 2.3 Revised Wilson and Cleary Model for Health-related quality of life

[3] Reprinted from Ferrans et al., 2005. *Conceptual model of health-related quality of life.* Journal of Nursing Scholarship, 37, p.338, with permission from Blackwell Publishing

2.2 Health behaviours

Risk factors for the above-mentioned adverse effects of childhood cancer include treatment-related factors (e.g., craniospinal irradiation, anthracycline) and sociodemographic factors (e.g., higher age, female sex, low socioeconomic status) [39, 105], but also unhealthy lifestyle factors (e.g., physical inactivity) [39, 105]. Negative health behaviours are known to influence an individual's risk of disease and may further increase the risk of adverse health problems [106]. Positive health behaviours include, but are not limited to, avoiding tobacco use, regularly exercising, having good nutritional habits, limiting alcohol use, and practicing sun protection. Engaging in a healthy lifestyle is particularly crucial for CAC and SCC to mitigate risk factors for other poor health outcomes and reduce the incidence of adverse effects. Indeed, adopting and maintaining healthy behaviours during and after cancer treatment could reduce the incidence of some adverse effects [107] and prevent or delay the accelerated aging process [39]. Understanding the uptake of risky health behaviours and related factors is imperative to promoting lifelong healthy behaviours and potentially reducing late effects that may be exacerbated by poor health behaviours [108]. Although all health behaviours are important, it is not possible in the scope of this thesis to cover all of them. Considering that a high interest for improving physical activity and eating healthy was found in SCC [109-

112] and that they are the most prominent health behaviours in pediatrics, the following section will focus on these two health behaviours.

2.2.1 Physical activity and nutrition among CAC

Children with cancer have reduced physical activity (PA) levels compared to their peers, as early as the first weeks following diagnosis [113] and throughout treatment [114]. In a study investigating the different aspects of PA behaviour in CAC, Stossel et al. [115] concluded that self-reported PA levels decreased tremendously during treatment, compared to before treatment, and did not fully recover after treatment. Furthermore, in that study, CAC reported significantly fewer minutes of moderate-intensity PA compared to healthy controls, during and after treatments. Causes of reduced PA include constraints associated with hospitalization such as medical apparatus, nausea and fatigue, which lead to sedentary bed rest [116]. In a study investigating parental perspectives on their child's physical activity during acute cancer treatment, parents described a spiral of physical inactivity that follows a diagnosis of cancer, highlighting the interplay between their child's ability to keep physically active, adverse treatment effects, hospital environments and compromised health [117]. Long-term motor impairment may also contribute to a reduced preference for physical activity and lifestyle choices, which compound metabolic disorders such as diabetes, obesity, and osteoporosis [85].

CAC also often encounter different dietary problems throughout the cancer trajectory. For example, CAC have frequently reported reduced food intake, poor appetite and/or loss of weight, resulting in the prevalence of cancer-related nutrition issues at one point during their treatment varying from 5 to 60% [118]. A study showed that, in the Netherlands, one out of four children with cancer had a form of eating disorder during treatment such as picky eating, excessive eating, food or texture refusal, and gastro-intestinal problems; resulting in diminished intake for two thirds of them and in excessive intake for the other third [119]. Cancer treatments often induce a change in taste, nausea and gastrointestinal side effects in patients, modifying their appetite and altering their eating behaviours [120]. This leads children to consume a poor quality diet with not enough fruits, vegetables and milk [121], and a preference for fat and savory food [122, 123], Other studies underscored that pickiness and cravings were the principal difficulties reported by parents during treatments [122, 124]. A decreased appetite can have a negative impact on the cancer outcome, as impaired nutritional status is associated with lower tolerance to treatments and higher prevalence of infections [125]. Consequently, it has been reported that parents can react by using a variety of strategies to make the child eat and often force them to eat [126, 127]. It is important to note that, even when adopting healthy diet behaviours, children

with cancer are at risk of malnutrition and excessive weight gain during treatments due to the use of corticosteroids [128].

Factors contributing to the development and maintenance of an unhealthy lifestyle among children with cancer include, but are not limited to, acute toxicities of cancer treatment and medical restrictions. Indeed, prolonged hospitalization, bed rest, activity restrictions and weight gain may promote sedentary behavior and poor food choices, compounding existing organ system damage, and impeding an active lifestyle [129].

2.2.2 Physical activity and nutrition among SCC

Studies have shown that poor health behaviours persist in the survivorship phase, with SCC failing to meet guidelines for PA and diet [130-132]. Studies have found that PA levels are lower in SCC than in healthy populations [132-136]. In studies conducted in North America, it is estimated that 48%-65% of survivors are not meeting the minimum PA guideline recommended by the Centers for Disease Control and Prevention [111, 137-140]. In another study conducted in Australia, 75.5% of survivors were considered insufficiently active (i.e., 1-419 min/week) [140]. The lack of adequate PA in this population has significant clinical importance and may contribute to their already heightened risk of morbidity and mortality. A review has concluded that survivors who are physically active, compared to those who are not, have a decreased risk of cardiovascular disease and mortality [141].

Furthermore, survivors who are physically fit, compared to those who are not, have increased neurocognition levels [141]. In a recent Canadian study, physical activity was identified as one significant predictor of perceived health in SCC along with pain and concerns related to health resources [142].

Regarding diet, food habits of SCC are suboptimal [143] and the quality of their diet is significantly poorer than their age-matched peers [144]. Factors such as picky eating, emotional overeating, and body mass index influence the diet quality in survivors [144]. A poor diet can lead to problems such as obesity, which has increased almost threefold in this population in the past two decades [145]. According to Ford, Barnett, & Werk [146] who conducted a review on health behaviours in SCC, even studies demonstrating a low to moderate levels of health-damaging behaviours are alarming for survivors because of their high vulnerability.

2.2.3 Promotion of health behaviours in pediatric oncology

The increasing number of long-term childhood cancer survivors, their risk of adverse effects, and their suboptimal health behaviours support the need for effective health promotion interventions or programs. Interventions promoting a healthy lifestyle in this population have been proven to be both safe and feasible [147] and studies with young adult cancer survivors have highlighted a need for

support [148] and information [149] regarding lifestyle and health risks after childhood cancer.

Evidence supporting exercise or physical activity interventions during and after treatment for pediatric cancer has been reported in reviews, which found positive effects on muscle strength [150, 151], cardiorespiratory fitness [150, 151], functional mobility [150, 152], and fatigue [150, 151]. Evidence supports the hypothesis that a hospital-based exercise program may reduce days of hospitalization in CAC [152]. Moreover, a study showed that supervised exercise interventions in this population seems to be safe, with a low occurrence of adverse events with consequences [153]. It has also been reported that being physically fit is associated with increased neurocognition [141] and decreased early mortality in CCS [141, 156]. Reviews of nutritional interventions offered early in the cancer continuum [147] and in the survivorship phase [157] were unfortunately unable to draw conclusions due to the paucity and heterogeneity of the studies. More information on this subject and on the effects of programs combining physical activity and nutrition interventions can be found in Manuscript 1 of this thesis.

In summary, there is preliminary evidence that HP interventions or programs are safe, feasible, and potentially beneficial to improve children affected by cancer or survivors' health behaviours and health outcomes. Even though the evidence is

growing, there remain gaps in the literature, such as understanding the best timing for interventions, the perspective of children affected by cancer, their families and HCPs regarding those interventions. We also still need to identify the most efficient methods to implement these interventions or programs in clinical contexts sustainably and to evaluate them.

CHAPTER 3: RATIONALE, OBJECTIVES, AND HYPOTHESES

3.1 Rationale

Over the last decades, advancements in pediatric oncology medical treatments (e.g., chemotherapy, radiation therapy, etc.) resulted in an impressive improvement in survival rates for most childhood cancers. Yet, it is also important to acknowledge that the adverse effects of cancer and associated treatments are causing short- and long-term activity limitations [79-91] and participation restriction [81,90,92-99]. Thus, there is a need to address those shortcomings using different and innovative approaches. Moving forward, interventions to influence behaviour change and reduce the severity of some adverse effects among children or adolescents affected by cancer are representing a promising area of research in pediatric oncology [129]. In the current litteraute, there is a gap regarding the development, implementation, and evaluation of HP interventions or programs. For example, there is a lack of knowledge on how to successfully implement interventions aiming at improving PA and diet in a sustainable way, in real clinical contexts. Understanding how we may influence the impact of adverse effects through tailored interventions is key to improving the care and well-being of

children or adolescents affected by cancer [105], from cancer diagnosis moving onto adulthood.

To address this important issue, this thesis aimed to contribute to the program evaluation of the *VIE project,* a HP program for children affected by cancer and their families implemented at CHU Ste-Justine (CHUSJ), in Montreal, Canada. In light of the importance of conducting a sound program evaluation in applied-intervention research, the studies included in this thesis used both qualitative and quantitative data within the evaluation procedure of the *VIE project* (see Appendices II and III for details of the program) to meet the objectives that will be detailed in the next section.

3.2. Objectives

The overarching objective in this thesis was to contribute to the program evaluation of the *VIE project* by conducting a scoping review and adding specific process and outcome evaluations. The objectives unfold as follow:

First, to report on the extent of what is known on the use of complex behavioural interventions (CBI) or multimodal programs addressing physical activity and diet

behaviour for children affected by cancer or survivors of childhood cancer and their reported findings.

Second, to conduct a process evaluation by determining the factors influencing:

- the participation in the program from the perspective of families affected by cancer;
- the implementation of the program from the perspective of healthcare professionals.

Third, to conduct an outcome evaluation by:

- assessing the acceptability of the program from the perspective of families affected by cancer;
- estimating the extent to which interventions received through the program in addition to standard care led to an improved functional outcome, compared to standard care only.

3.3. Hypotheses

This study tested the hypotheses that the program was acceptable at CHUSJ to participants and that participation in the program in addition to standard care could result in a clinically significant difference in functional outcome (i.e., performance

in activities of daily living) in comparison to standard care only in children and adolescents affected by cancer; independent of age, sex, type of cancer, and time since the end of treatment. No specific hypotheses were tested for the qualitative studies or arms of the studies.

CHAPTER 4: METHODOLOGY AND THEORETICAL FOUNDATIONS

4.1 Study design

A multiphase, mixed methods design was used for this thesis (see Figure 4.1). The studies were conducted with children and adolescents affected by cancer and their families who participated in a larger study, the *VIE project,* that took place at a single study site, a tertiary care hospital in Montreal, from 2018 to 2022. This design was chosen because it fit our study's purpose and was appropriate to obtain a complete understanding of the research problem within a feasible time frame.

First, we conducted a scoping review to situate our own study in the existing literature. Then, during the implementation of the *VIE project*, we conducted a process evaluation in the form of qualitative studies to determine the factors influencing i) participation in the program from the perspective of participants and ii) implementation of the program from the perspective of healthcare professionals. Then, at the end of the program, an outcome evaluation was conducted using a convergent mixed method design, to compare similarities and differences between

quantitative statistical results and qualitative findings obtained separately. Quantitative data was collected to document the acceptability of the program and its impact on the functional outcome of children and adolescents affected by cancer. Concurrently, an exit interview was conducted to assess acceptability in more depth as well as perceived benefits of having participated in the study.

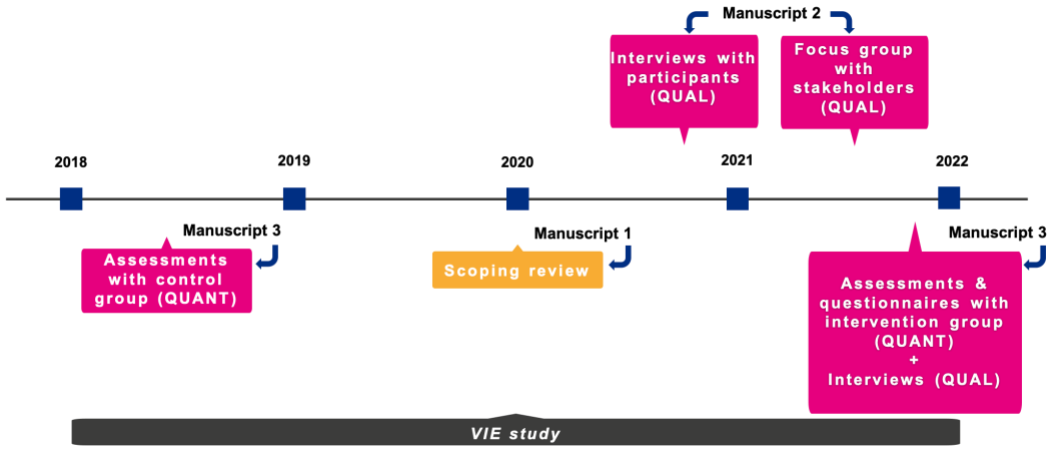

Figure 4.1 Study design

4.2 Philosophical & Theoretical Foundation

This section will give an overview of the philosophical and theoretical foundation behind the implementation and evaluation of HP programs or interventions in pediatric oncology.

4.2.1 Feasibility Study

Following the ORBIT model for developing behavioural treatments to prevent and/or manage chronic disease (Figure 4.2)[4], the present study is a Phase IIb study that aims to evaluate whether a behavioural treatment produces a clinically significant signal on the behavioural risk factors in the target population, compared to a comparison group, and that further aims to assess the feasibility of the trial protocol in preparation for an efficacy trial [158]. A feasibility study is a multi-component study that is often done in preparation for a main study, which may include qualitative research and developmental type questions. The Medical Research Council's guidance on complex intervention suggests a feasibility and a piloting phase as part of the work to eventually design and evaluate efficacy or effectiveness work [159]. It has a less rigid structure and there could be more variability in its conduct than a controlled trial, for example. An iterative approach to data collection in both quantitative and qualitative components may be taken, and the feasibility of delivering the intervention as well as running the trial may be a focus. Findings from feasibility pilot studies can facilitate protocol refinement and simplification in considering direct experience.

[4] Reprinted from Czajkowski et al., 2015. *From ideas to efficacy : The ORBIT model for developing behavioral treatments for chronic diseases*. Health psychology, 34(10), p.19, with permission from the American Psychological Association.

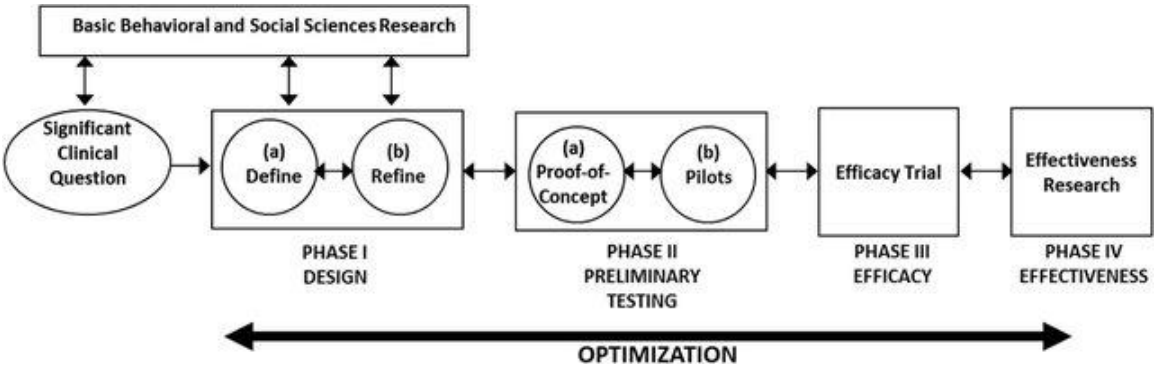

Figure 4.2 The ORBIT Model.

The pathway by which a behavioural treatment is hypothesized to work as proposed by the ORBIT model can be found in Figure 4.3[5]. We expected that following the interventions (A), the specific targets of the treatments (B) such as physical activity and diet journals could be implemented by the participant and lead to behavioural modification in children affected by cancer and their families (C). The behavioural modification (e.g. applied solving skills, healthy eating, frequent physical activity) would prevent or minimize some adverse effects of cancer and its treatment (D). At the end of the study, we expected that having fewer side effects would lead to an improved functional outcome (E). A fully-powered determination of the causal links between A and D or E would occur in an eventual efficacy trial [158].

[5] Reprinted from Czajkowski et al., 2015. *From ideas to efficacy : The ORBIT model for developing behavioral treatments for chronic diseases*. Health psychology, 34(10), p.20, with permission from the American Psychological Association.

Figure 4.3 Czajkowski's model of pathway by which a behavioural treatment is hypothesized to improve a clinical outcome.

CS Δ = Clinically Significant Change

4.2.1.1 Acceptability

Exploring acceptability is a key component of feasibility studies. It is increasingly acknowledged as an important consideration when designing, evaluating, and implementing healthcare interventions. It can be defined as a '*multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experiential cognitive and emotional responses to the intervention'* ([160], p.8). Successful implementation of complex interventions depends on the acceptability of the interventions to both interventions' deliverers and recipients [161, 162]. Persons who receive care are more likely to adhere to treatment recommendations and benefit from improved clinical outcomes if the recommendations are considered acceptable [163, 164]. From the clinician or researcher's perspective, the delivery of a particular intervention may not be delivered as intended if its acceptability is rated as low, which may have a negative impact on its effectiveness [165, 166].

4.2.1.2 Pragmatic study

This feasibility study is pragmatic in nature, as it is designed to evaluate the interventions in real-life routine practice conditions, rather than under optimal situations. If found effective in a pragmatic trial, an intervention is ready to be implemented in clinical practice. Indeed, as this research project aims to implement and evaluate an intervention in a real clinical context, pragmatism was used as the research paradigm. In pragmatism, the focus is on the consequences of research and on the use of multiple methods of data collection to inform the problems under study. As pragmatic trials are conducted in typical care settings, interventions and their delivery are allowed and expected to vary between participants by chance, by research team and participants' preference, and for organizational reasons. Thus, this research is pluralistic and oriented toward 'what works' and clinical practice.

4.2.2 Program evaluation

Any HP program necessitates a sound program evaluation, which is a structured process that intends to measure whether a program was successful in meeting its goals. The evaluation aims to answer the following question: '*was this program associated with improvement in individual or population health'* ([167], p.27)? In

addition to evaluating relevant outcomes, an evaluation should include a process evaluation which measures the way the program is provided [167]. That is, an evaluation should not be only concerned with program effectiveness but also the process of delivering programs [168].

Stufflebeam's CIPP Evaluation Model (Figure 4.4)[6], which stands for Context, Input, Process, and Product, was used to guide this program evaluation. This evaluation model is recommended to systematically guide the conception, design, implementation, and assessment of interventions or programs, and to provide feedback and judgment of the project's potential effectiveness for continuous improvement. The CIPP model adopts a pragmatic approach to evaluation. Its underlying theme is that evaluation's most important purpose is not to prove, but to improve the program itself [169]. The CIPP approach consists of four complementary types of evaluation studies: i) Context evaluation, to assess needs, problems, and opportunities within a defined environment; ii) Input evaluation, to assess competing strategies and the work plans and budgets of approaches chosen for implementation; iii) Process evaluation, to monitor, document and assess activities; iv) Product evaluation, to identify and assess short-term, long-term, intended, and unintended outcomes. In this thesis, we

[6] Reprinted from Stufflebeam, D., 2002. *The CIPP Evaluation Model,* in International handbook of educational evaluation, T. Kellaghan, D. Stufflebeam, and L. Wingate, Editors. 2003, Springer. p.33 with permission from Springer.

focused on the process and product evaluations since the context and input evaluation are steps that were taken in preparation to the implementation of the *VIE project* by the principal investigators.

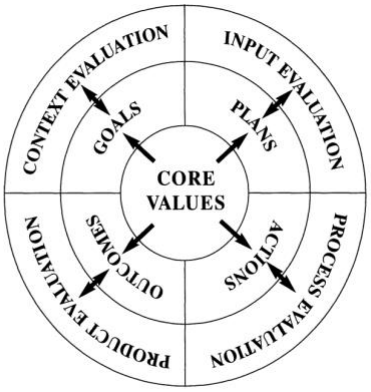

Figure 4.4 Key components of the Contexte, Input, Process, and Product (CIPP) Evaluation Model and associated relationships with programs

In summary, the research studies in this thesis were conducted to contribute ultimately to the program evaluation of the *VIE project*, which was implemented as a pragmatic feasibility study. To do so, we chose to use the CIPP evaluation model as a guide, a mixed methods approach, and an evaluation of acceptability.

CHAPTER 5: MANUSCRIPT 1

5.1 Preface

Before conducting the evaluation of the *VIE project* it was deemed important to conduct a scoping review to situate our own study in the existing literature. The purpose of this manuscript was to report on the extent of what is known on the use of HP complex interventions or programs in pediatric oncology, which was taken as a preliminary step towards establishing best practice guidelines and further advance research in this field. As the *VIE project* consists of a multidisciplinary program, integrating complex behavioural interventions (CBI) targeting physical activity and nutrition behaviours, this review focused on reviewing studies that used similar interventions in our target population. More specifically, the manuscript reports on the state of the evidence on the use and effects of CBI targeting physical activity and/or dietary behaviours in pediatric oncology. It also discusses gaps in the literature and proposes suggestions for studies in the field, which will guide the subsequent manuscripts.

Complex behavioural interventions targeting physical activity and dietary behaviours in pediatric oncology: A Scoping Review

Demers, C., Brochu, A., Higgins, J. & Gélinas, I.

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5.2 Abstract

As cancer and its treatment negatively impacts the long-term health and quality of life of survivors, there is a need to explore new avenues to prevent or minimize the impact of adverse effects in children with cancer and cancer survivors. Therefore, this scoping review aimed to report on the state of the evidence on the use and effects of complex behavioural interventions (CBI) targeting physical activity and/or dietary behaviours in pediatric oncology. Fourteen quantitative studies were included, evaluating interventions that used a combination of two or three different treatment modalities. Overall, studies demonstrated that it is feasible to implement CBI and that they can potentially improve physical activity and dietary behaviours as well as patient outcomes such as physical and psychological health. Unfortunately, due to a paucity of studies and the heterogeneity of the studies

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included in this review, no conclusive evidence favouring specific interventions were identified.

5.3 Introduction

Progress in childhood cancer diagnosis and treatment have resulted in childhood cancer survival rates of over 80% in developed countries in the past decades [1-3]. However, concurrent with this success comes an increased appreciation of the late effects resulting from the disease and its treatment that have been extensively described in the literature [4-6]. It is estimated that 62.3% of childhood cancer survivors (CCS) suffer from at least one chronic health condition, 27.5% have a severe or life-threatening condition [7], and 95% will have a significant health-related issue by the time they are 45 years of age [8].

For many cancer-related complications, behavioural modifications represent the primary method of risk modification available to children with cancer and survivors [9]. Although exercising, consuming a healthy diet, and adopting other healthy behaviours are beneficial for everyone, the importance of a healthy lifestyle is critical for children with cancer who are at increased risk of adverse health problems that could be potentially preventable. Adopting healthy behaviours is known to prevent or reduce risk factors for chronic diseases prevalent in this

population, such as cardiovascular disease, diabetes, and metabolic syndrome complications [10]. Interventions using one specific modality such as exercise interventions to improve physical activity (PA) or nutrition counselling to improve dietary behaviour have been the subject of reviews [11-14]. To the authors' knowledge, no guidelines provide guidance on the promotion of complex behavioural interventions (CBI) (i.e., the use of multiple modalities to change one or more health behaviours) in the pediatric oncology population. Therefore, little is known about the effectiveness of these interventions. As multifaceted interventions appear to be more appropriate to address the multiple health issues in pediatric oncology and as knowledge remains limited on how best to support children with cancer and CCS without adding to the burden on the family of the child affected by cancer, clinicians and researchers are in need of evidence-based knowledge on CBI to guide their action.

Hence, the purpose of this scoping review was to report on the extent of what is known on the use of CBI addressing PA and/or dietary behaviour in pediatric oncology and their reported findings. More specifically, the aims of this study were to examine the extent, range, and nature of (1) the study populations, (2) the interventions, and (3) the effects on health behaviours and patient outcomes as well as clinical recommendations.

5.4 Methods

The scoping review was conducted following the methodological framework by Arksey & O'Malley [15], with improved recommendations by Levac et al. [16] to examine and summarize the extent, range, and nature of CBI targeting PA and/or dietary behaviours in pediatric oncology. The adopted strategy involved searching for research evidence via electronic databases (Embase, CINAHL, Ovid MedLine, and PsychINFO), using snowballing technique of the reference lists of selected studies, and hand searching of key journals. For the electronic databases search, no limit in publication dates was set and a combination of key words and MeSH terms were used based upon the identified core concepts of the research question (see Table 5.1). The search strategy for electronic databases was developed from the research question and definitions of key concepts with the help of a librarian. Materials in English and French were included.

Prior to study selection, inclusion and exclusion criteria were created. Then, two reviewers (Catherine Demers and Annie Brochu) independently screened the title and abstract of studies for inclusion. Disagreements were resolved by consensus. Studies were included for full-text review if they involved: (i) children with cancer

or CCS who were diagnosed before the age of 21, (ii) CBI, and (iii) interventions targeting PA and/or dietary behaviours. Other health behaviours could also be targeted in combination with PA and/or dietary behaviours. According to the Medical Research Council (MRC) guidance [17], CBI can be defined as broad interventions that are built from several interacting components. Thus, CBI should consist of at least two different modalities (e.g., education, face-to-face intervention, self-management tools, etc.) that aim to change health behaviours and/or improve patient outcomes by affecting the actions that individuals take with regard to their health [18]. The second level of screening involved reading the full text of each article, which was done by Catherine Demers. Annie Brochu was consulted as needed for further clarification of any ambiguities. Full-text review included all methodologies and excluded syntheses or reviews of existing evidence, theoretical and empirical articles, conference abstracts, and editorials. Multiple articles that provided results from the same study were grouped together for analyses. For intervention studies that had been preceded by published pilot studies, only the more recent version was discussed.

In accordance with Levac et al. [16] and Colquhoun et al. [19] guidelines, we conducted a descriptive numerical and a thematic analysis. Pre-defined data extraction forms were created for both types of data, and the information was

extracted by the principal author (Catherine Demers). The descriptive numerical analysis focused on the characteristics of the studies. We retrieved the following data from the selected studies: authors, year of publication, study design, number of participants, age of participants, and program duration (see Table 5.2). We subsequently conducted a thematic analysis to answer our scoping review questions around the following themes: (i) population addressed, (ii) intervention description, (iii) outcome measures, and (iv) clinical implications. A pre-defined chart was used to organize and analyse the information using a deductive approach in an objective and systematic way for comparison purposes.

Following a method previously used to assess parental involvement on intervention results [20, 21], outcomes were categorized by positive or mixed results, as shown in Table 5.2. Positive results indicated that changes occurred in the desired directions among the majority of the outcomes. If there were positive changes, but only among one subgroup of participants or some of the outcomes measured, the results were labeled “mixed”. As some studies did not show positive changes for any of the outcomes under study, a third category named “no effect” was also added.

5.5 Results

5.5.1 Descriptive numerical results

The initial search included all studies published before December 2019, which is when the online searches were executed. As outlined in Fig. 5.2, a total of 831 articles were initially retrieved through the database search. Six additional studies were identified through cross-references and hand searching. Of those, 32 articles were retrieved for full-text review and 14 were retained for the final analysis. The two study designs employed were randomized control trials (RCT, 71%) and quasi-experimental designs with pre-/post-study assessments (29%). A summary of the studies included in this review is presented in Table 5.2.

Number and age of participants

Studies included a total of 1000 participants, ranging from 10 [22] to 267 participants [23]. The age of the participants ranged from 3 to 34 years old. Four studies targeted adolescents and/or young adults (11-34 years old) [22-25], seven included children and adolescents (4-20 years old) [26-32], and three were designed for the caregivers of younger children (3-13 years old) [33-35]. No studies included families of children younger than 3 years of age.

Intervention duration

The shortest intervention had a half-day duration, with the post-intervention assessment conducted 3 months following the intervention [24], whereas the longest proposed a 2.5-year program beginning after diagnosis and continuing through the end of treatment [28]. Most interventions had a duration ranging between 6 to 12 weeks.

5.5.2 Qualitative results

Population

Most studies included cancer patients regardless of their specific diagnosis, except for four studies that focused on acute lymphoblastic leukemia [28, 30, 33, 35], and one on leukemia and brain tumours [32]. Two studies that were designed specifically for CCS with obesity, defined as a body mass index (BMI) ≥ 85th percentile [30, 34], and one for survivors who reported symptoms of fatigue and had not engaged in PA in the previous 6 months [27].

In eight studies, the target of the interventions were the children with cancer or survivors themselves [22-25, 27, 29, 31, 32], five studies were family-oriented [26, 28, 30, 33, 35], and one was designed for parents only [34]. Participants in nine

studies were survivors [22-25, 27, 29, 30, 32, 34], whereas the remaining five studies recruited children undergoing treatment [26, 28, 31, 33, 35]. Nine studies were conducted in the United States [23-25, 28, 30, 32-35], two in Hong Kong [27, 31], one in Canada [22], one in the Netherlands [26], and one in Taiwan [29].

Interventions

Regarding the types of health behaviours addressed in each individual study, PA was targeted in 13 studies and dietary behaviours in seven (see Table 5.3). As studies could also include other health behaviours, smoking (n=2) [23, 25], alcohol consumption (n=1) [25], sun protection (n=1) [23], health accountability (n=1) [29], and self-examination (n=1) [23] were also addressed in the selected studies. More than half of the studies focused on one specific health behaviour, whereas the others addressed multiple health behaviours. Furthermore, studies evaluated a combination of modalities including educational interventions (n=11) [22-25, 27, 29-31, 33-35], individualized or group PA interventions (n=6) [22, 26, 28, 31-33], counseling (n=5), psychosocial support or training (n=6) [23, 24, 26, 28, 34, 35], reward system (i.e., healthy goods and services) (n=2) [25, 32], and adventure-based activities (n=1) [27]. Programs included between two and three different modalities.

Five studies were conducted in a hospital or clinic [23, 24, 26, 28, 29], four were delivered using various technologies (i.e., emails, text messages, online platforms) or telephone [25, 30, 34, 35], two were home-based [31, 33], and three were community-based [22, 27, 32].

Outcome

To evaluate the effectiveness of the interventions, 10 studies conducted the outcome assessments at short-term, either directly at the end of the intervention [28-30, 32, 33] or between 1 and 4 months postintervention [24, 25, 29, 30, 34]. The four remaining studies conducted long-term assessments, that is, 12 months after the program or interventions [22, 23, 26, 27].

Regarding the type of outcome assessed, four studies focused on health behaviours [23, 25, 29], three on patient outcomes [26, 28, 32], and seven conducted both [27, 30, 31, 33-35]. Health behaviour assessments included, but were not limited to, PA levels, dietary recalls, health behaviour self-efficacy, and consumption of alcohol (see Table 5.3). The most frequent patient outcomes were physical fitness [22, 26, 32, 33] and quality of life (QOL) [22, 26-28, 31, 32]. Most studies reported mixed results, meaning positive change was only found for some of the outcomes. For example, Zhang et al. [35] concluded that no significant

changes were observed for children's levels of PA, BMI, or waist circumference following a 12-week lifestyle intervention, but some positive changes were noted in regards to parenting practices and food consumption. One study from Lam et al. [31] demonstrated the effectiveness of an integrated programme with positive findings across all outcomes under study (e.g., cancer-related fatigue, level of PA, and QOL) (see Table 5.2). On the contrary, Berg et al. [25] and Cox et al. [28] did not report any effects for their online intervention targeting health-promoting behaviours as well as their physical therapy and motivation-based intervention, respectively. Of the six studies that included QOL as an outcome, only one reported improvement in QOL in participants, compared to the control group [31].

Eight studies also reported on feasibility outcomes, such as retention rate, acceptability, and participants' satisfaction [22, 25, 26, 29, 30, 32, 34, 35]. Globally, most studies reported positive findings, except for Gilliam et al. [32] who reported mixed findings, with near-perfect adherence to exercise delivered face-to-face with a mentor but low adherence to home exercise and daily web-based exercise log. The recruitment rate (i.e., eligible patients who were enrolled in the study) was variable with 39% for Braam et al.'s [26] study, while Wu et al. [29] reported a rate of 97%. The retention rate (i.e., patients enrolled who completed the study) ranged from 60% [32] to 92% [30, 31, 33].

Clinical implications

Various recommendations were made by the authors of the studies to guide either clinical practice or future studies (see Table 5.4). Some recommendations were made regarding important elements that should be included or considered, including supporting participants' self-efficacy. According to Wu et al. [29], interventions that address self-efficacy elements may increase children or survivors' confidence in their abilities to initiate and maintain healthy behaviours. In Lam et al.'s study [31], it was found that with increased self-efficacy, children with cancer were more likely to adopt and maintain regular PA. Also, psychological variables [26] and cognitive deficits [30] were deemed important to address.

The engagement of families, especially parents, was also found to be particularly important [35]. As caregivers serve as role models of healthy eating and PA, their engagement facilitateS family changes [34]. Gilliam et al. [32] showed that positive social interactions and encouragement with the mentor was associated with greater adherence to healthy behaviours, therefore recommending to enlist the support of parents or friends to provide additional social support to the CCS. To support lifetime commitment to health behaviours, Cox et al. [28] recommended having more frequent contact with study participants.

Another recommendation made by authors was to use targeted, individualized programs and age-appropriate approaches, that might be better than standard or generic programs to increase the effects of the program [22, 24, 26, 33]. Making the messages specific to the needs of CCS would likely enhance their relevance as well as increase the engagement and satisfaction of survivors with the content [25].

Furthermore, according to Huang et al. [30], the use of technology offers a feasible, relatively low-cost alternative to more in-person intensive interventions in this at-risk but sparse population because it can be distributed across time and geography; however, personal contact also appeared to help compliance with protocol and follow-up. Berg et al. [25] also suggest that an online intervention is feasible and acceptable among young CCS.

Finally, regarding the point over the course of treatment and survivorship that interventions might be best implemented, Cox et al. [28] concluded that it may not be feasible during early treatment owing to the child's responses to the disease and treatment. In this study, starting shortly after the diagnosis and following the participants through the end of therapy may have resulted in the study participants and/or parents being too sick and/or overwhelmed to complete the intervention

with the frequency and intensity necessary to improve function. Another study by Zhang et al. [35] concluded that conducting an early lifestyle intervention was feasible, but that results did not show significant changes in the targeted outcomes. For survivors, it was found that trying to recruit after treatment was difficult as families are often trying to forget their cancer and hospital experiences and, similarly, too long after (e.g. more than three years) was also difficult as families are likely to have created a new normal [34].

5.6 Discussion

The present scoping review sheds light on the dominant areas of research as well as gaps in terms of target population, intervention type, and outcomes for CBI targeting PA and/or dietary behaviours in pediatric oncology. The interventions typically focused on PA alone or in combination with other health behaviours, the majority had a short duration (<6 months) and were conducted during the survivorship phase.

The results of this study are consistent with other reviews for most of the feasibility outcomes; one concluding that dietary and PA interventions are feasible [14] and another one that lifestyle technology-based interventions demonstrated high feasibility and acceptability rates in the pediatric oncology and CCS populations

[36]. Moreover, a recent review of health behaviour interventions in CCS confirmed a gap in interventions designed for younger CCS (<8 years of age). Consistent with the recommendations from Stern et al. [34] and Zhang et al. [35] to engage families in CBI, a systematic review that examined parental involvement in diet and PA studies in CCS concluded that adding a parental component may improve health promotion interventions for CCS [20]. Indeed, in their review, studies with no or indirect parental involvement had lower amounts of success than studies with direct parental involvement. Furthermore, as some research has shown that parents remain involved in the healthcare of survivors even into adulthood [37], parental involvement should be considered throughout the continuum of care and regardless of the survivors' age. Parents of CCS are also known to experience psychosocial issues related to the child's cancer and treatment that can affect their family life [38], such as being overprotective and restricting children from participating in physical activities [39] or adopting a parenting style that is associated with increased junk food consumption [40]. Therefore, addressing parenting practises and offering psychosocial support or training to families may be beneficial for both parents and children with cancer.

Regarding the study design and methodology, rigorous experimental methods should be applied to behavioural studies. For example, researchers could use the

ORBIT model [41], which was developed to identify the most productive ways to implement durable behavioural studies. This model suggests the use of a progressive, transdisciplinary framework to encourage their testing in rigorous efficacy and effectiveness trials, promote success, and foster dissemination into clinical practice. Furthermore, methods must be devised to measure what was previously thought to be unmeasurable and assessments conducted in a reproducible and valid fashion, even for the measures of subjective states [42]. Esbenshade and Ness [14] have suggested to pick out outcomes that are reliable and reproducible as well as to standardize outcome measures so that studies can be compared and combined. For example, monitoring devices such as accelerometers, pedometers, and heart rate monitors can be used to objectively measure PA and a measure of weight, BMI, or body composition change to evaluate the impact of change in behaviour. Moreover, long-term follow-up may be needed to determine whether the downstream effects on the health outcome predicted by the change in behaviour occurred or whether the short-term changes, such as the change in behaviour, persisted [17]. Thus, implementing programs of longer duration should be encouraged. Collecting data over an extended period of time (e.g., more than 12 months after starting the intervention) would allow clinicians or researchers to evaluate the long-term effects and benefits of the interventions or program on outcomes such as QOL, which requires an extended

period to respond the intervention compared with other outcomes, for example levels of PA. Finally, according to the MRC Framework, process evaluation and qualitative research are essential to understanding the implementation of complex interventions and guide future efforts [43, 44]. However, studies included in this review used outcome evaluation and quantitative data exclusively; underpinning the need for qualitative and mixed methods study in the field. Adding a qualitative component in studies could contribute to gain a better understanding of how to support a sufficiently potent level of behaviour change to achieve meaningful change on a clinical outcome, for example, by evaluating barriers and facilitators to participation. Also, documenting the needs and experiences of children with cancer and their families in regards to CBI using qualitative data could help to optimize the recruitment, adherence, and effectiveness of the studies.

As for the gaps that should be addressed in future studies, no studies included families of children younger than 3 years of age or focused specifically on children with central nervous system or solid tumors. Knowing that healthy behaviours such as a healthy diet established during childhood continue into adulthood [45], intervening during early childhood is an opportunity to improve lifelong health outcomes. Data on race or ethnicity and socio-economic status were also not available for most studies, which would help identify and address health disparities.

Limitations from this review include the fact that this is a developing field of research, with the oldest article published in 1999, with few studies using CBI to date. The high variability in intervention type and outcome measures across studies made comparison of results difficult, and meant we were not able to identify attributes of studies that were effective. Furthermore, many of the included studies had small sample sizes and short follow-up duration. This review underlines the need for further well-designed trials using standardized outcome measures to be implemented in this population as well as addressing the gaps in the evidence base.

5.7 Conclusion

CBI targeting the adoption of a healthy diet and frequent PA have huge potential to make a positive impact on children with cancer or CCS, their families, and the overburdened healthcare system. However, this review also highlights the lack of studies in this area, especially for younger children and patients still undergoing cancer treatment. No conclusive evidence favouring specific interventions were identified, although there is preliminary evidence that CBI are feasible and potentially beneficial for children with cancer and survivors to improve their health behaviours and outcomes. The findings from this review will be useful for clinicians

or researchers who are developing or implementing CBI in this population. Future research is vital in identifying and defining the most efficient methods to implement CBI.

5.7.1 Acknowledgement

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5.7.2 Conflict of interest

The authors declare that there is no conflict of interest.

5.8 References

1. Pediatric Oncology Group of Ontario, Childhood Cancer in Ontario 1986 – 2015: A Surveillance Report from the Pediatric Oncology Group of Ontario. 2018, Pediatric Oncology Group of Ontario: Toronto.
2. American Cancer Society, Facts & Figures 2018, 2018. American Cancer Society: Atlanta, GA.
3. Nakata, K., et al., Childhood cancer incidence and survival in Japan and England: A population-based study (1993-2010). Cancer Sci, 2018. 109(2): p. 422-434.
4. Galligan, A.J., Childhood Cancer Survivorship and Long-Term Outcomes. Adv Pediatr, 2017. 64(1): p. 133-169.
5. Landier, W., S. Armenian, and S. Bhatia, Late effects of childhood cancer and its treatment. Pediatr Clin North Am, 2015. 62(1): p. 275-300.
6. Dickerman, J.D., The late effects of childhood cancer therapy. Pediatrics, 2007. 119(3): p. 554-68.
7. Oeffinger, K.C., et al., Chronic health conditions in adult survivors of childhood cancer. N Engl J Med, 2006. 355(15): p. 1572-82.
8. Hudson, M.M., et al., Clinical ascertainment of health outcomes among adults treated for childhood cancer. JAMA, 2013. 309(22): p. 2371-2381.
9. Demark-Wahnefried, W. and L.W. Jones, Promoting a healthy lifestyle among cancer survivors. Hematol Oncol Clin North Am, 2008. 22(2): p. 319-42, viii.
10. Nottage, K.A., et al., Metabolic syndrome and cardiovascular risk among long-term survivors of acute lymphoblastic leukaemia - From the St. Jude Lifetime Cohort. Br J Haematol, 2014. 165(3): p. 364-74.

11. Baumann, F.T., W. Bloch, and J. Beulertz, Clinical exercise interventions in pediatric oncology: a systematic review. Pediatr Res, 2013. 74(4): p. 366-74.

12. Braam, K.I., et al., Physical exercise training interventions for children and young adults during and after treatment for childhood cancer. Cochrane Database Syst Rev, 2016. 3: p. CD008796.

13. Huang, T.T. and K.K. Ness, Exercise interventions in children with cancer: a review. Int J Pediatr, 2011. 2011: p. 461512.

14. Esbenshade, A.J. and K.K. Ness, Dietary and Exercise Interventions for Pediatric Oncology Patients: The Way Forward. J Natl Cancer Inst Monogr, 2019. 2019(54): p. 157-162.

15. Arksey, H. and L. O'Malley, Scoping studies: towards a methodological framework Int J Soc Res Methodol, 2005. 8: p. 19-32.

16. Levac, D., H. Colquhoun, and K.K. O'Brien, Scoping studies: advancing the methodology. Implement Sci, 2010. 5: p. 69.

17. Craig, P., et al., Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ, 2008. 337: p. a1655.

18. Cutler, D.M., Behavioral Health Interventions: What Works and Why?, in Critical Perspectives on Racial and Ethnic Differences in Health in Late Life., B.R. Anderson NB, Cohen B, editors, 2004. National Academies Press Washington (DC).

19. Colquhoun, H.L., et al., Scoping reviews: time for clarity in definition, methods, and reporting. J Clin Epidemiol, 2014. 67(12): p. 1291-4.

20. Raber, M., et al., Parental involvement in exercise and diet interventions for childhood cancer survivors: a systematic review. Pediatr Res, 2016. 80(3): p. 338-46.

21. Hingle, M.D., et al., Parental involvement in interventions to improve child dietary intake: a systematic review. Prev Med, 2010. 51(2): p. 103-11.

22. Keats, M.R. and S.N. Culos-Reed, A community-based physical activity program for adolescents with cancer (project TREK): program feasibility and preliminary findings. J Pediatr Hematol Oncol, 2008. 30(4): p. 272-80.

23. Hudson, M.M., et al., Multi-component behavioral intervention to promote health protective behaviors in childhood cancer survivors: the protect study. Med Pediatr Oncol, 2002. 39(1): p. 2-1; discussion 2.

24. Mays, D., et al., Efficacy of the Survivor Health and Resilience Education (SHARE) program to improve bone health behaviors among adolescent survivors of childhood cancer. Ann Behav Med, 2011. 42(1): p. 91-8.

25. Berg, C.J., et al., Pilot results of an online intervention targeting health promoting behaviors among young adult cancer survivors. Psychooncology, 2014. 23(10): p. 1196-9.

26. Braam, K.I., et al., Effects of a combined physical and psychosocial training for children with cancer: a randomized controlled trial. BMC Cancer, 2018. 18(1): p. 1289.

27. Li, W.H.C., et al., Adventure-based training to promote physical activity and reduce fatigue among childhood cancer survivors: A randomized controlled trial. Int J Nurs Stud, 2018. 83: p. 65-74.

28. Cox, C.L., et al., Modifying bone mineral density, physical function, and quality of life in children with acute lymphoblastic leukemia. Pediatr Blood Cancer, 2018. 65(4).

29. Wu, L.M., et al., Tailored education enhances healthy behaviour self-efficacy in childhood cancer survivors: A randomised controlled study with a 4-month follow-up. Eur J Cancer Care (Engl), 2019. 28(4): p. e13063.

30. Huang, J.S., et al., Fit4Life: a weight loss intervention for children who have survived childhood leukemia. Pediatr Blood Cancer, 2014. 61(5): p. 894-900.

31. Lam, K.K.W., et al., An integrated experiential training programme with coaching to promote physical activity, and reduce fatigue among children with cancer: A randomised controlled trial. Patient Educ Couns, 2018. 101(11): p. 1947-1956.

32. Gilliam, M.B., et al., A Pilot Study Evaluation of a Web-Based Token Economy to Increase Adherence with a Community-Based Exercise Intervention in Child and Adolescent Cancer Survivors. Rehab Oncol, 2011. 29(2): p. 16-22.

33. Moyer-Mileur, L.J., L. Ransdell, and C.S. Bruggers, Fitness of children with standard-risk acute lymphoblastic leukemia during maintenance therapy: response to a home-based exercise and nutrition program. J Pediatr Hematol Oncol, 2009. 31(4): p. 259-66.

34. Stern, M., et al., NOURISH-T: Targeting caregivers to improve health behaviors in pediatric cancer survivors with obesity. Pediatr Blood Cancer, 2018. 65(5): p. e26941.

35. Zhang, F.F., et al., Early Lifestyle Intervention for Obesity Prevention in Pediatric Survivors of Acute Lymphoblastic Leukemia. Nutrients, 2019. 11(11).

36. Kopp, L.M., et al., Lifestyle behavior interventions delivered using technology in childhood, adolescent, and young adult cancer survivors: A systematic review. Pediatr Blood Cancer, 2017. 64(1): p. 13-17.

37. Kinahan, K.E., et al., Adult survivors of childhood cancer and their parents: experiences with survivorship and long-term follow-up. J Pediatr Hematol Oncol, 2008. 30(9): p. 651-8.

38. Long, K.A. and A.L. Marsland, Family adjustment to childhood cancer: a systematic review. Clin Child Fam Psychol Rev, 2011. 14(1): p. 57-88.

39. Wakefield, C.E., et al., Parental adjustment to the completion of their child's cancer treatment. Pediatr Blood Cancer, 2011. 56(4): p. 524-31.

40. Williams, L.K., K.E. Lamb, and M.C. McCarthy, Parenting Behaviors and Nutrition in Children with Leukemia. J Clin Psychol Med Settings, 2015. 22(4): p. 279-90.

41. Czajkowski, S.M., et al., From ideas to efficacy: The ORBIT model for developing behavioral treatments for chronic diseases. Health Psychol, 2015. 34(10): p. 971-82.

42. Streiner, D.L. and G.R. Norman, Health measurement scales: A practical guide to their development and use. 4th Edition ed. 2008, Oxford: Oxford University Press.

43. Medical Research Council, Developing and evaluating complex interventions: new guidance, 2008.

44. Medical Research Council, Process evaluation in complex interventions. 2015, UK MRC Population Health Science Research Network. 134p.

45. Movassagh, E.Z., et al., Tracking Dietary Patterns over 20 Years from Childhood through Adolescence into Young Adulthood: The Saskatchewan Pediatric Bone Mineral Accrual Study. Nutrients, 2017. 9(9).

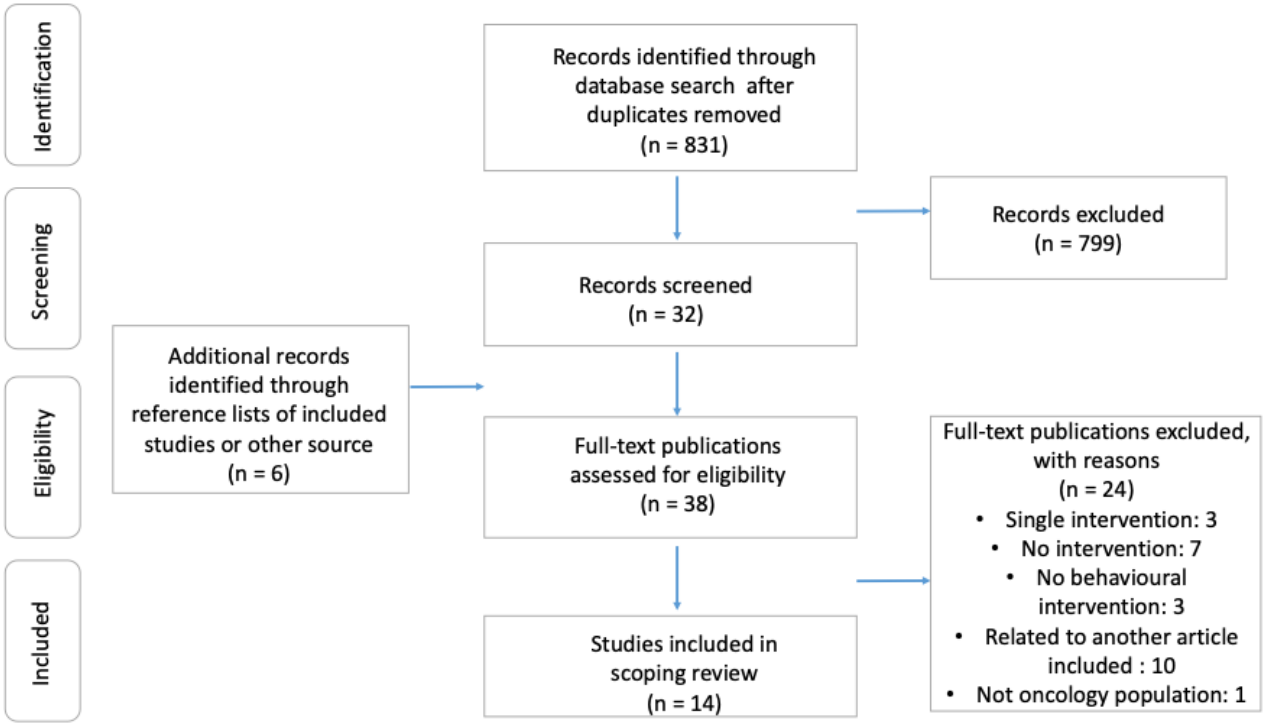

Figure 5.1 Flow diagram of the scoping review process

Table 5.1 Search strategy

Childhood cancer	Complex behavioural interventions
((((((leukemia) OR leukemia[MeSH Terms]) OR "childhood cancer") OR "pediatric cancer") OR "pediatric oncology"))	((((("health promotion") OR "lifestyle") OR "health behaviour*") OR "health behavior*")

Table 5.2 Studies of complex behavioural interventions targeting physical activity and/or diet in pediatric oncology

Authors, year (country)	Participants					Study Design	Program	Findings	Type of results
	n	Sex Male n(%)	Age	Specific population	Moment				
Keats & Culos-Reed, 2008 *Canada*	10	2 (20.0)	14-19	All diagnoses, for adolescents only	Survivorship	Quasi-experiment (Repeated measures longitudinal design)	Physical activity and educational interventions *Duration* = 16 weeks *Assessments* = baseline, 8 weeks, 16 weeks, 3 months postintervention, 1 year post study initiation	**Effectiveness**: Significant improvement in physical and psychological health, overall QOL, and general fatigue. Not conclusive for impact on QOL, PA behavior and physical fitness. **Feasibility**: 91% recruitment & 81.5% attendance (Participants in the study were successful in adhering to the intervention)	Mixed Positive
Mays et al., 2011 (Tercyak et al., 2006 Donze, 2006) *USA*	75	Intervention: 17 (44.7) Control: 19 (51.3)	11-21	All diagnoses, for adolescents only	Survivorship, one or more years post-treatment and cancer-free	RCT*	The Survivor Health and Resilience Education (SHARE) Program: single, group-based health education and health behavior counseling intervention for risk-reducing, lifestyle-related outcomes	**Effectiveness**: Milk consumption frequency ($p = 0.03$), past month calcium supplementation ($p < 0.001$), days in the past month with calcium supplementation ($p < 0.001$), and dietary calcium intake ($p = 0.04$) were significantly greater at 1-month follow-up among intervention participants	Mixed

							Duration = half-day *Assessments* = 1-month post-intervention	compared with control participants.	
Braam et al., 2018 *Netherlands*	59	Intervention: 16 (53.3) Control: 21 (55.2)	8-18	All diagnoses, children and parents	Currently receiving or within the first year following cancer treatment with chemotherapy and/or radiotherapy	RCT	Quality of Life in Motion (QLIM) intervention : combined physical exercise (2x 45min sessions per week) and psychosocial training intervention (once every 2 weeks) for the child and 2 psychosocial training session for the parents *Duration* = 12 weeks *Assessments* = at 4 & 12 months	**Effectiveness**: At 4-months: no significant differences in the effects of the intervention on physical fitness and psychosocial function at short-term (4 months). At 12-months, significantly larger improvements in lower body muscle strength in the intervention group when compared to the control group, no other significant difference between groups. **Feasibility**: Adherence and applicability of the intervention was satisfactory to good. Performing a 12-weeks combined physical exercise and psychosocial intervention is feasible for children both during and after cancer treatment	Mixed Positive

Li et al., 2018 (Chung et al., 2015) (Li et al., 2013) *Hong Kong*	222	Intervention: 33 (52.3) Control: 18 (48.6)	9-16	All diagnoses, who i) reported symptoms of fatigue and ii) had not engage in physical activity in the previous 6 months, children only	Survivorship. At least 6 months after completion of therapy	RCT	4-day integrated adventure-based training and health education program with activities such as educational talks, a workshop to develop a feasible individual action plan for regular physical activity, and adventure-based training activities *Duration* = 4 days over 6 months period	**Effectiveness**: Statistically significant main effect for intervention on physical activity and self-efficacy No statistically significant main effect for intervention on children's quality of life	Mixed
Hudson et al., 2002 (Cox, 2005) (Hudson, 1999) *USA*	267	Intervention: 57 (43.5) Control: 61 (45.1)	12-18	All diagnoses, adolescents only	Survivorship, in remission 2 or more years after completion of cancer therapy	RCT	The Protect Study: Multi-component behavioural health promotion study, educational counselling intervention to increase practice of health-protective behaviours (one face-to-face intervention, 2 telephone calls) *Duration* = Intervention + reinforcement follow-	**Effectiveness**: No change in health knowledge, perceptions, and behaviors Secondary analysis (Cox, 2005): Knowledge, breast or testicular self-examination increased as did perceptions about the need to change behaviors and the effort needed to stay healthy. In the treatment group, junk food consumption decreased and smoking abstinence was	Mixed

							up 3 & 6 months afterwards	maintained.	
Moyer-Mileur et al., 2009 *USA*	14	Intervention: 3 (50.0) Control: 4 (57.1)	4-10	Standard-risk acute lymphoblastic leukemia & parents	Maintenance therapy	RCT	Home-based exercise and nutrition program: exercise component incorporated an individualized, age-appropriate exercise program & nutrition education materials and nutrition-related activities *Duration* = 12 months	**Effectiveness**: Exercise and nutrition program children had greater improvement in physical activity and cardiovascular fitness between 6 and 12 months than control children	Mixed
Cox et al., 2018 *USA*	73	Intervention: 34 (64.2) Control: 36 (66.6)	4-18	Acute lymphoblastic leukemia patients & family	Within 10 days of diagnosis	RCT	Intervention consisting of 2 components: Physical therapy and motivation-based intervention beginning after diagnosis and continuing through the end of treatment *Duration* = 2.5 years	**Effectiveness**: No significant changes between groups in BMD or physical function and HRQL	No effect
Wu et al., 2019	69	37 (57.8)	8-20	All diagnoses, children/adolescents only	Cancer survivors in remission, within 2 months of completing	RCT	(a) A series of 6 individual patient sessions (45-60 min), (b) a handbook with	**Effectiveness:** scores at 4-months Significantly higher for health behaviours self-efficacy for intervention	Mixed

Taiwan					treatment		guidance and educational information, (c) follow-up telephone counselling, (d)bilateral communication *Duration* = 1 week *Assessment* = after 1 month and 4 months	group No significant treatment effects were observed between the two-groups for Health promotion lifestyle **Feasibility**: Intervention was acceptable; participants reported they were satisfied with the program, found it helpful and would attend a similar program again.	Positive
Berg et al., 2014 *USA*	24	7 (29.2)	18-34	All diagnoses, survivors only	Survivorship	Quasi-experiment design (On arm pre-posttest pilot trial)	Beta program targeting health promotion behaviours among young adult cancer survivors Web-based intervention based on semistructured interviews and 12 modules delivered by email bi-weekly *Duration* = 6 weeks	**Effectiveness:** Unable to document changes in health behaviours from pretest to posttest **Feasibility**: Successful rate recruitment of over 50% of participants who met eligibility criteria and maintain high adherence and retention. Acceptability: Vast majority (85.7%) were satisfied with the intervention and would recommend the	No effect Positive

								program (81%)	
Stern et al., 2018 (Stern et al., 2013) *USA*	37 dyads	Intervention : 14 (58.3) Control : 9 (52.9)	5-13	Parents of cancer survivors with obesity (BMI ≥ 85th)	Survivorship, 6 months to 4 years post treatment	RCT	Parent-focused six-session intervention, NOURISH-T (Nourishing our understanding of role modeling to improve support and health for healthy transitions) *Duration* = 6 weeks intervention *Assessment* = 4 months post-intervention follow-up	**Effectiveness:** Small but yet significant decrease on BMI, waist-hip ratio and total daily caloric intake No change with regard to daily fat and sugar intake Positive changes in their child's feeding behaviors **Feasibility**: An intervention targeting parents is feasible: reported sessions were enjoyable, relevant and they used the resources and handouts provided.	Mixed Positive
Zhang et al., 2019 *USA*	15	11 (73.3)	3-9	Acute lymphoblastic leukemia patients and one parent from each family	Maintenance therapy or within 2 years of treatment completion	Quasi-experiment design (Pre – post)	Healthy Eating and Active Living (HEAL) lifestyle intervention delivered remotely through web-based sessions and phone	**Effectiveness:** No significant changes for physical activity, BMI or waist circumference Increased dietary intake of milk, calcium, and protein	Mixed

							calls with a lifestyle coach *Duration* = 12 weeks	with some indications of improved carbohydrate quality No significant changes in parenting style, but parents reduced "pressure to eat" feeding practice **Feasibility**: 86.7 % completed the study	Positive
Huang et al., 2014 *USA*	38	15 (39.5)	8 - 18	Acute lymphoblastic leukemia patients with BMI ≥ 85th & parents	Survivors, having been off therapy for at least 2 years without relapse	RCT	Fit4Life : web, phone, and text message-delivered weight management intervention tailored for chidhood ALL survivors *Duration* = 4-month	**Effectiveness:** Fit4Life recipients ≥ 14 years demonstrated less weight gain and increased moderate-to-vigorous physical activity, but not statistically significant, and other parameters did not differ by treatment group. Intervention treatment effects on outcomes by age. All recipients reported reduced negative mood over time as compared to controls **Feasibility:** Most (80%) of the assigned curriculum was received by Fit4Life	Mixed Positive

								participants as compared to 50% among controls.	
Lam et al., 2018 *Hong Kong*	70	35 (50.0)	9 - 18	All diagnoses, children only	Diagnosed in previous month and undergoing active treatment	RCT	15-minute health education talk and integrated experiential training program with coaching at home (28 home visits) *Duration =* 6 months *Assessment =* baseline, 6 and 9 months	**Effectiveness**: Experimental group reported significantly lower levels of cancer-related fatigue, higher levels of physical activity and physical activity self-efficacy, greater right- and left-hand grip strength and better quality of life than the control group at 9 months	Positive
Gilliam et al., 2011 *USA*	20	10 (50.0)	6 -18	Leukemia and brain tumour survivors	One year off-treatment	Quasi-experiment design (On arm pre-posttest pilot trial)	« Healthy Heroes: Living the Cure », a manualized 6-session exercise intervention with critical components of behaviour and social cognitive theory *Duration =* 6 weeks *Assessment =* postintervention	**Effectiveness**: Intervention efficacy was demonstrated through significant changes in endurance, strength and functional mobility. No significant differences on the remaining physical fitness or quality of life measures. **Feasibility**: findings support the use of online token economy system to increase adherence, adherence was variable across settings and behaviours, 12/20 participants completed study	Mixed Mixed

Table 5.3 Details of interventions or programs

Authors, year (country)	Health behaviours	Outcome measures	Modalities	Location	Theoretical Framework
Keats & Culos-Reed, 2008 *Canada*	Physical activity	Physical activity level: • Godin Leisure-Time Exercise Questionnaire (GLTEQ) • Leisure score index (LSI) Physical fitness: Fitnessgram Fatigue: Pediatric Quality of Life Multidimensional Fatigue Scale (PedsQLMFS) Quality of life (QOL): Pediatric Quality of Life Inventory (PedsQL) Teen Version 4.0 Generic Core Scales	Group-based **physical activity** interventions **Educational** interventions	Community-based	Theory of Planned Behavior
Mays et al., 2011 (Tercyak et al., 2006 Donze, 2006) *USA*	Diet	Bone health knowledge: 6-item adapted from U.S. Department of Health and Human Services National Bone Health Campaign for children Calcium consumption self-efficacy: 11-item scale	Group-based **educational** interventions **Psychosocial training** (skill-building exercises)	Hospital- or clinic-based	PRECEDE-PROCEED model Health Belief Model, Transtheoretical model of behavior change and social cognitive theory

		Milk consumption frequency: 1-item adapted from the U.S. Department of Health and Human Services National Bone Health Campaign for children Dietary calcium intake: U.S. Department of Agriculture (USDA) five-step multiple pass 24-h recall method Recalled dietary data: Nutritionist Pro (Axxya Systems, Stafford, TX) Calcium supplementation: 1-item asking "On how many of the past 30 days did you take a calcium supplement?"			
Braam et al., 2018 *Netherlands*	Physical activity	Physical activity: Actical accelerometer (B series, Philips Respironics Actical MiniMitter, Murrysville, PA, USA) Physical fitness: Godfrey protocol Physical function: Grip strength with hand-held dynamometer (CITEC; C.I.T. Technics, Groningen, the Netherlands)	Individualized and supervised **physical activity** program **Psychosocial** intervention/training	Hospital- or clinic-based	None

		Body composition: Bone mineral density (BMD) as measured by dual energy X-ray absorptiometry (DEXA) Fatigue: PedsQL Multidimensional fatigue scale (acute version) Athletic competence and global self-worth: Athletic competence and global self-worth subscales of the 'Self-Perception Profile' Health-related quality of life (HRQOL): PedsQL Generic Core Scales for children aged 8–12 and 12–18 years			
Li et al., 2018 (Chung et al., 2015) (Li et al., 2013) *Hong Kong*	Physical activity	Physical activity level: • Chinese University of Hong Kong : Physical Activity Rating for Children and Youth (CUHK-PARCY) • Godin–Shephard Activity Questionnaire Modified for Adolescents	Group-based, **adventure-based** activities **Education**	Community-based	Kolb's experiential learning theory with inclusion of self-efficacy and transtheoretical model of behavior

		Physical exercise stage of change: Physical Activity Stages of Change Questionnaire (PASCQ) Physical activity self-confidence : Physical Activity Self-Efficacy (PA-SE) QOL: PedsQL			
Hudson et al., 2002 (Cox, 2005) (Hudson, 1999) *USA*	Diet Physical activity Smoking cessation Sun protection Self-examination	Health Protective Behaviors Questionnaire (75-item)	**Education** (individual) **Psychosocial training** (individualized health behaviour training modules)	Hospital- or clinic-based (long-term follow-up clinic)	The Health Belief Model
Moyer-Mileur et al., 2009 *USA*	Diet Physical activity	Food intake: Three-day records (2 weekdays and 1 weekend day - monthly) Physical activity level: • ACTIVITYGRAM Questionnaire • Pedometer (DIGI Walker SW-701, Optimal Health	Individualized, age-appropriate **physical activity** program Appropriate nutrition **education** material **Counselling** with dietetician	Home-based	None

		Products, San Antonio, TX) Physical fitness: • Progressive Aerobic Cardiovascular Endurance Run (PACER) • Push-ups • Sit and reach Body composition (muscle mass): Tibia peripheral quantitative computed tomography (pQCT; Stratec XCT 2000, Norland Medical Systems Inc, Fort Atkinson, WI)			
Cox et al., 2018 *USA*	Physical activity	Physical activity level: Accelerometer (SenseWear Pro III, BodyMedia, Pittsburgh, PA) Body composition: BMD measured by DEXA Physical function:	**Psychosocial**: Motivation-based intervention - Strategy aimed at supporting motivation for long-term behaviour change Set of routine **physical activity**	Hospital- or clinic-based	None

		• Muscular strength (hand grip, knee extension, dorsiflexion) • Ankle range of motion (measured by goniometry) • 6-Minute Walk Test • Bruininks-Oseretsky Test of Motor Proficiency Short Form (BOTSF-2) QOL: Child Health Questionnaire (CHQ)			
Wu et al., 2019 *Taiwan*	Diet Physical activity Health accountability	Health behaviour self-efficacy: 24-item questionnaire (healthy diet, exercise, well-being and health accountability) Health promotion lifestyle: 35-item questionnaire (nutrition, exercise behaviours, stress adaption, interpersonal support, self-achievement and healthy behaviours)	Individual **education** Follow-up telephone **counselling**	Hospital- or clinic-based	Self-efficacy theory by Bandura (1977)

Berg et al., 2014 *USA*	Physical activity Drinking Smoking	Health behaviour: Number of days they exercised in the past 7 days (moderate aerobic, vigorous aerobic, and strength training), number of days they consumed alcoholic drinks and five or more drinks on one occasion (binge drinking) in the past 30 days, and number of days of smoking in the past 30 days. Level of confidence (change): 10-point scale (physical activity, alcohol consumption, smoking).	**Education** (Technology-based modules delivered by emails) **Reward system**	Technology-based	Theory of Reasoned Action
Stern et al., 2018 (Stern et al., 2013) *USA*	Diet Physical activity	Diet behaviour: • Family eating and exercise behaviors questionnaire (28-item) • Child sugar sweet beverage and fast food	**Psychoeducational** sessions **Education** materials	Technology-based	Social Cognitive and Cognitive Behavioral Theories

		intake questionnaire (13-item) Dietary recall: Automated Self-administered 24-Hour Dietary Recall-2011 (ASA24) Physical activity level: • Pedometer (7 days) • Physical Activity Questionnaire for Children (PAQ-C) Parental approaches/attitudes: Child feeding questionnaire (31-item) Anthropometrics: • Body mass index (BMI) • Waist circumference			
Zhang et al., 2019 *USA*	Diet Physical activity	Dietary intake: Automated Self-Administered 24 hour (ASA24) Dietary Assessment Tool (National Cancer Institute) Physical activity level: Accelerometer (Actigraph GT1M Monitor)	**Education** **Psychosocial training** **Counselling**	Technology-based	Bandura's social cognitive theory and self-determination theory

		Anthropometrics: • BMI • Waist circumference Parenting Style and Practices : • Parenting Dimensions Inventory Short Version (PDI-S) • Child Feeding Questionnaire (CFQ)			
Huang et al., 2014 *USA*	Diet Physical activity	Dietary intake: Youth Adolescent Questionnaire (YAQ) Physical activity level: Actigraph accelerometer Anthropometrics: BMI Cardio-metabolic assessment : • Blood pressure, • Blood lipid profile Psychological behaviours: Children's Depression Inventory (CDI)	**Education** **Counselling**	Technology-based	Behavioral determinants model based on Bandura's social cognitive theory

Lam et al., 2018 *Hong Kong*	Physical activity	Physical activity level: Chinese University of Hong Kong Physical Activity Rating for Children and Youth (CUHK-PARCY) Self-efficacy: Physical Activity Self-Efficacy (PASE) scale Physical function: Grip strength with hand-held dynamometer QOL: 27-item Chinese version of the Paediatric Quality of Life Inventory cancer module v. 3.0	**Education** Individual **physical activity** program	Home-based	Bandura's social cognitive theory
Gilliam et al., 2011 *USA*	Physical activity	Physical fitness: 15-meter Progressive Aerobic Cardiovascular Endurance Run (PACER) Physical function: Grip strength with hand-held dynamometer (MicroFET2 Digital Muscle Tester, Hoggan Health Industries Inc., West Jordan, Utah, USA) Functional Mobility : • Sit-to-Stand Test • Lateral Step-Up Test	Individual **physical activity** program **Counselling** **Reward system**	Community-based	Social cognitive theory

		QOL: PedsQL 4.0 Generic Core Scales			

Table 5.4 Clinical implications

Authors, year; *country*	Clinical implications
Keats & Culos-Reed, 2008; *Canada*	-Individualized programming was essential for the overall success -Participation is optimized when a supportive group environment is provided -Need for greater efforts to educate adolescents with cancer about the risk of comorbid conditions associated with reduced/limited PA and how they can become committed participant in their long-term health and well-being -We need to better understand the normative process of both short and long-term adaptation to the disease
Mays et al., 2011; Tercyak et al., 2006; Donze, 2006 *USA*	-Those who lived farther away were more difficult to engage -It is important that risk-based care addresses individual-level survivor-related factors, including knowledge, self-efficacy, and motivation necessary to engage in a healthy lifestyle and address behavioural factors contributing to cancer late effects -Age-appropriate recommendations and approaches should be integrated across the continuum of cancer care to encourage young survivors to take increasing responsibility for their health and healthcare
Braam et al., 2018; *Netherlands*	-Targeted programs might be better than standard program to increase the applicability, motivation, self-worth and, at the end, the effects of the program -Psychological variables are important intervention targets to improve health-related quality of life
Li et al., 2018; Chung et al., 2015; Li et al., 2013; *Hong Kong*	-With increased self-efficacy, childhood cancer survivors were more likely to adopt and maintain regular physical activity -Four days of adventure-based training over 6-month period is sufficient to produce changes in physical activity behaviour among childhood cancer survivors
Hudson et al., 2002; Cox, 2005; Hudson, 1999; *USA*	- Brief, broad-based risk counselling approach may not be sufficient to achieve a substantial long term change in knowledge, health perceptions and health practices in this vulnerable patient group -More intensive intervention conducted over several sessions may be necessary to enhance the impact of our health counselling program -Provision of information related to adverse outcomes is necessary, but not sufficient -Risk counselling activities may need to account for the gender composition of the target population and according to specific health behaviours

Moyer-Mileur et al., 2009; *USA*	-Individualization of exercise program recommended -Home-based interventions was reinforced by follow-up calls and health provider counseling, thus recommending multiple modalities and social support
Cox et al., 2018; *USA*	-Consider intervention implementation during late maintenance therapy, extending into survivorship -More frequent contact with the interventionists as there needs to be the continuing support and emphasis on the lifelong commitment to physical activity to moderate the late effects of therapy -Different strategies for categories of patients may need to be considered
Wu et al., 2019; *Taiwan*	-Self-efficacy is important as interventions that address SE elements may increase participants' confidence in their abilities to initiate and maintain healthy behaviours -Research should consider the involvement of parents and their roles during intervention processes developed in this population
Berg et al., 2014; *USA*	-Tailoring the messaging specifically for the needs of individual young adult cancer survivors would likely enhance message relevance and increase their engagement and satisfaction with the content -Using a commercial approach was a win-win situation for cancer survivors and businesses -Participants indicated receptivity to having information specific to cancer and allow them to connect with others
Stern et al., 2018; Stern et al., 2013; *USA*	-Caregivers serving as role models of healthy eating and exercise to facilitate family changes -Trying to recruit soon after treatment was difficult as well as too long after treatment ends (e.g. after 3 years) -The importance of engaging in an intervention related to longer term cancer prevention issues seems less clear to families as the time since treatment ended increases despite evidence suggesting the particular importance of healthy lifestyle for childhood cancer survivors
Zhang et al., 2019; *USA*	-Family environment plays important roles in shaping children's dietary and activity behaviours -Web- and phone-based lifestyle interventions are feasible
Huang et al., 2014; *USA*	-Tailored approach, as opposed to generic weight management intervention, may be helpful to youth who have survived leukemia -The use of technology offers a feasible, relatively low-cost alternative to more in-person intensive interventions in this at-risk but sparse population because it can be distributed across time and geography -Psychological outcomes are important to address in this population -Cognitive deficits such as information processing problems need to be addressed (issues unique in this specific population)

	-Personal contact appeared to help compliance with protocol and follow-up -Multimodal approach have added to compliance and overall success in reaching targeted outcomes in interventions participants
Lam et al., 2018; *Hong Kong*	-Healthcare professionals should build multidisciplinary partnerships to sustain such programmes -With increased physical activity self-efficacy, children with cancer are more likely to adopt and maintain regular physical activity and achieve quality of life
Gilliam et al., 2011; *USA*	-Shorter interventions are more feasible and efficient (i.e., 6-week program) -To include both short and long-term follow-up to evaluate whether lasting changes in survivors' physical activity can be achieve -Social support is an important component, so involving families or more support from healthcare professionals

CHAPTER 6: MANUSCRIPT 2

6.1 Preface

Recommendations for future studies in the previous manuscripts included conducting a process evaluation and qualitative research, as they are essential to understanding the implementation of complex interventions. More precisely, it was suggested that adding a qualitative component in studies could contribute to gain a better understanding of how to support a sufficiently potent level of behaviour change to achieve meaningful change on a clinical outcome, such as evaluating barriers and facilitators to participation. Thus, this next study uses a qualitative design to conduct a process evaluation of the *VIE project* and gather insights from study participants who were adolescents (≥ 13 years old) affected by cancer and parents of children or adolescents affected by cancer. As the children were only directly targeted in the physical activity component of the study and as we were seeking to have a global appreciation of the program, the perspective of children were not taken into account in this study. Furthermore, recommendations in Manuscript 1 also included conducting studies in this area of research to identify and define the most efficient methods to implement CBI in clinical care. To achieve

this goal, gaining the perspective of HCPs working in this population is essential. HCP's extensive knowledge of the field can provide a better understanding on how to implement interventions in a sustainable manner; because "why bother with what is effective, if it is also fleeting" [162] (p.2066)?. Thus, we also gathered the perspective of healthcare professionals, who were clinicians working at the cancer center where the *VIE project* was tested.

More precisely, this study analyses the perspectives of families affected by childhood cancer regarding the factors influencing their participation in the *VIE project* and healthcare professionals regarding the factors influencing the implementation of the *VIE project* in their clinical context.

Implementing health promotion interventions in a pediatric oncology setting: a qualitative study among families affected by cancer and healthcare professionals

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6.2 Abstract

Introduction: Children affected by cancer often suffer from various adverse effects. One way to prevent or minimize these adverse effects is to adopt and maintain of healthy behaviours across the cancer care continuum, including frequent physical activity (PA) and a healthy diet. However, little is known on how to successfully implement health promotion (HP) interventions in clinical settings. This study aimed to determine the factors influencing participation in a HP program from the perspective of families affected by cancer and the factors influencing its implementation within a pediatric oncology setting from the perspective of healthcare professionals (HCPs). **Methods:** Semi-structured interviews with families affected by cancer who participated in a HP program and focus groups including HCPs who were exposed to the program in their clinical practice were conducted. Data were analysed using thematic analysis. **Results:** A total of 14 adolescents affected by cancer or parents, and 11 HCPs were interviewed. Four major themes were determined: (1) facilitators, (2) barriers, (3) perceived benefits, behaviour change, and attitude, and (4) suggestions for improvement. Factors

identified as keys to participation include tailoring the interventions to the families' specific needs and social support. Organizational barriers, health issues, and a lack of interest or need hampered participation in the program. Lack of embedment of interventions in clinical care and of HCPs' involvement affected the implementation. **Conclusion:** The results highlight the need and relevance for HP interventions and for interventions beyond what is presently offered in standard clinical care.

6.3 Introduction

As children and adolescents are increasingly surviving cancer, there has been a paradigm shift in pediatric oncology from attaining survival at all costs to survival with optimal quality of life. There is evidence that children affected by cancer are at greater risk of suffering from various adverse effects secondary to cancer and its treatment (1-4). Health promotion (HP) interventions represent a promising avenue to address the prevention or mitigation of some acute and long-term adverse effects (5) such as cardiometabolic complications, osteoporosis, and obesity (6, 7). Health behaviours are known to be negatively affected by cancer diagnosis and treatments (8-10) but positively impacted by HP interventions (11, 12). Consequently, researchers and clinicians have highlighted the importance of developing and testing innovative interventions aimed at reducing the impact of

these adverse effects using HP (13-15) and at supporting children affected by cancer throughout their journey (i.e., from diagnosis to survivorship). In recent years, an increasing number of HP interventions have been developed in pediatric oncology and reviews underscore their potential in modifying behaviours and improving health outcomes (16-18).

However, little research has been conducted to support the integration of these interventions into pediatric oncology standard care. Indeed, the studies have focused mainly on evaluating the interventions and few have been implemented in a way that is sustainable following the study period (19). Therefore, there is a growing need to consider how best to implement HP strategies in pediatric oncology settings. Identifying implementation challenges is important to understand why interventions fail or succeed and facilitate translation into practice. Furthermore, we lack knowledge on effective ways to promote healthy behaviours and on how families experience HP interventions while going through the pediatric cancer journey. Identifying the factors that influence the adoption of healthy behaviours of families affected by cancer is essential for implementing effective interventions that improve their health and well-being (20) and supporting the sustainability of the interventions (21). There is a need for qualitative or mixed methods studies in the field (17) to better understand how to support a level of

behaviour change that is sufficient to improve clinical outcomes. The purpose of this study is twofold. First, to analyse the perspectives of families affected by cancer regarding their participation in a HP program to determine which factors can facilitate or hamper behaviour change. Second, to determine the factors influencing the implementation of an innovative HP program within a clinical pediatric oncology setting, from the perspective of healthcare professionals (HCPs)

6.4 Methods

6.4.1 Clinical Context

The present study was part of a larger, nonrandomized feasibility study conducted at CHU Sainte-Justine (CHUSJ) in Montreal, Canada. The VIE project consists of a two-year, family-oriented multidisciplinary interventional program. The program, delivered between January 2018 and December 2021, integrates psychosocial support, nutrition education and counseling, and physical activity interventions (22). The objective of this program is to optimize the health outcomes of children and adolescents affected by cancer by encouraging the adoption of healthy behaviours across the continuum of care. Children or adolescents newly diagnosed with cancer and treated at CHUSJ were offered to participate in the program from February 2018 to December 2019 if they were (a) less than 21 years

old at diagnosis, (b) treated with radiation therapy or chemotherapy, (c) able to give informed consent (by parents or legal tutors if < 18 years old), and (d) less than 12 weeks postdiagnosis. More information on the VIE project can be found in Table 6.1.

6.4.2 Population

Families affected by cancer

Families affected by cancer in the present study: (a) had been participating in the VIE project for at least 1.5 years and (b) were either adolescents affected by cancer ≥ 13 years old or parents of a child or adolescent affected by cancer. The first inclusion criteria ensured that participants could reflect on their experience during the different treatment phases (i.e., acute, maintenance, survivorship) and the second that they were old enough to understand and answer the interview questions. Furthermore, children did not participate in the psychosocial component of the program and only adolescents were invited to participate in the nutrition component, depending on their interest. As we were seeking for a global appreciation of the program, children were not included in this part of the study.

A total of 34 families were eligible for the study and we expected to recruit a minimum of 12 families, following a recommendation from Guest, Bunce and Johnson (23), who determined that data saturation generally occurs within the first

12 interviews. Participants were contacted by telephone about their willingness to participate in the interviews prior to a visit at the oncology clinic. If they were interested in participating but not available during their visit at the clinic, an interview delivered remotely was proposed. Purposive sampling was used to recruit a variety of participants across different diagnosis groups (leukemia, lymphoma, other), age groups (0-5, 6-12, ≥13 years old), and sex (male, female). The sample was also a convenience sample to the extent that the people invited to take part were those attending the clinic when we were doing fieldwork.

Healthcare professionals

HCPs in the present study: (a) were clinicians who worked at CHUSJ during the program implementation (i.e., from 2018 to 2021), (b) had been exposed to the program, and (c) were either oncologists, pivot nurses, rehabilitation professionals, nutritionists, psychosocial workers, or hospital-based teachers. Participants were conveniently recruited by email from a list of employees of the hematology-oncology division in November 2021. A first round of emails was sent to all potential participants by the first author (CD) Then, to have a sample that adequately reflects the diversity of HCPs in pediatric oncology, the researchers ensured the sample's internal diversity by sending another round of emails specifically to members of professions who had not responded in the first round.

Ethical approval for this study was obtained from the CHU Ste-Justine Research Ethics Board (#2021-3129, #2021-3278). Written informed consent was obtained from parents or adolescents ≥ 18 years old and verbal consent from adolescents < 18 years old. Data was anonymized to ensure confidentiality.

6.4.3 Guiding Conceptual Framework

The Theory of Planned Behavior (TPB) was used as a conceptual framework to guide the development of the interviews with families affected by cancer. According to the TPB, attitudes towards behaviour, subjective norms, and perceived behaviour control can gauge the readiness of an individual to engage in that behaviour (24). Studies have provided preliminary data that support the TPB's utility in the pediatric oncology population (8, 25, 26). Furthermore, to classify the barriers and facilitators, we used the Consolidated Framework for Implementation Research (CFIR). We chose to use the CFIR as it is one of the most recognized frameworks for systematically assessing barriers and facilitators and for identifying improvements to implementation strategies. The constructs of the CFIR (27), arranged across five domains (i.e., intervention characteristics, outer setting, inner setting, characteristics of individuals, process), were used to classify factors (i.e. barriers and facilitators) from interviews with both families affected by cancer and HCPs. See Table 6.2 for a description of each domain.

6.4.4 Procedures

Families affected by cancer

We undertook a qualitative study using semi-structured, individual interviews. The interviews were conducted in-person or virtually using the Zoom platform, according to participants' preferences by the first author (CD) from November 2020 to January 2021. A semi-structured interview guideline was developed for this study based on i) a literature review, ii) the TPB, and iii) discussions with the research team and a patient partner (i.e., a young adult who works collaboratively with the research team by bringing her perspective as an expert from living with and surviving childhood cancer) to ensure its relevance. The interviews were conducted in a conversational style to create an open interaction. The order and wording of the questions were adapted to each participant. If needed, we used probes to seek more information or for clarification. The major themes addressed were (1) barriers and facilitators to participation in the program; (2) attitude, subjective norms, perceived behaviour control, and intention to change in relation to the adoption of healthy behaviours; and (3) suggestions of strategies that could support their participation in the program and change in their behaviour. All interviews were audiotaped and verbatim were transcribed by the first author (CD).

Healthcare professionals

Two 90-minute focus groups were conducted with 5-6 participants per group. The discussion was led by one group leader (CD) and one moderator (JK), who also took field notes. The interview guideline was developed based on the CFIR and consisted of semi-structured, open-ended questions on their perspective regarding (1) the program and (2) the program's implementation. Focus groups were audiotaped and verbatim were transcribed by the first author (CD).

6.4.5 Data analysis

Descriptive statistics were used to analyse the demographic and clinical characteristics of the participants. In terms of qualitative data, thematic analysis was used to capture the perspective of the participants, which is a method for identifying, analyzing, and reporting patterns (themes) within data (28). A basic coding tree was first developed using a deductive approach using the conceptual frameworks. Then, an inductive approach was used to complement the coding tree with codes emerging from the data, using NVivo software (version 1.6.2). Thematic analysis (28) consists of six steps: (i) close reading of text to ensure familiarity with the material, (ii) generating initial codes, (iii) creation of categories or themes, (iv) reviewing themes, (v) defining and writing a detailed analysis of each theme, and (vi) continuing revision and refinement of category/theme system. The coding tree

was discussed with another author and refined for clarity, then 20% of the data were coded independently by two authors (CD & KL for families affected by cancer and CD & JK for HCPs). All discrepancies in coding were resolved by discussion and final changes were made to the coding tree. Tobin and Begley principles regarding methodological rigor were used to establish trustworthiness, goodness, and authenticity (29).

6.5 Results

6.5.1 Participants demographic and clinical characteristics

Families affected by cancer

Fourteen families were approached, of which two declined participation (no time, no interest), resulting in the inclusion of 12 families (Table 6.3). As two families were composed of two participants, 14 interviews were conducted. After interviewing 14 participants, saturation was considered reached; participants in the last interviews did not indicate any significant new barriers or facilitators to participation. Nine participants were parents (five mothers, four fathers) and five were adolescents (range 14 to 20 years old). For seven families, the child affected by cancer was female (58%). The cancer diagnoses represented were leukemia (n=7; 58%), extracranial solid tumor (n=3; 25%) and lymphoma (n=2; 17%). All children or adolescents were in remission at the time of the interview and were 11

months since treatment completion on average. The interviews ranged in duration between 8 and 38 min (median 13 min).

Healthcare professionals

Eleven HCPs were recruited. All participants were current employees of the oncology department: rehabilitation professionals (n=5, 45%), hospital-based teachers (n=2, 18%), a nutritionist (9%), a psychologist (9%), a nurse (9%) and an oncologist (9%) (see Table 6.4). Participants were in majority women (n=8, 72%). All participants had more than 5 years of clinical experience (median 16, range 5 – 35 years), including more than 5 years of experience in pediatric oncology (median 12, range 5 – 25 years).

6.5.2 Themes

Four major themes were determined when analyzing the data according to the frameworks used: (1) facilitators, (2) barriers, (3) perceived benefits, behaviour change, and attitude, and (4) suggestions for improvement (see Table 6.5 for coding tree of the first two themes). For data presentation, all quotations were translated from French to English as all interviews were held in French.

Theme 1: Facilitators

Some elements of the inner setting were viewed as facilitators. For example, families had long waiting hours at the oncology clinic and during their hospitalisation, and they were happy to fill those hours with the program interventions. Characteristics of the interventions that were reported as facilitators were the flexibility and adaptability in the delivery of the program, and the tailoring of the interventions to their individuals' needs. Moreover, the interventions could be delivered remotely (i.e., Zoom meetings or telephone), which was viewed as very convenient, especially considering the COVID-19 pandemic that occurred during the second half of the program. Regarding personal characteristics, families who had a good understanding of the potential benefits of the interventions or a positive attitude towards the adoption of healthy behaviours had a higher level of participation in the program.

Families reported that the opinion of significant others, or the subjective norms according to the TPB, influenced their participation. Having positive relationships and trust in the research team members was a motivation for participating as well as including siblings or other family members in the interventions. Regarding opinion leaders, defined in the CFIR as individuals in an organization who influence

attitudes and beliefs towards an intervention, most parents or adolescents said they had received support from members of the clinical team to participate.

> "*I would say they were all in favor of [the VIE project]. When you talk to the nurses and all, they talk about it with interest… they are enthusiastic about this program…" (L., parent of a 13-year-old[8])*

The facilitators reported by HCPs related to the characteristics of the individuals (i.e., themselves), the interventions, and the inner setting. Overall, HCPs perceived that there was a need for this type of intervention. They felt that the type of intervention was well-chosen and that they were filling a clinical gap, especially towards the end of treatment phase or during the survivorship phase, when the clinicians are less involved with their patients.

> *"When they presented the project to us, I found that it looked relevant for the families, to be able to empower them in various aspects of their lives in which it was difficult to keep a balance, with the illness installing and all" (E., Physiotherapist)*

[8] Age at diagnosis

A HCP also mentioned that implementing those interventions supported a much needed cultural shift towards the promotion of healthy behaviours in the oncology setting, not just a focus on recovery and survivorship:

> *"When I started working here, what was important was that children eat during chemotherapy treatments. They could eat anything, but they had to eat. So, the VIE project for me, it was like 'wow'. We can tell people, you can eat well, we are going to give you the best advice possible, so you can eat better and better" (T., Nutritionist)*

Finally, another aspect that encouraged HCPs to support the interventions was the fact that the patients appreciated and benefit from the interventions: "*from the comments that I had from patients, it was extra appreciated*" (*A., Nurse*). The playful aspect of the physical activity interventions was particularly appreciated by the younger participants and it helped adolescents get back to "normal life".

Theme 2: Barriers

Families reported several barriers to participation. The most important barriers were time and organizational constraints, which were related to the inner setting of the program. Other barriers related mostly to their personal characteristics, including lack of interest or need, physical or mental health issues, and perceived

difficulty of the intervention or burden. For some parents, feeling overwhelmed hampered their participation, particularly at the beginning of the cancer journey when treatments are intensive and the shock of the cancer diagnosis still present:

> "*You know, of course it is very challenging, in a moment where… it is not going really well… when you know you have already lost balance and you are trying to get back on your feet and it is difficult… and you have homework given to you […] you are already psychologically exhausted and you have to do that on top of it…" (L., parent of a 5-year-old)*

The age of the children or adolescents affected by cancer was also noted as an important factor impacting their level of participation and motivation. Indeed, barriers related to personal characteristics, particularly lack of motivation, were reported more frequently by adolescents or parents of adolescents compared to parents of younger children.

> "*If he had not been an old teenager, also […], you know if he had been younger, like 10 or 12 years old, he probably would have felt the need to be active" (N., parent of a 16-year-old).*

HCPs have also identified a lot of challenges and barriers during the implementation process at different levels (e.g., personal characteristics,

intervention characteristics, inner setting): *"We all recognize the relevance […], but it is how to implement it so that it can be beneficial for everybody and realistic in the clinical context, which is the most important." (R., Oncologist)*. Barriers that were identified by HCPs were the lack of publicity for certain elements (e.g., nutrition workshops) and the fact that the HCPs in general had a low level of knowledge of what the interventions entailed. This prevented them from acting as facilitators or from championing the interventions with their patients. Furthermore, HCPs felt that their high-level of expertise in the field had not been considered when developing and implementing the interventions. This resulted in them not feeling involved in the project and overlooked.

As for the intervention characteristics, the main barriers identified by HCPs were the added burden both for them and the families and the negative impact on their work: *"It was a great project, enjoyed by the patients. But it was extremely demanding from a clinician's point of view"* (*A., nurse*). For the inner setting, the embedment of the research interventions in the clinical context has been difficult. The need for better coordination, collaboration and communication between the research and clinical teams was viewed as an important barrier: "*Regarding my work, it was conflictual […], I was sometimes not able to do my work*" (*S., Occupational Therapist*). Some interventions were perceived as overlapping,

rather than complementing each other. Furthermore, HCPs mentioned that it has been difficult to establish a trusting relationship with some research team members, mainly because there was a lot of different intervention deliverers, that they did not have a lot of experience or training in the field. Since it was a research study, some parents also felt like the interventions were not well-integrated in clinical care. One parent also mentioned that engaging with multiple health professionals made it difficult to build significant relationships and trust with everyone:

> "*There are already so many stakeholders who gravitate that at some point, making effort everywhere, we become exhausted and hum… we struggle to see the added value of everybody" (P., parent of a 13-year-old)*

Theme 3: Perceived benefits, behaviour change, and attitude

Regarding the benefits of the program, most families reported that it had a positive impact on their nutrition or physical activity health behaviour practices during cancer treatment. Families also reported that they felt that the program improved their overall physical and mental health and brightened up their days at the hospital.

"*Of course, it helped me to sustain healthy behaviours. Doing some exercises, once in a while, things like that, because if I had only listened to myself…" (L., 16-year-old participant)*

The TPB states that behavioural achievement depends on both motivation (i.e., intention) and ability (i.e., behavioural control). During cancer treatment, even if families wanted to maintain healthy behaviours, suffering from symptoms of cancer and side effects of treatment limit the perceived behavioural control of children and adolescents. For example, physical symptoms such as pain or fatigue limit participation in physical activities and cravings for unhealthy food or nausea negatively affect children and adolescents' diet. All families reported having a positive attitude towards the adoption of healthy behaviours and half of them mentioned having the intention to make positive behavioural change in the future or to maintain the change in the long term: *"I have seen the importance of being active... we will keep this new way of living" (K., parent of a 5-year-old)*. Whereas half of the families think they will benefit in the long term from having participated in the program, the other half don't plan on making long-term changes: *"But I don't think that it will make a long-term difference. It did make a huge difference during the illness, though." (I., parent of a 5-year-old).*

Theme 4: Suggestions for Improvement

Participants suggested various ways of improving the program. The most common suggestion from both families and HCPs was to better integrate HP interventions into clinical care. A parent also suggested making HP interventions mandatory. In his opinion, *"If it is that important to adopt healthy behaviours, well… it should not be done on a voluntary basis. It has to be part of the cancer treatment […] more imposed than optional" (J., parent of a 4-year-old).* Furthermore, HCPs want to be involved in the different project phases and that the roles of each professional and intervention beacons need to be well-defined and very clear before implementation. When asked about how she felt regarding a future implementation of the project in her clinical context, an HCP said:

> *"if it is exactly the same… I am not really enthusiastic. If the roles are well-defined, everybody's tasks, the why, the how, the timing [then, yes]" (N., Occupational Therapist).*

Other recommendations included increasing the frequency of physical activity interventions, adding more educational activities, and providing online material such as exercise videos guided by the physical activity team members. An adolescent suggested that having more information on the purpose and goals of

the interventions could increase the motivation of participants: *"I think it could have helped me to understand why I was doing this, not just 'you have to do it'" (M., 18-year-old participant).* Another idea proposed by a HCP would be to develop group activities that focus on educating children and their families regarding the adoption of healthy nutrition and physical activity behaviours.

> *"Maybe there is another way, other ways that it could be implemented […] If you had, let's say in the VIE project, a small group activity that we could develop […] on a day that we have a number of the same age group, we could find […] a workshop that will talk about nutrition, to the kid, and with his parent." (I., psychologist)*

Additional aspects of the program could be improved. For example, HCPs suggested revising the admissibility criteria and timing of intervention delivery. It could be helpful to adapt the interventions for each type of diagnosis, treatment regimen, or age. Some participants proposed to focus on delivering interventions with at-home interventions using technology and to integrate the interventions later in the cancer continuum:

> *"But I think that from my clinical experience, hum, in the continuum of care […], I would see this coming a little bit later. To let the 'storm' of the*

diagnosis pass, to pass the acute adverse effects, then can we maintain the healthy behaviours?" (L., physiotherapist)

6.6 Discussion

The purpose of this qualitative study was to analyse the perspective of families affected by cancer and HCPs to gain more insight into the implementation process of a HP program in pediatric oncology. Our results highlight the need for HP interventions, but also the challenge of successfully implementing new interventions into a clinical setting. Our results suggest that embedding the innovative interventions in clinical care and involving all HCPs is essential.

In this study, the social context and enjoyment of the activities were important for the families, such as playing games with siblings during the physical activity interventions. This finding is supported by previous research demonstrating that fun during exercising was the main motivation during treatment for children with cancer (30) and that social interactions were important to the overall physical activity experience (31). Another identified facilitator that should be kept in future initiatives is to have flexible, individualized interventions that are tailored to the specific needs of children and families. It is thought to have helped overcome some of the barriers to behaviour change that were also reported in other studies, such

as having fatigue, organizational constraints, or negative feelings about one's self (32). Similar to the results in our study, another exercise-based rehabilitation program within an adult cancer unit was perceived by clinicians to initiate a cultural change (33). In this study, key practical elements for success included delivering consistent, positive messaging about exercise from a broad range of hospital staff and facilitated by the fact that it was filling a service gap. To generate a sustainable culture shift, all HCPs should be well-informed about the interventions and involved in their development and/or implementation. Involving them early in implementation is important (34) and enhances success (35). The *VIE project* was indeed developed by researchers in collaboration with clinicians, but the clinical team in its whole was not solicited in the intervention development to think about its implementation. Furthermore, the long-term implementation and sustainability of HP intervention can occur by working in collaboration to plan for sustainability from the start (36). Future initiatives should place more emphasis on trying to better integrate interventions in clinical care and having support from the clinical team by involving them as early as possible.

Participants identified that some barriers (e.g., intervention burden, health issues) were mostly present at the beginning of the cancer care continuum, when families are often disrupted and consumed by the intensity of cancer therapy (32, 37).

Another study has also reported difficulties in implementing their interventions around that time, because of the complexity of initial cancer treatments and the difficulties in asking patients to take on more than getting through their treatments (38). We would therefore suggest waiting until families are emotionally and cognitively available before integrating HP interventions in their clinical care. Another difficulty that was faced by the research team is that adolescents in our study showed less interest or motivation towards behaviour change interventions. Similarly, another study investigating attitudes towards improving lifestyle behaviour after cancer treatment found that parents were more interested in having their child participate than adolescents themselves (39). Thus, developing targeted strategies for adolescents or providing age-appropriate support will be crucial in future initiatives. We also have to consider that the target population in our study is confronted with complex emotional and organizational challenges (40). A lot of the barriers related to the difficulty in the organization of the interventions and with the concern of wanting to support patients, not adding on to their already heavy burden. A practical solution offered by HCPs was to revisit the onset of some interventions, to initiate them more gradually, or to lessen their intensity during the acute phase of treatment. Focusing on the survivorship phase, where patients often experience a service gap, is also a good idea especially for educational activities on the long-term benefits of adopting healthy behaviours. Using

technology or various platforms is also recommended to facilitate the organization of the interventions and integration of the recommendations in their everyday life. Another study that aimed to describe what needed to be considered in implementing an integrative care program in a pediatric oncology department concluded that a highly flexible program was the solution to address the complexity of the clinical context (41).

Regarding program refinement, adding educational activities was suggested by participants and could be one way to increase their intention to change. According to Gotte et al. (30), educational strategies can be used to inform children affected by cancer and their families about how barriers such as lack of energy and bad mood can be influenced by physical activity and thus improve their participation. The importance of the “teachable moment” (p.156) (42), a phrase that has been used to describe life transitions or health events thought to motivate health behaviour change, should be considered when deciding the timing to initiate such interventions and they should be adapted to the different target groups (i.e., children, adolescents, or parents) (38). It is important to note that in-person nutrition education and cooking workshops have been developed and tested in our clinical context, but difficult to implement (15). Education should also go further than just disseminating information; intervention providers have to support

participants in making meaning of and taking an active role in their behaviour change. Additionally, it is recommended to use theory-based behaviour change strategies (43), that could help to meet the participants where they are in the change process. This way, participants' readiness to change can be addressed, instead addressing change in health behaviours prematurely, and possibly ineffectively. Interventions that act by changing attitudes towards health behaviours may have a lasting impact on intention to change or engagement (26). For example, providing extensive training in motivational interviewing (44, 45) to intervention providers or integrating Prochaska's stages of change (46) in their practice could be helpful. A study using a motivational intervention in childhood cancer survivors found significant improvement in PA and secondary outcomes such as cancer-related fatigue and quality of life (47). Finally, working on changing the perception of families affected by cancer and HCPs regarding the importance and necessity of integrating HP interventions in clinical care to optimize health outcomes is crucial.

6.6.1 Strengths and limitations

This research addresses a gap in the literature by gathering the perspective from both families affected by cancer and healthcare professionals on this subject. Limitations also need to be considered when interpreting the findings. As a single-

center study, the findings cannot be generalized to the entire pediatric cancer population and HCPs, which may limit the transferability of the recommendations. Furthermore, our sample is small and even though we have tried to have a representative sample for families and HCPs, some perspectives may not have been taken into account even if data saturation is said to have been achieved. In future studies, it would be interesting to add the perspective of children and to have more participants by considering the various perspectives (i.e., children, adolescents, and parents) as distinct groups. There may also be some degree of selection bias in our sample; that is, individuals who agreed to be interviewed may differ in important ways from those who did not or from individuals who dropped out of the study. Another limitation is the fact that the first author who conducted and analysed the interviews was a member of the research team. We acknowledge that may have limited participants' willingness to share negative experiences with us due the social desirability.

Further research is needed to identify ways to promote and facilitate long-term sustainability of HP interventions in clinical settings. The next steps will be to refine the program proposed by the *VIE project* based on the views and perceptions gathered from families and clinicians, and to develop strategies aimed at

eliminating the identified barriers and increasing the sustainability of participants' behaviour change.

6.7 Conclusion

This study provides researchers and clinicians several insights into the perspectives of families affected by cancer and HCPs to promote effectively healthy behaviours in this population. The results highlight the need for HP interventions and the relevance of implementing interventions beyond what is presently offered in regular clinical care. For optimal future implementation, we recommend involving researchers, patients, and clinicians as early as possible to ensure the HP interventions will be used and are adapted to the clinical context. We hope to facilitate the integration of HP promotion interventions into clinical practice and contribute to improving health services and care in pediatric oncology and the quality of life of families affected by cancer.

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6.7.2 Conflicts of interest

The authors have no conflicts of interest to declare that are relevant to the content of this article and have no financial or non-financial interests to disclose.

6.7.3 Authors' contributions and statement

All authors contributed to the study conceptualization. Material preparation and data collection was conducted by CD. Data analysis was performed by CD, KL and JK. The first draft of the manuscript was written by CD, all authors commented on previous versions of the manuscript, and read and approved the final manuscript.

6.8 References

1. Landier W, Armenian S, Bhatia S. Late effects of childhood cancer and its treatment. Pediatr Clin North Am. 2015;62(1):275-300.

2. Dickerman JD. The late effects of childhood cancer therapy. Pediatrics. 2007;119(3):554-68.

3. Galligan AJ. Childhood Cancer Survivorship and Long-Term Outcomes. Adv Pediatr. 2017;64(1):133-69.

4. Lemay V, Caru M, Samoilenko M, Drouin S, Alos N, Lefebvre G, et al. Prevention of Long-term Adverse Health Outcomes With Cardiorespiratory Fitness and Physical Activity in Childhood Acute Lymphoblastic Leukemia Survivors. J Pediatr Hematol Oncol. 2019;41(7):e450-e8.

5. Hudson MM, Patte C. Education and health promotion in adolescent and young adult cancer survivors. Pediatr Blood Cancer. 2008;50(5 Suppl):1105-8.

6. Mertens AC, Yasui Y, Neglia JP, Potter JD, Nesbit ME, Jr., Ruccione K, et al. Late mortality experience in five-year survivors of childhood and adolescent cancer: the Childhood Cancer Survivor Study. J Clin Oncol. 2001;19(13):3163-72.

7. Nottage KA, Ness KK, Li C, Srivastava D, Robison LL, Hudson MM. Metabolic syndrome and cardiovascular risk among long-term survivors of acute lymphoblastic leukaemia - From the St. Jude Lifetime Cohort. Br J Haematol. 2014;165(3):364-74.

8. Caru M, Curnier D, Levesque A, Sultan S, Marcil V, Laverdiere C, et al. The impact of cancer on theory of planned behavior measures and physical activity levels during the first weeks following cancer diagnosis in children. Support Care Cancer. 2021;29(2):823-31.

9. Stössel S, Neu MA, Oschwald V, al. e. Physical activity behaviour in children and adolescents before, during and after cancer treatment. Sport Sci Health. 2020(16):347–53

10. Fuemmeler BF, Pendzich MK, Clark K, Lovelady C, Rosoff P, Blatt J, et al. Diet, physical activity, and body composition changes during the first year of treatment for childhood acute leukemia and lymphoma. J Pediatr Hematol Oncol. 2013;35(6):437-43.

11. Caru M, Curnier D, Levesque A, Sultan S, Marcil V, Laverdiere C, et al. Children's physical activity behavior following a supervised physical activity program in pediatric oncology. J Cancer Res Clin Oncol. 2020;146(11):3037-48.

12. Wurz A, McLaughlin E, Lategan C, Ellis K, Culos-Reed SN. Synthesizing the literature on physical activity among children and adolescents affected by cancer: evidence for the international Pediatric Oncology Exercise Guidelines (iPOEG). Transl Behav Med. 2021;11(3):699-708.

13. Robison LL, Hudson MM. Survivors of childhood and adolescent cancer: life-long risks and responsibilities. Nat Rev Cancer. 2014;14(1):61-70.

14. Caru M, Duhamel G, Marcil V, Sultan S, Meloche C, Bouchard I, et al. The VIE study: feasibility of a physical activity intervention in a multidisciplinary program in children with cancer. Support Care Cancer. 2020;28(6):2627-36.

15. Beaulieu-Gagnon S, Belanger V, Meloche C, Curnier D, Sultan S, Laverdiere C, et al. Nutrition education and cooking workshops for families of children with cancer: a feasibility study. BMC Nutr. 2019;5:52.

16. Morales JS, Valenzuela PL, Rincon-Castanedo C, Takken T, Fiuza-Luces C, Santos-Lozano A, et al. Exercise training in childhood cancer: A

systematic review and meta-analysis of randomized controlled trials. Cancer Treat Rev. 2018;70:154-67.

17. Demers C, Brochu A, Higgins J, Gelinas I. Complex behavioral interventions targeting physical activity and dietary behaviors in pediatric oncology: A scoping review. Pediatr Blood Cancer. 2021:e29090.

18. Braam KI, van der Torre P, Takken T, Veening MA, van Dulmen-den Broeder E, Kaspers GJ. Physical exercise training interventions for children and young adults during and after treatment for childhood cancer. Cochrane Database Syst Rev. 2016;3:CD008796.

19. Daeggelmann J, Wurz A, San Juan AF, Albinati N, Bloch W, Culos-Reed SN. Translating research to practice: Taking the next step to get children diagnosed with cancer moving. Ann Physio Occul Therap. 2019;2(000141).

20. Arroyave WD, Clipp EC, Miller PE, Jones LW, Ward DS, Bonner MJ, et al. Childhood cancer survivors' perceived barriers to improving exercise and dietary behaviors. Oncol Nurs Forum. 2008;35(1):121-30.

21. Wurz A, McLaughlin E, Chamorro Vina C, Grimshaw SL, Hamari L, Gotte M, et al. Advancing the Field of Pediatric Exercise Oncology: Research and Innovation Needs. Curr Oncol. 2021;28(1):619-29.

22. Ste-Justine C. Le Projet VIE : Valorisation - Implication - Éducation Montréal, Canada: CHU Ste-Justine; 2021 [Available from: https://www.chusj.org/fr/soins-services/H/Hematologie/Projet-Vie.

23. Guest G, Bunce A, Johnson L. How many interviews are enough?: An experiment with data saturation and variability. Filed Methods. 2006;18(59).

24. Ajzen I. The theory of planned behaviour. Organizational Behavior and Humain Decision Processes. 1991;50:179-201.

25. Keats MR, Culos-Reed SN, Courneya KS, McBride M. Understanding physical activity in adolescent cancer survivors: an application of the theory of planned behavior. Psychooncology. 2007;16:448-57.

26. Hullmann SE, Biederman E, Monahan PO, Champion VL, Pradhan KR. Psychometric Testing of Attitudes Toward Physical Activity Scale for Adolescent and Young Adult Survivors of Pediatric Cancer. J Adolesc Young Adult Oncol. 2021.

27. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.

28. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006;3(2):77-101.

29. Tobin GA, Begley CM. Methodological rigour within a qualitative framework. J Adv Nurs. 2004;48(4):388-96.

30. Gotte M, Kesting S, Winter C, Rosenbaum D, Boos J. Experience of barriers and motivations for physical activities and exercise during treatment of pediatric patients with cancer. Pediatr Blood Cancer. 2014;61(9):1632-7.

31. Craike MJ, Hose K, Courneya KS, Harrison SJ, Livingston PM. Perceived benefits and barriers to exercise for recently treated patients with multiple myeloma: a qualitative study. BMC Cancer. 2013;13:319.

32. Ross WL, Le A, Zheng DJ, Mitchell HR, Rotatori J, Li F, et al. Physical activity barriers, preferences, and beliefs in childhood cancer patients. Support Care Cancer. 2018;26(7):2177-84.

33. Dennett AM, Peiris CL, Tan G, Shields N. Clinician's perspectives of implementing exercise-based rehabilitation in a cancer unit: a qualitative study. Support Care Cancer. 2021;29(12):8019-26.

34. Pronovost PJ, Berenholtz SM, Needham DM. Translating evidence into practice: a model for large scale knowledge translation. BMJ. 2008;337:a1714.

35. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q. 2004;82(4):581-629.

36. Shelton RC, Cooper BR, Stirman SW. The Sustainability of Evidence-Based Interventions and Practices in Public Health and Health Care. Annu Rev Public Health. 2018;39:55-76.

37. van Dijk-Lokkart EM, Braam KI, Huisman J, Kaspers GJ, Takken T, Veening MA, et al. Factors influencing childhood cancer patients to participate in a combined physical and psychosocial intervention program: Quality of Life in Motion. Psychooncology. 2015;24(4):465-71.

38. Ganz PA. A teachable moment for oncologists: cancer survivors, 10 million strong and growing! J Clin Oncol. 2005;23(24):5458-60.

39. Touyz LM, Cohen J, Cohn RJ, Garnett SP, Anazodo A, Gohil P, et al. Childhood cancer survivors report preferring lifestyle interventions delivered in person rather than online: An adolescent and parent perspective. Pediatr Blood Cancer. 2019;66(10):e27922.

40. Beaulieu-Gagnon S, Belanger V, Marcil V. Food habits during treatment of childhood cancer: a critical review. Nutr Res Rev. 2019;32(2):265-81.

41. Rutert B, Stritter W, Eggert A, Auge U, Laengler A, Seifert G, et al. Development of an Integrative Care Program in a Pediatric Oncology Unit. Complement Med Res. 2021;28(2):131-8.

42. McBride CM, Emmons KM, Lipkus IM. Understanding the potential of teachable moments: the case of smoking cessation. Health Educ Res. 2003;18(2):156-70.

43. Brown MC, Sharp L, Sniehotta FF, Skinner R, Araujo-Soares V. The development of health behaviour change interventions for childhood cancer survivors: The need for a behavioural science approach. Pediatr Blood Cancer. 2020;67(9):e28500.

44. Miller WR, Rollnick S. Motivational Interviewing: Preparing People To Change Addictive Behavior. New York: Guilford Press; 1991.

45. Dewez S, Laurin C, Ogez D, Bourque CJ, Curnier D, Laverdiere C, et al. Elaboration and refinement of a motivational communication training program for healthcare professionals in pediatric oncology: a feasibility and acceptability study. Health Psychol Behav Med. 2021;9(1):220-38.

46. Prochaka JO, Velicer WF. The transtheoretical model of health behavior change. Am J Health Promot. 1997;12(1):38-48

47. Cheung AT, Li WHC, Ho LLK, Chan GC, Lam HS, Chung JOK. Efficacy of Mobile Instant Messaging-Delivered Brief Motivational Interviewing for Parents to Promote Physical Activity in Pediatric Cancer Survivors: A Randomized Clinical Trial. JAMA Netw Open. 2022;5(6):e2214600.

Table 6.1 *VIE project* components

Components	Description
Psychosocial support	- Six sessions (i.e., four individual sessions, offered to each parent, and two couple sessions) to support parents of children affected by cancer - In blended families, each parent could participate in the program with their new partner and the individual sessions were also offered to single parents - A manual for healthcare professionals (provider manual) provided specific instructions to convey the information in a standardized manner. A manual for parents included toolkits for individual and couple sessions, as well as strategies related to communication and dyadic coping. - Program adapted from existing programs and based on cognitive behavioural and systemic theories, developed for this study - Provided either at the hospital, at home, or remotely - Aim: to strengthen parents' sense of control and problem-solving skills training (PSST). Individual sessions focused on PSST, as well as acquiring, developing, and maintaining simple problem-solving skills to meet the needs of families facing childhood cancer. The couple sessions aimed to enhance parents' communication and resilience by improving their ability to manage real difficulties associated with childhood cancer together.
Physical activity	- Physical activity sessions, goal setting, and counselling for behavioural changes with a team of trained kinesiologists

	- Assessment of patients' physical fitness, quality of life, and level of physical activity at four time points (baseline, one-year post-diagnosis, two-year post-diagnosis, end of the study) - Sessions were conducted at the hospital during the medical appointments or hospitalization, or remotely - Aim: to promote physical activity during and after the treatment as well as the adoption of an active lifestyle for the participants and their family
Nutrition	- Personalized assessment, goal setting, and counseling for behavioural changes with a registered dietitian (RD) - Initial assessment, then follow-up visits every two months for the first year, and as needed thereafter - Personalized counseling focused on addressing nutritional issues related to cancer or treatments and promoting healthy eating behaviours - Aim: to ensure normal growth and development of the patient, weight maintenance after treatment, and prevention of long-term health complications

Table 6.2 Consolidated Framework for Implementation Research (CFIR) Domains

CFIR Domain	Description
Intervention characteristics	- Features of an **intervention** that might influence implementation - Includes: perceived internal or external origin, evidence quality and strength, relative advantage, adaptability, trialability, complexity, design quality and presentation, and cost.
Inner setting	- Features of the **organization** that might influence implementation - Includes: team culture, compatibility and relative priority of the intervention, structures for goal-setting and feedback, leadership engagement, and the implementation climate.
Outer setting	- Features of the **external context** or **environment** that might influence implementation - Includes: patient needs and resources, cosmopolitanism or the level at which the implementing organization is networked with other organizations, peer pressure, and external policies and incentives.

Characteristics of individuals	- Characteristics of **individuals** involved in implementation that might influence implementation - Includes: individuals' beliefs, knowledge, self-efficacy and personal attributes.
Implementation process	- **Strategies** that might influence implementation - Includes: stages of implementation such as planning, executing, reflecting and evaluating, and the presence of key intervention stakeholders and influencers including opinion leaders, stakeholder engagement, and project champions.

Table 6.3 Sociodemographic and Clinical Characteristics of Families

Characteristics	Adolescents (n=5) n (%)	Parents (n=9) n (%)
Age of the child at diagnosis (years)		
0-4	0 (0)	3 (33)
5-12	0 (0)	4 (44)
13 and +	5 (100)	2 (22)
Sex of the child		
Male	3 (60)	3 (33)
Female	2 (40)	6 (67)
Race/ethnicity		
White/Caucasian	4 (80)	8 (89)
Other	1 (20)	1 (11)
Cancer diagnosis of the child		
Leukemia	3 (60)	5 (56)
Lymphoma	1 (20)	1 (11)
Central Nervous System Tumors	0 (0)	0 (0)
Extra cranial solid tumor	1 (20)	3 (33)
Highest level of education attained		
Unfinished high school	-	0 (0)
High school	-	5 (56)
Professional school	-	1 (11)
Entry-level college	-	1 (11)
Graduate school	-	2 (22)
Marital status		
Common-law partners or married	-	8 (89)
Separated	-	1 (11)

Table 6.4 Sociodemographic and professional characteristics of healthcare professionals

Characteristics	Health care professionals (n=11)
Gender – female *n* (%)	8 (73)
Years of clinical experience *median* (range)	16 (5-35)
Years of experience in oncology *median* (range)	12 (5-25)
Discipline *n* (%)	
Nurse	1 (9)
Oncologist	1 (9)
Rehabilitation professionals	5 (45)
Nutritionist	1 (9)
Psychologist	1 (9)
Hospital-based teachers	2 (18)

Table 6.5 Coding tree for factors affecting participation and implementation

	Participants affected by cancer	Healthcare professionals
Intervention characteristics		
Facilitators	- Flexibility and adaptability - Tailored to individuals' needs - Perceived benefits of the interventions	- Use of a playful approach - Enjoyed by participants - Relevant and answering a need
Barriers	- Perceived difficulty of intervention or burden - Too many intervention-deliverers	- Burden of the intervention for families - Too many intervention-deliverers, not involved for long period of time - Perceived lack of training or experience to work with a vulnerable and complex population
Inner setting		

Facilitators	- Convenience - Support from HCPs	- Cultural shift towards health promotion - Complementarity of some interventions with clinical care
Barriers	- Time or organizational constraints - Lack of integration in clinical care	- Added burden to clinician's work - Negative implementation climate - Lack of collaboration and interdisciplinary work between teams - Difficulty to embed intervention in clinical care - Overlap of some interventions
Outer setting		
Facilitators	- COVID-19 pandemic led to increase the offer for online interventions, which was appreciated by some participants	- Gap in health promotion interventions or services in this population - COVID-19 pandemic led to an increased use of technology and at-home interventions

Barriers	- Demotivation due to the pandemic or no interest in online interventions	- COVID-19 pandemic hampered communication and collaboration between teams
Characteristics of individuals		
Facilitators	- Knowledge and positive beliefs about intervention - Social support - Trusting relationships with intervention-deliverers	- Trusting relationship established with individuals involved in the long term
Barriers	- Health issues (physical and mental) - Lack of need - Lack of interest or motivation	- Lack of need for these interventions as perceived by families, possible lack of knowledge
Implementation process		
Facilitators		- Identification of some clinicians as project

		champions before the implementation
Barriers	- Inconsistency in the delivery of interventions across time	- Lack of publicity for some interventions - Lack of knowledge of clinicians regarding the interventions and the study in general (e.g., goals, criteria, interventions, etc.) - Lack of engagement and involvement of clinicians in the different steps (i.e., intervention development, planning, implementation, evaluation).

CHAPTER 7: MANUSCRIPT 3

7.1 Preface

The previous manuscript described the challenges and limitations of implementing the *VIE project* simultaneously with its opportunities and promise. In addition to implementation, we are also interested in outcomes to see if the benefits of the program occur in spite of the documented challenges of implementing it. Following the CIPP Model, the study presented in this manuscript focused on the Product Evaluation of the *VIE project*. At the end of the study, an outcome evaluation was conducted using a convergent mixed methods design. The larger research team has evaluated specific outcomes for each study component (i.e., PA, nutrition, psychosocial), associated with the interventions' purpose (e.g., PA levels, anthropometry, stress levels). These outcomes have been evaluated by other researchers on the team and thus are not part of this thesis. To add a rehabilitation professionals' perspective to the study, we chose to evaluate the functional outcome of participants. As this work is part of a pilot study and undergoing preliminary testing, we acknowledge that the benefits to the target population may not be achieved until later on in the research process (e.g., efficacy trial, Phase III in the ORBIT model). Nonetheless, including a focus on outcomes when

implementing a program in a specific population is critical for assessing suitability and promise [163].

As suggested in Manuscript 1, we used a mixed methods design. Semi-structured interviews were embedded in the study design for the purpose of explaining the quantitative results with in-depth qualitative data with a subgroup of participants. Furthermore, documenting the experiences of children with cancer and their families in regard to complex behavioural interventions (CBI) using qualitative data could help to optimize the recruitment, adherence, and effectiveness of the studies. We used both a questionnaire and interviews to gain a better understanding of the families' views of the program.

Acceptability and functional benefits of a health promotion program in pediatric oncology: A mixed methods study

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7.2 Abstract

Objective. The purpose of this study is to assess a health promotion (HP) program's acceptability from the perspective of families affected by cancer and to estimate the extent to which the interventions received through the program led to an improved functional outcome, compared to standard care. **Methods.** A mixed methods study was used. Acceptability was assessed using a questionnaire with parents who participated in the program (n=30) and a semi-structured, exit interview with a subgroup of adolescents (n=6) and parents (n=12). Potential effectiveness to improve the functional outcome was evaluated using an age-appropriate performance-based assessment (Movement ABC-2 [MABC-2] for children < 10 years old or Assessment of Motor and Process Skills [AMPS] for children and adolescents aged ≥ 10 years old) with participants (n=45), compared to a control group (n=29). **Results.** Conducting a HP program in pediatric oncology is acceptable to families affected by cancer and has a positive impact on patient experience. However, no significant benefit for the intervention group over the control group for the functional outcome were found. **Conclusion.** The

preliminary results support the acceptability of implementing a HP program in a pediatric oncology clinical context. More research is needed to understand how such interventions can improve the functional outcome of participants.

7.3 Introduction

Children and adolescents affected by cancer are surviving more than ever, with the 5-year survival rate exceeding 80% in high-income countries (American Cancer Society, 2021; Ellison, Xie, & Sung, 2021; Lam, Howard, Bouffet, & Pritchard-Jones, 2019), compared to only 58% in the mid-1970s (American Cancer Society, 2021). However, improvement in survival rate has come at the cost of adverse, cumulative effects from cancer and its treatment, which can leave cancer survivors disabled or with a suboptimal level of function (National Academies of Sciences, 2021). Less than an optimal function in the physical and cognitive domains may diminish a survivor's daily living activities and ability to participate fully in expected and desired roles at home, school, and work (Ness et al., 2010). Furthermore, a majority of survivors will develop a chronic health condition within 30 years of diagnosis (Hudson et al., 2013). These complications may further limit activities and restrict participation in daily life experiences (Janzen & Spiegler, 2008) as well as decrease their quality of life (Shin, Bartlett, & De Gagne, 2019).

Developing and implementing health promotion (HP) initiatives that support the adoption of healthy behaviours, such as a healthy diet and frequent physical activity, can be an effective way to prevent or minimize the impacts of adverse effects. Indeed, adopting and sustaining healthy behaviours is well-known to improve health in both the general and at-risk populations (WHO, 2008), particularly for chronic diseases, such as cardiovascular disease and diabetes, that are prevalent in the pediatric oncology population (Nottage et al., 2014). Furthermore, benefiting from HP interventions in addition to standard care during the pediatric cancer continuum (i.e., from diagnosis to survivorship) could result in improved functional outcome.

The scientific literature on HP has examined the feasibility and effectiveness of HP interventions in pediatric oncology. Reviews of exercise or physical activity interventions during and after treatment for pediatric cancer show beneficial effects on muscle strength (Braam et al., 2016; Coombs, Schilperoort, & Sargent, 2020), cardiorespiratory fitness (Braam et al., 2016; Coombs et al., 2020), functional mobility (Coombs et al., 2020; Morales et al., 2018), and fatigue (Coombs et al., 2020; Malysse et al., 2021). A review of nutritional interventions for survivors of childhood cancer was unable to draw conclusion regarding their effectiveness, but suggested that interventions designed to improve the nutritional intake

could improve health behaviours in this population (Cohen, Wakefield, & Cohn, 2016). A review of complex behavioural interventions (CBI) targeting multiple health behaviours in childhood cancer patients or survivors concluded that implementing CBI is feasible and that these interventions can potentially improve physical activity and dietary behaviours and diminish cancer effects on children's physical and psychological health (Demers, Brochu, Higgins, & Gelinas, 2021). Studies that have included an acceptability assessment of CBI, defined as a construct that reflects the extent to which people delivering or receiving the intervention consider it to be appropriate (Sekhon, Cartwright, & Francis, 2017), have concluded that most participants were satisfied with the program (Berg, Stratton, Giblin, Esiashvili, & Mertens, 2014; Wu, Chen, Hsu, Liu, & Su, 2019) and found it helpful (Stern et al., 2018; Wu et al., 2019). However, very little research has been conducted on the views and experiences of the participants who took part in HP interventions during their cancer journey that goes beyond a short, quantitative questionnaire at the end of an intervention or program. Furthermore, the vast majority of the studies included in these reviews have used assessments of health behaviours such as physical activity level or diet and/or health indicators such as body mass index, strength or quality of life to assess the effectiveness of their interventions. Thus, little is known about the potential for these interventions to improve the *functional outcome* of children affected by cancer. Therefore, the

purpose of this study was twofold: first, to assess a HP program's acceptability and explore views of participants regarding the program; second, to determine its potential effectiveness to improve the functional outcome (i.e., performance in activities of daily living) in children and adolescents affected by cancer, compared to standard care.

7.4 Methods

7.4.1 Design

Mixed-method study consisting of semi-structured interviews with families affected by cancer (n=6 adolescents and n=12 parents), self-report questionnaires with parents (n=29), and functional assessments with children and adolescents affected by cancer (n=73).

7.4.2 Clinical context

This study is part of the larger *VIE project* which is a HP program implemented as a non-randomized, controlled pilot study at the CHU Sainte-Justine (CHUSJ) (Montreal, Canada). The *VIE project* is multidisciplinary and has three components: psychosocial support, nutrition counselling, and physical activity interventions (see Appendix II for details). The design of the different interventions were described in details in previous publications (Belanger et al., 2022; Caru et

al., 2020; Ogez et al., 2019). The overall objective of the program was to motivate and sustain health behaviour practices to prevent or attenuate long-term adverse health effects of children and adolescents with cancer across the continuum of care. The primary aim of the *VIE project* study was to evaluate the feasibility of implementing a multidisciplinary, integrated intervention program in pediatric oncology. This study adds to the evaluation of the *VIE project* by focusing on the acceptability and potential effectiveness to improve the functional outcome.

7.4.3 Participants

Parents and children newly diagnosed with cancer, treated at CHUSJ and meeting the inclusion criteria were recruited in the *VIE project* study from February 2018 to December 2019 by the study coordinator. Inclusion criteria were as follows: (1) less than 21 years old at diagnosis, (2) treated with radiation therapy or chemotherapy, (3) less than 12 weeks post-diagnosis, and (4) able to give an informed consent (by parents or legal tutors if < 18 years old). Concurrently, the participants for the comparison group were also recruited from patients diagnosed at CHUSJ two years prior to study initiation, and were not exposed to the *VIE project*. The inclusion criteria were the same as for the intervention group, except for criteria 3.

Ethical approval for this study was obtained from the CHUSJ Research Ethics Board was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from parents or adolescents ≥ 18 years old and verbal consent for children and adolescents < 18 years old.

7.4.4 Procedure and data collection

Acceptability questionnaires were sent by email to all families who participated in the *VIE project* by the study coordinator as part of the end-of-program survey regrouping questionnaires from all the study components. The questionnaire was self-rated at a convenient time by the family and sent back electronically when completed. For the functional assessments, participants in both the intervention and control groups were contacted by telephone by the study coordinator to schedule the assessments during a visit at the oncology clinic. Exit interviews were conducted with a subgroup of participants from the intervention group to assess acceptability in more depth as well as perceived benefits of having participated in the study. A convenient sample of adolescents and parents who were available and had not participated in a previous interview during the study were invited to participate in the interview. Adolescents and parents were interviewed together if both accepted to participate, as it was more convenient. Interviews were audio-recorded, transcribed verbatim, and anonymized.

7.4.5 Measures

Acceptability

The program's acceptability was measured using a 7-item questionnaire for parents specifically developed for this study. Three questions were adapted from an existing acceptability questionnaire, the Acceptability of treatment programmes questionnaire from the Specialist Parkinson's Integrated Rehabilitation Team Trial (Gage H, 2014), for which psychometric properties were not reported. Four additional questions were added following a discussion with other members of the research team to address their needs. The final version of the questionnaire was revised by experts in the field and a patient-partner. The questionnaire consisted of seven questions rated on a 5-point Likert scale (0 = strongly disagree – very unsatisfied to 4 = strongly agree – very satisfied) that related to the different aspects of the program (e.g., team, support received, complementarity of the interventions) and general satisfaction. It also included an open box to collect any additional comment.

Exit interviews were conducted by the first author (CD) and followed a semi-structured interview guide, which was adjusted as new information emerged. Major themes addressed were 1) general experience in the program, 2) perceived

benefits of the program, and 3) recommendations for potential improvement. The order and the wording of questions were freely chosen to allow for an open and free discussion and the questions were adapted according to the age of the participant.

Functional outcome

The Movement Assessment Battery for Children, second edition (MABC-2) was used for children < 10 years old and the Assessment of Motor and Process Skills (AMPS) for children and adolescents aged ≥ 10 years old. All assessments were performed by the first author (CD) or other trained occupational therapists and/or physiotherapists. The MABC-2 (Henderson, Sugden, & Barnett, 2007) is an individually administered standardized measure of movement impairment for children 3–16.11 years of age that consists of eight standardized tasks divided in three subsections: hand function, ball skills, and balance skills. This test has fair to good reliability (Henderson et al., 2007; Valentini, Ramalho, & Oliveira, 2014; Wuang, Su, & Huang, 2012), excellent content validity (Henderson et al., 2007; Schulz, Henderson, Sugden, & Barnett, 2011), and has been previously used in this population (De Luca et al., 2013; Hartman, Hop, Takken, Pieters, & van den Heuvel-Eibrink, 2013; Hartman et al., 2009; Hartman, van den Bos, Stijnen, & Pieters, 2006; Kandula et al., 2018; H. Reinders-Messelink et al., 1999). The total

score of the MABC-2 is transformed by age-related norms into a percentile score. The AMPS (Fisher & Jones, 2010) is a standardized objective measure of the quality of activity of daily living (ADL) task performance. It evaluates 16 motor skills and 20 process skills that are the smallest observable units of ADL task performance and the scores are transformed by age-related norms into a percentile score. The AMPS skills are goal-directed actions and the quality of each skill is evaluated within the context of the person performing daily life tasks. The AMPS is reported as the best measure to evaluate ADL performance or capacity for children and adolescents of all ages and it is the only measure of activities of daily living that evaluates underlying motor and cognitive deficits in task performance (James, Ziviani, & Boyd, 2014). Furthermore, children typically enjoy and engage willingly in this assessment (Payne & Howell, 2005) and it has been used previously in this population (Demers, Gelinas, & Carret, 2016; Gerber et al., 2006; Parks, Rasch, Mansky, & Oakley, 2009; Sabel et al., 2017). Regarding the feasibility of conducting the functional assessment, based on other studies assessing the feasibility of an intervention for children and their parents, acceptability is achieved if ≥ 70% of participants complete the assessment and feasibility if ≥ 85% of participants do so (Blake et al., 2016; Knox et al., 2019).

7.4.6 Sample size

We calculated the sample size required for the functional outcome, for which a multiple linear regression test was required based on a dichotomous predictor variable and a continuous outcome with confounders. Green (Green, 1991) indicates that adequate power (80%) can be achieved for moderate effect sizes with a sample size $n > 50 + 8m$, where m is the number of covariates to be modelled. There were no covariates in this study. We adjusted for four potential confounders (i.e., age, sex, type of cancer and time since end of treatment) by adding 1 additional subject per level (1) or per degree of freedom (df), thus a total of 58 participants were required. Consequently, we had a sufficient number of participants to reach significance for motor performance. However, our study was underpowered for the cognitive performance analysis as only the participants ≥ 10 years old had results for the cognitive outcome.

7.4.7 Data analysis

Participants' characteristics were described using median, ranges, and percentages. Normality assumptions of continuous variables were verified using the Shapiro-Wilk test. The distributions of participants' characteristics were compared using Mann-Whitney U test for continuous variables and Chi square-test for categorical variable, between a) intervention group and control group, b)

participants and non-participants in the intervention group, and c) participants and non-participants in the control group.

For the functional outcome data, we first checked for assumption of normality, homoscedasticity, and absence of multicollinearity. As the normality assumption was violated, we used the log-transformation as a correction strategy to fix the problem. Then, significance of the difference in the mean for motor and cognitive abilities between both groups were determined using multiple linear regression ($p<0.05$), adjusting for age, sex, type of cancer, and time since end of treatment as confounders. For motor abilities, results for the MABC-2 were used for the participants < 10 years old or the AMPS for participants ≥ 10 years old, as they are on the same scale (i.e., percentiles). For the cognitive abilities, only the percentile score from the AMPS assessment were used for the participants ≥ 10 years old, as this measure was not available for younger participants. In addition, frequencies and percentages of scores under the test norms were reported. Scoring resulted in two descriptive categories: normal (>pc15, >-1SD), or below average scores (pc≤15, ≤-1SD). Statistical analyses were performed using SPSS (Version 28).

For qualitative data, thematic analysis was used with NVivo Software (Version 13). The first author (C.D.) identified major overarching themes, using interview transcripts. The themes were then discussed with another author (J.K.) to confirm that the themes reflected and transcended the interviews. An inductive approach was used as there was no theoretical background or existing knowledge supporting the choice of themes.

Subsequently, to integrate the quantitative and qualitative findings obtained separately, we integrated the results in a side-by-side table and discussed how the qualitative results either confirm, disconfirm, or complement the quantitative results.

7.5 Results

7.5.1 Sample and clinical characteristics

For the intervention group, 62 participants were recruited over the two-year recruitment period, with a recruitment rate of 67%. Six participants died and three dropped-out of the study, resulting in 53 participants eligible for the end-of-program assessment and 45 assessed (see Figure 7.1). When comparing sociodemographic and clinical characteristics between participants who were assessed and those who weren't, no statistical differences were found. Eighty-two

participants were recruited for the control group. For feasibility reason (i.e., non-availability of the facilities or therapist for assessment), it was not possible to conduct the functional assessment with all the participants from the control group. Thus, a convenient sample was recruited comprising of 29 (35.4%) participants. When comparing sociodemographic and clinical characteristics, we found that age at diagnosis was lower for participants in the control group, compared to non-participants. No other statistical differences were found.

Among the 74 participants (45 in intervention group, 29 in control group), approximately half were male (48.6%) and age ranged from 3 to 18 years (median 7). Time since diagnosis ranged from 18 to 48 months (median 28 months) and time since end of treatment from 0 to 31 (median 12 months), with 10 participants still receiving treatments or who had completed treatment since less than one month. About half of participants (n=36, 48.6%) had a diagnosis of leukemia, 12 (16.2%) of lymphoma, 6 (8.1%) of central nervous system tumour, and 18 (27.0%) presented other diagnoses. When comparing sociodemographic and clinical characteristics of the different groups (i.e. intervention group vs control group, participants vs non-participants in intervention group, participants vs non-participants in control group) in relation to sociodemographic and clinical characteristics, we found that time since end of treatment was longer in the

intervention group, compared to the control group (U=421, p=0.01), and that age a diagnosis was lower for participants in the control group, compared to non-participants. No other statistical differences were found (Table 7.1).

7.5.2 Acceptability

The acceptability questionnaire was completed by 30 (56.6%) participants. Figures 7.2 and 7.3 show the responses obtained. Almost nine participants out of ten expressed they would recommend the program to other cancer patients (86.7%) and indicated they were either satisfied or very satisfied with the current program (86.7%). In addition, the majority of participants found that the multidisciplinary team was responsive to their needs, that the interventions were complimentary with other clinical activities, and that the program format was suitable (86.7%, 73.3%, and 63.3% somewhat agree or strongly agree, respectively). They also appreciated the support provided by the program (76.7% somewhat agree or strongly agree). Half of the participants agreed that they learned new and useful information regarding the importance of adopting healthy behaviours (50.0% somewhat agree or strongly agree).

All the exit interviews were conducted by the first author (C.D.) between May 2021 and March 2022, face-to-face at the oncology clinic (n=13) or virtually using the

Zoom platform (n=1). Fourteen families were approached, all of which accepted. As four families had two participants (i.e. one adolescent and one parent), 18 individuals were interviewed. After interviewing 18 participants, data saturation was considered reached. Twelve participants were parents (eight mothers, four fathers) and six were adolescents (range 12 to 17 years old) (see Table 7.2). The interviews ranged in duration between 5 and 26 minutes (median 12 minutes). The results are presented according to the overarching themes covered in the interviews.

Theme 1: Experience in the program

Overall, participants reported having a positive experience in the program: "*It was like a silver lining with everything that had happened… It allowed [my son] to have fun, through it all. When he was coming to the hospital, it was fun to do [physical activity interventions]. Or, by Zoom, it was a privilege for him. He could benefit from that, when nobody else could*" (Mother of a 13-year-old participant). The positive aspects of the program identified were the adaptability and flexibility in the delivery of interventions, and the trust and positive relationships established with the intervention deliverers. Frequently reported negative aspects of the program was having to fill out numerous, lengthy questionnaires (e.g., three-day food records) and the burden of the cancer experience that prevented them from participating:

"At a certain point in time, […] particularly at the end, it's too much of everything. […] I think at a certain point, we are like overwhelmed" (Mother of a 7-year-old participant). Regarding the experience with remote interventions, some participants reported that it resulted into an increased participation while others had no interest.

Theme 2: Perceived benefits of the program

The main perceived benefit of participating in the program was the improvement in their patient experience. The physical activity component in particular allowed children to have fun, get distracted from the treatment, and be busy during the long days at the hospital. Another important perceived benefit was receiving counselling and additional support to improve their health behaviours: *"If I had not seen the kinesiologists, I would probably not have had… well, had been willing to go back to practicing sports. And I would still be depressed. So, I would have just gotten worst. So, it really helped me"* (12-year-old participant).

Theme 3: Suggestions for improvement

Suggestions for program improvements were provided for each program component. For the physical activity component, it was suggested to have more material (e.g., stationary bikes) and more availability (i.e., every day of the week).

For the nutrition component, participants would have appreciated having group or individual kitchen activities. For the psychosocial component, more flexibility in the scheduling would have increased participation rate as it was offered near diagnosis, at a moment when many parents felt too overwhelmed, tired, or preoccupied to engage in the proposed intervention.

7.5.3 Functional assessments

Regarding feasibility, the functional assessments were conducted with 84.9% of eligible participants from the intervention group. Reasons for non-evaluation included no availability (n=4), refusal (n=3), or lost to follow-up (n=1). The multiple regression analysis revealed no significant difference between the intervention and control groups for motor ($p>0.05$) and cognitive abilities ($p>0.05$), after adjusting for age, sex, type of cancer, and time since end of treatment (see table 7.3). All 74 participants assessed had results for motor abilities and 31 participants ≥10 years old also had results for cognitive abilities. In the intervention group, 18 (40.0%) participants had motor abilities under the age norms (i.e., ≤15th percentile) and one (5.9%) for cognitive abilities. In the control group, 7 (24.1%) had motor abilities under the age norms (i.e., ≤15th percentile) and one (7.1%) for cognitive abilities.

Qualitative data showed that regarding the direct impact on the adverse effects of cancer or their functional outcome, some participants reported positive changes in their health, resulting from the participation in the program: *"It was giving me more energy. So I was less tired. It was easier to do my activities"* (13-year-old participant). One participant reported suffering less from fatigue and thus being able to go back to his daily activities faster than expected (e.g., attending the regular physical education courses at school). However, most participants did not see direct or indirect impact of the program on their health or functional outcome.

7.5.4 Integration

Table 7.4 shows a joint display of quantitative and qualitative results. Results from the interviews support and complement the quantitative results.

7.6 Discussion

This study aimed to assess a HP program's acceptability, to explore views of participants regarding the program, and to determine its potential effectiveness to improve the functional outcome of children or adolescents affected by cancer. Results show that the *VIE project* is acceptable and has a positive impact on patient experience among families affected with cancer during their cancer journey. Our study also demonstrated that using a functional outcome assessment

is feasible in this population, but no functional benefit for the group who received HP interventions in addition to standard care was found over standard care only. These results are supported by the qualitative data indicating that most participants could not really see the concrete benefits of the program on their health and functional outcome approximately two years after diagnosis.

In our cohort, 41.9% of participants < 10 years old assessed using the MABC-2 to measure motor performance showed impaired motor outcome, which is a greater proportion than what was reported in other studies that also used this standardised assessment and found that between 25 to 33 % of children affected by cancer scored below the 15th percentile (De Luca et al., 2013; Hartman et al., 2006; H. A. Reinders-Messelink et al., 1996). For the AMPS assessment, our results are similar to another study (Sabel et al., 2017) that did not report a significant difference between the intervention and control groups after testing the effects of a physically active video gaming on cognitive function and execution of activities of daily living among children 7-17 years old who completed treatment for a brain tumor 1 to 5 years earlier. The authors concluded that their intervention was not intense enough to have an effect on cognitive outcome measures, or that a longer intervention period would have been required to see a measurable effect (Sabel et al., 2017). Similarly, another study evaluating the effect of physical activity and

motivation-based interventions during leukemia treatments concluded that delivering the interventions at the level and intensity required to improve function may not be feasible during early treatment (Cox et al., 2018). In our study, it is also possible that the intensity of interventions was not sufficient or that a longer follow up would have been needed to see an impact on the functional outcome of participants. Furthermore, helping children and their family to make sense of their experience could help them to make more sustainable behaviour change and see the impact. This could be done by adding education or reflective sessions towards the end of the program. For example, a study evaluating the effect of a psychosocial support program for young adults who were cancer survivors that used a reflective activity on the observed effects of the seminar and its applicability (Pletschko et al., 2021).

A major strength of this study is the use of a mixed-method design, which allowed us to better understand why the outcome under study was not favorable. Qualitative studies are useful when trying to make sense of why promising clinical interventions do not always work in the real world or how patients experience care (Greenhalgh et al., 2016). Having the participants' feedback using qualitative data allowed us to explain further the results obtained quantitatively. Another strength is the use of a functional outcome assessment that evaluates both the physical

and cognitive outcomes, as few studies have evaluated the impact of health behaviours on survivors' cognitive abilities in task performance (Kunin-Batson, Klosky, Carlson-Green, & Brinkman, 2021).

This study also has some limitations that should be considered when interpreting the results. First, the groups were highly heterogeneous, the small sample size prevented us from doing subgroup analyses and the study was underpowered for the cognitive abilities as we only had results for participants ≥ 10 years old. Furthermore, participation rate for the functional outcome in the control group and for the acceptability questionnaire were low (35.4% and 56.6% respectively), which could have introduced a selection bias. Second, the design of the study only allowed us to compare the outcomes, rather than the change in the outcomes (i.e., pre-post design) and did not allow for double or single-blinding. The recruitment process also introduced a selection bias by attributing participants to a group according to criteria (i.e., treatment status at the time of the study), rather than using randomisation. Thus, the sample may not be representative of the population and the difference in the outcomes can be due to chance or group attrition, rather than the intervention itself. It is possible that families who have less functional impact at the end of their cancer treatment were more incline to participate in the control group. Finally, we have to acknowledge that the main outcome was broad

and may not have been sensitive to the expected change. Our experience and knowledge of the literature supports the use of outcomes that are as specific as possible to the target of the intervention (Kazak, 2005), in this case the change in health behaviours.

The results from this study are supportive of future work that could evaluate the program using a larger randomized design. Future research with a bigger sample size and rigorous methodology, such as an randomized controlled trial, is required to measure the impact of the program on children with cancer's functional outcome with less bias. In future studies, including a functional outcome would be important to prove that our innovative interventions are worth being implemented in clinical care as they can have a positive impact on outcomes that are meaningful to clinical practice and relevant to the target population, such as how their improved motor and cognitive skills allow them to better function in their day-to-day life.

7.7 Conclusion

The HP program was well-accepted and appreciated by families affected by cancer during their cancer journey, however it did not result in an improved functional outcome for the children or adolescents who received the program in addition to standard care. More research is needed to understand how such interventions

can lead to improvement in functional outcomes.

7.8 References

American Cancer Society. (2021). *Cancer Facts & Figures*. Atlanta: American Cancer Society (ACS)

Belanger, V., Delorme, J., Napartuk, M., Bouchard, I., Meloche, C., Curnier, D., . . . Marcil, V. (2022). Early Nutritional Intervention to Promote Healthy Eating Habits in Pediatric Oncology: A Feasibility Study. *Nutrients, 14*(5). doi:10.3390/nu14051024

Berg, C. J., Stratton, E., Giblin, J., Esiashvili, N., & Mertens, A. (2014). Pilot results of an online intervention targeting health promoting behaviors among young adult cancer survivors. *Psychooncology, 23*(10), 1196-1199. doi:10.1002/pon.3526

Braam, K. I., van der Torre, P., Takken, T., Veening, M. A., van Dulmen-den Broeder, E., & Kaspers, G. J. (2016). Physical exercise training interventions for children and young adults during and after treatment for childhood cancer. *Cochrane Database Syst Rev, 3*, CD008796. doi:10.1002/14651858.CD008796.pub3

Blake, H., Quirk, H., Leighton, P., Randell, T., Greening, J., Guo, B., & Glazebrook, C. (2016). Feasibility of an online intervention (STAK-D) to promote physical activity in children with type 1 diabetes: protocol for a randomised controlled trial. Trials, 17(1), 583. doi:10.1186/s13063-016-1719-0

Caru, M., Duhamel, G., Marcil, V., Sultan, S., Meloche, C., Bouchard, I., . . . Curnier, D. (2020). The VIE study: feasibility of a physical activity intervention in a multidisciplinary program in children with cancer. *Support Care Cancer, 28*(6), 2627-2636. doi:10.1007/s00520-019-05085-5

Cohen, J. E., Wakefield, C. E., & Cohn, R. J. (2016). Nutritional interventions for survivors of childhood cancer. *Cochrane Database Syst Rev*(8), CD009678. doi:10.1002/14651858.CD009678.pub2

Coombs, A., Schilperoort, H., & Sargent, B. (2020). The effect of exercise and motor interventions on physical activity and motor outcomes during and after medical intervention for children and adolescents with acute lymphoblastic leukemia: A systematic review. *Crit Rev Oncol Hematol, 152*, 103004. doi:10.1016/j.critrevonc.2020.103004

Cox, C. L., Zhu, L., Kaste, S. C., Srivastava, K., Barnes, L., Nathan, P. C., . . . Ness, K. K. (2018). Modifying bone mineral density, physical function, and quality of life in children with acute lymphoblastic leukemia. *Pediatr Blood Cancer, 65*(4). doi:10.1002/pbc.26929

De Luca, C. R., McCarthy, M., Galvin, J., Green, J. L., Murphy, A., Knight, S., & Williams, J. (2013). Gross and fine motor skills in children treated for acute lymphoblastic leukaemia. *Dev Neurorehabil, 16*(3), 180-187. doi:10.3109/17518423.2013.771221

Demers, C., Brochu, A., Higgins, J., & Gelinas, I. (2021). Complex behavioral interventions targeting physical activity and dietary behaviors in pediatric oncology: A scoping review. *Pediatr Blood Cancer*, e29090. doi:10.1002/pbc.29090

Demers, C., Gelinas, I., & Carret, A. S. (2016). Activities of Daily Living in Survivors of Childhood Brain Tumor. *Am J Occup Ther, 70*(1), 7001220040p7001220041-7001220048. doi:10.5014/ajot.2016.014993

Ellison, L. F., Xie, L., & Sung, L. (2021). *Trends in paediatric cancer survival in Canada, 1992 to 2017*. Statitics Canada

Fisher, A. G., & Jones, K. B. (2010). *Assessment of Motor and Process Skills* (7th ed. ed. Vol. Vol. 1: Development, Standardization, and Administration Manual). Fort Collins, CO: Three Star Press.

Gage H, G. L., Ting S, et al. Methods. . (2014). Specialist rehabilitation for people with Parkinson's disease in the community: a randomised controlled trial. In N. J. Library (Ed.), *Health Services and Delivery Research, No. 2.51*. Retrieved from Available from: https://www.ncbi.nlm.nih.gov/books/NBK263805/

Gerber, L. H., Hoffman, K., Chaudhry, U., Augustine, E., Parks, R., Bernad, M., . . . Mansky, P. (2006). Functional outcomes and life satisfaction in long-term survivors of pediatric sarcomas. *Arch Phys Med Rehabil, 87*(12), 1611-1617. doi:10.1016/j.apmr.2006.08.341

Green, S. B. (1991). How Many Subjects Does It Take To Do A Regression Analysis. *Multivariate Behav Res, 26*(3), 499-510. doi:10.1207/s15327906mbr2603_7

Greenhalgh, T., Annandale, E., Ashcroft, R., Barlow, J., Black, N., Bleakley, A., . . . Ziebland, S. (2016). An open letter to The BMJ editors on qualitative research. *BMJ, 352*, i563. doi:10.1136/bmj.i563

Hartman, A., Hop, W., Takken, T., Pieters, R., & van den Heuvel-Eibrink, M. (2013). Motor performance and functional exercise capacity in survivors of pediatric acute lymphoblastic leukemia. *Pediatr Blood Cancer, 60*(3), 494-499. doi:10.1002/pbc.24243

Hartman, A., te Winkel, M. L., van Beek, R. D., de Muinck Keizer-Schrama, S. M., Kemper, H. C., Hop, W. C., . . . Pieters, R. (2009). A randomized trial investigating an exercise program to prevent reduction of bone mineral density and impairment of motor performance during treatment for childhood acute lymphoblastic leukemia. *Pediatr Blood Cancer, 53*(1), 64-71. doi:10.1002/pbc.21942

Hartman, A., van den Bos, C., Stijnen, T., & Pieters, R. (2006). Decrease in motor performance in children with cancer is independent of the cumulative dose of vincristine. *Cancer, 106*(6), 1395-1401. doi:10.1002/cncr.21706

Henderson, S. E., Sugden, D. A., & Barnett, A. L. (2007). *Movement assessment battery for children-2: Movement ABC-2: Examiner's manual*: Pearson.

Hudson, M. M., Ness, K. K., Gurney, J. G., Mulrooney, D. A., Chemaitilly, W., Krull, K. R., . . . Robison, L. L. (2013). Clinical ascertainment of health outcomes among adults treated for childhood cancer. *JAMA, 309*(22), 2371-2381. doi:10.1001/jama.2013.6296

James, S., Ziviani, J., & Boyd, R. (2014). A systematic review of activities of daily living measures for children and adolescents with cerebral palsy. *Dev Med Child Neurol, 56*(3), 233-244. doi:10.1111/dmcn.12226

Janzen, L. A., & Spiegler, B. J. (2008). Neurodevelopmental sequelae of pediatric acute lymphoblastic leukemia and its treatment. *Dev Disabil Res Rev, 14*(3), 185-195. doi:10.1002/ddrr.24

Kandula, T., Farrar, M. A., Cohn, R. J., Mizrahi, D., Carey, K., Johnston, K., . . . Park, S. B. (2018). Chemotherapy-Induced Peripheral Neuropathy in Long-term Survivors of Childhood Cancer: Clinical, Neurophysiological, Functional, and Patient-Reported Outcomes. *JAMA Neurol, 75*(8), 980-988. doi:10.1001/jamaneurol.2018.0963

Kazak, A. E. (2005). Evidence-based interventions for survivors of childhood cancer and their families. *J Pediatr Psychol, 30*(1), 29-39. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/15610982

Knox, E., Glazebrook, C., Randell, T., Leighton, P., Guo, B., Greening, J., . . . Blake, H. (2019). SKIP (Supporting Kids with diabetes In Physical activity): Feasibility of a randomised controlled trial of a digital intervention for 9-12

year olds with type 1 diabetes mellitus. BMC Public Health, 19(1), 371. doi:10.1186/s12889-019-6697-1

Kunin-Batson, A. S., Klosky, J. L., Carlson-Green, B., & Brinkman, T. M. (2021). Health Behaviors and Neurocognitive Function in Survivors of Childhood Cancer. *J Clin Oncol, 39*(16), 1786-1794. doi:10.1200/JCO.20.02512

Lam, C. G., Howard, S. C., Bouffet, E., & Pritchard-Jones, K. (2019). Science and health for all children with cancer. *Science, 363*(6432), 1182-1186. doi:doi: 10.1126/science.aaw4892.

Malysse, C., Romero-Galisteo, R. P., Merchán-Baeza, J. A., Durán-Millán, J. I., González-Sánchez, M., & Galan-Mercant, A. (2021). Physical Activity Promotion Programmes in Childhood Cancer Patients and Their Impact on Fatigue and Pain: A Systematic Review. *Children 8*, 1119. doi:https://doi.org/10.3390/ children8121119

Morales, J. S., Valenzuela, P. L., Rincon-Castanedo, C., Takken, T., Fiuza-Luces, C., Santos-Lozano, A., & Lucia, A. (2018). Exercise training in childhood cancer: A systematic review and meta-analysis of randomized controlled trials. *Cancer Treat Rev, 70*, 154-167. doi:10.1016/j.ctrv.2018.08.012

National Academies of Sciences, E., and Medicine. (2021). *Childhood Cancer and Functional Impacts Across the Care Continuum.* . Washington, DC: The National Academies Press

Ness, K. K., Morris, E. B., Nolan, V. G., Howell, C. R., Gilchrist, L. S., Stovall, M., . . . Neglia, J. P. (2010). Physical performance limitations among adult survivors of childhood brain tumors. *Cancer, 116*(12), 3034-3044. doi:10.1002/cncr.25051

Nottage, K. A., Ness, K. K., Li, C., Srivastava, D., Robison, L. L., & Hudson, M. M. (2014). Metabolic syndrome and cardiovascular risk among long-term

survivors of acute lymphoblastic leukaemia - From the St. Jude Lifetime Cohort. *Br J Haematol, 165*(3), 364-374. doi:10.1111/bjh.12754

Ogez, D., Bourque, C. J., Péloquin, K., Ribeiro, R., Bertout, L., Curnier, D., . . . Sultan, S. (2019). Definition and improvement of the concept and tools of a psychosocial intervention program for parents in pediatric oncology: a mixed-methods feasibility study conducted with parents and healthcare professionals. *Pilot Feasibility Stud, 5*, 20. doi:10.1186/s40814-019-0407-8

Parks, R., Rasch, E. K., Mansky, P. J., & Oakley, F. (2009). Differences in activities of daily living performance between long-term pediatric sarcoma survivors and a matched comparison group on standardized testing. *Pediatr Blood Cancer, 53*(4), 622-628. doi:10.1002/pbc.22101

Payne, S., & Howell, C. (2005). An evaluation of the clinical use of the assessment of motor and process skills with children. . *Br J Occup Ther, 68*, 277-280.

Pletschko, T., Krottendorfer, K., Schlifelner, J., Schwarzinger, A., Fohn-Erhold, V., Weiler-Wichtl, L., . . . Leiss, U. (2021). A Psychosocial Support Program for Young Adult Childhood Cancer Survivors in Austria: a Qualitative Evaluation Study. *J Cancer Educ*. doi:10.1007/s13187-021-02083-2

Reinders-Messelink, H., Schoemaker, M., Snijders, T., Goeken, L., van Den Briel, M., Bokkerink, J., & Kamps, W. (1999). Motor performance of children during treatment for acute lymphoblastic leukemia. *Med Pediatr Oncol, 33*(6), 545-550. doi:10.1002/(sici)1096-911x(199912)33:6<545::aid-mpo4>3.0.co;2-y

Reinders-Messelink, H. A., Schoemaker, M. M., Hofte, M., Goeken, L. N., Kingma, A., van den Briel, M. M., & Kamps, W. A. (1996). Fine motor and handwriting problems after treatment for childhood acute lymphoblastic

leukemia. *Med Pediatr Oncol, 27*(6), 551-555. doi:10.1002/(SICI)1096-911X(199612)27:6<551::AID-MPO8>3.0.CO;2-K

Sabel, M., Sjolund, A., Broeren, J., Arvidsson, D., Saury, J. M., Gillenstrand, J., . . . Lannering, B. (2017). Effects of physically active video gaming on cognition and activities of daily living in childhood brain tumor survivors: a randomized pilot study. *Neurooncol Pract, 4*(2), 98-110. doi:10.1093/nop/npw020

Schulz, J., Henderson, S. E., Sugden, D. A., & Barnett, A. L. (2011). Structural validity of the Movement ABC-2 test: factor structure comparisons across three age groups. *Res Dev Disabil, 32*(4), 1361-1369. doi:10.1016/j.ridd.2011.01.032

Sekhon, M., Cartwright, M., & Francis, J. J. (2017). Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res, 17*(1), 88. doi:10.1186/s12913-017-2031-8

Shin, H., Bartlett, R., & De Gagne, J. C. (2019). Health-Related Quality of Life Among Survivors of Cancer in Adolescence: An Integrative Literature Review. *J Pediatr Nurs, 44*, 97-106. doi:10.1016/j.pedn.2018.11.009

Stern, M., Bleck, J., Ewing, L. J., Davila, E., Lynn, C., Hale, G., & Mazzeo, S. (2018). NOURISH-T: Targeting caregivers to improve health behaviors in pediatric cancer survivors with obesity. *Pediatr Blood Cancer, 65*(5), e26941. doi:10.1002/pbc.26941

Valentini, N. C., Ramalho, M. H., & Oliveira, M. A. (2014). Movement assessment battery for children-2: translation, reliability, and validity for Brazilian children. *Res Dev Disabil, 35*(3), 733-740. doi:10.1016/j.ridd.2013.10.028

World Health Organization. (2008). *Behaviour change strategies and health: the role of health systems.* . Tbilisi, Georgia: World Health Organization (WHO)

Wu, L. M., Chen, C. M., Hsu, H. T., Liu, Y., & Su, H. L. (2019). Tailored education enhances healthy behaviour self-efficacy in childhood cancer survivors: A randomised controlled study with a 4-month follow-up. *Eur J Cancer Care (Engl), 28*(4), e13063. doi:10.1111/ecc.13063

Wuang, Y. P., Su, C. Y., & Huang, M. H. (2012). Psychometric comparisons of three measures for assessing motor functions in preschoolers with intellectual disabilities. *J Intellect Disabil Res, 56*(6), 567-578. doi:10.1111/j.1365-2788.2011.01491.x

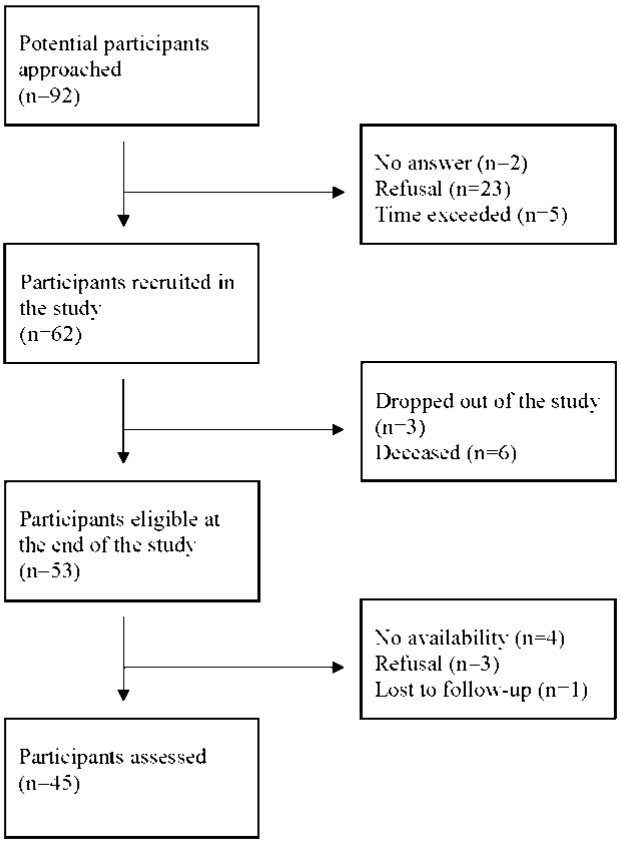

Figure 7.1 Flow chart of participants in the intervention group

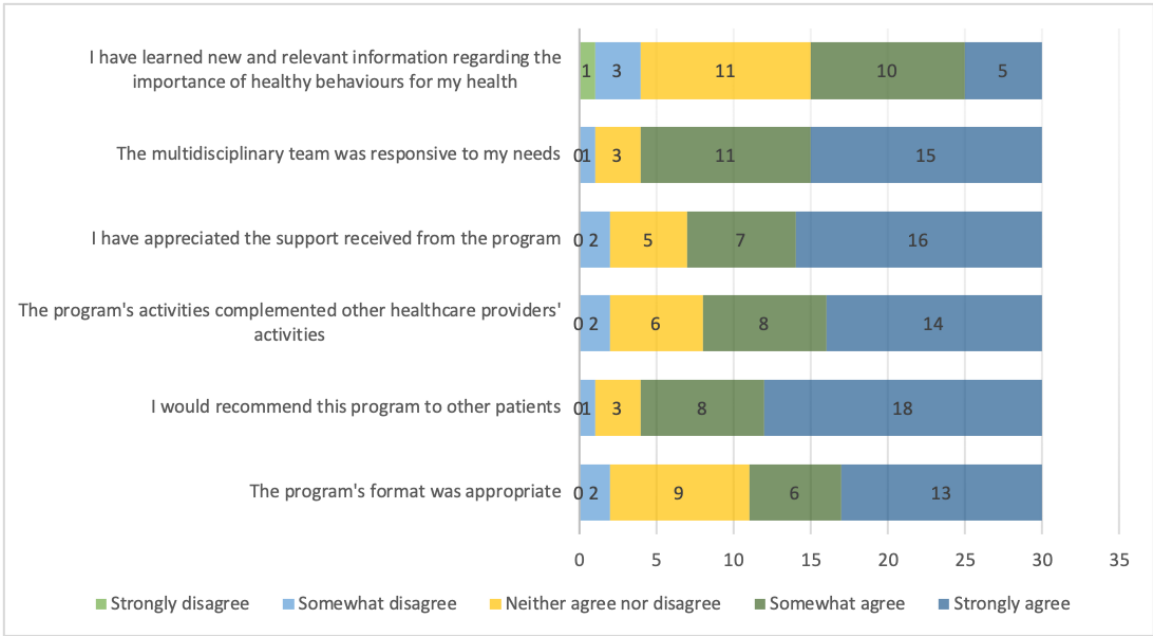

Figure 7.2 Acceptability questionnaire

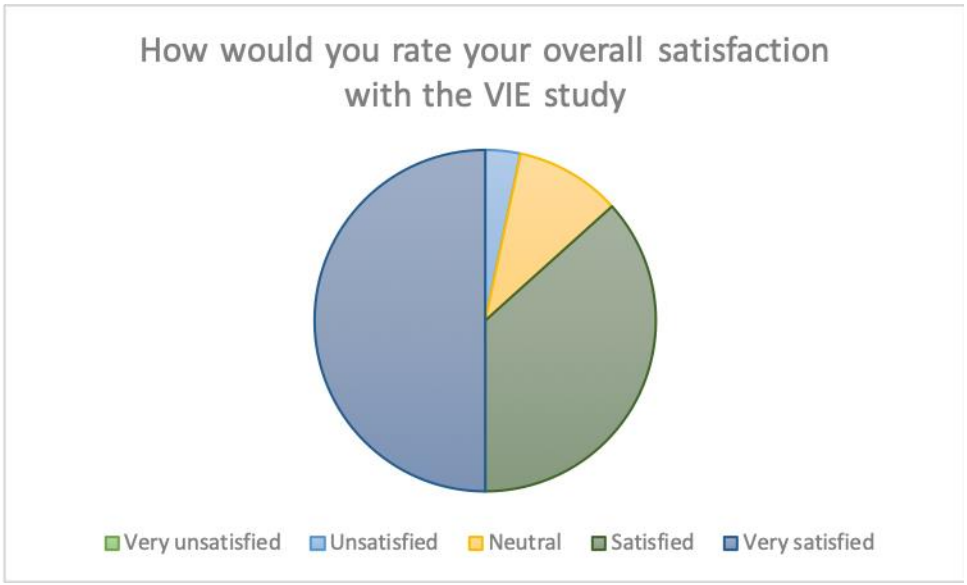

Figure 7.3 Participants' satisfaction level in the program

Table 7.1 Characteristics of the study participants (n=74)

Characteristics	Intervention group (n=45) *n (%) or median (range)*	Control group (n=29) *n (%) or median (range)*	Whitman-U or X^2 intervention vs. control group	*p*
Sex				
Male	24 (53.3)	12 (41.4)	1.01	0.32
Female	21 (46.7)	17 (58.6)		
Type of cancer				
Leukemia	23 (51.1)	13 (44.8)	0.28	0.60
Other	22 (48.9)	16 (55.2)		
Age at dx (years)	8 (3-18)	7 (4-18)	626	0.76
Time since diagnosis (months)	28 (20-48)	28 (18-47)	618	0.70
Time since end of treatments (months)	16 (0-31)	10 (0-23)	421	0.01

Table 7.2 Characteristics of interviewed participants

Characteristics	Adolescents (n=6) median (range) or n (%)	Parents (n=12) median (range) or n (%)
Age of the child or adolescents (years)	13.5 (13-17)	10.5 (5-17)
Sex		
Male	3 (50.0)	2 (17)
Female	3 (50.0)	10 (83)
Race/ethnicity		
White/Caucasian	6 (100.0)	12 (100.0)
Other	0 (0.0)	0 (0.0)
Type of cancer		
Leukemia	4 (60.0)	5 (41.7)
Lymphoma	1 (20.0)	2 (16.7)
Central Nervous System Tumors	0 (0.0)	2 (16.7)
Extra cranial solid tumor	1 (20.0)	3 (25.0)
Education level		
Unfinished high school	N/A	2 (16.7)
High school or professional school		6 (50.0)
University, Bachelor degree		4 (33.3)
University, Graduate degree		0 (0)

Table 7.3 Functional outcome

	Intervention group *mean (SD)*	Control group *mean (SD)*	F	p
Motor skills (n=74)	29.8 (30.6)	47.8 (34.0)	1.64	0.15
Process skills (n=31)	44.0 (26.7)	65.4 (28.9)	1.90	0.12

*Models adjusted for age, sex, type of cancer, and time since end of treatment

Table 7.4 Joint display of results

Quantitative results	Qualitative results
Acceptability and view of the program	
50.0% of participants reported that they did not learn new and relevant information (neither agree nor disagree; somewhat disagree; or strongly disagree)	“It was very nice, but what I would have liked, would be to have had more explanation” (Mother of a 5-year-old participant)
86.7% of participants reported that they would recommend the program to other patients (somewhat agree or strongly agree) and 86.7% that they were satisfied (satisfied or very satisfied)	“Honestly, I think that a lot of children could benefit from that. Especially during a pandemic when you can’t get out of your room. It was important” (Mother of a 7-year-old participant)

	“I hope that it continues. […] I wish it for the children, I wish it very much because, because it helps” (Mother of a 7-year-old).
76.7% of participants appreciated the support provided by the program (somewhat agree or strongly agree)	“We feel supported, through the years, the two year of treatment. You know, when we have questions, they can counsel us a little.” (Mother of a 13-year-old participant) “Personally, I want to say a big thank you to the team that has shown adaptation skills and remarkable flexibility, and that, we have appreciated it a lot” (Father of a 13-year-old participant)
Functional outcome	
No significant difference for motor abilities, between intervention and control group ($p>0.05$)	“I cannot say there has been a major impact. Of course it is always good to have alternatives on the side you can take, especially when you are going through an illness” (Father of a 8-year-old participant) “Not really improved my [fitness] because I haven’t done enough [physical activity interventions] to

	really be able to say something about that" (17-year-old participant)
No significant difference for cognitive abilities, between intervention and control group ($p>0.05$)	"The doctor tells us, that some can develop… because they take so much medications, attention deficits disorders or something else, so maybe more exercises regarding concentration, it would have been, well in my case, I would have appreciated it" (Mother of a 5-year-old participant)

CHAPTER 8: DISCUSSION & CONCLUSION

8.1 Summary of findings

The overall aim of the thesis was to contribute to the program evaluation of the *VIE project,* a health promotion (HP) program consisting of complex behavioural interventions (CBI) across the cancer trajectory in a pediatric oncology clinical context. The main objective of the thesis unfolded into three specific objectives, that is to conduct a scoping review as well as a process evaluation and an outcome evaluation of the *VIE project*. The scoping review allowed us to situate our own study in the context of the existing literature and was a preliminary step towards establishing best-practice guidelines and further advance research in the field. Evaluating the process of implementation and preliminary outcomes of an innovative HP program such as the *VIE project* was a first step toward encouraging HP in pediatric oncology. This doctoral work was operationalized in three distinct manuscripts. The first manuscript consists of a scoping review report on the extent of what is known on the use of complex behavioural interventions (CBI) or multimodal programs addressing physical activity and diet behaviour for children affected by cancer or survivors of childhood cancer and their reported findings. The second manuscript addresses the process evaluation of the HP program by

determining the factors influencing i) the participation in the program from the perspectives of children affected by cancer and their families, and ii) the implementation of the program from the perspective of healthcare professionals (HCPs). Finally, the third manuscript addresses the outcome evaluation by assessing the program's acceptability from the perspective of families affected by cancer and by estimating the extent to which interventions received through the VIE project in addition to standard care led to an improved functional outcome (i.e., performance in activities of daily living), compared to standard care only.

Manuscript 1 sheds light on the dominant areas of research as well as gaps in the literature in terms of target population, intervention type and outcomes for CBI targeting PA and/or dietary behaviours in pediatric oncology. The studies included in the scoping review demonstrated that it is feasible to implement CBI in pediatric oncology and that they can potentially improve PA and dietary behaviours as well as patient outcomes such as physical and psychological health. Unfortunately, due to a paucity and heterogeneity of the studies included in this review in terms of population, type of interventions, and outcomes, no conclusive evidence favouring specific interventions were identified. Gaps in the literature include studies in younger children and patients still undergoing cancer treatment. Suggestions for studies in the field included incorporating mixed methods or qualitative

components in studies, implementing programs of longer duration, and using reliable and standardized outcome measures.

Manuscript 2 reports on a process evaluation of the *VIE project* that offers important insights into essential elements for success, as well as the challenges of implementing CBI in a pediatric oncology clinical context. Factors that hampered or facilitated the participation in or implantation of the *VIE project* were provided by study participants and HCPs. Key facilitators were identified by study participants and HCPs that were critical for success: the fact that the HP interventions were filling a clinical gap, the tailoring of interventions to individual needs, and social support. Time conflicts or other organizational constraints and lack of communication or collaboration between the research and clinical team were the main barriers to participation and implementation. Both groups provided suggestions for improvements that will be used to refine the program. Moving forward, future implantation of the program should consider the following changes, among others: adding different types of interventions such as group activities, educational workshops, and online PA exercise programs, identifying one reference person to facilitate communication and to provide more information on the purpose of the program, allowing more flexibility and tailoring in the dosage and timing of interventions, minimizing intervention burden, providing on-going

training and support to the research team, and better integrating interventions in clinical care. More details can be found in Appendix IV.

The general conclusion from Manuscript 3 is that conducting a program consisting of CBI in a pediatric oncology clinical context is acceptable to families of children affected by cancer and has a positive impact on patient experience. However, in our study, no benefits were found for the children's functional outcome between participants of the study who received HP interventions addition to standard care and children who received standard care only.

8.2 Discussion and clinical implications

8.2.1 Implications for children or adolescents affected by cancer and their families

One of the purposes of the studies presented in this thesis was to identify ways to improve the *VIE project* for future implementation locally and in different clinical settings. Another purpose was to document implementation and lessons learned to facilitate the widespread adoption of HP interventions or programs in pediatric oncology. Following steps would consist in refining the proposed interventions and testing them again using appropriate and rigorous scientific methodologies (e.g., randomized controlled trial, mixed methods). Ultimately, once the refined *VIE*

project is proven effective in a clinical trial, it could be implemented locally in a sustainable manner and exported to other pediatric cancer centers to improve health outcomes and quality of life of children or adolescents affected by cancer. Consequently, a greater number of children and adolescents affected by cancer will be able to experience the benefits of adopting and maintaining health behaviour practices across the cancer continuum. In Manuscript 2, the results indicated that the families affected by cancer considered that participating in the *VIE project* improved their patient experience and that they felt supported throughout the difficult journey of experiencing pediatric cancer treatments. According to the Institute for Healthcare Improvement, one of the "Triple Aim" recommended for health interventions, in addition to improving health of populations and lowering the per capita costs, is to improve the experience of care [170]. We are therefore confident that upscaling the implementation of a refined *VIE project* to other pediatric cancer centers will benefit children or adolescents affected by cancer and their families by improving their care experience during cancer treatment as well as their health, function, and quality of life, from cancer diagnosis to long-term survivorship.

8.2.2 Implications for the implementation of HP interventions in pediatric oncology rehabilitation: Lessons learned and key considerations moving forward

The manuscripts included in this thesis are critical to advance knowledge in the field and spur changes to clinical practice in pediatric oncology rehabilitation. This work can help build the growing body of evidence needed to continually move the field of pediatric oncology rehabilitation forward. As rehabilitation professionals, we want to deepen our understanding on how children and adolescents function during and after pediatric cancer as well as how rehabilitation services can contribute to achieving the best outcomes possible. More specifically, this thesis is an opportunity to share knowledge and strategies for organizations interested in incorporating tertiary prevention and HP interventions or programs to improve their practice. This section is organized around several practical strategies for future HP and lessons that could guide clinical practice.

We need a shift towards multidimensional pediatric oncology rehabilitation programs

Historically, pediatric cancer rehabilitation consisted mainly of impairment-specific interventions during cancer treatments to restore, remediate, or improve specific changes in physical or cognitive functions. Rehabilitation interventions have great

potential to mitigate the impact of cancer and its treatment such as developmental delays or loss of function. Current literature suggests that cancer and related treatments can cause a wide range of persistent and distressing activity limitations and participation restrictions during, but also after, cancer. Therefore, rehabilitative interventions can also focus on reducing long-term morbidity. The future of pediatric cancer rehabilitation may lie in broader considerations of rehabilitative interventions that incorporate HP interventions to improve functional performance and quality of life. Such a model of rehabilitation programs exist in adult oncology, for example for women with breast cancer [171], but have yet to be developed and implemented in pediatric oncology. As pointed out by HCPs in Manuscript 2, the interventions proposed in the *VIE project* were relevant for the target population and filling an important clinical gap in the clinic.

> *Early health promotion interventions are important and should be integrated in pediatric rehabilitation oncology, but it may not always be realistic early in the cancer care continuum.*

In a complex setting like pediatric oncology, one must consider that children and their families can be overwhelmed with the illness experience and might not be physically, cognitively, or emotionally available for interventions that do not

address their short-term survival. This unavailability might be especially exacerbated at the time of diagnosis and during the acute phase of treatment. Even though we know that early interventions can lead to better outcomes, the manuscripts of this thesis point to how it is not always realistic from the perspective of families affected by cancer and HCPs. Both families and HCPs have identified intervention burden as a barrier to participation. Furthermore, changes in behaviour often require long-term interventions. It is not because an individual shows no interest or motivation at one point in time that it will never work. For example, some parents who declined participation in one of the study components (e.g., psychosocial support at the beginning of cancer continuum) mentioned they would have been interested in participating later in the continuum. It is important for HCPs to meet each individual where they are on the behaviour change cycle and allow enough time to process [172]. Thus, long-term interventions should be favoured and flexibility in the dosage and timing of the interventions should be allowed to meet each individual's needs and response. It has also been reported in studies that recruiting survivors of childhood cancer can be difficult as families are trying to forget their cancer experience and to move forward by creating a new normal [173]. Therefore, HP interventions should be initiated during cancer treatment, but after the initial shock of cancer diagnosis and adjustment to treatments. Further, interventions-deliverers should remain as stable as possible

during intervention period to favor therapeutic relationship and the trust with the clinical team.

Rehabilitation professionals play a crucial role to promote the health of children affected by cancer, but as interdisciplinary team members.

To provide comprehensive oncology rehabilitation services, specialists trained in multiple disciplines are required [21]. Especially in HP, we must keep interdisciplinarity and interprofessional collaboration (IPC) in mind. In fact, to meet the complex needs of clients, IPC and education are viewed as the best path forward [174]. Various health disciplines, clinicians, or researchers, must partner to provide coordinated care. Health behaviours are best promoted if they come from more than one health professional; it needs to be a team effort, including but not limited to occupational therapists, physiotherapists, exercise specialists, nutritionists, psychologists, and nurses. In addition to improving health outcomes and client satisfaction [175], collaborative care promotes sustainable programs [176]. There is growing evidence from the literature that rehabilitation interventions [171], PA interventions [177], and nutrition interventions [178] in oncology are more effective if delivered by an interdisciplinary team of health professionals. The various professions have complementary skillsets that, when well-integrated

together and working as a team, can optimize patient care in cancer rehabilitation [177]. The results in Manuscript 2 underscore the challenges of integrating new interventions and working as a team, in synergy. However, it is necessary and there needs to be a cultural shift in pediatric oncology departments supported by all HCPs and care providers to look beyond survivorship and to promote the well-being and health of all children or adolescents affected by cancer and their families.

> *Participating in health promotion interventions during cancer care is* ***important****. However, in order for the interventions to spur changes, it also has to be* ***meaningful*** *for the families affected by cancer.*

We must not think that families affected by cancer will understand how important it is to make changes in their life or will make the changes just because a professional told them to or because they participated in PA interventions or received nutritional counseling. As one parent mentioned during the interviews, she does not think that her child will 'subconsciously' know she has to move more and stay active in the long term just because she participated in some PA activities during her cancer treatments. Finding meaning and value in an activity or occupation is conveyed as essential aspect of engagement in this activity or

occupation [179]. As professionals, we have to help individuals make sense of the experience and to take the time to educate them properly. Some practical strategies that can be used are to set realistic, collaborative goals that will be revised periodically, to use educational activities while considering the "teachable moment" ([180],p.156), when participants are available to receive and process the information, and to include reflective activities to address the experience, probably during the survivorship phase, to guide their future.

Changing behaviours is hard.

H. L. Mencken, a famous cultural critic, once said that for every complex problem there is an answer that is clear, simple – and wrong ([181],p.158*)*. There is, truly, no simple answer to how we can help families affected by cancer make sustainable changes to their health behaviours for the better. Due to the complex nature of their disease, treatments, and the many barriers faced by this population, complex interventions are required to successfully change health behaviours [182, 183]. It is important to adopt targeted, evidence-based strategies. Each individual and family has a different background, different needs. Keys to success are tailored, individualized, and age-appropriate interventions that target and address both intrinsic and environmental factors (e.g., psychological factors, cognitive deficits,

etc.). Practical recommendations that emerged from the studies in this thesis include using a different approach according to age and diagnosis of the participants, and to offer options (e.g., in-person vs virtual, intensity of follow-ups, etc.). Strategies grounded in psychosocial research and health behaviour theories are also needed [184], such as a training in motivational interviews, to address the psychological determinants of behaviour [185]. As stated by the National Cancer Institute in their guide for health promotion practice, *'interventions based on health behaviour theory are not guaranteed to succeed, but they are much more likely to produce desired outcomes'* ([186],p.1). Interventions including behavioural, cognitive, and/or social support components, such as in-vivo exercise training, psychoeducation, self-monitoring, behavioral reinforcement or including family members or friends, may better promote sustainable behaviour [187] resulting in better short- and long-term outcome. Finally, targeting the family unit and including significant others may increase the change of favorable outcomes as social support has been identified as a key facilitator in changing behaviours.

8.3 Limitations

While this project provided a review on the state of the evidence on the use and effects of CBI targeting PA and/or dietary behaviours in pediatric oncology and contributed to the program evaluation of the *VIE project*, an innovative HP

program, there are a few limitations that should be acknowledged. Firstly, cautiousness is warranted when interpreting the results and trends in the data from the functional outcome in Manuscript 3 as it was not the intent to test this outcome in the initial *VIE project*. Rather, the goal was to test the feasibility and acceptability of the program in our clinical context. Furthermore, although clinically relevant, the functional outcome evaluated in this study was not directly related to the goals and targets of the interventions and we have to consider that complex interventions have a wide spread and person-varying effects which may not be best represented by the changes on a single outcome variable [188].

Secondly, there might be some selection bias in our study population. In the intervention group, it is possible that our participants had more positive beliefs and attitudes towards adopting healthy behaviours and participating in HP interventions than non-participants. Families who were more interested in HP were more likely to enrol in the study in the beginning, and more likely to have participated in the interviews and assessments. In the control group, it is possible that families of children or adolescents who had fewer adverse effects of cancer were more willing to participate than more affected families and, therefore, may have biased our results.

Thirdly, the design of the study had shortcomings. To allow all new children who were diagnosed to benefit from the *VIE project*, we recruited the control group from patients who had already finished their treatments and the intervention group from newly diagnosed patients; therefore, we did not use randomisation for group distribution. Furthermore, the heterogeneity of the target population, which comprises children of various ages, diagnoses, and treatments, was a challenge for both the interventions and the assessments. The interventions greatly varied from one participant to the other and we had to use two different assessment measures for the functional outcome, one for the younger participants and another one for the older participants. Both assessments were using the same scale (i.e., percentile), but they did not measure exactly the same constructs.

Lastly, it must be acknowledged that this study solely included participants from one hospital so that findings cannot be generalized to the population of pediatric cancer patients and healthcare professionals working in pediatric oncology. It may also not be applicable to other pediatric oncology settings, where culture, health service organisation, staffing, or resources may vary from ours.

8.4 Directions for future studies

This thesis fits into the larger context of the program evaluation of the *VIE project*, which was implemented as a feasibility study. The results from this study are supportive of future work that could evaluate the program using a larger, randomized design. Future research with a higher a number of participants and rigorous methodology is required to measure the impact of the program on children and adolescents affected by cancer's various outcomes (i.e., health behaviours, health outcomes, functional outcome, and quality of life).

However, one important step before conducting a larger trial would be to refine the interventions according to the feedback received from families affected by cancer and HCPs. Circling back to the CIPP Model for program evaluation introduced in Chapter 4, the underlying theme of this thesis was not to prove, but to improve the program. Furthermore, the results suggest that, in order to be successful and well accepted, the program needs to foster effective partnerships between researchers, clinicians, and the target population. In future work, researchers must work in close collaboration with the clinical team to develop and implement innovative interventions, and to evaluate their impact on behavioural and health outcomes as this may be a key determinant of scalability. This study also proved that delivering evidence-based HP interventions or programs and prescription of healthy

behaviours are not enough to generate sustainable behaviour change that will have a positive impact on health, functional outcome, and quality of life. One key element is to help children or adolescents affected by cancer and families make sense of their experience. Another key element will be to work on the positive attitude towards HP and the involvement of all HCPs to create a culture change in the pediatric oncology setting, so that the HP message is ubiquitous.

Regarding methodology, our results highlighted the importance of process evaluation and support the use of mixed methods when evaluating innovative programs for vulnerable populations to ensure they are acceptable in real-life, clinical context. This information can be useful to design or implement interventions in new sites by taking advantage of this new knowledge created, our experience, and lessons learned.

Finally, more studies are required in the area of tertiary prevention and rehabilitation in pediatric oncology to find ways to optimize children affected by cancer and survivors' functional outcome and quality of life.

8.5 Final conclusion and summary

In summary, by conducting a scoping review, a process evaluation, and an

outcome evaluation during the implementation of the *VIE project*, an innovative HP program in pediatric oncology, we were able to contribute to its program evaluation. The results of the studies included in this thesis support the integration of HP interventions to pediatric rehabilitation oncology services. This doctoral project also provides guidance for clinical practice by informing rehabilitation specialists on the most effective way to approach HP in this population.

REFERENCES

1. Alvarez, J.A., et al., *Long-term effects of treatments for childhood cancers.* Curr Opin Pediatr, 2007. **19**(1): p. 23-31.
2. Bottomley, S.J. and E. Kassner, *Late effects of childhood cancer therapy.* J Pediatr Nurs, 2003. **18**(2): p. 126-33.
3. Hong, H.C., A. Min, and Y.M. Kim, *A systematic review and pooled prevalence of symptoms among childhood and adolescent and young adult cancer survivors.* J Clin Nurs, 2022.
4. Dickerman, J.D., *The late effects of childhood cancer therapy.* Pediatrics, 2007. **119**(3): p. 554-68.
5. Galligan, A.J., *Childhood Cancer Survivorship and Long-Term Outcomes.* Adv Pediatr, 2017. **64**(1): p. 133-169.
6. Landier, W., S. Armenian, and S. Bhatia, *Late effects of childhood cancer and its treatment.* Pediatr Clin North Am, 2015. **62**(1): p. 275-300.
7. Marcoux, S., et al., *The PETALE study: Late adverse effects and biomarkers in childhood acute lymphoblastic leukemia survivors.* Pediatr Blood Cancer, 2017. **64**(6).
8. Levy, E., et al., *Cardiometabolic Risk Factors in Childhood, Adolescent and Young Adult Survivors of Acute Lymphoblastic Leukemia - A Petale Cohort.* Sci Rep, 2017. **7**(1): p. 17684.
9. CHU Ste-Justine. *Le Projet VIE : Valorisation - Implication - Éducation*. 2021; Available from: https://www.chusj.org/fr/soins-services/H/Hematologie/Projet-Vie.
10. Brier, M.J., L.A. Schwartz, and A.E. Kazak, *Psychosocial, health-promotion, and neurocognitive interventions for survivors of childhood cancer: a systematic review.* Health Psychol, 2015. **34**(2): p. 130-48.

11. Canadian Cancer Society. *Childhood cancer statistics*. 2021 [cited 2021 August 25th]; Available from: https://www.cancer.ca/en/cancer-information/cancer-101/childhood-cancer-statistics/?region=nl.
12. Ellison, L.F., L. Xie, and L. Sung, *Trends in paediatric cancer survival in Canada, 1992 to 2017*. 2021, Statistics Canada.
13. Gatta, G., et al., *Childhood cancer survival in Europe 1999-2007: results of EUROCARE-5--a population-based study.* Lancet Oncol, 2014. **15**(1): p. 35-47.
14. Ward, E., et al., *Childhood and adolescent cancer statistics, 2014.* CA Cancer J Clin, 2014. **64**(2): p. 83-103.
15. Canadian Cancer Society, *Canadian Cancer Statistics 2019*, S. Canada, Editor. 2019, Canadian Cancer Society: Toronto, Ontario.
16. Reaman, G.H., *Pediatric cancer research from past successes through collaboration to future transdisciplinary research.* J Pediatr Oncol Nurs, 2004. **21**(3): p. 123-7.
17. American Cancer Society, *Cancer Facts & Figures 2016*. 2016, American Cancer Society: Atlanta, GA.
18. Canadian Cancer Society, *Childhood Cancer Statitstics*. 2011. p. p. 63-79.
19. Ruland, C.M., G.A. Hamilton, and B. Schjodt-Osmo, *The complexity of symptoms and problems experienced in children with cancer: a review of the literature.* J Pain Symptom Manage, 2009. **37**(3): p. 403-18.
20. World Health Organization, *Towards a Common Language for Functionary, Disability and Health: ICF Beginner's Guide*. 2002, WHO Press: Geneva, Switzerland.
21. Tanner, L., et al., *Cancer Rehabilitation in the Pediatric and Adolescent/Young Adult Population.* Semin Oncol Nurs, 2020. **36**(1): p. 150984.
22. Erickson, J.M., et al., *Symptoms and symptom clusters in adolescents receiving cancer treatment: a review of the literature.* Int J Nurs Stud, 2013. **50**(6): p. 847-69.

23. Kestler, S.A. and G. LoBiondo-Wood, *Review of symptom experiences in children and adolescents with cancer.* Cancer Nurs, 2012. **35**(2): p. E31-49.
24. Miller, E., E. Jacob, and M.J. Hockenberry, *Nausea, pain, fatigue, and multiple symptoms in hospitalized children with cancer.* Oncol Nurs Forum, 2011. **38**(5): p. E382-93.
25. Ameringer, S., et al., *Symptoms and Symptom Clusters Identified by Adolescents and Young Adults With Cancer Using a Symptom Heuristics App.* Res Nurs Health, 2015. **38**(6): p. 436-48.
26. Ameringer, S., Elswick, R. K., Jr., Shockey, D. P., & Dillon, R. *A pilot exploration of symptom trajectories in adolescents with cancer during chemotherapy*, 2013. Cancer Nurs, **36**(1): p.60-71.
27. Rodgers, C., et al., M. Children's coping strategies for chemotherapy-induced nausea and vomiting. Oncol Nurs Forum, 2012. 39(2): p. 202-209.
28. Tomlinson, D., et al., *The lived experience of fatigue in children and adolescents with cancer: a systematic review.* Support Care Cancer, 2016. **24**(8): p. 3623-31.
29. Hockenberry-Eaton, M. and P.S. Hinds, *Fatigue in children and adolescents with cancer: evolution of a program of study.* Semin Oncol Nurs, 2000. **16**(4): p. 261-72; discussion 272-8.
30. Park, S.B., et al., *Chemotherapy-induced peripheral neurotoxicity: a critical analysis.* CA Cancer J Clin, 2013. **63**(6): p. 419-37.
31. Kandula, T., et al., *Pediatric chemotherapy induced peripheral neuropathy: A systematic review of current knowledge.* Cancer Treat Rev, 2016. **50**: p. 118-128.
32. Skeens, M.A., et al., *Perspectives of Childhood Cancer Symptom-Related Distress: Results of the State of the Science Survey.* J Pediatr Oncol Nurs, 2019. **36**(4): p. 287-293.

33. Board, P.P.T.E. *PDQ Late Effects of Treatment for Childhood Cancer.* . 2021 [cited 2021 02/12]; Available from: Available at: https://www.cancer.gov/types/childhood-cancers/late-effects-pdq. .
34. Friedman, D.L., et al., *Subsequent neoplasms in 5-year survivors of childhood cancer: the Childhood Cancer Survivor Study.* J Natl Cancer Inst, 2010. **102**(14): p. 1083-95.
35. Oeffinger, K.C., P.C. Nathan, and L.C. Kremer, *Challenges after curative treatment for childhood cancer and long-term follow up of survivors.* Hematol Oncol Clin North Am, 2010. **24**(1): p. 129-49.
36. Hudson, M.M., et al., *Clinical ascertainment of health outcomes among adults treated for childhood cancer.* JAMA, 2013. **309**(22): p. 2371-2381.
37. Gibson, T.M. and L.L. Robison, *Impact of Cancer Therapy-Related Exposures on Late Mortality in Childhood Cancer Survivors.* Chem Res Toxicol, 2015. **28**(1): p. 31-7.
38. American Academy of Pediatrics Section on Hematology/Oncology Children's Oncology Group, *Long-term follow-up care for pediatric cancer survivors.* Pediatrics, 2009. **123**(3): p. 906-15.
39. Pluijm, S.M.F., *Accelerated Aging as a Paradigm to Understand the Late Effects of Cancer Therapies.* Front Horm Res, 2021. **54**: p. 16-24.
40. Yeh, J.M., et al., *Life Expectancy of Adult Survivors of Childhood Cancer Over 3 Decades.* JAMA Oncol, 2020. **6**(3): p. 350-357.
41. Armstrong, G.T., et al., *Aging and risk of severe, disabling, life-threatening, and fatal events in the childhood cancer survivor study.* J Clin Oncol, 2014. **32**(12): p. 1218-27.
42. Armstrong, G.T., *Long-term survivors of childhood central nervous system malignancies: the experience of the Childhood Cancer Survivor Study.* Eur J Paediatr Neurol, 2010. **14**(4): p. 298-303.
43. Gocha Marchese, V., L.A. Chiarello, and B.J. Lange, *Strength and functional mobility in children with acute lymphoblastic leukemia.* Med Pediatr Oncol, 2003. **40**(4): p. 230-2.

44. American Cancer Society, *Cancer facts & figures*. 2014, American Cancer Society Atlanta.
45. Qaddoumi, I., et al., *Carboplatin-associated ototoxicity in children with retinoblastoma.* J Clin Oncol, 2012. **30**(10): p. 1034-41.
46. Mulrooney, D.A., et al., *Cardiac Outcomes in Adult Survivors of Childhood Cancer Exposed to Cardiotoxic Therapy: A Cross-sectional Study.* Ann Intern Med, 2016. **164**(2): p. 93-101.
47. Meacham, L.R., et al., *Cardiovascular risk factors in adult survivors of pediatric cancer--a report from the childhood cancer survivor study.* Cancer Epidemiol Biomarkers Prev, 2010. **19**(1): p. 170-81.
48. Barnea, D., et al., *Obesity and Metabolic Disease After Childhood Cancer.* Oncology (Williston Park), 2015. **29**(11): p. 849-55.
49. Diller, L., et al., *Chronic disease in the Childhood Cancer Survivor Study cohort: a review of published findings.* J Clin Oncol, 2009. **27**(14): p. 2339-55.
50. van Deuren, S., et al., *Prevalence and risk factors of cancer-related fatigue in childhood cancer survivors: A DCCSS LATER study.* Cancer, 2021.
51. Phillips, N.S., et al., *Neurotoxic Effects of Childhood Cancer Therapy and Its Potential Neurocognitive Impact.* J Clin Oncol, 2021. **39**(16): p. 1752-1765.
52. Conklin, H.M., et al., *Acute neurocognitive response to methylphenidate among survivors of childhood cancer: a randomized, double-blind, cross-over trial.* J Pediatr Psychol, 2007. **32**(9): p. 1127-39.
53. Duffner, P.K., *Risk factors for cognitive decline in children treated for brain tumors.* Eur J Paediatr Neurol, 2010. **14**(2): p. 106-15.
54. Glauser, T.A. and R.J. Packer, *Cognitive deficits in long-term survivors of childhood brain tumors.* Childs Nerv Syst, 1991. **7**(1): p. 2-12.

55. Janzen, L.A. and B.J. Spiegler, *Neurodevelopmental sequelae of pediatric acute lymphoblastic leukemia and its treatment.* Dev Disabil Res Rev, 2008. **14**(3): p. 185-95.
56. Mahoney, D.H., Jr., et al., *Acute neurotoxicity in children with B-precursor acute lymphoid leukemia: an association with intermediate-dose intravenous methotrexate and intrathecal triple therapy--a Pediatric Oncology Group study.* J Clin Oncol, 1998. **16**(5): p. 1712-22.
57. Mariotto, A.B., et al., *Long-term survivors of childhood cancers in the United States.* Cancer Epidemiol Biomarkers Prev, 2009. **18**(4): p. 1033-40.
58. Mulhern, R.K. and R.W. Butler, *Neurocognitive sequelae of childhood cancers and their treatment.* Pediatr Rehabil, 2004. **7**(1): p. 1-14; discussion 15-6.
59. Robinson, K.E., et al., *Working memory in survivors of childhood acute lymphocytic leukemia: functional neuroimaging analyses.* Pediatr Blood Cancer, 2010. **54**(4): p. 585-90.
60. Shuper, A., et al., *Methotrexate treatment protocols and the central nervous system: significant cure with significant neurotoxicity.* J Child Neurol, 2000. **15**(9): p. 573-80.
61. Mulhern, R.K. and S.L. Palmer, *Neurocognitive late effects in pediatric cancer.* Curr Probl Cancer, 2003. **27**(4): p. 177-97.
62. van der Plas, E., et al., *Cognitive Impairment in Survivors of Pediatric Acute Lymphoblastic Leukemia Treated With Chemotherapy Only.* J Clin Oncol, 2021. **39**(16): p. 1705-1717.
63. Brinkman, T.M., et al., *Psychological Symptoms, Social Outcomes, Socioeconomic Attainment, and Health Behaviors Among Survivors of Childhood Cancer: Current State of the Literature.* J Clin Oncol, 2018. **36**(21): p. 2190-2197.

64. Schultz, K.A., et al., *Behavioral and social outcomes in adolescent survivors of childhood cancer: a report from the childhood cancer survivor study.* J Clin Oncol, 2007. **25**(24): p. 3649-56.
65. Prasad, P.K., et al., *Psychosocial and Neurocognitive Outcomes in Adult Survivors of Adolescent and Early Young Adult Cancer: A Report From the Childhood Cancer Survivor Study.* J Clin Oncol, 2015. **33**(23): p. 2545-52.
66. Brinkman, T.M., et al., *Suicide ideation and associated mortality in adult survivors of childhood cancer.* Cancer, 2014. **120**(2): p. 271-7.
67. Stuber, M.L., et al., *Prevalence and predictors of posttraumatic stress disorder in adult survivors of childhood cancer.* Pediatrics, 2010. **125**(5): p. e1124-34.
68. Pépin, A.L., C.; Sultan, S. , *Survivre à un cancer pédiatrique: quelles conséquences et quelles prises en charge psychologiques?* Psychologie Québec, 2017. **33**(3).
69. Korhonen, L.M., et al., *Suicides and deaths linked to risky health behavior in childhood cancer patients: A Nordic population-based register study.* Cancer, 2019. **125**(20): p. 3631-3638.
70. Marchak, J.G. *Mental health care needs in childhood cancer patients and survivors* in *The 53th Annual Congress of the International Society of Paediatric Oncology* 2021. Virtual.
71. Wakefield, C. E., et al., *The psychosocial impact of completing childhood cancer treatment: a systematic review of the literature.* J Pediatr Psychol, 2010. 35(3), p. 262-274.
71. Sundberg, K.K., et al., *Positive and negative consequences of childhood cancer influencing the lives of young adults.* Eur J Oncol Nurs, 2009. **13**(3): p. 164-70.
73. Barakat, L. P., Alderfer, M. A., & A.E. Kazak. *Posttraumatic growth in adolescent survivors of cancer and their mothers and fathers.* J Pediatr Psychol, 2006. **31**(4): p. 413-419.

74. Reiter-Purtill, J., et al., *A controlled longitudinal study of the social functioning of children who completed treatment of cancer.* J Pediatr Hematol Oncol, 2003. **25**(6): p. 467-473.
75. Duran, B. *Posttraumatic growth as experienced by childhood cancer survivors and their families: a narrative synthesis of qualitative and quantitative research.* J Pediatr Oncol Nurs, 2013. 30(4): p. 179-197.
76. Koutna, V., Jet al., *Predictors of Posttraumatic Stress and Posttraumatic Growth in Childhood Cancer Survivors.* Cancers (Basel), 2017. **9**(3).
77. Global Burden of Disease Cancer 2019 Cancer Collaboration, *Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-Adjusted Life Years for 29 Cancer Groups From 2010 to 2019: A Systematic Analysis for the Global Burden of Disease Study 2019.* JAMA Oncol, 2021.
78. Ness, K.K. and J.G. Gurney, *Adverse late effects of childhood cancer and its treatment on health and performance.* Annu Rev Public Health, 2007. **28**: p. 279-302.
79. Deisenroth, A., et al., *Muscle strength and quality of life in patients with childhood cancer at early phase of primary treatment.* Pediatr Hematol Oncol, 2016. **33**(6): p. 393-407.
80. Ness, K.K., et al., *Skeletal, neuromuscular and fitness impairments among children with newly diagnosed acute lymphoblastic leukemia.* Leuk Lymphoma, 2015. **56**(4): p. 1004-11.
81. Gaser, D., et al., *Analysis of self-reported activities of daily living, motor performance and physical activity among children and adolescents with cancer: Baseline data from a randomised controlled trial assessed shortly after diagnosis of leukaemia or non-Hodgkin lymphoma.* Eur J Cancer Care (Engl), 2022. **31**(2): p. e13559.
82. Gotte, M., et al., *Motor performance in children and adolescents with cancer at the end of acute treatment phase.* Eur J Pediatr, 2015. **174**(6): p. 791-9.

83. Sontgerath, R. and K. Eckert, *Impairments of Lower Extremity Muscle Strength and Balance in Childhood Cancer Patients and Survivors: A Systematic Review.* Pediatr Hematol Oncol, 2015. **32**(8): p. 585-612.
84. Hooke, M.C., A.W. Garwick, and J.P. Neglia, *Assessment of physical performance using the 6-minute walk test in children receiving treatment for cancer.* Cancer Nurs, 2013. **36**(5): p. E9-E16.
85. Kandula, T., et al., *Chemotherapy-Induced Peripheral Neuropathy in Long-term Survivors of Childhood Cancer: Clinical, Neurophysiological, Functional, and Patient-Reported Outcomes.* JAMA Neurol, 2018. **75**(8): p. 980-988.
86. Hartman, A., et al., *Decrease in motor performance in children with cancer is independent of the cumulative dose of vincristine.* Cancer, 2006. **106**(6): p. 1395-401.
87. Phillips, N.S.e.a., *Physical fitness and neurocognitive outcomes in adult survivors of childhood acute lymphoblastic leukemia: a report from the St. Jude Lifetime cohort.* Cancer, 2020. **126**: p. 640-648.
88. Ness, K.K., et al., *Body composition, muscle strength deficits and mobility limitations in adult survivors of childhood acute lymphoblastic leukemia.* Pediatr Blood Cancer, 2007. **49**(7): p. 975-81.
89. Ness, K.K., et al., *Chemotherapy-related neuropathic symptoms and functional impairment in adult survivors of extracranial solid tumors of childhood: results from the St. Jude Lifetime Cohort Study.* Arch Phys Med Rehabil, 2013. **94**(8): p. 1451-7.
90. Ness, K.K., et al., *Limitations on physical performance and daily activities among long-term survivors of childhood cancer.* Ann Intern Med, 2005. **143**(9): p. 639-47.
91. Hudson, M.M., et al. *Longitudinal changes in health status of the childhood cancer survivor cohort*. in *43rd Congress of the International Society of Paediatric Oncology*. 2011. Auckland, NZ.

92. Vance, Y.H. and C. Eiser, *The school experience of the child with cancer.* Child Care Health Dev, 2002. **28**(1): p. 5-19.
93. Gotte, M., S. Taraks, and J. Boos, *Sports in pediatric oncology: the role(s) of physical activity for children with cancer.* J Pediatr Hematol Oncol, 2014. **36**(2): p. 85-90.
94. Ness, K.K., et al., *Physical performance limitations among adult survivors of childhood brain tumors.* Cancer, 2010. **116**(12): p. 3034-44.
95. Kunin-Batson, A., et al., *Predictors of independent living status in adult survivors of childhood cancer: a report from the Childhood Cancer Survivor Study.* Pediatr Blood Cancer, 2011. **57**(7): p. 1197-203.
96. Gurney, J.G., et al., *Social outcomes in the Childhood Cancer Survivor Study cohort.* J Clin Oncol, 2009. **27**(14): p. 2390-5.
97. Ness, K.K., et al., *The impact of limitations in physical, executive, and emotional function on health-related quality of life among adult survivors of childhood cancer: a report from the Childhood Cancer Survivor Study.* Arch Phys Med Rehabil, 2008. **89**(1): p. 128-36.
98. Rueegg, C.S., et al., *Physical performance limitations in adolescent and adult survivors of childhood cancer and their siblings.* PLoS One, 2012. **7**(10): p. e47944.
99. Mattsson, E., B. Lindgren, and L. Von Essen, *Are there any positive consequences of childhood cancer? A review of the literature.* Acta Oncol, 2008. **47**(2): p. 199-206.
100. Ferrans, C.E., et al., *Conceptual model of health-related quality of life.* J Nurs Scholarsh, 2005. **37**(4): p. 336-42.
101. Wilson, I.B. and P.D. Cleary, *Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes.* JAMA, 1995. **273**(1): p. 59-65.
102. Yeh, J.M., et al., *Chronic Conditions and Utility-Based Health-Related Quality of Life in Adult Childhood Cancer Survivors.* J Natl Cancer Inst, 2016. **108**(9).

103. San Juan, A.F., et al., *Functional capacity of children with leukemia.* Int J Sports Med, 2008. **29**(2): p. 163-7.
104. Zebrack, B.J. and M.A. Chesler, *Quality of life in childhood cancer survivors.* Psychooncology, 2002. **11**(2): p. 132-41.
105. Dixon, S.B., et al., Factors influencing risk-based care of the childhood cancer survivor in the 21st century. CA Cancer J Clin, 2018. 68(2): p. 133-152.
106. Children's Oncology Group. *Long-term Follow-up Guidelines for Survivors of Childhood, Adolescent and Young Adult Cancers, Version 5.0*. 2018 [cited 2020; Available from: www.survivorshipguidelines.org.
107. Amireault, S., A.J. Fong, and C.M. Sabiston, *Promoting Healthy Eating and Physical Activity Behaviors: A Systematic Review of Multiple Health Behavior Change Interventions Among Cancer Survivors.* Am J Lifestyle Med, 2018. **12**(3): p. 184-199.
108. Werk, R.S. and J.S. Ford, *Covariates of risky health behaviors in pediatric cancer survivors during adolescence.* J Psychosoc Oncol, 2020: p. 1-15.
109. Demark-Wahnefried, W., et al., *Survivors of childhood cancer and their guardians.* Cancer, 2005. **103**(10): p. 2171-80.
110. Reeves, M., et al., *Health behaviours in survivors of childhood cancer.* Aust Fam Physician, 2007. **36**(1-2): p. 95-6.
111. Badr, H., et al., *Health-related quality of life, lifestyle behaviors, and intervention preferences of survivors of childhood cancer.* J Cancer Surviv, 2013. **7**(4): p. 523-34.
112. Belanger, L.J., et al., *A survey of physical activity programming and counseling preferences in young-adult cancer survivors.* Cancer Nurs, 2012. **35**(1): p. 48-54.
113. Caru, M., et al., *The impact of cancer on theory of planned behavior measures and physical activity levels during the first weeks following cancer diagnosis in children.* Support Care Cancer, 2021. **29**(2): p. 823-831.

114. Fuemmeler, B.F., et al., *Diet, physical activity, and body composition changes during the first year of treatment for childhood acute leukemia and lymphoma.* J Pediatr Hematol Oncol, 2013. **35**(6): p. 437-43.
115. Stössel, S., et al., *Physical activity behaviour in children and adolescents before, during and after cancer treatment.* Sport Sci Health, 2020(16): p. 347–353
116. Aznar, S., et al., *Physical activity during treatment in children with leukemia: a pilot study.* Appl Physiol Nutr Metab, 2006. **31**(4): p. 407-13.
117. Grimshaw, S.L., et al., *Physical activity for children undergoing acute cancer treatment: A qualitative study of parental perspectives.* Pediatr Blood Cancer, 2020. **67**(6): p. e28264.
118. Ladas, E.J., et al., *A multidisciplinary review of nutrition considerations in the pediatric oncology population: a perspective from children's oncology group.* Nutr Clin Pract, 2005. **20**(4): p. 377-93.
119. Brinksma, A., et al., *Eating and feeding problems in children with cancer: Prevalence, related factors, and consequences.* Clin Nutr, 2020. **39**(10): p. 3072-3079.
120. Skolin, I., et al., *Altered food intake and taste perception in children with cancer after start of chemotherapy: perspectives of children, parents and nurses.* Support Care Cancer, 2006. **14**(4): p. 369-78.
121. Cohen, J., et al., *Poor Diet Quality in Children with Cancer During Treatment.* J Pediatr Oncol Nurs, 2021. **38**(5): p. 313-321.
122. Gibson, F., et al., *What's it like when you find eating difficult: children's and parents' experiences of food intake.* Cancer Nurs, 2012. **35**(4): p. 265-77.
123. Shams-White, M., et al., *Food craving and obesity in survivors of pediatric ALL and lymphoma.* Appetite, 2016. **96**: p. 1-6.
124, Williams, L.K. and M.C. McCarthy, *Parent perceptions of managing child behavioural side-effects of cancer treatment: a qualitative study.* Child Care Health Dev, 2015. **41**(4): p. 611-9.

125. Gurlek Gokcebay, D., et al., *Assessment of Nutritional Status in Children With Cancer and Effectiveness of Oral Nutritional Supplements.* Pediatr Hematol Oncol, 2015. **32**(6): p. 423-32.
126. Skolin, I., U.K. Hursti, and Y.B. Wahlin, *Parents' perception of their child's food intake after the start of chemotherapy.* J Pediatr Oncol Nurs, 2001. **18**(3): p. 124-36.
127. Smith, D.E., M.C. Stevens, and I.W. Booth, *Malnutrition at diagnosis of malignancy in childhood: common but mostly missed.* Eur J Pediatr, 1991. **150**(5): p. 318-22.
128. Reilly, J.J., et al., *Effect of glucocorticoid therapy on energy intake in children treated for acute lymphoblastic leukemia.* J Clin Endocrinol Metab, 2001. **86**(8): p. 3742-5.
129. Wilson, C.L., P.L. Gawade, and K.K. Ness, *Impairments that influence physical function among survivors of childhood cancer.* Children (Basel), 2015. **2**(1): p. 1-36.
130. Nathan, P.C., et al., *Health behaviors, medical care, and interventions to promote healthy living in the Childhood Cancer Survivor Study cohort.* J Clin Oncol, 2009. **27**(14): p. 2363-73.
131. Rabin, C., *Review of health behaviors and their correlates among young adult cancer survivors.* J Behav Med, 2011. **34**(1): p. 41-52.
132. Zhang, F.F., et al., *Do Childhood Cancer Survivors Meet the Diet and Physical Activity Guidelines? A Review of Guidelines and Literature.* Int J Child Health Nutr, 2012. **1**(1): p. 44-58.
133. Florin, T.A., et al., *Physical inactivity in adult survivors of childhood acute lymphoblastic leukemia: a report from the childhood cancer survivor study.* Cancer Epidemiol Biomarkers Prev, 2007. **16**(7): p. 1356-63.
134. Tillmann, V., et al., *Male sex and low physical activity are associated with reduced spine bone mineral density in survivors of childhood acute lymphoblastic leukemia.* J Bone Miner Res, 2002. **17**(6): p. 1073-80.

135. Wampler, M.A., et al., *Physical activity among adult survivors of childhood lower-extremity sarcoma.* J Cancer Surviv, 2012. **6**(1): p. 45-53.
136. Wright, M.J., V. Galea, and R.D. Barr, *Proficiency of balance in children and youth who have had acute lymphoblastic leukemia.* Phys Ther, 2005. **85**(8): p. 782-90.
137. Ness, K.K., et al., *Predictors of inactive lifestyle among adult survivors of childhood cancer: a report from the Childhood Cancer Survivor Study.* Cancer, 2009. **115**(9): p. 1984-94.
138. Murnane, A., et al., *Adolescents and young adult cancer survivors: exercise habits, quality of life and physical activity preferences.* Support Care Cancer, 2015. **23**(2): p. 501-10.
139. Belanger, L.J., et al., *Physical activity and health-related quality of life in young adult cancer survivors: a Canadian provincial survey.* J Cancer Surviv, 2011. **5**(1): p. 44-53.
140. Ha, L., et al., *Accuracy of perceived physical activity and fitness levels among childhood cancer survivors.* Pediatr Blood Cancer, 2021. **68**(9): p. e29134.
141. Wogksch, M.D., et al., *Physical activity and fitness in childhood cancer survivors: a scoping review.* Aging Cancer, 2021. **2**(4): p. 112-128.
142. Young-Speirs, M., et al., *Perceived Health among Adolescent and Young Adult Survivors of Childhood Cancer.* Curr Oncol, 2021. **28**(1): p. 825-836.
143. Zhang, F.F., et al., *Comparison of childhood cancer survivors' nutritional intake with US dietary guidelines.* Pediatr Blood Cancer, 2015. **62**(8): p. 1461-7.
144. Fleming, C.A.K., et al., *Poor diet quality and adverse eating behaviors in young survivors of childhood cancer.* Pediatr Blood Cancer, 2022. **69**(1): p. e29408.
145. Rogers, P.C., et al., *Obesity in pediatric oncology.* Pediatr Blood Cancer, 2005. **45**(7): p. 881-91.

146. Ford, J.S., M. Barnett, and R. Werk, *Health Behaviors of Childhood Cancer Survivors.* Children (Basel), 2014. **1**(3): p. 355-73.
147. Zhang, F.F., M.J. Kelly, and A. Must, *Early Nutrition and Physical Activity Interventions in Childhood Cancer Survivors.* Curr Obes Rep, 2017. **6**(2): p. 168-177.
148. van Erp, L.M.E., et al., *Support needs of Dutch young adult childhood cancer survivors.* Support Care Cancer, 2022.
149. Vetsch, J., et al., *"Forewarned and forearmed": Long-term childhood cancer survivors' and parents' information needs and implications for survivorship models of care.* Patient Educ Couns, 2017. **100**(2): p. 355-363.
150. Coombs, A., H. Schilperoort, and B. Sargent, *The effect of exercise and motor interventions on physical activity and motor outcomes during and after medical intervention for children and adolescents with acute lymphoblastic leukemia: A systematic review.* Crit Rev Oncol Hematol, 2020. **152**: p. 103004.
151. Braam, K.I., et al., *Physical exercise training interventions for children and young adults during and after treatment for childhood cancer.* Cochrane Database Syst Rev, 2016. **3**: p. CD008796.
152. Morales, J.S., et al., *Exercise training in childhood cancer: A systematic review and meta-analysis of randomized controlled trials.* Cancer Treat Rev, 2018. **70**: p. 154-167.
153. Malysse, C., et al., *Physical Activity Promotion Programmes in Childhood Cancer Patients and Their Impact on Fatigue and Pain: A Systematic Review.* Children 2021. **8**: p. 1119.
154. Morales, J.S., et al., *Inhospital exercise benefits in childhood cancer: A prospective cohort study.* Scand J Med Sci Sports, 2020. **30**(1): p. 126-134.

155. Gauss, G., et al., *Adverse Events During Supervised Exercise Interventions in Pediatric Oncology-A Nationwide Survey.* Front Pediatr, 2021. **9**: p. 682496.
156. Scott, J.M., et al., *Association of Exercise With Mortality in Adult Survivors of Childhood Cancer.* JAMA Oncol, 2018. **4**(10): p. 1352-1358.
157. Cohen, J.E., C.E. Wakefield, and R.J. Cohn, *Nutritional interventions for survivors of childhood cancer.* Cochrane Database Syst Rev, 2016(8): p. CD009678.
158. Czajkowski, S.M., et al., *From ideas to efficacy: The ORBIT model for developing behavioral treatments for chronic diseases.* Health Psychol, 2015. **34**(10): p. 971-82.
159. Medical Research Council, *Developing and evaluating complex interventions: new guidance*. 2008, London: Medical Research Council
160. Sekhon, M., M. Cartwright, and J.J. Francis, *Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework.* BMC Health Serv Res, 2017. **17**(1): p. 88.
161. Diepeveen, S., et al., *Public acceptability of government intervention to change health-related behaviours: a systematic review and narrative synthesis.* BMC Public Health, 2013. **13**: p. 756.
162. Stok, F.M., et al., *Hungry for an intervention? Adolescents' ratings of acceptability of eating-related intervention strategies.* BMC Public Health, 2016. **16**: p. 5.
163. Fisher, P., et al., *Evaluation of specific and non-specific effects in homeopathy: feasibility study for a randomised trial.* Homeopathy, 2006. **95**(4): p. 215-22.
164. Hommel, K.A., et al., *Telehealth behavioral treatment for medication nonadherence: a pilot and feasibility study.* Eur J Gastroenterol Hepatol, 2013. **25**(4): p. 469-73.

165. Borrelli, B., et al., *A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research.* J Consult Clin Psychol, 2005. **73**(5): p. 852-60.
166. Proctor, E.K., et al., *Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges.* Adm Policy Ment Health, 2009. **36**(1): p. 24-34.
167. Silverman, B., Mai, C., Boulet, S., & O'Leary, L. . *Logic models for planning and evaluation*, T.D.o.B.D.a.D.D. (DBDDD), Editor. 2009, Centers for Disease Control and Prevention (CDC): Atlanta, GA.
168. Howlett, M., M. Ramesh, and A. Perl, *Studying Public Policy: Policy Cycles and Policy Subsystems*. 2009, Toronto: Oxford University Press.
169. Stufflebeam, D., *The CIPP model of evaluation*, in *International handbook of educational evaluation*, T. Kellaghan, D. Stufflebeam, and L. Wingate, Editors. 2003, Springer. p. 31-62.
170. Institute for Healthcare Improvement. *The IHI triple aim*. 2016; Available from: http://www.ihi.org/engage/initiatives/tripleaim/pages/default.aspx.
171. Raj, V.S., et al., *The Who, What, Why, When, Where, and How of Team-Based Interdisciplinary Cancer Rehabilitation.* Semin Oncol Nurs, 2020. **36**(1): p. 150974.
172. Prochaska, J. O., & W.F. Velicer, *The transtheoretical model of health behavior change*. Am J Health Promot, *1997.* **12(**1), p. 38-48.
173. Stern, M., et al., *NOURISH-T: Targeting caregivers to improve health behaviors in pediatric cancer survivors with obesity.* Pediatr Blood Cancer, 2018. **65**(5): p. e26941.
174. Moyers, P.A. and C.A. Metzler, *Interprofessional collaborative practice in care coordination.* Am J Occup Ther, 2014. **68**(5): p. 500-5.
175. World Health Organization. *Framework for action on interprofessional education and collaborative practice*. 2010; Available from: http://www.who.int/hrh/resources/framework_action/en/.
176. Uhlig, P. and W.E. Raboin, *Field guide to collaborative care: Implementing the future of healthcare*. 2015, Overland Park, KS: Oak Prairie Press.

177. Coletta, A.M., et al., *Synergy Between Licensed Rehabilitation Professionals and Clinical Exercise Physiologists: Optimizing Patient Care for Cancer Rehabilitation.* Semin Oncol Nurs, 2020. **36**(1): p. 150975.
178. Gan, T., H.L. Cheng, and M.Y.M. Tse, *A systematic review of nurse-led dietary interventions for cancer patients and survivors.* Asia Pac J Oncol Nurs, 2022. **9**(2): p. 81-87.
179. Black, M.H., et al., *Understanding the meaning and use of occupational engagement: Findings from a scoping review.* British Journal of Occupational Therapy, 2019. **82**(5): p. 272-287.
180. McBride, C.M., Emmons, K.M. & I.M. Lipkus. *Understanding the potential of teachable moments: the case of smoking cessation*. Health Educ Res. 2003. **18**(2): p. 156-70.
181. Mencken, H.L., *Prejudices: Second Series*. Vol. 2. 1920, New York, USA: Alfred A., Knopf.
182. Gilliam, M.B. and D.C. Schwebel, *Physical Activity in Child and Adolescent Cancer Survivors: A Review.* Health Psychol Rev, 2013. **7**(1): p. 92-110.
183. Wurz, A., et al., *Advancing the Field of Pediatric Exercise Oncology: Research and Innovation Needs.* Curr Oncol, 2021. **28**(1): p. 619-629.
184. Barnes, M.J., C. K., and H. Austin, *Strategies to promote regular exercise in adolescent and young adult cancer survivors.* Clinical Oncology in Adolescents and Young Adults, 2015. **5**: p. 103-113.
185. Michie, S., et al., *The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions.* Ann Behav Med, 2013. **46**(1): p. 81-95.
186. Rimer, B.K. and K. Glanz, *Theory at a glance: A guide for health promotion practice*, U.D.o.H.a.H. Services, Editor. 2005, National Institutes of Health, National Cancer Institute: Bethesda, MD.

187. Raynor, H.A., *Evidence-based treatments for childhood obesity*. Handbook of Childhood and Adolescent Obesity, ed. E. Jelalian and R.G. Steele. 2008, New York: Springer Science + Business Media.
188. Mayo, N.E. and S. Scott, *Evaluating a complex intervention with a single outcome may not be a good idea: an example from a randomised trial of stroke case management.* Age Ageing, 2011. **40**(6): p. 718-24.

APPENDIX I

CONSENT FORMS

VIE project – Intervention group

APPROUVÉ PAR LE COMITÉ D'ÉTHIQUE
16 AVRIL 2018
#2017-1413
CHU SAINTE-JUSTINE

FORMULAIRE D'INFORMATION ET DE CONSENTEMENT

Titre: Programme VIE - Valorisation-Implication-Éducation

CHU Sainte-Justine
Le centre hospitalier universitaire mère-enfant
Pour l'amour des enfants

Université de Montréal

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Le Service d'hématologie-oncologie du CHU Sainte-Justine participe à des projets de recherche dans le but d'améliorer les traitements et la compréhension des cancers

pédiatriques. Nous sollicitons aujourd'hui votre participation ou celle de votre enfant. Nous vous invitons à lire ce formulaire d'information afin de décider si vous désirez participer à ce projet. Il est important de bien comprendre ce formulaire. N'hésitez pas à poser des questions. Prenez le temps nécessaire pour prendre votre décision.

Par souci de simplicité, dans le reste du document, le terme "vous" doit être compris comme vous-même ou votre enfant, et le terme "je" doit être compris comme moi-même ou mon enfant.

Quelle est la nature de ce projet ?

Vous êtes invité à participer à cette étude parce que vous avez été diagnostiqué d'un cancer. Suite à l'importante amélioration des protocoles de traitements, le taux de guérison des cancers pédiatriques a significativement augmenté au cours des années. Cependant, suite à de précédentes études, il a été constaté que comparativement à leurs pairs, les survivants des cancers pédiatriques présentent plus de risque de développer de l'hypertension, des anomalies du cholestérol ou des triglycérides ou du diabète de type 2. Il a aussi été démontré qu'ils sont plus à risque de développer des problèmes cardiaques comme de l'insuffisance cardiaque et l'infarctus du myocarde. Les survivants de cancer ont une capacité d'effort réduite d'environ 15% par rapport à la population et plus des deux tiers ne suivent pas les niveaux d'activités physiques quotidiennes pour rester en santé. Même s'il est avancé que certaines composantes du traitement comme des agents de chimiothérapie particuliers ou des traitements de radiothérapie contribuent au développement de ces complications, les mécanismes entrainant ces complications demeurent peu compris. Pour cette raison, une attention particulière a été portée au rôle de la nutrition et du mode de vie, incluant l'activité physique, chez ces patients en traitement. Aussi, de nombreuses études ont mis en évidence l'impact que pouvait avoir le cancer pédiatrique au sein d'une famille : une détresse émotionnelle des parents, incluant un niveau de stress élevé au diagnostic, un faible soutien social, et un sentiment de fardeau important. Les difficultés psychologiques des parents pouvant avoir des répercussions sur la capacité de l'enfant à surmonter les moments douloureux, il est souhaitable que la détresse familiale soit identifiée précocement et qu'un soutien soit proposé.

But de l'étude

Les buts de ce projet de recherche sont d'une part de soutenir la modification des comportements de santé pour améliorer la qualité nutritionnelle et l'activité physique de la famille et d'autre part de soulager la détresse émotionnelle au plan familial en permettant aux participants de retrouver un sentiment de capacité et de contrôle pendant les traitements.

Déroulement de l'étude

L'étude se compose de plusieurs rencontres qui ont lieu pour la plupart dans le Service d'hématologie-oncologie du CHU Sainte-Justine. Tout au long de votre traitement et jusqu'à un maximum de 5 ans post diagnostic, vous bénéficierez de ces rencontres qui se

dérouleront les mêmes jours que vos rendez-vous pour un traitement ou votre suivi à la clinique.

Lors de votre première visite, vous rencontrerez une coordonnatrice de recherche clinique qui vous posera quelques questions d'ordre général, votre histoire personnelle et/ou familiale ainsi que sur votre histoire médicale passée et présente. L'équipe de recherche consultera aussi votre dossier médical pour obtenir les informations pertinentes à cette recherche.

Lors de l'entrée dans l'étude et lors de la dernière visite (maximum 5 ans après le diagnostic), un échantillon d'urine (30ml) et un prélèvement sanguin (30 ml) seront effectués (cholestérol, diabète, santé osseuse, cardiaque, hormones, recherche de biomarqueurs…etc.). Le prélèvement sera fait en même temps que vos prélèvements prévus par la clinique. Selon votre âge, il est possible que ces prélèvements soient fractionnés dans le temps.

Pour tout examen effectué dans le cadre de cette étude, si une anomalie significative pour votre santé était détectée nous vous dirigerons vers les services de santé appropriés (référence à un professionnel de santé).

Du côté de l'alimentation…
La santé métabolique se rapporte au traitement et transformation des aliments par les différents organes, assurant ainsi leur fonctionnement optimal. Or, certaines situations de santé peuvent causer des problèmes de fonctionnement perturbant l'équilibre métabolique, ce qui pourrait engendrer des désordres tels que l'obésité, le diabète, l'hypertension artérielle et des anomalies du cholestérol ou des triglycérides.
Les objectifs du volet métabolique de ce projet sont de :

1) Favoriser un état nutritionnel optimal afin d'augmenter la probabilité de réaction favorable aux traitements, de permettre une meilleure tolérance à leurs effets secondaires et d'améliorer la qualité de vie.
2) Encourager l'adoption de comportements alimentaires sains afin de permettre une croissance et un développement normaux de l'enfant, un maintien du poids après le traitement et la prévention des complications à long terme.

L'approche nutritionnelle de ce projet de recherche comprendra :
● Dans les 2 mois après le diagnostic, une rencontre individuelle initiale de 90 min avec la nutritionniste de recherche. Lors de cette entrevue, la nutritionniste :
-évaluera vos besoins nutritionnels, vos habitudes alimentaires et celles de votre famille
-complètera avec vous un rappel alimentaire de 24 heures, un questionnaire de préférence de vos goûts ainsi qu'un questionnaire d'insécurité alimentaire
-vous remettra des journaux alimentaires de 3 jours pour remplir à la maison. Il s'agit d'un formulaire dans lequel vous noterez vos repas au cours de 3 journées : 2 jours en semaine et un jour en fin de semaine (possibilité de les compléter via le site web du programme VIE)

- au cas où tous les prélèvements nécessaires à l'étude n'auraient pas pu être prélevés lors de votre enrôlement, il se peut qu'un nouveau prélèvement (30ml) soit demandé quelques semaines plus tard. Ce prélèvement serait fait à jeun et préférentiellement dans votre cathéter central.
-vous demandera une collecte de selles. Cette collecte consiste en une méthode simple qui est effectuée par vous-même à la maison en utilisant un tube de collection que nous vous fournirons. Après la collecte, vous enverrez l'échantillon par la poste dans l'enveloppe retour déjà affranchie que nous vous fournirons.

● À chaque visite à l'hôpital, des mesures anthropométriques (poids, taille, indice de masse corporelle, plis cutanés et composition corporelle) seront réalisées.
● Tous les deux mois au cours de la première année, lors de vos visites pour un traitement ou un contrôle programmé par l'hôpital, des rencontres de suivi nutritionnel d'une durée de 30 à 45 minutes seront effectuées.
Lors de ces rencontres, la nutritionniste :
-évaluera en personne votre état nutritionnel et l'atteinte de vos objectifs de changements
-ajustera votre plan de traitement nutritionnel
-établira de nouveaux objectifs en collaboration avec vous
-complètera avec vous un rappel alimentaire de 24 heures et un questionnaire de préférence de vos goûts
-vous remettra des journaux alimentaires de 3 jours pour remplir à la maison
-évaluera l'atteinte des objectifs des exercices physiques en collaboration avec les kinésiologues impliqués dans le projet
● Les mois où vous ne serez pas rencontré en personne (un mois sur deux), nous vous proposerons un suivi à distance via une plateforme en ligne sécurisée.
●À la fin de la première année, l'atteinte des objectifs sera évaluée et le plan de suivi sera ajusté. A l'issue de cette évaluation, une intervention comportementale et motivationnelle pourrait vous être proposée en combinaison avec la continuité du suivi nutritionnel et de l'exercice physique. Pour certains patients, le suivi sera espacé en fonction de leurs besoins et réévalué en fonction du protocole de traitement.
●À la fin des traitements, vous complèterez un questionnaire d'insécurité alimentaire
●Afin de vous offrir des solutions pratiques, la participation à des ateliers éducatifs de cuisine et de nutrition vous sera proposée sur une base régulière.
● Des évaluations de la masse osseuse, de la masse de gras et de la masse maigre seront réalisées par ostéodensitométrie (DXA). Le test DXA ressemble à une radiographie, mais la dose de radiation reçue ne représente qu'une infime portion (1%) de la dose reçue lors d'une radiographie des poumons par exemple. Ce test se fait dans le service de radiologie du CHU Sainte-Justine et ne prend que quelques minutes. Pendant la durée du test, vous devrez demeurer immobile et aucune prise de médicament n'est nécessaire.
En cas de difficulté à modifier vos comportements vis-à-vis de l'alimentation, il est possible que la nutritionniste fasse appel à une spécialiste de la motivation dans ce domaine. Il vous sera proposé une réévaluation (1 rencontre), et une ou deux rencontres avec la spécialiste visant à lever les barrières au progrès.

Du côté de l'activité physique…

Plusieurs études ont démontré que certains médicaments bien que très efficaces pour traiter la maladie doivent être utilisés de façon limitée compte tenu de leurs effets secondaires sur différents systèmes du corps humain. Il a été avancé que l'activité physique aurait le potentiel de minimiser les effets secondaires à court et long terme de certains traitements en ayant des effets positifs sur le système squelettique, musculo-squelettique, le système cardiovasculaire, le système immunitaire et sur le profil inflammatoire. De plus, la pratique d'activité physique diminuerait la perception d'effort du patient face aux activités de la vie quotidienne.

Les objectifs de ce projet en rapport avec l'activité physique sont :

1) Minimiser les effets de la maladie et de ses traitements.
2) Améliorer la condition physique du patient pendant ses traitements.
3) Éduquer le patient et sa famille sur les bénéfices de l'activité physique et d'une bonne aptitude physique.
4) Implanter durablement de bonnes habitudes de vie concernant l'activité physique chez les patients et leur famille.

Ainsi l'approche de ce projet de recherche concernant l'activité physique comprendra :

Si vous avez 5 ans et moins :

● Une rencontre individuelle de 60 min avec un physiothérapeute et un ergothérapeute de la clinique. Lors de cette entrevue, une batterie de tâches tant motrices que ludiques seront réalisées afin d'évaluer le développement moteur global et fin.

Si vous avez plus de 5 ans :

● Dans les 2 mois après le diagnostic, une rencontre individuelle initiale de 90 min avec le kinésiologue de recherche. Lors de cette entrevue, le kinésiologue :

-complètera avec vous un questionnaire d'activité physique et calculera votre dépense énergétique quotidienne.

-évaluera vos craintes, vos limitations et vos besoins spécifiques

-évaluera votre condition physique à l'aide de divers tests :

a) Un test d'effort maximal qui consiste en une marche dans un couloir ou sur un tapis roulant. Il est possible que lors de ce test votre tension artérielle et vos échanges gazeux soient contrôlés et qu'un électrocardiogramme soit réalisé. Un électrocardiogramme : c'est un examen indolore et sans risque qui permet d'enregistrer votre activité cardiaque. Pour les besoins de l'examen, on vous installera au niveau de la poitrine et du dos, douze petites électrodes (petits disques métalliques collés sur la peau grâce à des patchs). Votre fréquence cardiaque et votre perception de l'effort seront évaluées au décours du test.
b) Une analyse des échanges gazeux par une mesure de l'oxygène à la bouche. L'appareil appelé VO2 est portable et est muni d'un embout en caoutchouc d'environ un pouce de diamètre, dans lequel vous devrez respirer.
c) Un test de préhension qui permet d'évaluer votre force générale de façon très simple. Votre bras gauche le long du corps, sans appui sur celui-ci, vous serrerez le plus fort possible la poignée d'un appareil appelé dynamomètre. L'effort ne dure que quelques

dizaines de secondes, vous réaliserez 4 essais. Selon votre condition, si ce test s'avère trop difficile, il pourra être remplacé par le test de Pinch qui consiste à serrer fortement une petite pince entre le pouce et l'index.

d) Un test qui permet de mesurer votre puissance musculaire lors d'un saut sur une plateforme appelée la plateforme de Leonardo. On vous demandera donc de réaliser une série de sauts avec 2 pieds sur la plateforme. Selon votre condition, si ce test s'avère trop difficile, il pourra être remplacé par le test de saut Sargent qui est un simple saut vertical.
e) Un test d'équilibre et d'agilité
f) Il se peut qu'un test d'évaluation de la fonction cognitive vous soit proposé si vous avez entre 8 et 12 ans. Ce test d'une durée de moins de 15 min permet de mesurer l'attention et les fonctions exécutives de l'enfant. Il sera administré par ordinateur lors des rencontres des suivis secondaires.

A la fin de cette première évaluation le kinésiologue pourra vous prescrire un premier plan d'entraînement dont il vous fera la démonstration sur place.

● Au cours de la première année tous les deux mois, des rencontres de suivi avec le kinésiologue d'une durée d'une heure seront effectuées par l'intermédiaire d'une plateforme Web.

Lors de ces rencontres, le kinésiologue :

-évaluera votre condition physique

-évaluera l'atteinte de vos objectifs et votre motivation à poursuivre

-ajustera au besoin votre plan d'entrainement

-établira de nouveaux objectifs en collaboration avec vous

-réalisera un atelier éducatif d'une durée 45 min s'adressant au patient et aux parents

● Une évaluation secondaire sera réalisée à votre inclusion dans l'étude, puis 2 mois, 12 mois et 24 mois après votre inclusion dans le but d'évaluer l'évolution de votre condition physique. Le kinésiologue :

- complètera avec vous un questionnaire d'activité physique en rapport avec votre tranche d'âge

-évaluera votre condition physique à l'aide de divers tests :

a) Un test de la condition physique : test de marche maximal ou test sur le tapis
b) Un test de préhension ou test de Pinch
c) Un test de saut sur la plateforme Leonardo ou le test de saut Sargent
d) Un test d'équilibre et d'agilité
e) Une évaluation de la fonction cognitive

A la fin de cette seconde évaluation d'une durée de 60 min, le kinésiologue pourra adapter votre plan d'entrainement et ajouter des recommandations spécifiques.

Un carnet d'entrainement web sera accessible sur la plate-forme du projet VIE. Lors de chaque rencontre, le kinésiologue s'assurera de l'adhérence au programme d'entrainement concernant les exercices effectués ainsi que leur durée et les intensités réalisées; des éventuels symptomes liés à l'exercice tels que l'essouflement et la fatigue. Le programme d'entrainement sera discuté afin d'apporter des ajustements mineurstels que la complexification des exercices ou leur facilitation ainsi que l'ajustement de

l'environnement physique de la séance. Le Kinésiologue répondra à toutes les questions de l'enfant ou des parents afin de permettre la réalisation optimale de l'entrainement et documentera la réalisation des séances. Il vous sera demandé de noter l'ensemble de vos activités quotidiennes pour permettre au kinésiologue de faire un suivi précis et personnalisé. La famille sera sollicitée pour assurer la complétion régulière du carnet afin de permettre une prise en charge de meilleure qualité par le kinésiologue.
En cas de difficulté à modifier vos comportements vis-à-vis de l'activité physique, le kinésiologue pourra communiquer avec vous pour vous apporter de l'aide. Il est possible que le kinésiologue fasse appel à une spécialiste de la motivation dans ce domaine. Il vous sera proposé une réévaluation (1 rencontre), et une ou deux rencontres avec la spécialiste visant à lever les barrières au progrès.

Du côté de l'autonomie…
Les périodes d'hospitalisation répétées ou le fait de recevoir des traitements lourds peut influencer les habiletés fonctionnelles et l'autonomie dans la réalisation des activités de la vie quotidiennes et domestiques. L'effort, la sécurité, l'efficacité et l'aide requise à la réalisation des activités quotidiennes renseignent sur le niveau d'indépendance général à vivre dans la communauté.

L'approche de ce projet de recherche concernant l'ergothérapie se déroulera en deux temps :

● Une fois vos traitements terminés et dans l'intérieur de 2 ans après la fin de ceux-ci, un entretien téléphonique d'environ 30 minutes sera réalisé auprès de vous par une ergothérapeute du département d'hémato-oncologie. Durant cet appel, elle vous questionnera sur votre niveau de fonctionnement actuel au quotidien et choisira en accord avec vous deux tâches à réaliser.

● Suite à cet entretien téléphonique, une ergothérapeute vous proposera une rencontre d'évaluation formelle lors d'une de vos venues à l'hôpital Sainte-Justine. Cette entrevue d'une durée d'environ 45 min. consistera en la réalisation des deux taches choisies lors de l'entretien téléphonique.

Du côté de la qualité de vie…
En raison d'une détresse aiguë après le diagnostic, les parents peuvent ne pas avoir les ressources nécessaires pour aborder des activités comme la gestion du régime alimentaire ou de l'exercice physique. Au-delà de la promotion de la qualité de vie à court terme, soulager la détresse et augmenter les ressources des parents deviennent des objectifs qui permettront l'engagement dans les autres activités du programme.

L'objectif de ce projet en rapport avec la qualité de vie est de :
Soutenir les parents en optimisant leur sentiment de contrôle. Pour cela, le programme inclut un entraînement à la résolution des problèmes concrets rencontrés.

L'approche de ce projet de recherche se décompose ainsi :
En fonction de vos réponses à une échelle de bien-être, des rencontres pourront vous être proposées dans les 2 mois après le diagnostic :
- 4 rencontres individuelles parentales avec une assistante interne en psychologie formée à l'intervention. Ces séances auront pour but d'acquérir, développer et maintenir des compétences simples de résolution de problème pour répondre aux besoins rencontrés face au diagnostic de cancer. La première rencontre individuelle avec l'assistante durera environ 90 min. Les séances suivantes 2, 3, 4 dureront 1h. Ces 4 séances auront lieu chaque semaine et seront prévues dans le temps imparti lors des visites prévues à l'hôpital.
- Si vous êtes en couple 2 rencontres avec le couple de parents à domicile (séances 5 et 6) visant à améliorer la capacité des parents à gérer ensemble les difficultés concrètes associées au cancer de leur enfant. Le couple de parents est un élément important de résilience que l'on doit renforcer pour mieux aborder les problèmes concrets et prévenir le stress : améliorer la communication, protéger le temps de qualité ensemble et diminuer le stress relationnel. Des rendez-vous spécifiques seront pris pour les deux séances à la maison, incluant des arrangements pour la garde des enfants présents à la maison (frais de gardienne prise en charge par le chercheur) pendant la discussion avec les parents**.** Chacune de ces 2 séances durera 1h. Les séances à la maison seront proposées pour toutes les personnes vivant en couple et assumant un rôle parental auprès de l'enfant (incluant les couples divorcés, les familles recomposées, les familles d'accueil, etc.)

Pour garantir la qualité de l'intervention, les séances seront enregistrées. De plus, avant, pendant et après le volet psychosocial, une série de questionnaires vous sera proposée pour évaluer les stratégies de résolution de problème, le sentiment de contrôle, le niveau de stress et le bien-être général. Une partie de ces questionnaires pourront être remplis sur le site web de l'intervention.

À l'issue des 6 séances, il est possible que vous soyez contacté pour un entretien afin de connaître votre avis sur la pertinence du programme car votre avis pourra servir à améliorer cette partie du programme pour mieux aider les autres parents. Un rendez-vous vous sera dans ce cas proposé par l'assistante.

Transfert de données et d'échantillons à la bio banque
Pour faciliter la recherche sur le cancer pédiatrique, nous vous invitons également à participer au projet de biobanque qui est un outil indispensable à la réalisation des objectifs de ce projet.
Il est possible que certains tests soient développés dans le futur afin d'identifier les individus à risque de développer des complications liées au traitement. Conséquemment, en plus de vous demander votre consentement afin d'utiliser vos échantillons de sang et d'urine pour cette étude, nous demandons également votre consentement d'utiliser une partie de vos échantillons biologiques pour des tests futurs dans le seul but de poursuivre

la recherche pour pouvoir mieux comprendre la maladie, le traitement et les effets secondaires et en faire bénéficier les sujets à risque dans le futur. Dans ce but, nous conservons des échantillons de sang, d'urine ainsi que des données (données médicales, neuro-psycho-sociales et socio-démographiques, réponses aux questionnaires, journaux alimentaires et entretiens enregistrés) qui pourront être partagés avec d'autres chercheurs et servir à d'autres recherches. Ces projets sur le cancer et maladies associées seront approuvés par un comité d'éthique de la recherche compétent.

Pour les besoins de cette banque, votre échantillon ne sera pas spécifiquement identifié mais seulement un code reliera votre nom à l'échantillon. Toutes les données et échantillons recueillis ainsi que la clé du code seront sous la responsabilité du chercheur principal Daniel Sinnett, PhD au CHU Ste-Justine Les échantillons seront conservés dans un laboratoire du CHU Sainte-Justine aussi longtemps que le Service d'hématologie-oncologie du CHU Sainte-Justine pourra y assurer la bonne gestion.

Vous pouvez participer à cette recherche même si vous refusez de participer au volet biobanque.

Quels sont les avantages et bénéfices ?

La collaboration étroite des équipes cliniques et de recherche vous permet de bénéficier d'une prise en charge novatrice et personnalisée concernant l'alimentation, le conditionnement physique et les tensions psychologiques. Ce qui vous aidera à adopter de meilleures habitudes de vie. Ce projet est familial, il s'adresse au patient, mais aussi à ses parents.

Les informations recueillies au cours de cette étude serviront à améliorer nos connaissances sur les effets du cancer et de son traitement et potentiellement améliorer les soins prodigués aux patients.

Quels sont les inconvénients et les risques ?

Le temps pris pour compléter les questionnaires, réaliser les différents examens peut être considéré comme un inconvénient. Certaines questions pourraient occasionner un stress ou de l'anxiété. Vous n'êtes pas obligé de répondre à toutes les questions. Les tests d'activités physiques, l'évaluation de la force musculaire (saut sur plateforme) pourraient occasionner de la fatigue. Des pauses et rafraîchissements vous seront proposés.

L'examen DEXA comporte une exposition à des radiations correspondant à une infime portion (1%) de la dose reçue lors d'une radiographie des poumons par exemple.

Risques socio-économiques : Un des risques associés au projet de recherche est lié à l'obtention et la divulgation de résultats sur la santé. Ces résultats pourront permettre de vous offrir un meilleur suivi médical tant au plan de la prévention que du traitement. Par contre, cette information pourrait dans certains cas compromettre vos chances d'assurabilité (assurance-vie, invalidité ou santé) ou augmenter le montant de vos assurances.

Comment la confidentialité est-elle assurée ?
Tous les renseignements obtenus sur vous dans le cadre de ce projet de recherche seront confidentiels, à moins d'une autorisation de votre part ou d'une exception de la loi. Pour ce faire, ces renseignements ainsi que les échantillons seront codés et seul Daniel Sinnett ou un délégué aura les informations nécessaires pour relier le code à votre identité. Tous les dossiers de recherche seront conservés sous clé sous la responsabilité du Dr Caroline Laverdière à l'unité de recherche en hématologie-oncologie du CHU Sainte-Justine et seront conservés pour une durée de 7 ans après la fin de l'étude ou plus longtemps si vous acceptez de participer à la biobanque.
Aux fins de vérification de la saine gestion de l'étude, il est possible qu'un délégué du comité d'éthique de la recherche du CHU Sainte-Justine consulte les données de recherche et votre dossier médical.
Les résultats de cette étude pourront être publiés ou communiqués dans un congrès scientifique mais aucune information pouvant vous identifier ne sera alors dévoilée.

Communication des résultats
Les résultats spécifiques à cette recherche ne feront pas partie de votre dossier médical. Par contre dans le cas ou un résultat scientifiquement validé et significatif pour votre santé serait trouvé et que des mesures préventives ou un traitement sont disponibles, vous en serez informé par un médecin. Les résultats seront alors inscrits dans votre dossier médical pour assurer un suivi.

Possibilité de commercialisation
L'analyse de vos échantillons de matériel biologique pourrait contribuer à la création de produits commerciaux dont vous ne pourrez retirer aucun avantage financier.

Participation volontaire
La participation à ce projet de recherche est libre et volontaire. Toute nouvelle connaissance susceptible de remettre en question la décision de continuer à participer à la recherche vous sera communiquée.
Vous pouvez vous retirer de cette recherche en tout temps, dans ce cas tous les échantillons de sang et d'urines non utilisés seront détruits ainsi que les données non encore analysées. Quelle que soit votre décision cela n'affectera pas la qualité des services de santé qui vous sont offerts.

Responsabilité
En cas de préjudice résultant des procédures requises par cette recherche, vous recevrez tous les soins médicaux nécessaires et couverts par la Régie d'assurance-maladie du Québec ou par votre régime d'assurance-médicaments. Vous devrez débourser la portion des coûts qui ne sont pas couverts.

Toutefois, en signant ce formulaire de consentement, vous ne renoncez à aucun de vos droits prévus par la loi. De plus, vous ne libérez pas les investigateurs et le promoteur de leur responsabilité légale et professionnelle.

Compensation prévue pour vos dépenses et inconvénients
Il n'y a aucune compensation financière prévue. Si une gardienne est nécessaire pour les enfants présents à la maison lors des deux séances parentales à la maison, le chercheur en assumera le coût.

Avec qui pouvez-vous communiquer en cas de questions ou de difficultés?
Pour plus d'information concernant cette étude, vous pouvez contacter :
Dr Caroline Laverdière au (514) 345-4969 ou
Laurence Bertout la coordonnatrice de recherche clinique au **514 345 4931, poste : 6326**

Pour tout renseignement sur vos droits à titre de participant vous pouvez contacter le commissaire local aux plaintes et à la qualité des services du CHU Sainte-Justine au (514) 345-4749

CONSENTEMENT : banque de tissus biologiques et de données cliniques
J'accepte ☐ (initiales)_____ ou je n'accepte pas ☐ (initiales)___
_____ que mes échantillons biologiques et mes données de l'étude soient versés dans la biobanque pour des tests futurs dans le but de tenter de mieux comprendre le cancer ou des maladies associées.

CONSENTEMENT ET ASSENTIMENT À L'ETUDE
Programme VIE : VALORISATION-IMPLICATION-ÉDUCATION
On m'a expliqué la nature et le déroulement du projet de recherche. J'ai pris connaissance du formulaire de consentement et on m'en a remis un exemplaire. J'ai eu l'occasion de poser des questions auxquelles on a répondu à ma satisfaction. Après réflexion, j'accepte de participer (18 ans et plus) ou que mon enfant participe à ce projet de recherche. J'autorise l'équipe de recherche à consulter mon dossier médical (18 ans et plus) ou celui de mon enfant pour obtenir les informations pertinentes à ce projet.

_____ _____
_____
Nom de l'enfant (Lettres moulées) Signature de l'enfant Date

Ou Assentiment verbal de l'enfant incapable de signer mais capable de comprendre la nature de ce projet recueilli par : _____

_____ _____
_____
Nom du parent, tuteur ou participant de 18 ans et plus (Lettres moulées) Signature du parent, tuteur ou participant de 18 ans et plus Date

CONSENTEMENT DU PÈRE ET DE LA MERE : Après réflexion, comme parent, j'accepte de participer au projet de recherche VIE : oui ☐ non ☐

_____ _____
_____
Nom du père, Signature
Date
(Lettres moulées)

_____ _____
_____
Nom de la mère, Signature
Date
(Lettres moulées)

J’ai expliqué aux participants tous les aspects pertinents de ce projet de recherche et j’ai répondu aux questions qu’ils m’ont posées. Je leur ai indiqué que la participation au projet est libre et volontaire et que la participation peut être cessée en tout temps.

Nom de la personne qui a obtenu le consentement	Signature	Date

CHU Sainte-Justine
Le centre hospitalier universitaire mère-enfant

Pour l'amour des enfants

Université de Montréal

Titre: Programme VIE - Valorisation-Implication-Éducation

Investigateur principal
Daniel Sinnett, Ph.D, service d'hématologie-oncologie

Investigateur responsable au CHU Sainte-Justine
Caroline Laverdière, MD, Service d'hématologie-oncologie

Co-investigateur
Daniel Curnier, Ph.D, service de cardiologie,
Valérie Marcil, Dt. P., Ph.D, service gastrologie-hépatologie-nutrition
Serge Sultan,Ph.D, Service d'hématologie-oncologie

Collaborateurs
Centre de recherche du CHU Ste Justine et Université de Montréal :
Nathalie Alos, MD; Gregor Andelfinger MD; Maja Krajinovic, PhD; Monia Marzouki, MD; Marie-Josée Raboisson, MD; Elizabeth Rousseau,MD

Centre de recherche du CHU Ste Justine : David Ogez; PhD
Université de Montréal : Katherine Péloquin; PhD

Source de financement :
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Le Service d'hématologie-oncologie du CHU Sainte-Justine participe à des projets de recherche dans le but d'améliorer les traitements et la compréhension des cancers pédiatriques. Nous sollicitons aujourd'hui votre participation et celle de votre enfant. Nous vous invitons à lire ce formulaire d'information afin de décider si vous désirez participer à ce projet. Il est important de bien comprendre ce formulaire. N'hésitez pas à poser des questions. Prenez le temps nécessaire pour prendre votre décision.

Par souci de simplicité, dans le reste du document, le terme "vous" doit être compris comme vous-même et votre enfant, et le terme "je" doit être compris comme moi-même ou mon enfant.

Quelle est la nature de ce projet ?
Vous êtes invité à participer à cette étude en tant que participant « contrôle » parce que vous avez été diagnostiqué d'un cancer. Afin d'améliorer nos traitements et la prise en charge de nos jeunes patients traités pour un cancer, nous étudierons aussi des patients ayant terminé leur traitement. Pour cette raison, nous souhaiterions réaliser auprès de vous, un bilan nutritionnel, physique et psychologique à la fin de votre traitement.

But de l'étude
Les buts de ce projet de recherche sont d'une part de soutenir la modification des comportements de santé pour améliorer la qualité de l'alimentation et l'activité physique de la famille et d'autre part de soulager la détresse émotionnelle au plan familial en permettant aux participants de retrouver un sentiment de capacité et d'être en contrôle pendant les traitements.

Déroulement de l'étude
Vous serez contactez par une coordonnatrice de recherche clinique qui vous posera quelques questions d'ordre général, votre histoire personnelle et/ou familiale ainsi que sur votre histoire médicale passée et présente. L'équipe de recherche consultera aussi votre dossier médical pour obtenir les informations pertinentes à cette recherche.

Parmi le personnel de l'équipe de recherche, vous rencontrerez une nutritionniste, un kinésiologue et une assistante en psychologie. Ces rencontres auront lieu dans le Service d'hématologie-oncologie du CHU Sainte-Justine.

Un échantillon d'urine (30ml) et un prélèvement sanguin (30 ml) seront collectés (profil lipidique, diabète, santé osseuse, cardiaque, hormones, etc… ainsi que la recherche de biomarqueurs). Le prélèvement sera fait en même temps que vos prélèvements prévus par la clinique.

Pour tout examen effectué dans le cadre de cette étude, si une anomalie significative pour votre santé était détectée nous vous dirigerons vers les services de santé appropriés (référence à un professionnel de santé).

Du côté de l'alimentation…
La santé métabolique se rapporte au traitement et transformation des aliments par les différents organes, assurant ainsi leur fonctionnement optimal. Or, certaines situations de santé peuvent causer des problèmes de fonctionnement perturbant l'équilibre métabolique, ce qui pourrait engendrer des désordres tels que l'obésité, le diabète, l'hypertension artérielle et des anomalies du cholestérol ou des triglycérides.

Le volet nutritionnel pour les participants « contrôles » comprendra :
● Une rencontre individuelle de 90 min avec la nutritionniste de recherche. Lors de cette entrevue, la nutritionniste :
-complètera avec vous un rappel alimentaire de 24 heures, un questionnaire de préférence de vos goûts ainsi qu'un questionnaire d'insécurité alimentaire
-vous remettra des journaux alimentaires de 3 jours pour remplir à la maison. Il s'agit d'un formulaire dans lequel vous noterez vos repas au cours de 3 journées : 2 jours en semaine et un jour en fin de semaine (possibilité de les compléter via le site web du programme VIE)
-au cas où tous les prélèvements nécessaires à l'étude n'auraient pas pu être prélevés lors de votre enrôlement, il se peut qu'un nouveau prélèvement (30ml) soit demandé

quelques semaines plus tard. Ce prélèvement serait fait à jeun dans votre bras ou dans votre cathéter central
-vous demandera une collecte de selles. Cette collecte consiste en une méthode simple qui est effectuée par vous-même à la maison en utilisant un tube de collection que nous vous fournirons. Après la collecte, vous enverrez l'échantillon par la poste dans l'enveloppe retour déjà affranchie que nous vous fournirons.

● Des mesures anthropométriques (poids, taille et plis cutanés) seront aussi effectuées lors de votre visite.

● Des évaluations de la masse osseuse, de la masse de gras et de la masse maigre seront réalisées par ostéodensitométrie (DXA). Le test DXA ressemble à une radiographie, mais la dose de radiation reçue ne représente qu'une infime portion (1%) de la dose reçue lors d'une radiographie des poumons par exemple. Ce test se fait dans le service de radiologie du CHU Sainte-Justine et ne prend que quelques minutes. Pendant la durée du test, vous devrez demeurer immobile et aucune prise de médicament n'est nécessaire.

Du côté de l'activité physique…
Plusieurs études ont démontré que certains médicaments bien que très efficaces pour traiter la maladie doivent être utilisés de façon limitée compte tenu de leurs effets secondaires sur différents systèmes du corps humain. Il a été avancé que l'activité physique aurait le potentiel de minimiser les effets secondaires à court et long terme de certains traitements en ayant des effets positifs sur le système squelettique, musculo-squelettique, le système cardiovasculaire, le système immunitaire et sur le profil inflammatoire. De plus, la pratique d'activité physique diminuerait la perception d'effort du patient face aux activités de la vie quotidienne.

Ainsi le volet proposé aux participants « contrôles » concernant l'activité physique comprendra :

Si vous avez 5 ans et moins :
● Une rencontre individuelle de 60 min avec un physiothérapeute et un ergothérapeute de la clinique. Lors de cette entrevue, une batterie de tâches tant motrices que ludiques seront réalisées afin d'évaluer le développement moteur global et fin.

Si vous avez plus de 5 ans :
● Une rencontre individuelle de 90 min avec le kinésiologue de recherche. Lors de cette entrevue, le kinésiologue :
-complètera avec vous un questionnaire d'activité physique et calculera votre dépense énergétique quotidienne.
-évaluera votre condition physique à l'aide de divers tests :

g) Un test d'effort maximal qui consiste en une marche dans un couloir ou sur un tapis roulant. Il est possible que lors de ce test votre tension artérielle et vos échanges gazeux soient contrôlés et qu'un électrocardiogramme soit réalisé. Un électrocardiogramme : c'est un examen indolore et sans risque qui permet

d'enregistrer votre activité cardiaque. Pour les besoins de l'examen, on vous installera au niveau de la poitrine et du dos, douze petites électrodes (petits disques métalliques collés sur la peau grâce à des patchs). Votre fréquence cardiaque et votre perception de l'effort seront évaluées au décours du test.

h) Une analyse des échanges gazeux par une mesure de l'oxygène à la bouche. L'appareil appelé VO2 est portable et est muni d'un embout en caoutchouc d'environ un pouce de diamètre, dans lequel vous devrez respirer.
i) Un test de préhension qui permet d'évaluer votre force générale de façon très simple. Votre bras gauche le long du corps, sans appui sur celui-ci, vous serrerez le plus fort possible la poignée d'un appareil appelé dynamomètre. L'effort ne dure que quelques dizaines de secondes, vous réaliserez 4 essais. Selon votre condition, si ce test s'avère trop difficile, il pourra être remplacé par le test de Pinch qui consiste ….
j) Un test qui permet de mesurer votre puissance musculaire lors d'un saut sur une plateforme appelée la plateforme de Leonardo. On vous demandera donc de réaliser une série de sauts avec 2 pieds sur la plateforme. Selon votre condition, si ce test s'avère trop difficile, il pourra être remplacé par le test de saut Sargent qui est un simple saut vertical dont le but est d'aller toucher le plus haut point dur un mur
k) Un test d'équilibre et d'agilité
l) Il se peut qu'un test d'évaluation de la fonction cognitive vous soit proposé si vous avez entre 8 et 12 ans.

Du côté de l'autonomie…

Les périodes d'hospitalisation répétées ou le fait de recevoir des traitements lourds peut influencer les habiletés fonctionnelles et l'autonomie dans la réalisation des activités de la vie quotidiennes et domestiques. L'effort, la sécurité, l'efficacité et l'aide requise à la réalisation des activités quotidiennes renseignent sur le niveau d'indépendance général à vivre dans la communauté.

Ainsi le volet proposé aux participants « contrôles » concernant l'ergothérapie se déroulera en deux temps :

● Un entretien téléphonique d'environ 10 minutes pendant lequel une ergothérapeute du département d'hémato-oncologie vous questionnera sur votre niveau de fonctionnement actuel au quotidien et choisira en accord avec vous deux tâches à réaliser.

● Une rencontre d'évaluation formelle d'une durée d'environ 45 min sera réalisée lors d'une de vos venues à l'hôpital Sainte-Justine. Elle consistera en la réalisation des deux taches choisies lors de l'entretien téléphonique.

Du côté de la qualité de vie…
Les études montrent que même longtemps après les traitements, la famille est encore bouleversée par le cancer. Pour cette raison, nous vous proposerons de réaliser un portrait des aspects psychosociaux suivants : bien-être général et difficultés émotionnelles, sentiment de contrôle, capacité à gérer le stress, habiletés de résolution de problème, unité et résilience du couple parental. Cela sera fait simplement par des questionnaires que nous vous demanderons de remplir seul et au calme (environ 30 min). Une partie de ces questionnaires pourront être remplis sur le site web de l'intervention. Une assistante sera disponible pour vous aider si vous en éprouvez le besoin. Ces données seront ensuite comparées quantitativement et qualitativement à celles des familles qui auront suivi l'intervention.

Il est possible que vous soyez sollicité pour participer à un entretien avec une interne en psychologie afin de nous permettre de bénéficier de votre expérience de parents. Cet entretien sera proposé à quelques familles afin de recueillir vos recommandations sur le meilleur contenu et format des programmes de soutien, et connaître votre avis sur la pertinence et la faisabilité de l'intervention psychosociale qui sera proposée au groupe « intervention ». Cet entretien sera enregistré et analysé par ordinateur afin de dégager les thèmes les plus importants. Si vous êtes d'accord, de courtes séquences des enregistrements pourront être utilisées pour construire une vidéo de 15 min destinée aux parents dont l'enfant commence ses traitements.

Transfert de données et d'échantillons à la biobanque
Pour faciliter la recherche sur le cancer pédiatrique, nous vous invitons également à participer au projet de biobanque qui est un outil indispensable à la réalisation des objectifs de ce projet.
Il est possible que certains tests soient développés dans le futur afin d'améliorer nos traitements. Conséquemment, en plus de vous demander votre consentement afin d'utiliser vos échantillons de sang et d'urine pour cette étude, nous demandons également votre consentement de recueillir et de conserver un échantillons de 6 ml de sang qui pourraient servir pour des tests futurs dans le seul but de poursuivre la recherche pour pouvoir mieux comprendre la maladie, le traitement et les effets secondaires et en faire bénéficier les sujets à risque dans le futur.
Les échantillons et les données (données médicales, neuro-psycho-sociales et socio-démographiques, réponses aux questionnaires, journaux alimentaires et entretiens enregistrés) pourront être partagés avec d'autres chercheurs et servir à d'autres recherches. Ces projets sur le cancer et maladies associées seront approuvés par un comité d'éthique de la recherche compétent.
Pour les besoins de cette banque, votre échantillon ne sera pas spécifiquement identifié mais seulement un code reliera votre nom à l'échantillon. Toutes les données et échantillons recueillis ainsi que la clé du code seront sous la responsabilité du chercheur principal Daniel Sinnett. Les échantillons seront conservés dans un laboratoire du CHU Sainte-Justine aussi longtemps que le Service d'hématologie-oncologie du CHU Sainte-Justine pourra y assurer la bonne gestion.

Vous pouvez participer à cette recherche même si vous refusez de participer au volet biobanque.

Quels sont les avantages et bénéfices ?
Vous ne retirerez aucun bénéfice direct en participant à cette étude. Votre participation pourrait éventuellement favoriser la découverte de nouveaux tests ou traitements. Les informations recueillies au cours de cette étude serviront à améliorer nos connaissances sur les effets du cancer et de son traitement et potentiellement améliorer les soins prodigués aux patients.

Quels sont les inconvénients et les risques?
Le temps pris pour compléter les questionnaires, réaliser les différents examens peut être considéré comme un inconvénient. Certaines questions pourraient occasionner un stress ou de l'anxiété. Vous n'êtes pas obligé de répondre à toutes les questions. Les tests d'activités physiques, l'évaluation de la force musculaire (saut sur plateforme) pourraient occasionner de la fatigue. Des pauses et rafraîchissements vous seront proposés.
L'examen DEXA comporte une exposition à des radiations correspondant à une infime portion (1%) de la dose reçue lors d'une radiographie des poumons par exemple.
Risques socio-économiques : Un des risques associés au projet de recherche est lié à l'obtention et la divulgation de résultats sur la santé. Ces résultats pourront permettre de vous offrir un meilleur suivi médical tant au plan de la prévention que du traitement. Par contre, cette information pourrait dans certains cas compromettre vos chances d'assurabilité (assurance-vie, invalidité ou santé) ou augmenter le montant de vos assurances.

Comment la confidentialité est-elle assurée ?
Tous les renseignements obtenus sur vous dans le cadre de ce projet de recherche seront confidentiels, à moins d'une autorisation de votre part ou d'une exception de la loi. Pour ce faire, ces renseignements ainsi que les échantillons seront codés et seul Daniel Sinnett ou un délégué aura les informations nécessaires pour relier le code à votre identité. Tous les dossiers de recherche seront conservés sous clé sous la responsabilité du Dr Caroline Laverdière à l'unité de recherche en hématologie-oncologie du CHU Sainte-Justine et seront conservés pour une durée de 7 ans après la fin de l'étude ou plus longtemps si vous acceptez de participer à la biobanque. Aux fins de vérification de la saine gestion de l'étude, il est possible qu'un délégué du comité d'éthique de la recherche du CHU Sainte-Justine0 consulte les données de recherche et votre dossier médical.
Les résultats de cette étude pourront être publiés ou communiqués dans un congrès scientifique mais aucune information pouvant vous identifier ne sera alors dévoilée.
Communication des résultats
Les résultats spécifiques à cette recherche ne feront pas partie de votre dossier médical. Par contre dans le cas ou un résultat scientifiquement validé et significatif pour votre santé serait trouvé et que des mesures préventives ou un traitement sont disponibles,

vous en serez informé par un médecin. Les résultats seront alors inscrits dans votre dossier médical pour assurer un suivi.

Possibilité de commercialisation
L'analyse de vos échantillons de matériel biologique pourrait contribuer à la création de produits commerciaux dont vous ne pourrez retirer aucun avantage financier.

Participation volontaire
La participation à ce projet de recherche est libre et volontaire. Toute nouvelle connaissance susceptible de remettre en question la décision de continuer à participer à la recherche vous sera communiquée.

Vous pouvez vous retirer de cette recherche en tout temps, dans ce cas les données de recherche et les échantillons seront aussi retirés. Quelle que soit votre décision cela n'affectera pas la qualité des services de santé qui vous sont offerts. En cas de retrait, tous les échantillons de sang et d'urines non utilisés seront détruits ainsi que les données non encore analysées.

Responsabilité
En cas de préjudice résultant des procédures requises par cette recherche, vous recevrez tous les soins médicaux nécessaires et couverts par la Régie d'assurance-maladie du Québec ou par votre régime d'assurance-médicaments. Vous devrez débourser la portion des coûts qui ne sont pas couverts.
Toutefois, en signant ce formulaire de consentement, vous ne renoncez à aucun de vos droits prévus par la loi. De plus, vous ne libérez pas les investigateurs et le promoteur de leur responsabilité légale et professionnelle.

Compensation prévue pour vos dépenses et inconvénients
Il n'y a aucune compensation financière prévue.

Avec qui pouvez-vous communiquer en cas de questions ou de difficultés?
Pour plus d'information concernant cette étude, vous pouvez contacter au CHU Sainte-Justine :
Dr Caroline Laverdière au (514) 345-4931 poste : 4639
Laurence Bertout, la coordinatrice de recherche clinique **: au 514 345 4931 poste : 6326.**

Pour tout renseignement sur vos droits à titre de participant vous pouvez contacter le commissaire local aux plaintes et à la qualité des services du CHU Sainte-Justine au (514) 345-4749.

CONSENTEMENT : banque de tissus biologiques et de données cliniques
J'accepte ☐ (initiales)_____ ou je n'accepte pas ☐ (initiales)___
_____ que mes échantillons biologiques et mes données de l'étude soient versés dans la biobanque pour des tests futurs dans le but de tenter de mieux comprendre le cancer ou des maladies associées.

CONSENTEMENT ET ASSENTIMENT À L'ETUDE
Programme VIE : VALORISATION-IMPLICATION-ÉDUCATION
On m'a expliqué la nature et le déroulement du projet de recherche. J'ai pris connaissance du formulaire de consentement et on m'en a remis un exemplaire. J'ai eu l'occasion de poser des questions auxquelles on a répondu à ma satisfaction. Après réflexion, j'accepte de participer (18 ans et plus) ou que mon enfant participe à ce projet de recherche. J'autorise l'équipe de recherche à consulter mon dossier médical (18 ans et plus) ou celui de mon enfant pour obtenir les informations pertinentes à ce projet.

_____ _____ _____

Nom de l'enfant (Lettres moulées) Signature de l'enfant Date

Ou Assentiment verbal de l'enfant incapable de signer mais capable de comprendre la nature de ce projet recueilli par : _____

_____ _____ _____

Nom du parent, tuteur ou participant de 18 ans et plus (Lettres moulées) Signature du parent, tuteur ou participant de 18 ans et plus Date

CONSENTEMENT DU PÈRE ET DE LA MERE : Après réflexion, comme parent, j'accepte de participer au projet de recherche VIE : oui ☐ non ☐

_____ _____ _____

Nom du père, Signature
Date
(Lettres moulées)

_____ _____ _____

Nom de la mère, Signature
Date
(Lettres moulées)

J’ai expliqué aux participants tous les aspects pertinents de ce projet de recherche et j’ai répondu aux questions qu’ils m’ont posées. Je leur ai indiqué que la participation au projet est libre et volontaire et que la participation peut être cessée en tout temps.

Nom de la personne qui a obtenu le consentement	Signature	Date

CHU Sainte-Justine
Le centre hospitalier universitaire mère-enfant
Université de Montréal

FORMULAIRE D'INFORMATION ET DE CONSENTEMENT

Titre du projet de recherche

Barrières et facilitateurs à l'implantation d'un programme de promotion de la santé en oncologie pédiatrique : un projet de transfert des connaissances

Nom des chercheurs

Chercheur principale
Catherine Demers, ergothérapeute, CHU Ste-Justine et candidate au doctorat, Université McGill

Co-chercheurs
Isabelle Gélinas, PhD, Université McGill
Johanne Higgins, PhD, Université de Montréal
Caroline Laverdière, MD, CHU Ste-Justine
Kristopher Lamore, PhD, Université de Paris
Claude Julie Bourque, PhD, Université de Montréal
Johanne Kerba, DtP, Université de Montréal

Source de financement

Fondation des Gouverneurs de l'Espoir

Invitation à participer à un projet de recherche

Le département d'hémato-oncologie du CHU Ste-Justine (CHUSJ) participe à des recherches dans le but d'améliorer la santé globale et la qualité de vie des enfants et adolescents atteints de cancer pendant et après leur trajectoire de soin.

Nous sollicitons aujourd'hui votre participation. Nous vous invitons à lire ce formulaire d'information afin de décider si vous êtes intéressé à participer à ce projet de

recherche. Il est important de bien comprendre ce formulaire. N'hésitez pas à poser des questions. Prenez le temps nécessaire pour prendre votre décision

Quelle est la nature de cette recherche ?

Un programme d'interventions personnalisées et intégratives a été développé et est présentement en étude de faisabilité au CHU Sainte-Justine pour sensibiliser et éduquer les enfants et adolescents atteints de cancer et leur famille sur les bienfaits d'adopter de saines habitudes de vie sur la guérison et la prévention des effets à long terme. Ce programme appelé VIE (Valorisation, Implication, Éducation) leur permettra de participer activement au processus de guérison et de prévention des séquelles à court et long terme. Le programme VIE est novateur car il vise à revoir la façon de concevoir la prise en charge des patients en oncologie pédiatrique et à favoriser ainsi leur qualité de vie à long terme en les outillant pour faire face aux complications inhérentes aux traitements subis. Ultimement, le but est d'implanter une version améliorée du programme à grande échelle afin de diminuer les effets négatifs de la maladie et des traitements pour optimiser la qualité de vie à long terme des survivants de cancer pédiatrique.

Comme le programme est présentement en étude de faisabilité, il est important de recueillir la perception des intervenants face au projet VIE afin de pouvoir l'améliorer pour les implantations futures.

Il s'agit d'un projet local au cours duquel nous comptons recruter environ 12 intervenants qui seront actifs dans le projet VIE au CHUSJ au moment de réaliser l'étude.

Comment se déroulera le projet ?

Un questionnaire sera utilisé pour recueillir votre avis par rapport à certains enjeux qui ont été soulevés au cours du projet.

Quels sont les avantages et bénéfices ?

Le principal avantage que vous retirerez de cette étude est de contribuer à l'avancement des connaissances ainsi qu'à l'amélioration du programme de promotion des saines habitudes de vie en oncologie pédiatrique.

Quels sont les inconvénients et les risques ?

Il n'y a aucun risque ni inconvénient physique ou psychologique à participer à cette recherche. Le seul inconvénient est le temps que prendrez pour participer au projet.

Comment la confidentialité est-elle assurée ?

Tous les renseignements obtenus sur vous pour ce projet de recherche seront confidentiels, à moins d'une autorisation de votre part ou d'une exception de la loi. Pour ce faire, ces renseignements seront codés et gardés sous clé au CHU Sainte-Justine. Les questionnaires seront détruits 7 années après la fin du projet de recherche

Cependant, aux fins de vérifier le bon déroulement de la recherche et d'assurer votre protection, il est possible qu'un délégué du comité d'éthique de la recherche du CHU Sainte-Justine consulte les données de recherche.

Par ailleurs, les résultats de cette recherche pourront être publiés ou communiqués dans un congrès scientifique mais aucune information pouvant vous identifier ne sera alors dévoilée.

Responsabilité

En signant ce formulaire de consentement, vous ne renoncez à aucun de vos droits prévus par la loi. De plus, vous ne libérez pas les investigateurs et le promoteur de leur responsabilité légale et professionnelle.

Liberté de participation

Votre participation à ce projet de recherche est libre et volontaire. Vous pouvez vous retirer de cette recherche en tout temps. Quelle que soit votre décision cela n'affectera pas votre relation de travail dans le service. Si vous vous retirez aucune nouvelle donnée ne sera collectée, les données déjà obtenues seront détruites sauf si elles ont été déjà analysées.

En cas de questions ou de difficultés, avec qui peut-on communiquer ?

Pour plus d'information concernant cette recherche, contactez le chercheur responsable de cette recherche au CHU Sainte-Justine :

Catherine Demers, candidate au doctorat en sciences de la réadaptation
au (514) 345-4931 poste 3063
catherine.demers@mail.mcgill.ca

Pour tout renseignement sur les droits de votre enfant à titre de participant à ce projet de recherche, vous pouvez contacter le Commissaire local aux plaintes et à la qualité des services du CHU Sainte-Justine au (514) 345-4749.

Consentement

Titre du projet : Barrières et facilitateurs à l'implantation d'un programme de promotion de la santé en oncologie pédiatrique : un projet de transfert des connaissances

On m'a expliqué la nature et le déroulement du projet de recherche. J'ai pris connaissance du formulaire de consentement et on m'en a remis un exemplaire. J'ai eu l'occasion de poser des questions auxquelles on a répondu à ma satisfaction. Après réflexion, j'accepte de participer à ce projet de recherche.

_____ _____
_____

Nom du participant (Lettres moulées) Consentement (signature)
Date

J'ai expliqué au participant tous les aspects pertinents de la recherche et j'ai répondu aux questions qu'il/elle m'a posées. Je lui ai indiqué que la participation au projet de recherche est libre et volontaire et que la participation peut être cessée en tout temps.

_____ _____
_____

Nom de la personne qui a obtenu Signature
Date
le consentement (Lettres moulées)

CHU Sainte-Justine
Le centre hospitalier universitaire mère-enfant
Université de Montréal

FORMULAIRE D'INFORMATION ET DE CONSENTEMENT

Titre du projet de recherche

Évaluation de l'acceptabilité d'un programme d'interventions intégrées chez les enfants atteints de cancer

Nom des chercheurs

Chercheur principale
Catherine Demers, ergothérapeute, CHU Ste-Justine et candidate au doctorat, Université McGill

Co-chercheurs
Isabelle Gélinas, PhD, Université McGill
Johanne Higgins, PhD, Université de Montréal

Source de financement

Fondation des Gouverneurs de l'Espoir

Invitation à participer à un projet de recherche

Le département d'hémato-oncologie du CHU Ste-Justine (CHUSJ) participe à des recherches dans le but d'améliorer la santé globale et la qualité de vie des enfants et adolescents atteints de cancer pendant et après leur trajectoire de soin.

Nous sollicitons aujourd'hui votre participation. Nous vous invitons à lire ce formulaire d'information afin de décider si vous êtes intéressé à participer à ce projet de recherche. Il est important de bien comprendre ce formulaire. N'hésitez pas à poser des questions. Prenez le temps nécessaire pour prendre votre décision

Quelle est la nature de cette recherche ?

Un programme d'interventions personnalisées et intégratives a été développé et est présentement en étude de faisabilité au CHU Sainte-Justine pour sensibiliser et éduquer les enfants et adolescents atteints de cancer et leur famille sur les bienfaits d'adopter de saines habitudes de vie sur la guérison et la prévention des effets à long terme. Ce programme appelé VIE (Valorisation, Implication, Éducation) leur permettra de participer activement au processus de guérison et de prévention des séquelles à court et long terme. Le programme VIE est novateur car il vise à revoir la façon de concevoir la prise en charge des patients en oncologie pédiatrique et à favoriser ainsi leur qualité de vie à long terme en les outillant pour faire face aux complications inhérentes aux traitements subis. Ultimement, le but est d'implanter une version améliorée du programme à grande échelle afin de diminuer les effets négatifs de la maladie et des traitements pour optimiser la qualité de vie à long terme des survivants de cancer pédiatrique.

Comme le programme est présentement en étude de faisabilité, il est important de recueillir la perception des parties prenantes face au projet VIE afin de pouvoir l'améliorer pour les implantations futures. En outre, évaluer l'acceptabilité du programme par les différents professionnels de la santé ayant été en contact avec le *projet VIE* peut permettre d'améliorer l'implantation future du programme dans les différents milieux cliniques.

Il s'agit d'un projet local au cours duquel nous comptons recruter environ 12 professionnels de la santé qui ont été en contact avec le *projet VIE* au CHUSJ.

Comment se déroulera le projet ?

Si vous acceptez de participer, vous serez invité à une rencontre d'environ une heure au cours de laquelle vous participerez à un groupe de discussion de 4 à 6 participants. Dépendamment de votre préférence et des mesures sanitaires en cours, l'entrevue aura lieu soit au CHUSJ ou en visio-conférence. Lors de cette rencontre, nous aborderons l'acceptabilité d'intégrer des interventions de prévention ou promotion de la santé en clinique, l'utilité du projet VIE pour les patients en oncologie et des recommandations pour améliorer le programme. La rencontre sera enregistrée et retranscriptes afin de bien recueillir et analyser l'information donnée par les participants. Les fichiers audios seront détruits au terme de la recherche.

Quels sont les avantages et bénéfices ?

Grâce à cette étude, les chercheurs et les cliniciens seront informés sur la meilleure façon d'adresser la promotion des saines habitudes de vie et d'implanter le projet VIE. Les résultats de cette étude pourront servir à améliorer les interventions, dont le but est d'implanter une version améliorée du projet VIE au CHU Ste-Justine et dans les autres centres de cancérologie au Québec pour diminuer les effets négatifs de la maladie

et des traitements pour optimiser la qualité de vie à long terme des survivants de cancer pédiatrique.

Quels sont les inconvénients et les risques ?

Il n'y a aucun risque ni inconvénient physique ou psychologique à participer à cette recherche. Le seul inconvénient est le temps que prendrez pour participer au projet.

Comment la confidentialité est-elle assurée ?

Tous les renseignements obtenus sur vous pour ce projet de recherche seront confidentiels, à moins d'une autorisation de votre part ou d'une exception de la loi. Pour ce faire, ces renseignements seront codés et gardés sous clé au CHU Sainte-Justine. Les données de recherche seront détruites 7 années après la fin du projet de recherche

Cependant, aux fins de vérifier le bon déroulement de la recherche et d'assurer votre protection, il est possible qu'un délégué du comité d'éthique de la recherche du CHU Sainte-Justine consulte les données de recherche.

Par ailleurs, les résultats de cette recherche pourront être publiés ou communiqués dans un congrès scientifique mais aucune information pouvant vous identifier ne sera alors dévoilée.

Responsabilité

En signant ce formulaire de consentement, vous ne renoncez à aucun de vos droits prévus par la loi. De plus, vous ne libérez pas les investigateurs et le promoteur de leur responsabilité légale et professionnelle.

Liberté de participation

Votre participation à ce projet de recherche est libre et volontaire. Vous pouvez vous retirer de cette recherche en tout temps. Quelle que soit votre décision cela n'affectera pas votre relation de travail dans le service. Si vous vous retirez aucune nouvelle donnée ne sera collectée, les données déjà obtenues seront détruites sauf si elles ont été déjà analysées.

En cas de questions ou de difficultés, avec qui peut-on communiquer ?

Pour plus d'information concernant cette recherche, contactez le chercheur responsable de cette recherche au CHU Sainte-Justine :

Catherine Demers, candidate au doctorat en sciences de la réadaptation
au (514) 345-4931 poste 2940
catherine.demers@mail.mcgill.ca

Pour tout renseignement sur les droits de votre enfant à titre de participant à ce projet de recherche, vous pouvez contacter le Commissaire local aux plaintes et à la qualité des services du CHU Sainte-Justine au (514) 345-4749.

Consentement

On m'a expliqué la nature et le déroulement du projet de recherche. J'ai pris connaissance du formulaire de consentement et on m'en a remis un exemplaire. J'ai eu l'occasion de poser des questions auxquelles on a répondu à ma satisfaction. Après réflexion, j'accepte de participer à ce projet de recherche.

_____ _____ _____

Nom du participant (Lettres moulées) Consentement (signature)
Date

J'ai expliqué au participant tous les aspects pertinents de la recherche et j'ai répondu aux questions qu'il/elle m'a posées. Je lui ai indiqué que la participation au projet de recherche est libre et volontaire et que la participation peut être cessée en tout temps.

_____ _____ _____

Nom de la personne qui a obtenu Signature
Date
le consentement (Lettres moulées)

CHU Sainte-Justine
Le centre hospitalier universitaire mère-enfant
Université de Montréal

APPROUVÉ PAR LE COMITÉ D'ÉTHIQUE
4 FÉV. 2021
#2021-3278
CHU SAINTE-JUSTINE

FORMULAIRE D'INFORMATION ET DE CONSENTEMENT

Titre du projet de recherche

Évaluation de l'acceptabilité d'un programme d'interventions intégrées chez les enfants atteints de cancer

Nom des chercheurs

Chercheur principale
Catherine Demers, ergothérapeute, CHU Ste-Justine et candidate au doctorat, Université McGill

Co-chercheurs
Isabelle Gélinas, PhD, Université McGill
Johanne Higgins, PhD, Université de Montréal

Source de financement

Fondation des Gouverneurs de l'Espoir

Invitation à participer à un projet de recherche

Le département d'hémato-oncologie du CHU Ste-Justine participe à des recherches dans le but d'améliorer la santé globale et la qualité de vie des enfants et adolescents atteints de cancer pendant leur trajectoire de soins y compris après la fin des traitements oncologiques.

Nous sollicitons aujourd'hui votre participation. Nous vous invitons à lire ce formulaire d'information afin de décider si vous êtes intéressé à participer à ce projet de recherche. Il est important de bien comprendre ce formulaire. N'hésitez pas à poser des questions. Prenez le temps nécessaire pour prendre votre décision

Quelle est la nature de cette recherche ?

Les avancées médicales des dernières décennies ont rendu possible la guérison à long terme de plus de 80 % des enfants atteints de cancer Malheureusement, ce succès est accompagné d'une panoplie d'effets secondaires dus à la maladie et aux traitements qui ont été largement rapportés dans la littérature scientifique. Ces effets secondaires ont un impact négatif sur le statut fonctionnel ainsi que la qualité de vie à long terme des survivants. Dans ce contexte, vous avez accepté de participer au projet VIE, qui vise à vous permettre de participer activement au processus de guérison et de prévention des effets à long terme du cancer en vous faisant prendre part à des interventions personnalisées. Toutefois, comme il s'agit d'un nouveau programme, nous aimerions recueillir vos impressions face à celui-ci dans le but d'y apporter des modifications et de l'améliorer. Il est important pour nous de bien comprendre vos besoins et de connaître votre opinion.

L'objectif de cette recherche est donc d'évaluer l'acceptabilité du programme, du point de vue des participants du *projet VIE* au CHU Ste-Justine.

Comment se déroulera le projet ?

Si vous acceptez de participer, un questionnaire vous sera remis. Remplir ce questionnaire prend environ 10 minutes. De plus, certains participants seront invités à participer à une entrevue individuelle, d'une durée approximative de 20 minutes. Les entrevues seront enregistrées et retranscriptes pour fins d'analyses. Les fichiers audios seront détruits au terme de la recherche. Si vous participez à l'entrevue, nous vous questionnerons sur votre perception de l'impact du programme, votre satisfaction face aux interventions reçues, des recommandations pour améliorer le projet VIE et l'impact de la pandémie de COVID-19 sur votre participation.

Le questionnaire et l'entrevue seront jumelés à votre évaluation finale dans le cadre de la fin du projet VIE, au CHU Ste-Justine.

L'équipe de recherche consultera le dossier médical de votre enfant pour obtenir les informations pertinentes à cette recherche (ex. temps depuis fin des traitements).

Quels sont les avantages et bénéfices ?

Vous ne retirerez aucun avantage direct en participant à cette recherche.

Grâce à cette étude, les chercheurs et les cliniciens seront informés sur la meilleure façon d'adresser la promotion des saines habitudes de vie et d'implanter le projet VIE. Les résultats de cette étude pourront servir à améliorer les interventions, dont le but est d'implanter une version améliorée du projet VIE au CHU Ste-Justine et dans les autres centres de cancérologie au Québec pour diminuer les effets négatifs de la maladie et des traitements ainsi que pour optimiser la qualité de vie à long terme des survivants de cancer pédiatrique.

Quels sont les inconvénients et les risques ?

Il n'y a aucun risque ni inconvénient physique ou psychologique à participer à cette recherche. Le seul inconvénient est le temps que vous prendrez pour participer au projet.

Comment la confidentialité est-elle assurée ?

Tous les renseignements obtenus sur vous pour ce projet de recherche seront confidentiels, à moins d'une autorisation de votre part ou d'une exception de la loi. Pour ce faire, ces renseignements seront codés et conservés sur un disque dur protégé au CHU Sainte-Justine. Seule l'équipe de recherche aura accès au lien entre le code et votre nom. Les données seront détruites 7 années après la fin du projet de recherche

Cependant, aux fins de vérifier le bon déroulement de la recherche et d'assurer votre protection, il est possible qu'un délégué du comité d'éthique de la recherche du CHU Sainte-Justine consulte les données de recherche et votre dossier médical.

Par ailleurs, les résultats de cette recherche pourront être publiés ou communiqués dans un congrès scientifique mais aucune information pouvant vous identifier ne sera alors dévoilée.

Responsabilité

En signant ce formulaire de consentement, vous ne renoncez à aucun de vos droits prévus par la loi. De plus, vous ne libérez pas les investigateurs et le promoteur de leur responsabilité légale et professionnelle.

Liberté de participation

Votre participation à ce projet de recherche est libre et volontaire. Toute nouvelle connaissance susceptible de remettre en question la décision que votre enfant continue de participer à la recherche vous sera communiquée.

Vous pouvez vous retirer de cette recherche en tout temps. Quelle que soit votre décision cela n'affectera pas la qualité des services de santé qui vous sont offerts. Si vous vous retirez aucune nouvelle donnée ne sera collectée, les données déjà obtenues seront détruites sauf si elles ont été déjà analysées.

En cas de questions ou de difficultés, avec qui peut-on communiquer ?

Pour plus d'information concernant cette recherche, contactez le chercheur responsable de cette recherche au CHU Sainte-Justine :

Catherine Demers, candidate au doctorat en sciences de la réadaptation
au (514) 345-4931 poste 2940
catherine.demers@mail.mcgill.ca

Pour tout renseignement sur les droits de votre enfant à titre de participant à ce projet de recherche, vous pouvez contacter le Commissaire local aux plaintes et à la qualité des services du CHU Sainte-Justine au (514) 345-4749.

Consentement et assentiment

On m'a expliqué la nature et le déroulement du projet de recherche. J'ai pris connaissance du formulaire de consentement et on m'en a remis un exemplaire. J'ai eu l'occasion de poser des questions auxquelles on a répondu à ma satisfaction. Après réflexion, j'accepte que moi et mon enfant participions à ce projet de recherche. J'autorise l'équipe de recherche à consulter le dossier médical de mon enfant pour obtenir les informations pertinentes à ce projet.

_____	_____
Nom de l'enfant	Assentiment de l'enfant si capable de
Date	
(Lettres moulées)	comprendre la nature du projet)
	(signature)

Assentiment verbal de l'enfant incapable de signer mais capable de comprendre la nature de ce projet: oui___ non___

_____	_____
Nom du parent, tuteur	Consentement (signature)
Date	
ou du participant de 18 ans et plus	
(Lettres moulées)	

J'ai expliqué au participant et/ou à son parent/tuteur tous les aspects pertinents de la recherche et j'ai répondu aux questions qu'ils m'ont posées. Je leur ai

indiqué que la participation au projet de recherche est libre et volontaire et que la participation peut être cessée en tout temps.

_____ _____
_____

Nom de la personne qui a obtenu le consentement (Lettres moulées) Signature Date

APPENDIX II

VIE project - INTERVENTION DETAILS

	Intervention Group	Control Group
Who	-Research coordinator nurse -Trained psychologists, 2 post-doctoral students -Team of trained kinesiologists (1 phD student, 2 MSc students, interns in kinesiology supervised by trained kinesiologists) - Trained nutritionists (1 phD student, 1 Msc student) - Clinical Team (oncologists, doctors, nurses, occupational therapists, physiotherapists, speech therapist, psychologists, social workers, specialised child educators, etc.)	Clinical Team (oncologists, doctors, nurses, occupational therapists, physiotherapists, speech therapist, psychologists, social workers, specialised child educators, etc.)
What	Multimodal health promotion program: -Taking back control together: a six in-person intervention sessions to support parents of children with cancer. The program was adapted from existing programs and developed for this study. It aims to strengthen parents' sense of control and problem-solving skills training (PSST) and focus on dyadic coping to prevent distress. This program is based on cognitive behavioural and systemic theories. It includes six sessions: four individual sessions, offered to each parent, and two couple sessions. The individual sessions focus on PSST, as well as	Clinical team follow-up

	acquiring, developing, and maintaining simple problem-solving skills to meet the needs of families facing childhood cancer. These sessions take place at the hospital during the child's treatment. They can also be offered to single-parent families. Both couple sessions are based on CBT and systemic therapy. They aim to enhance parents' communication and resilience by improving their ability to manage real difficulties associated with childhood cancer together. Couple session are provided either at the hospital or at the parents' residence according to the parents' preference. In blended families, each parents can participate in the program with their new partner. A manual for healthcare professionals (provider manual) provides specific instructions for each intervention to be used in every program session. Furthermore, the provider manual offers numerous transcripts examples to convey the information to parents adequately and in a standardized manner. A manual for parents includes PSST toolkits for individual and couple sessions, as well as strategies related to communication and dyadic coping (Ogez et al., 2019). - The physical activity component has a 2 to 4-year duration and includes personalized assessment at 4 time points (baseline, one-year post-diagnosis, 2-year post-diagnosis, end of the study) and physical activity sessions, goal setting, and counselling for behavioural changes with a team of trained kinesiologists. Physical activity sessions are conducted at the hospital during the medical appointments or	depending on their protocol and needs

	hospitalization and from home by telemedicine if participants are interested. The initial session also comprises education regarding possible motor problems resulting from cancer therapy and the potential positive effect of physical activity on motor performance. The aim is to promote physical activity during and after the treatment as well as the adoption of an active lifestyle for the participants and their family -The nutritional intervention includes personalized assessment, goal setting, and counselling for behavioural changes with a registered dietitian (RD) every 2 months as well as 4 group nutrition education and cooking workshops providing complementary information. The personalized counselling will focus on the adoption of a healthy diet (eg. Mediterranean dietary pattern) and adequate nutritional status during cancer treatments. The aim is to increase the tolerance to treatments, to improve the prognosis, and enhance the quality of life of participants. The research- and practice-based curriculum consists of 4 lessons developed by a team of researchers and RD and validated by the hematology-oncology clinical nutrition team at CHUSJ. The workshops are designed to provide reliable, up-to-date nutritional information geared to address specific themes and associated with cooking demonstrations facilitated by a RD and a chef. The workshop aims are to increase knowledge relative to the following: (1) children's nutrition during and after cancer treatments; (2) healthy, quick, and economical food preparation, cooking techniques, and food safety specific for children with cancer; and (3) development of	

	food preferences during childhood and parental feeding practices. -Clinical team follow-up depending on their protocol and needs	
How	One-on-one, in person, during their hospital appointments at the oncology clinic or hospitalization by following the predetermined schedule for the research team over 2 years. Some psychology session can be delivered at the participants' home or remotely using the Zoom platform if more convenient for them. Some physical intervention can be delivered by telemedicine and nutrition counselling can be done over the phone, following the participants' preferences.	Hospital appointment at the oncology clinic or hospitalization or remotely (phone, visuoconference)
Where	CHUSJ tertiary care hospital Cancer center or remotely if possible	CHUSJ Cancer center
When	2 years from recruitment during appointment or hospitalization, between treatments, during waiting time or before or after their appointments, at the time of their convenience	1 or 2 days, 2 years after diagnosis, at the same time as other clinic appointment or any other day, at the time of their convenience

APPENDIX III

VIE project – Brochure

APPENDIX IV

VIE project – RECOMMENDATIONS

1. Recrutement	
Participants	Parties prenantes
Thèmes identifiés lors des entrevues ***Raisons principales pour s'être enrôlé dans le projet :*** ● Pour aider la recherche ● Ne voyaient pas de raisons de ne pas participer ● Pour répondre à un besoin qu'ils avaient (ex. enfant avait des problèmes au niveau de l'équilibre dans son alimentation, famille avait besoin de conseils à ce niveau) ● Pour les bénéfices anticipés des interventions (ex. famille acceptait de participer à n'importe quelle intervention qui allait leur permettre d'améliorer leurs chances de mieux s'en sortir)	**Thèmes identifiés lors des entrevues** ***Facteurs influençant le recrutement dans le projet :*** ● Familles qui disent oui à tout, peuvent toutefois avoir mauvaise compréhension du projet ● Peut des fois être le 10ème projet de recherche qui leur est présenté, ce qui nuit à leur intérêt ***Suggestion pour prochaine implantation*** ● Passer par le médecin, infirmier.ère ou autre intervenant de confiance pour présenter l'étude initialement avant l'équipe de recherche

2. Barrières et facilitateurs	
Participants	Parties prenantes
Facteurs influençant la participation dans le projet Les facteurs sont considérés des facilitateurs si leur présence supporte la participation aux différentes interventions proposées. Les facteurs sont considérés comme des barrières si leur présence nuit à la participation aux différentes interventions proposées. Un même facteur peut être à la fois une barrière et un facilitateur. **Barrières** ***Barrières organisationnelles*** • Manque de disponibilités de la part des intervenants (ex. activité physique n'étaient pas disponible 5 jours semaine pendant un moment) et manque de prévisibilité dans l'horaire (ex. viennent à l'hôpital sans savoir s'ils vont pouvoir participer ou pas à une séance d'activité physique) • Manque de temps : ne veulent pas rester à l'hôpital plus longtemps que nécessaire, ont trop de rendez-vous ou ont des traitements prenants qui laissent peu de temps, par exemple radiothérapie tous les jours à l'extérieur de Ste-Justine. • Ne pas avoir eu beaucoup de relances suite à des refus de participation. Certains participants ont mentionné qu'ils auraient potentiellement participé si on les avait relancés plus tard dans leur parcours de soins. ***Barrières reliées aux individus*** • Problèmes de santé physique ou mentale : être trop fatigué, trop nauséeux, trop déprimé pour participer *(enfants)*	**Facteurs influençant l'implantation du projet** Les facteurs sont considérés des facilitateurs si leur présence supporte l'implantation des différentes interventions proposées dans le milieu clinique. Les facteurs sont considérés comme des barrières si leur présence nuit à l'implantation des différentes interventions proposées dans le milieu clinique. Un même facteur peut être à la fois une barrière et un facilitateur. **Barrières** ***Barrières organisationnelles*** • Arrimage difficile entre les activités de la clinique et les activités de recherche (ex. nombreux conflits d'horaire) ***Barrières reliées aux interventions*** • Rôles et responsabilités, balises d'interventions et objectifs pas assez bien définis. Par conséquent, les interventions ont pu se dédoubler, plutôt que de se complémenter. ***Barrières reliées aux individus*** • Manque d'information et de compréhension du personnel de la clinique par rapport aux interventions, aux objectifs, au but du projet. • Lien de confiance n'a pas été établi entre certains intervenants de la clinique et de la recherche. Plusieurs facteurs : beaucoup d'intervenants, stagiaires avec peu d'expérience et de formation, manque d'ouverture perçu, quelques incidents rapportés.

• Manque de besoin (ex. famille qui s'alimente déjà bien ou qui est déjà très active) ou ne pas voir les besoins (ex. parent qui met l'emphase sur les besoins de son enfant et ne voit pas ses propres besoins au niveau d'un support psychologique). • Mauvaise compréhension des services offerts : mauvaise compréhension du projet en général et de ses objectifs, de ce que sont les interventions ou de ce qu'elles peuvent apporter, qui fait en sorte que les participants ne voient pas les besoins *(parents et enfants)* • Ne pas avoir d'intérêt et/ou de motivation à participer aux interventions proposées *(parents et enfants)* • Se sentir déjà surchargé et cognitivement indisponible à s'investir dans d'autres activités / interventions / relations thérapeutiques *(parents)* • Comme il s'agissait d'un projet pilote, réticence à s'ouvrir sur quelque chose de très personnel dans le cadre d'une intervention qui est « testée » et sentiment que le protocole peut être un peu rigide et ne pas répondre aux besoins spécifiques *(volet psychologique)* ***Contexte externe*** • La pandémie a fait en sorte que moins d'interventions étaient offertes aux participants, ce qui a évidemment nuit à leur niveau de participation (ex. pas de kinésiologie sur place). Certaines familles avaient également peu d'intérêt pour les interventions en virtuelles.	***Contexte interne*** • Les interventions du projet VIE ont ajouté une charge de travail pour les cliniciens ***Contexte externe*** • La pandémie a nui à la communication entre les équipes, qui était déjà difficile. ***Processus*** • Manque de publicité et de diffusion pour certaines interventions. Par exemple, les ateliers culinaires n'ont pas été beaucoup publicisés et les capsules vidéos n'étaient pas disponibles pour les gens en hospitalisation. • Manque de collaboration et de canaux de communication entre les deux équipes (en début de projet majoritairement, puis pendant pandémie)
Facilitateurs ***Facilitateurs organisationnels*** • Beaucoup de temps d'attente et de temps libre lors des journées de clinique externe	**Facilitateurs** ***Facilitateurs reliés aux interventions*** • Interventions appréciées par les participants • Approche ludique, approprié avec clientèle cible • Interventions pertinentes, qui répondent à un besoin clinique

Facilitateurs reliés aux individus • Relations positives avec les intervenants et lien de confiance • Intérêt pour les saines habitudes de vie • Voir ou anticiper les bénéfices des interventions ***Facilitateurs reliés aux interventions*** • Adaptation aux besoins spécifiques de chaque individu • Flexibilité dans la façon dont les interventions étaient délivrées : offrir des interventions en virtuel, changer l'horaire, droit de refuser • Environnement sécuritaire (ex. se sentent plus en sécurité de faire bouger leurs enfants avec les kinésiologues que d'amener leur enfant au parc) • Possibilité de faire participer autres membres de la famille ***Contexte externe*** • La pandémie a fait en sorte que plusieurs interventions étaient offertes en virtuel, ce qui était très pratique pour beaucoup de famille et a permis de bénéficier de plus de stabilité dans la fréquence des interventions offertes (ex. séance activité physique 1 fois par semaine).	• Interventions introduisent un changement de culture sur l'unité vers la promotion des saines habitudes de vie ***Contexte externe*** • Pandémie a permis plus d'interventions à distance pour certains participants, au domicile, ce qui répondait à un besoin dans la clinique.
3. Suggestions pour les implantations futures	
Participants	Parties prenantes
Thèmes identifiés lors des entrevues ***Au niveau des interventions*** • Ajout d'autres types d'interventions ou d'activités. Quelques exemples : faire de la cuisine individuellement ou en groupe (comme les petits chefs), interventions axées sur les symptômes cognitifs (attention,	**Thèmes identifiés lors des entrevues** ***Au niveau des interventions*** • Ajout d'interventions de types « workshop » ou éducationnelles. Par exemple, possible de s'inspirer des journées dédiées en hémophilie qui regroupent quelques patients de la même tranche d'âge et offrent des

concentration), plus d'activités qui encouragent le jeune à sortir de sa chambre lorsqu'hospitalisé, suivi psychologique au niveau familial (enfants & parents).

- Ajout de composantes d'éducation à travers les activités pour supporter le changement de comportement souhaité
- Suivi encore plus individualisé, selon les besoins spécifiques des patients. Par exemple, ne pas trop pousser dans les séances d'activités physiques ou utiliser une approche différente de type défi pour l'alimentation pour accrocher davantage le jeune.
- Avoir plus d'information sur le projet VIE en général : les objectifs, les résultats, les détails des interventions.
- Conserver l'option d'offrir les interventions en virtuel
- Ajout de plus de matériel pour les séances d'activités physiques. Par exemple, tapis de yoga et vélo stationnaire
- Augmenter la fréquence des interventions en activité physique.
- Avoir accès à des capsules en ligne, fait par les intervenants du projet VIE pour des activités ou exercices physiques
- Adapter le moment de l'entrée dans l'étude à la réalité et contraintes familiales

Au niveau de l'organisation

- Améliorer la coordination avec l'équipe clinique. Par exemple, que tous les intervenants se parlent et même fassent des interventions conjointes (ex. kin et physio), que les activités de VIE fasse partie de leur horaire, que tous les prélèvements (sang ou selles) soient gérés par les infirmière de la clinique et intégrées dans les soins pour alléger la tâche des familles
- Revoir le « timing » de certaines interventions et l'adapter aux besoins spécifiques de chaque famille. Par exemple, si la famille est débordée et non disponible pendant la phase de traitements actifs, offrir les interventions plus tard dans le continuum. Certaines autres familles

activités éducationnelles aux jeunes et leurs parents avec différents professionnels sur différents sujets liés à leur maladie (ex. physio, psycho). S'appliquerait surtout pour les survivants et les adolescents, pourrait couvrir des sujets comme comment lire une étiquette de nourriture, comment bien choisir ses aliments, comment faire un plan d'activité physique, etc.

- Rôles des intervenants et balises des interventions mieux définis. Garder la complémentarité avec les interventions cliniques déjà en place comme priorité.

Au niveau de l'implantation

- Plus de collaboration entre les équipes de clinique et recherche. Prendre le temps d'établir un lien de confiance. Suggestions : moins d'intervenants et moins de roulement, toujours avoir un intervenant « sénior » avec expérience et formation qui chapeaute les interventions et qui est stable toute la durée du projet
- Mieux cibler la clientèle, plutôt que de viser tout le monde, ou offrir des interventions plus adaptées à chaque type de clientèle (ex. différente approche pour un jeune LAL avec 2 ans de traitement vs un ado avec lymphome qui a 4-5 mois de traitements).
- Avant la prochaine implantation, disséminer les résultats du projet pilote et « vendre » le nouveau projet. Les cliniciens veulent savoir ce que le projet a donné et les modifications qui ont été faites pour la prochaine phase. Les cliniciens veulent également être consultés, ne pas sentir qu'on leur « impose » le prochain projet
- Garder en tête la pérennité des interventions. S'assurer que ce soit réaliste de pouvoir implanter ce type d'interventions à long terme dans la clinique.

auraient pris au contraire les interventions (ex. psychologie) plus tôt (famille recrutée plus tard dans le projet qui avait eu plus de délais que les familles recrutées au début). • Rendre les activités offertes par VIE plus obligatoires, comme un rendez-vous clinique • Faire plus de relance aux familles après qu'ils aient refusés certaines interventions à un moment dans leur parcours. • Avoir une seule personne-ressource avec qui communiquer, car il y avait beaucoup d'intervenants et pouvait être difficile de savoir à qui s'adresser • Offrir la possibilité de rencontres en personne et/ou en ligne pour accommoder selon les préférences de chacun et selon la réalité de chacune des familles • Trouver des moyens afin de simplifier la vie des parents le plus possible pendant les traitements • Offrir les services du projet VIE à tous, en tant que programme régulier plutôt qu'un projet de recherche limité dans le temps	
4. Adapter les interventions spécifiquement pour les adolescents	
Participants	Parties prenantes
Thèmes identifiés lors des entrevues avec les adolescents et les parents ***esoins/suggestions d'amélioration*** • Besoin d'aide pour savoir comment ramener le jeune à son 100% après la fin des traitements • Considérer le contexte social et scolaire des plus vieux adolescents	**Thèmes identifiés lors des discussions de groupe et des questionnaires écrits** ***Caractéristiques des interventions*** • Adapter et personnaliser les interventions en fonction des besoins et priorités des adolescents traités pour un cancer, les rendre attrayantes • Individualiser le moment du début des interventions

• Continuer de personnaliser les interventions proposées et adapter les séances en fonction de la compréhension de l'adolescent et de ses parents • Privilégier les interventions de groupes en kinésiologie afin d'augmenter la motivation des adolescents • Respecter la décision de l'adolescent s'il ne veut pas participer à une intervention avec les kinésiologues • Prendre en considération l'horaire et la réussite scolaire de l'adolescent lors de la planification des rencontres • Soutenir les parents pour la réussite scolaire de leur jeune • Fournir plus d'explications théoriques aux adolescents plus âgés, en plus des interventions en kinésiologie et en nutrition	• Consulter les adolescents afin de connaître leurs préférences avant de développer une intervention pour eux/inclure des patients-partenaires • Offrir la possibilité d'interventions individuelles ou en groupe (avec autres jeunes atteints de cancer) selon les préférences de l'adolescent • Inclure la famille et les amis dans certaines séances • Moderniser les interventions/inclure du numérique pour accrocher les adolescents • Établir les objectifs conjointement avec l'adolescent et les inclure dans les prises de décision • Mesurer l'évolution/la progression de l'adolescent au cours de l'intervention et célébrer les succès • Limiter le nombre d'intervenants/favoriser la stabilité des intervenants sur le long terme • Avoir des activités distinctes pour les adolescents et les parents, tout en favorisant les occasions de communication, et privilégier des moments seuls avec l'adolescent, sans présence parentale • Éviter les documents et les activités développés pour des jeunes enfants • Porter une attention particulière aux parents qui obligent leurs adolescents à participer aux interventions; s'assurer que le besoin vienne de l'adolescent plutôt que d'imposer une intervention ou un suivi • Mentionner aux adolescents que les interventions sont offertes à tous les jeunes en oncologie. Certains adolescents ayant une image corporelle fragile pourraient penser que les interventions leurs sont suggérées qu'en raison de leur apparence physique ou d'un gain pondéral récent

	Approche à adopter avec adolescents • S'assurer que le premier contact soit fait par une personne qui a déjà un lien avec l'adolescent plutôt qu'un membre de l'équipe de recherche et porter une attention particulière à l'endroit où le premier contact avec l'adolescent ainsi que les contacts subséquents sont effectués; favoriser un lieu autre que la chambre d'hôpital et ambiance décontractée • Prévoir un espace convivial réservé uniquement aux adolescents traités en hémato-oncologie • Rassembler les jeunes afin de leur permettre d'échanger entre eux • S'adresser directement à l'adolescent plutôt que de parler à ses parents • Favoriser autant que possible la normalité • Développer un lien de confiance et une complicité avec l'adolescent • Démontrer un intérêt sincère envers le jeune et ses passions • Apprendre à connaître l'unicité de chacun des adolescents • Conserver un cadre et des règles malgré le diagnostic et les traitements • Adresser les deuils auxquels les adolescents sont confrontés avant de débuter les interventions • Valoriser la participation des adolescents • Tenir compte du fait que l'adolescent fait partie d'une réalité familiale • Démontrer de l'empathie envers les difficultés vécues par l'adolescent • Garder à l'esprit que l'adolescent vit possiblement une journée difficile • Prendre en considération les effets secondaires de certains traitements sur l'humeur

	• Garder un équilibre entre la constance et l'acharnement • Aider l'adolescent à retrouver son autonomie • Favoriser des enseignements non moralisateurs • Éviter d'utiliser la santé à long terme comme motivateur pour les adolescents, focuser sur le concret et le court terme • Favoriser les messages concis • Donner des conseils/recommandations même si l'adolescent ne semble pas très intéressé ; les messages sont souvent retenus malgré l'apparence d'indifférence démontrée par l'adolescent. • Donner aux adolescents le temps de prendre leurs décisions • Laisser la possibilité aux adolescents de changer d'idée s'ils ont refusé de participer au départ