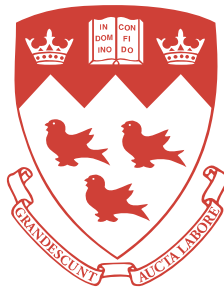


**Enhancing exercise motivation in young adults with lymphoma: A self-determination  
theory-guided intervention**



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## Table of contents

<b>Table of contents</b> .....	<b>1</b>
<b>Acknowledgements</b> .....	<b>i</b>
<b>Abstract</b> .....	<b>iii</b>
<b>Abrégé</b> .....	<b>v</b>
<b>List of figures</b> .....	<b>viii</b>
<b>List of tables</b> .....	<b>ix</b>
<b>List of abbreviations</b> .....	<b>x</b>
<b>Preface</b> .....	<b>xi</b>
Thesis structure .....	xi
Contributions of authors .....	xiii
Contributions to original knowledge .....	xv
<b>Chapter 1. Introduction</b> .....	<b>1</b>
<b>Chapter 2. Literature review</b> .....	<b>2</b>
2.1 Young adults with lymphoma .....	2
2.2 Physical activity and lymphoma-related health outcomes .....	4
2.3 Exercise interventions targeting cancer survivors .....	6
2.4 Theoretical framework – Self-determination theory .....	11
2.5 The <i>Lymfit</i> intervention .....	14
2.6 Manuscript I – Concept analysis of “motivation for health promotion” .....	18
<b>Bridge statement 1</b> .....	<b>42</b>
<b>Chapter 3. Methodology</b> .....	<b>43</b>
3.1 Rationales for conducting a pilot feasibility study .....	43
3.2 Refinement of the <i>Lymfit</i> intervention .....	43
3.3 Manuscript II – Review of control group designs .....	47
3.4 Detailed description of the outcome measurements .....	77
3.5 Ethical considerations .....	81
<b>Bridge statement 2</b> .....	<b>82</b>
<b>Chapter 4. Results</b> .....	<b>83</b>
4.1 Manuscript III – Pilot randomized controlled trial of <i>Lymfit</i> .....	83

<b><i>Chapter 5. Discussion and conclusions</i></b> .....	<b><i>113</i></b>
5.1 Main outcomes and implications .....	113
5.2 Strengths and limitations.....	119
5.3 Future directions .....	121
5.4 Overall conclusion .....	122
<b><i>References</i></b> .....	<b><i>124</i></b>
<b><i>List of appendices</i></b> .....	<b><i>146</i></b>

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## Abstract

**Background.** Despite the rapidly emerging evidence on the contributions of physical activity to improving cancer-related health outcomes, adherence to physical activity guidelines among young adults with lymphoma remains suboptimal. Lack of motivation is a frequently reported psychological barrier to physical activity engagement in this population. This warrants the development of interventions that can enhance exercise motivation and physical activity levels sufficiently to improve cancer outcomes. Self-determination theory (SDT) posits that autonomy, competence, and relatedness are three essential psychological needs that contribute to developing autonomous motivational patterns. Extensively supported by empirical evidence, SDT has been instrumental in elucidating the factors underlying sustained engagement in physical activities among individuals affected by cancer. Guided by the SDT, the virtual exercise intervention named *Lymfit* was developed. *Lymfit*, a 12-week individualized exercise program supplemented with bi-weekly kinesiologist support and activity tracking, aimed to enhance exercise motivation among young adults diagnosed with lymphoma. In this doctoral thesis, a conceptual analysis was first conducted to explore the concept of “*health promotion motivation*” in the context of cancer survivorship. Then, a comprehensive review was conducted to evaluate the methodological considerations in exercise intervention research for cancer survivors, particularly focusing on control group designs in randomized controlled trials. The findings of these two works informed the refinement of the preliminary version of *Lymfit* and the design of its pilot study.

**Objective.** The objective of this thesis was to conduct a pilot feasibility randomized controlled trial (RCT) to evaluate the feasibility, acceptability and preliminary effects of *Lymfit* on four self-reported study outcomes: psychological need satisfaction, exercise motivation, physical activity level, and health-related quality of life among young adults with lymphoma.

**Methodology.** A two-armed pilot RCT was conducted to assess the feasibility, acceptability and preliminary effects of the *Lymfit* intervention (clinical trial registration: NCT05259657). Study participants were recruited from two university-affiliated hospitals in Montréal, Québec, Canada. Consented participants were randomly assigned one-to-one, with stratification by chemotherapy status, into the intervention group or a wait-list control group. Feasibility was assessed by a set of predetermined a-priori benchmarks. Acceptability was evaluated using a 10-item survey, with responses rated on a five-point Likert scale, administered post-intervention. Preliminary effects

were assessed using validated questionnaires collected at baseline prior to randomization and post-intervention on four self-reported study outcomes. Analysis of covariance models were used to compare post-intervention group differences for the study outcomes between the two groups. For each outcome, an effect size of at least 0.2 was set as the benchmark. Additionally, the minimal important change (MIC) was calculated for quality of life domains, with a threshold of four T-score points change to be considered meaningful.

**Results.** In the pilot RCT of *Lymfit*, a total of 41 YAs with lymphoma were initially screened for eligibility, of which 26 eligible participants (63.4%) enrolled in the study and were randomized into the two study groups: intervention group  $n = 13$  and wait-list control group  $n = 13$ . All a-priori feasibility benchmarks were met, including a 100% retention rate of the wait-list control group participants, confirming the feasibility of the study control group design. Intervention acceptability assessment showed high ratings, with eight out of ten items receiving >80% high ratings (a score of four or above on a five-point Likert scale). The benchmark for an effect size of at least 0.2 was met on all four main study outcomes. *Lymfit* also led to meaningful within-group changes ( $\text{MIC} = \text{T-score change} > 4$ ) in six quality of life domains (anxiety, depression, fatigue, sleep disturbance, social roles and activities, and pain interference) in the intervention group, as well as meaningful between-group comparisons in seven domains (physical function, anxiety, depression, fatigue, and sleep disturbance, social roles and activities, and pain interference).

**Conclusion.** This thesis contributes to the literature by advancing our understanding of exercise motivation in the context of cancer survivorship and highlighting methodological considerations essential for the evaluation of exercise interventions. The results of the pilot RCT suggest that *Lymfit* is a highly feasible and accepted intervention among young adults with lymphoma. Further, the findings support *Lymfit* as a promising means to promote psychological needs, exercise motivation, physical activity level and quality of life in this group. A fully powered efficacy trial is warranted to assess the validity of these findings in a larger population. If further corroborated, SDT-guided interventions may be more broadly implemented to promote exercise motivation and quality of life among young adults affected by cancer.

**Keywords.** young adult cancer survivors, lymphoma, exercise motivation, exercise intervention, self-determination theory, pilot feasibility study, randomized controlled trial

## Abrégé

**Contexte.** Malgré l'émergence rapide de preuves sur les contributions de l'activité physique à l'amélioration des résultats de santé liés au cancer, le respect des directives en matière d'activité physique chez les jeunes adultes atteints de lymphome reste sous-optimal. Le manque de motivation est un obstacle psychologique fréquemment signalé à la pratique d'une activité physique dans cette population. Cela justifie le développement d'interventions qui peuvent renforcer la motivation pour l'exercice et les niveaux d'activité physique de manière suffisante pour améliorer les résultats du cancer. La théorie de l'autodétermination (TAD) postule que l'autonomie, la compétence et la relation sont trois besoins psychologiques essentiels qui contribuent au développement de modèles de motivation autonomes. Largement appuyée par des preuves empiriques, la TAD a permis d'élucider les facteurs qui sous-tendent l'engagement durable dans des activités physiques chez les personnes touchées par le cancer. Guidée par la TAD, l'intervention d'exercice virtuel nommée *Lymfit* a été développée. *Lymfit*, un programme d'exercice individualisé de 12 semaines renforcé par un soutien bihebdomadaire d'un kinésologue et d'un suivi de l'activité, vise à renforcer la motivation pour l'exercice chez les jeunes adultes diagnostiqués avec un lymphome.

Dans ce travail de doctorat, une analyse conceptuelle a d'abord été menée pour explorer le concept de "motivation pour la promotion de la santé" dans le contexte de la survie au cancer. Ensuite, un examen complet a été effectué pour évaluer les considérations méthodologiques dans la recherche sur les interventions en matière d'exercice pour les survivants du cancer, en se concentrant particulièrement sur les modèles de groupes de contrôle dans les essais contrôlés randomisés. Les résultats de l'analyse conceptuelle et de cette revue méthodologique ont permis d'affiner la version préliminaire de *Lymfit* et la conception de l'essai contrôlé randomisé pilote.

**Objectif de la thèse.** L'objectif de cette thèse était de mener un essai contrôlé randomisé (ECR) pilote de faisabilité pour évaluer la faisabilité, l'acceptabilité et les effets préliminaires de *Lymfit* sur quatre résultats d'étude auto-rapportés : satisfaction du besoin psychologique, motivation pour l'exercice, niveau d'activité physique et qualité de vie liée à la santé auprès de jeunes adultes récemment diagnostiqués avec un lymphome.

**Méthodologie.** Un essai clinique randomisé pilote comportant deux groupes a été réalisé pour évaluer la faisabilité, l'acceptabilité et les effets préliminaires de l'intervention *Lymfit*



(enregistrement de l'essai clinique : NCT05259657). Les participants à l'étude ont été recrutés dans deux hôpitaux universitaires de Montréal, Québec, Canada. Les participants consentants ont été assignés au hasard, un par un, avec stratification par statut de chimiothérapie, au groupe d'intervention ou à un groupe témoin sur liste d'attente. La faisabilité a été évaluée à l'aide d'un ensemble de critères a-priori prédéterminés. L'acceptabilité a été évaluée après l'intervention à l'aide d'un questionnaire comportant 10 items, dont les réponses ont été évaluées sur une échelle de Likert en cinq points. Les effets préliminaires ont été évalués à l'aide de questionnaires validés, recueillis avant la randomisation et après l'intervention, sur les quatre résultats de l'étude auto-rapportés. Des modèles d'analyse de covariance ont été utilisés pour comparer les différences entre les deux groupes après l'intervention pour les résultats de l'étude. Pour chaque résultat, une taille d'effet d'au moins 0,2 a été fixée comme référence. En outre, le changement minimal important (CMI) a été calculé pour les domaines de la qualité de vie, avec un seuil de quatre points de changement de score T pour être considéré comme significatif.

**Résultats.** Dans l'ECR pilote de *Lymfit*, un total de 41 participants atteints de lymphome ont été initialement sélectionnés pour l'admissibilité, dont 26 participants admissibles (63,4 %) ont été inscrits à l'étude et ont été répartis de façon aléatoire dans les deux groupes d'étude : groupe d'intervention n = 13 et groupe de contrôle sur liste d'attente n = 13. L'évaluation de l'acceptabilité de l'intervention a montré des indices élevés, avec huit éléments sur dix recevant > 80 % d'indices élevés (un score de quatre ou plus sur une échelle de Likert en cinq points). Le critère d'une taille d'effet d'au moins 0,2 a été respecté pour les quatre principaux résultats de l'étude. *Lymfit* a également entraîné des changements significatifs au sein du groupe (CMI = changement du score T > 4) dans six domaines de la qualité de vie (anxiété, dépression, fatigue, perturbations du sommeil, capacité à participer à des rôles sociaux et à des activités sociales, perturbations causées par la douleur) dans le groupe d'intervention, ainsi que des comparaisons significatives entre les groupes dans sept domaines (capacité physique, anxiété, dépression, fatigue, perturbations du sommeil, capacité à participer à des rôles sociaux et à des activités sociales, perturbations causées par la douleur).

**Conclusion.** Cette thèse contribue à la littérature en faisant progresser notre compréhension de la motivation à l'exercice dans le contexte de la survivance au cancer et en soulignant les considérations méthodologiques essentielles pour l'évaluation des interventions en matière d'exercice. Les résultats ont montré que *Lymfit* est une intervention très faisable et acceptée par

les jeunes adultes atteints de lymphome. En outre, ils confirment que *Lymfit* est un moyen prometteur de promouvoir les besoins psychologiques, la motivation pour l'exercice, le niveau d'activité physique et la qualité de vie au sein de ce groupe. Un essai d'efficacité à pleine puissance est justifié pour évaluer la validité de ces résultats dans une population plus large. Si ces résultats sont corroborés, les interventions guidées par la TAD pourraient être mises en œuvre à plus grande échelle pour promouvoir la motivation pour l'exercice et la qualité de vie chez les jeunes adultes touchés par le cancer.

**Mots clés.** jeunes adultes ayant survécus à un cancer, lymphome, motivation pour l'exercice, intervention sur l'exercice, théorie de l'autodétermination, étude pilote de faisabilité, essai contrôlé randomisé

## List of figures

<b>Figure 2.1</b> Organismic integration theory .....	12
<b>Figure 2.2</b> Basic psychological needs theory.....	13
<b>Figure 2.3</b> Logic model of the Lymfit intervention.....	15
<b>Figure 3.1</b> Study selection flow diagram.....	76
<b>Figure 4.1</b> Lymfit intervention components .....	87
<b>Figure 4.2</b> Lymfit study procedures.....	89
<b>Figure 4.3</b> A-priori feasibility benchmarks and results .....	92
<b>Figure 4.4</b> Consolidated standards of reporting trials (CONSORT) flow diagram .....	98

## List of tables

<b>Table 2.1</b> Data source characteristics .....	24
<b>Table 2.2</b> Health behavior theories on motivation and measurement scales/ instruments .....	27
<b>Table 2.3</b> Motivation for health promotion: Defining attributes, antecedents, consequences, and related concepts .....	29
<b>Table 3.1</b> Template for intervention description and replication (TIDieR) intervention components and procedures of the pilot RCT of Lymfit .....	44
<b>Table 3.2</b> Search strategy for CINAHL .....	71
<b>Table 3.3</b> Comparison of control and intervention group components in exercise intervention RCTs for cancer survivors .....	72
<b>Table 4.1</b> Acceptability assessment survey results .....	93
<b>Table 4.2</b> Participant demographic and clinical characteristics .....	96
<b>Table 4.3</b> Analysis of covariance results .....	100
<b>Table 4.4</b> Quality of life domains – Minimal important changes (MIC) .....	103

## List of abbreviations

Abbreviation	Full text
ACSM	American College of Sports Medicine
ANCOVA	Analysis of covariance
App	Application
BMI	Body mass index
BREQ-3	Behavioral regulation in exercise questionnaire – version 3
CARE	Combined Aerobic and Resistance Exercise trial
CERT	Consensus on Exercise Reporting Template
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CONSORT	CONsolidated Standards Of Reporting Trials
DLBCL	Diffuse large B-cell lymphoma
EMBASE	Excerpta Medica dataBASE
ES	Effect size
EXCEL	EXercise for Cancer to Enhance Living Well study
HL	Hodgkin’s lymphoma
LTPA-Q	Godin–Sephard leisure–time physical activity questionnaire
MIC	Minimal important change
MRC	Medical Research Council
MVPA	Moderate to vigorous–intensity physical activity
NHL	Non-hodgkin’s lymphoma
PNSE	Psychological need satisfaction in exercise scale
PROPr	Patient–reported outcomes measurement information system® – Preference
RAI	Relative autonomy index
RCT	Randomized controlled trial
REB	Research ethics board
SCT	Social cognitive theory
SD	Standard deviation
SDT	Self–determination theory
TIDieR	Template for Intervention Description and Replication
YAs	Young adults

## Preface

### Thesis structure

In agreement with the thesis supervisor, Dr. Christine Maheu, and thesis committee members, Drs. Carmen G. Loiselle, Nathalie Johnson, Maude Hébert, and Ross Andersen, I chose to submit a thesis dissertation by manuscript. The doctoral thesis is composed of five chapters and three manuscripts – brief bridging sections are used to unify the different elements of this thesis together. The structure of this thesis is as follows:

The **first chapter** includes the introduction, which provides an overview of the rationale and the overarching objective of the thesis. The **second chapter** presents a review of the literature. This chapter starts by introducing the prevalence of lymphoma among young adults and discussing cancer survivorship in this patient population. The following section introduces exercise-oncology and its impact on health outcomes among individuals with cancer. Subsequently, a review of current research on exercise interventions for individuals affected by cancer is presented. Further, this chapter describes the theoretical framework used to guide the development of an exercise intervention, “*Lymfit*.” The initial testing of the preliminary version of *Lymfit* will also be presented. This chapter closes with **the first published manuscript**: “*Motivation for health promotion in cancer survivors: An evolutionary concept analysis*.” This manuscript aims to clarify the concept of “motivation for health promotion” based on the existing operationalization noted in current cancer survivorship literature.

The **third chapter**, methodology, first discusses the rationales associated with conducting a pilot randomized controlled trial. Then, the chapter presents the intervention components and the study procedures for the pilot feasibility randomized controlled trial of *Lymfit*, followed by the **second published manuscript**: “*Considerations of control conditions designs in randomized controlled trials of exercise interventions for cancer survivors*.” In this manuscript, I examine issues surrounding control condition designs in randomized controlled trials of exercise intervention for cancer survivors. The result of this manuscript also informs the study design of the pilot randomized controlled trial of *Lymfit*. This chapter closes with the methodological details of the trial.

The **fourth chapter** presents the results of the pilot randomized controlled trial of *Lymfit*, which is outlined in the **third published manuscript**: “*Pilot randomized controlled trial of Lymfit: A theory-guided exercise intervention for young adults with lymphoma.*”

The last chapter, **chapter 5**, includes the discussion and conclusion, which summarizes this thesis with an overview of the main research findings and contributions, as well as the strengths and limitations of this thesis, and directions for future research. Overall, this thesis is the product of four years of intensive learning, fruitful and stimulating collaboration with colleagues, and both professional and personal development.

## **Contributions of authors**

This doctoral thesis comprises three manuscripts of which I, Wing Lam Tock, am the first author, written under the guidance of my supervisor, Dr. Christine Maheu, and my committee members: Drs. Carmen G. Loiselle, Nathalie Johnson, Maude Hébert, and Ross Andersen. The following section describes the contributions of each author listed in the respective manuscript.

**Manuscript I (chapter 2):** Motivation for health promotion in cancer survivors: An evolutionary concept analysis.

**Author:** Wing Lam Tock

I was the sole author, and I was involved in conceptualization, data collection and analysis, writing (original draft, review, and editing), and publication efforts.

**Manuscript II (chapter 3):** Considerations of control conditions designs in randomized controlled trials of exercise interventions for cancer survivors.

**Authors:** Wing Lam Tock, Christine Maheu, Nathalie Johnson

I was involved in conceptualization, data collection and analysis, writing (original draft, review, and editing), and publication efforts. The two co-authors (Christine Maheu and Nathalie Johnson) were involved in reviewing and editing the manuscript's final draft.

**Manuscript III (chapter 4):** Pilot randomized controlled trial of *Lymfit*: A theory-guided exercise intervention for young adults with lymphoma.

**Authors:** Wing Lam Tock, Nathalie Johnson, Ross Anderson, Matthew Salaciak, Christopher Angelillo, Carmen G. Loiselle, Maude Hébert, Christine Maheu

I was involved in conceptualization, recruitment, intervention administration, data collection and analysis, interpretation, writing (original draft, review, and editing), and publication efforts. The thesis supervisor (Christine Maheu) and all thesis committee members (Carmen Loiselle, Nathalie Johnson, Maude Hébert, and Ross Andersen) were involved in the conceptualization, advise and review of data analyses, and critical revisions of the manuscript. The two co-authors, graduate students Matthew Salaciak and Christopher Angelillo, were involved in the intervention administration, data collection and analysis of the study.



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**Tock, W. L.** (2021). Motivation for health promotion in cancer survivors: An evolutionary concept analysis. *Advances in Nursing Sciences*, 47(2).

<https://doi.org/10.1097/ANS.0000000000000394>

**Tock, W. L., Maheu, C., & Johnson, N. A.** (2022). Considerations of control conditions designs in randomized controlled trials of exercise interventions for cancer survivors. *Canadian Journal of Nursing Research*, 54(4), 377–391. <https://doi.org/10.1177/08445621211062467>

**Tock, W. L., Johnson, N. A., Andersen, R. E., Salaciak, M., Angelillo, C., Loiselle, C. G., Hébert, M., & Maheu, C.** (2024). Pilot randomized controlled trial of *Lymfit*: A theory-guided exercise intervention for young adults with lymphoma. *Healthcare*, 12(11), 1101.

<https://doi.org/10.3390/healthcare12111101>

## Contributions to original knowledge

This doctoral thesis makes several distinct contributions to the field of cancer survivorship research, particularly focusing on exercise intervention targeting young adults diagnosed and treated for lymphoma. Through three inter-related manuscripts, the thesis advances knowledge in the following key areas:

The first manuscript provides a comprehensive conceptual analysis of *motivation for health promotion*, specifically in the context of cancer survivorship. By elucidating the multifaceted nature of motivation within this population, this work offers a rational basis for developing targeted health promotion interventions. This contribution extends beyond existing literature by synthesizing theoretical frameworks, empirical evidence, and clinical insights to enhance the conceptual clarity and practical applicability of motivation concepts in cancer survivorship research.

In the second manuscript, a review of control group designs in randomized controlled trials of exercise interventions for cancer survivors<sup>1</sup> offers critical insights into methodological considerations essential for designing rigorous and informative trials. By evaluating the benefits and limitations of various control conditions, this work provides practical guidance for researchers in selecting appropriate control designs to optimize the validity and interpretability of intervention effects. This contribution addresses a notable gap in the literature and informs future trial design decisions in behavioral interventions within cancer survivorship research.

Following the insights gained in the concept analysis, the methodological review, and the application of theoretical concepts to the preliminary version of the *Lymfit*, an exercise intervention for young adults with lymphoma, the refined version of the intervention was subsequently tested in a pilot randomized controlled trial. Following the proof-of-concept study conducted in 2020-2021, which examined the logistical and technical issues of the preliminary version of the *Lymfit*, this present pilot randomized controlled trial established

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<sup>1</sup> I acknowledge debates surrounding the term “survivor.” While some view it as potentially minimizing the challenges faced by individuals with a cancer diagnosis (Berry, 2019), others see it as a symbol of community and hope. Acknowledging that study participants may have identified as “survivors” to varying degrees, I minimize the use of the term “survivor” when referring to study participants. I refer to the study population in my thesis as “young adults with lymphoma” or “young adults affected by lymphoma,” and I used “individuals affected by cancer” or “cancer survivors” in the rest of the thesis to refer to people at any point on the cancer continuum from diagnosis onward.

Reference: Berry, L. L., Davis, S. W., Godfrey Flynn, A., Landercasper, J., & Deming, K. A. (2019). Is it time to reconsider the term “cancer survivor”? *Journal of Psychosocial Oncology*, 37(4), 413–426. <https://doi.org/10.1080/07347332.2018.1522411>

benchmarks for assessing intervention feasibility, acceptability, and preliminary effects, thus offering valuable insights into the potential effectiveness of the *Lymfit* intervention. The study results also provided a strong foundation for future testing of *Lymfit* on a larger scale.

Apart from these three manuscripts, this thesis synthesizes and presents an overview of the current literature on exercise-oncology and exercise interventions targeting cancer survivors, highlights the impact of exercise on health outcomes among individuals with cancer, and discusses issues related to the design, implementation, and effectiveness of exercise interventions in this patient population.

## Chapter 1. Introduction

Lymphoma, which is a cancer of the lymphatic system, is commonly diagnosed in young adults (YAs) (Canadian Cancer Society, 2021). While lymphoma can be highly curable with chemotherapy and/or radiotherapy, the treatments can lead to serious short and long-term toxicities, including cardiovascular complications, fatigue, anxiety and depression, all of which, in turn, result in lowered quality of life. Although physical activity has been shown to enhance both physical and psychosocial cancer-related health outcomes among cancer survivors, the engagement in physical activities among YAs with lymphoma remains sub-optimal (Boyle et al., 2017a; Vermaete et al., 2013). Lack of motivation is a frequently reported psychological barrier to physical activity engagement in this population (Elshahat et al., 2021). Fortunately, human motivation is potentially modifiable through interventions (Manninen et al., 2022).

Self-determination theory (SDT) represents a broad theoretical framework for the study of human motivation, and it is relevant to understanding the mechanisms of health behavior change, including the engagement and maintenance of exercise (Fortier et al., 2012; Hagger & Chatzisarantis, 2008; Ntoumanis et al., 2020). YAs affected by lymphoma can benefit from an SDT-guided exercise intervention aimed at enhancing exercise motivation near the end of cancer treatments. However, a wide range of variability exists among the current evidence in terms of the effectiveness of interventions in promoting exercise engagement and adherence in cancer survivors. Given the complexity, an optimal design of exercise interventions in this population continues to be a topic of ongoing research.

The *Lymfit* intervention was developed guided by SDT, which aimed to assist YAs with lymphoma to attain exercise motivation through the provision of three psychological needs support: autonomy, competency, and relatedness. Initially, the preliminary version of *Lymfit* intervention was tested in a proof-of-concept study (Angelillo et al., 2024). The objective of my thesis study is then to conduct a pilot randomized controlled trial to evaluate the feasibility, acceptability, and preliminary effects of the intervention in enhancing exercise motivation and engagement in physical activities among YAs diagnosed and treated for lymphoma.

## Chapter 2. Literature review

### 2.1 Young adults with lymphoma

In Canada, a burgeoning interest in cancer in young adults (YAs) is reflected in the establishment of the Canadian Task Force on Adolescents and YAs with Cancer in 2008. Funded by the Canadian Partnership Against Cancer, this task force is a national initiative aiming to develop specific cancer control strategies to improve coordination and level of care for adolescents and YAs with cancer (Canadian Partnership Against Cancer, 2017; Depauw et al., 2019).

Adolescents and YAs are identified as distinct patient populations, comprised of individuals whose cancer diagnoses occur between the ages of 15 to 39 (Canadian Partnership Against Cancer, 2017; National Institutes of Health, 2006). Specifically, individuals between the ages of 18 to 39 are classified as YAs (Colabroy, 2021). Cancer incidence rates among YAs in Canada have increased substantially in the last two decades, with approximately 7,600 new cases of cancer diagnosed each year (Canadian Partnership Against Cancer, 2019; Miller et al., 2022). YAs aged 18-39 are considered one of the fastest-growing groups of cancer survivors in Canada (Canadian Partnership Against Cancer, 2019). Among YAs, Hodgkin's lymphoma (HL) and non-Hodgkin's lymphoma (NHL), especially diffuse large B-cell lymphoma (DLBCL), are collectively the most commonly diagnosed cancers (Canadian Cancer Society, 2023).

Lymphoma encompasses malignancy of lymph nodes and the lymphatic system, and is traditionally treated with multi-agent chemotherapy, with or without radiation, and/or immunotherapy (Swerdlow et al., 2016). The most common treatment agents for HL are doxorubicin, bleomycin, vinblastine and dacarbazine and for DLBCL, cyclophosphamide, doxorubicin, vincristine, prednisone and rituximab, with the latter being an antibody targeting the B-lymphocyte antigen CD20. Even in the advanced stage setting, these regimens induce remission in over 80% of HL and 50% of DLBCL patients, respectively. In the relapse setting, the treatment is salvage chemotherapy followed by an autologous stem cell transplant, which can cure an additional 30 to 50% of patients (Leyfman, 2018). Furthermore, recent novel agents and cellular therapies have markedly improved the outcomes of patients with aggressive lymphomas (Neelapu et al., 2018). Taken together, the various treatment options have dramatically improved lymphoma patients' survival rates over the past years (Hoppe et al., 2020). In YAs, lymphoma

has become one of the most curable cancers, and the five-year relative survival rates for HL and NHL in this age group exceed 94% and 83% (Miller et al., 2022). In fact, cure rates for lymphoma have increased so dramatically that the major cause of mortality among individuals with lymphoma, especially for young people with early- or intermediate-stage disease, is often attributed to the treatment's long-term effects (Divakaran et al., 2021; Hoppe et al., 2020). Treatment-induced toxicity in YAs treated for lymphoma may include a wide range of health issues (Marks, 2021). For instance, radiation treatments to the neck, supraclavicular, and/or mediastinal region increase the risk of radiation-induced hypothyroidism and pulmonary toxicities (Lo et al., 2021).

YAs with lymphoma are also susceptible to cardiovascular complications owing to the exposure to anthracycline-based regimens and mediastinal/thoracic radiation therapy (Boyne et al., 2018; Okwuosa et al., 2017). Specifically, the risks of developing post-treatment myocardial infarction, arrhythmias, and congestive heart failure among lymphoma survivors are significantly higher than in the general population (Divakaran et al., 2021; Van Nimwegen et al., 2017). Besides the treatment-induced long-term effects, YAs with lymphoma encounter a variety of psychological and functional challenges upon the completion of their cancer treatments. These challenges include cancer-related fatigue (Nowe et al., 2017) and decreased cognitive capability (Jones et al., 2020), both of which can lead to decreased productivity and quality of life (Darbà & Marsà, 2021; Warner et al., 2016). Furthermore, according to a longitudinal, population-based survey conducted in the Netherlands, YAs with lymphoma reported more psychological distress (e.g., anxiety and depression) and lower quality of life compared to the general population (Husson et al., 2017; Jones et al., 2020).

The experiences of YAs with cancer are unique. Due to their developmental status, the spectrum of cancerous diseases found in YAs is distinct from the pediatric, adolescent, and older adult cancer populations (Ketterl et al., 2019; Lewis et al., 2014). A lymphoma diagnosis, and the subsequent treatment's long-term effects, can be devastating when it occurs at a time that YAs are developing both personal and social identities (Nicoll et al., 2020). For instance, a majority of YAs living with lymphoma are also pursuing education, launching careers, becoming independent, forming extended social relationships, and planning for their future (Nicoll et al., 2020). The diagnosis and treatment of cancer can negatively impact and delay the achievement of important life milestones in YAs (Jones et al., 2020).

While every patient with newly diagnosed lymphoma has an overwhelming likelihood of being cured with the appropriate treatments, the potential physical and psychological issues induced by treatments remain important considerations among YAs with lymphoma. Given their particular psycho-social needs, YAs require developmental status-specific, person-centered cancer survivorship care (Depauw et al., 2019). The issues of treatment toxicities, psychological issues, and decreased functioning are often compounded by inactivity and sedentary lifestyles (Boyle et al., 2017b). Interventions addressing physical activity engagement can minimize the long-term treatment side effects, further optimizing cancer-related health outcomes for YAs with lymphoma.

## **2.2 Physical activity and lymphoma-related health outcomes**

Physical inactivity contributes to chronic disease risk, and its consequences are amplified in populations with compromised health, including individuals affected by cancer (Giza et al., 2017; Lee & Cartmell, 2021). While researchers have discovered a myriad of health promotion interventions (e.g., dietary or nutritional modification) that can benefit the health of cancer patients and survivors, the positive effect of physical activity remains the most promising option, demonstrating the highest therapeutic value on both psychological and physical health (Adams et al., 2021; Campbell et al., 2019; Friedenreich et al., 2020). Early experimental studies in the 1980s demonstrated the usefulness of physical activity in improving cancer symptoms, body composition, and aerobic capacity among breast cancer patients (MacVicar et al., 1989). The interest in the effects of physical activity on psychosocial and physiological health in cancer patients has surged since the late 1990s (Friedenreich et al., 2020). This growth also fueled the emergency of a field called “exercise-oncology” (Courneya et al., 2005).

In 2010, the American College of Sports Medicine (ACSM) conducted a roundtable and developed a physical activity guideline for cancer patients (Schmitz et al., 2010). Since the publication of this guideline, the amount of evidence reporting positive associations between physical activity and cancer-related health outcomes grew exponentially over the next decade (Adams et al., 2021; Campbell et al., 2019). The 2010 ACSM evidence-based exercise guidelines targeting cancer survivors were updated in 2018 during a roundtable on Physical Activity and Cancer Prevention and Control (Campbell et al., 2019). The updated guidelines target cancer survivors during treatment and post-cancer therapy. The recommendations, named the FITT principles, suggest cancer survivors perform exercises: a minimum of 3 times per week

(Frequency); at a moderate to vigorous level (Intensity); for 30 minutes each session, for at least 8 to 12 weeks (Time); and, with aerobic activity favored over resistance training (Type). Compliance with these guidelines has demonstrated improvement in fatigue levels, anxiety, depressive symptoms, quality of life, and physical function in cancer survivors (Campbell et al., 2019).

Given the growing number of epidemiologic studies and clinical trials in the field of exercise-oncology, substantial systematic review evidence has been reported on physical activities' association with a wide range of cancer-related health outcomes. Some commonly reported cancer outcomes include quality of life (Mishra et al., 2012; Segal et al., 2017; Zhi et al., 2019), physical functioning (Nadler et al., 2019; Stout et al., 2017; Sweegers et al., 2018), anxiety and depression (Bergenthal et al., 2014; Hunter et al., 2017a), cancer-related fatigue (Carayol et al., 2013; Hunter et al., 2017b), and sleep quality (Bernard et al., 2019; Liu et al., 2019). Post-diagnosis physical activities also show improved physiological health, minimized risks of cancer recurrence, reduced all-cause and cancer-specific mortality, and improved survival outcomes among breast, prostate and colorectal cancer survivors (Friedenreich et al., 2016).

Evidence reporting on the effects of physical activity, specifically on individuals with lymphoma, is scarce, but the literature base has progressively increased in the past ten years. For instance, in a prospective cohort analysis conducted by Pophali and colleagues from 2017 to 2018, the data among 3,129 adult lymphoma survivors showed that a higher level of usual physical activities prior to diagnosis had significantly better overall survival outcome [HR 0.81, 95% CI 0.68-0.97] after diagnosis compared to those who were less engaged in physical activities (Pophali et al., 2017; Pophali et al., 2018). Moreover, continuous physical activity levels three years post-diagnosis also showed significantly improved survival outcomes [HR 0.81, 95% CI 0.63-1.04] (Pophali et al., 2017; Pophali et al., 2018). Similarly, data from another prospective cohort study of 5,135 hematologic cancer survivors reported that both pre- and post-diagnosis physical activity were associated with lower risks of all-cause mortality [HR 0.61, 95% CI = 0.50–0.74] (Schmid et al., 2018).

In terms of quality of life, a cross-sectional survey conducted among 1,339 adult lymphoma survivors reported that individuals with higher-level moderate to vigorous-intensity physical activity (MVPA) per week, compared to less active individuals, was associated with



higher quality of life [beta=3.8; CI 2.2/5.3, p<0.01], higher physical functioning [beta=7.8; CI 5.7/9.9, p<0.01], and lower fatigue [beta=-7.8; CI -10.9/ -4.8, p<0.01] (Vlooswijk et al., 2021). Cancer-related fatigue experienced by lymphoma survivors can be moderated by regular physical activities (Fischetti et al., 2019; Husson et al., 2015; Krishnan et al., 2021; Liu et al., 2019; Macpherson et al., 2015). Finally, a 2018 comprehensive review examining the effects of physical activity on physiological health outcomes among adolescents with lymphoma reported positive effects of physical activity on cardiovascular health, flexibility, muscle strength, functional mobility, and body composition (Zucchetti et al., 2018).

Yet, despite the wealth of evidence, engagement in recommended physical activity guidelines among individuals with lymphoma remains suboptimal. A 2013 systematic review of 13 exercise intervention studies reported that merely 21% to 29% of the individuals affected by lymphoma had met ACSM exercise guidelines (Vermaete et al., 2013). Likewise, a 2017 cross-sectional study involving 156 NHL survivors found that a majority of the participants lead a sedentary lifestyle after treatment, with only 12% of the participants meeting the physical activity guidelines (Boyle et al., 2017b). Many cancer-related health consequences experienced by YA with lymphoma have complex etiologies involving overlapping mechanisms. This complexity generates a strong rationale to explore multi-targeted prevention and treatment strategies, such as exercise interventions.

### **2.3 Exercise interventions targeting cancer survivors**

Exercise intervention is categorized as a sub-type of behavior intervention, of which the content comprises training that involves bodily movement aiming at increasing energy expenditure (i.e., physical activities). Exercise training comprises structured, repetitive, and purposeful activities geared towards enhancing or preserving one or more components of physical health (e.g., cardiorespiratory endurance, balance, flexibility, and musculoskeletal strength) (Campbell et al., 2019; Caspersen et al., 1985; Wolin et al., 2012). In this thesis, exercise intervention is conceived of as the means to increase physical activity levels. The physical activity recommendations for the general public might be less realizable for cancer survivors who suffer from adverse treatment effects such as deteriorated physical functioning and cardiopulmonary fitness (Rogers et al., 2018). Various exercise interventions in cancer survivors have been evaluated in terms of modality, dosage, timing, format, setting, and mode of

delivery. These features surrounding study design are essential considerations in exercise interventions targeting cancer survivors (Mina et al., 2018).

Regarding the modalities of physical activity in exercise interventions, aerobic exercises have demonstrated stronger evidence on cancer outcomes (Bergenthal et al., 2014; Ferrer et al., 2011). Along with the conventional aerobic or resistive exercise regimes, interventions using a variety of exercise modalities (i.e., strength, balance, and flexibility exercises such as yoga, Tai Chi, and dance) have also shown effectiveness in improving overall health status among cancer survivors (Duncan et al., 2017; Stout et al., 2017).

Mixed results have also been reported regarding the optimal dosage (i.e., frequency, intensity, duration) of physical activity in exercise interventions for cancer survivors. In general, at least six to 12 weeks of structured exercise, with a frequency of two to three times per week (or 60 to 90 minutes per week), are required to produce meaningful effects on health outcomes (Campbell et al., 2019). Regarding intervention formats, the evidence overwhelmingly suggests that supervised or coached exercise intervention yields superior effects on cancer-related health outcomes (Segal et al., 2017; Stout et al., 2017; Sweegers et al., 2018). Individualized exercise programs are superior to standardized exercise prescriptions, given that exercise should be planned according to an individual's baseline fitness (Mina et al., 2018).

Further, although evidence suggests that exercise is beneficial and safe both during and after cancer treatments (Campbell et al., 2019), medical clearance and pre-screening assessments should be conducted to evaluate the effects of disease, treatments, and comorbidities prior to starting exercise regimens, (Segal et al., 2017). Finally, in terms of intervention settings, stronger intervention effects are associated with clinic-based programs in general, whereas reduced participant burdens are associated with home-based interventions (Wong et al., 2018). Driven by technological advances, exercise interventions increasingly incorporate components that can be delivered remotely, such as activity-tracking devices (Ha et al., 2021; Mercer et al., 2016), mobile health (Sporrel et al., 2021) and digital health technologies (Roberts et al., 2017).

In recent years, there has been a growing body of studies aimed at examining the effectiveness of large-scale exercise interventions in improving physical activity levels among cancer survivors in Canada. In 2020, a team of researchers from Alberta launched a multi-province (Alberta, Nova Scotia, and Ontario), five-year hybrid effectiveness-implementation

trial, named the EXercise for Cancer to Enhance Living Well (EXCEL) study (Culos-Reed et al., 2022). The study aimed to examine the effectiveness of a multimodal progressive exercise intervention and its implementation strategies to reach individuals with cancer (mixed diagnoses) from rural and remote areas in Canada. The EXCEL study consisted of a single exercise intervention group (i.e., without a control group). The exercise intervention was a 12-week, virtually delivered and structured program, where participants attend a twice weekly, 60-minute classes via videoconferencing with a qualified exercise professionals (e.g., clinical exercise physiologist, or registered kinesiologists) in a group of eight to sixteen (Culos-Reed et al., 2022). Throughout the 12-week program, participants in the intervention also received educational materials during each exercise class, which aimed to enhance the adoption and maintenance of physical activity (Culos-Reed et al., 2022). Recently, the research team published results on the first-year implementation of the EXCEL study as guided by the RE-AIM framework, specifically on the “Reach,” “Adoption,” and “Implementation” outcomes (Wagoner et al., 2023). Overall, the intervention was feasible and safe. In the first year of implementation, the EXCEL study recruited 290 participants, with an 81.4% retention rate. Researchers reported that the intervention adherence rate (78%; a range of 76–82% across study sites) in EXCEL was lower than that of recently published online exercise-oncology interventions of 86–91% (Wagoner et al., 2023). Further, the study outcome assessment completion rates were around 85% at pre- and post-intervention. According to the research team, the key focus of the continued implementation of EXCEL would be to improve intervention adherence rate, and to improve follow-up assessment completion rates to be greater than 90% (Wagoner et al., 2023).

Another multi-site exercise intervention study named the Combined Aerobic and Resistance Exercise (CARE) trial was conducted across three Canadian provinces: Alberta, Ontario, and British Columbia (An et al., 2020). In this three-arm RCT, 301 adults with breast cancer undergoing chemotherapy were randomized into one of the following supervised exercise groups: 1) a standard dose of 25–30 min of aerobic exercise, 2) a higher dose of 50–60 min of aerobic exercise, or 3) a combined dose of 50–60 min of aerobic and resistance exercise. The exercise intervention length ranged from 12 to 18 weeks, and the exercise sessions were delivered in-person three times per week, and under the supervision of qualified exercise physiologists. Participants completed self-reported outcome follow-up assessments at six, 12 and 24 months after the intervention. The study results showed that participants who self-reported

adherence to exercise guidelines in the “combined does” group during follow-up also reported significantly better patient-reported outcomes and health-related fitness, indicating the superiority of combining resistance and aerobic exercises. However, the study results showed that a modest exercise adherence rate was observed, especially in the “high dose” and “combined dose” groups, indicating a challenge for participants to adhere to exercise programs during chemotherapy (An et al., 2020).

Despite the promising outcomes observed in the EXCEL and CARE trials, critical gaps persist in addressing the unique needs of individuals affected by cancer. Recent literature underscores several shortcomings in exercise interventions directed at cancer survivors. Specifically, Doré et al. (2022) have emphasized a general lack of cancer-specific physical activity programs tailored to meet the unique needs of individuals undergoing cancer treatment (Doré et al., 2022). Additionally, there is a dearth of interventions specifically designed for YAs with cancer, a population that is often overlooked in research efforts (Crowder et al., 2022). The findings from Crowder et al. (2022)’s systematic review underscore the need for personalized physical activity components incorporating behavior change techniques to maximize improvements in physical health and quality of life among YAs with cancer.

Besides the challenges in intervention implementation efforts, numerous barriers impeding exercise participation and adherence among YA cancer survivors have been reported. Physical or physiological barriers include treatment-related side effects such as fatigue, pain, and physical impairments, which hinder engagement in physical activities, especially in individuals who have completed treatments recently (Clifford et al., 2018). Social barriers, including lack of support from family and friends, limited access to suitable exercise facilities, and financial constraints, further hinder exercise participation among cancer survivors (Farah et al., 2021). Further, psychological barriers, such as depression, anxiety, and fear of injury or disease recurrence, contribute to lack of motivation and adherence to exercise programs (Elshahat et al., 2021; Hardcastle et al., 2018). Among the aforementioned exercise barriers, lack of motivation is cited as one of the most cited psychological barriers to exercise engagement (Hardcastle et al., 2018). A concept analysis was conducted to further examine the concept of “*motivation for health promotion*” in the context of cancer survivorship and is presented at the end of this chapter as **Manuscript I**. In the literature, “*motivation*” emerges as one of the modifiable determinants influencing health behavior change among individuals affected by cancer (Tock,

2021). The significance of the concept of *motivation* in the context of cancer survivorship research lies in its pivotal role as a catalyst for initiating and sustaining health behavior change (Wilson et al., 2008). In the literature, a notable gap remains in understanding how to effectively enhance motivation to promote exercise engagement within this population (Knittle et al., 2018). This challenge is exacerbated by the multifaceted health issues cancer survivors often face, which may undermine their motivation to engage in exercise (Elshahat et al., 2021).

To address this issue, implementing theory-guided interventions has been recommended to improve the effectiveness of behavior change efforts in exercise intervention studies (Ester et al., 2021). However, a significant critique within the literature is the lack of a clear theoretical framework guiding the design and implementation of exercise interventions for cancer survivors. For instance, a recently published systematic review on behavioral change theory-guided exercise interventions for cancer survivors observed inconsistencies in the measurement and interpretation of results in relation to theory across studies (Rodrigues et al., 2023). This inconsistency suggests that the use of theory in these interventions may be insufficient (Rodrigues et al., 2023). Such inconsistent utilization of theoretical frameworks in exercise interventions can contribute to variations in intervention effectiveness and hinder the identification of active ingredients necessary for motivating exercise behavior among cancer survivors.

In summary, while there is consensus on the beneficial effects of key ingredients in exercise interventions for cancer-related health outcomes, there remains considerable variability in intervention design and characteristics across the current evidence. This variability underscores the ongoing need for research to optimize the design of exercise interventions tailored to the needs of individuals affected by cancer (Courneya et al., 2015; Hecksteden et al., 2018). Additionally, YAs affected by cancer are notably underrepresented in the literature of exercise-oncology, highlighting a gap in our understanding of their unique needs. Furthermore, there is criticism regarding the insufficient incorporation of theoretical frameworks in exercise intervention research. To address these research gaps, I utilize self-determination theory to explore the motivating factors that could promote exercise behavior engagement among YAs with cancer in the following section.

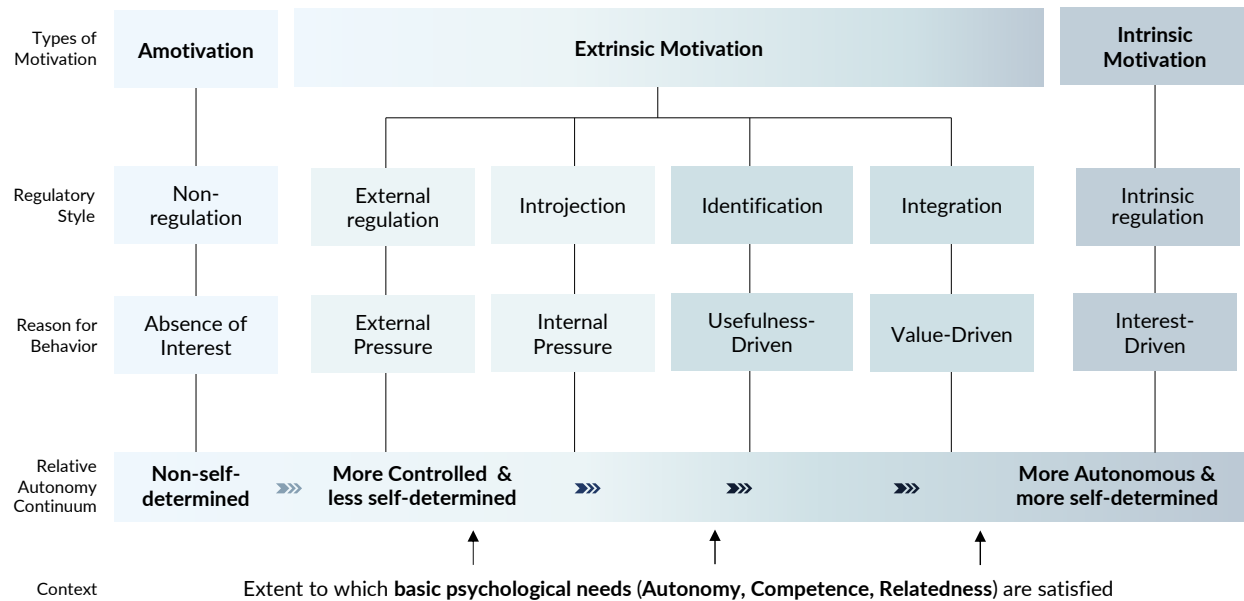
## 2.4 Theoretical framework – Self-determination theory

Self-determination theory (SDT), developed by Deci and Ryan in 1985, is a comprehensive macro-theory of human potential and motivated behavior. SDT has received significant empirical support as a theoretical framework to assist in predicting and explaining persistent health behavioral changes (Deci & Ryan, 2008b; Gunasekare, 2016). Unique among some common behavioral change theories (e.g., theory of planned behavior and self-efficacy theory), which are centered on the social-cognitive paradigm, SDT originated from a humanistic/organismic perspective (Deci & Ryan, 2000; Rhodes et al., 2019). SDT emphasizes an individual's inherent motivational propensity for growth, and how its process can be supported (Ryan & Deci, 2020).

One sub-theory within SDT is the organismic integration theory (Ryan & Deci, 2002) (**Figure 2.1**). This theory suggests that there are three general domains of motivation that regulate an individual's behaviors. The three domains, namely autonomous motivation, controlled motivation, and amotivation (**Figure 2.1**), are located along a continuum corresponding to the degrees of relative autonomy (Deci & Ryan, 1985, 2000). The organismic view also draws a distinction between intrinsic motivation, which involves engaging in behavior from internalized drives (e.g., for interests, challenge and enjoyment), and extrinsic forms of motivation, which involves engaging in a behavior as an instrument to achieving a separate consequence (e.g., ego fulfillment, or avoiding self-inflicted punishments such as guilt or shame) (Deci & Ryan, 1985). As shown in **Figure 2.1**, the different forms of motivation correspond to six different forms of behavioral regulation styles (Deci & Ryan, 2000). More specifically, **intrinsic, integrated and identified regulations** are the relatively more autonomous and self-determined types of motivation (Deci & Ryan, 2000). Intrinsic motivation stems from inherent enjoyment, pleasure, curiosity, and seeking new challenges; integrated regulation stems from the alignment with the person's system of values, needs, and goals constituting the "self," and identified regulation stems from social importance and personal values (Deci & Ryan, 2000). Whilst **introjected and external regulations** would form the relatively more controlled and less self-determined types of motivation. Introjected regulation emerges from the fulfillment of internal contingencies, such as the improvement of self-esteem or the avoidance of guilt, and external regulation emerges from the compliance with external demands, such as obtaining rewards or avoiding punishments (Deci & Ryan, 2000). Finally, **amotivation** represents the full

absence of self-determination due to the lack of perceived competence or value of the given action (Deci & Ryan, 2000).

**Figure 2.1** *Organismic integration theory*<sup>2</sup>



According to the basic psychological needs theory (**Figure 2.2**), which is another sub-theory within SDT, three human innate psychological needs for autonomy, competence and relatedness must be supported in order to foster more autonomous motivational patterns as well as optimal psychological well-being (Deci & Ryan, 2000, 2008a; Reis et al., 2000; Ryan & Deci, 2000). As shown in **Figure 2.2**, autonomy is the feeling of having control of one's behavior, competence is the ability to be effective in producing one's desired outcome, and relatedness is the sense of belonging and connectedness with others (Ryan & Deci, 2020).

<sup>2</sup> Adapted from: Deci, E. L., & Ryan, R. M. (2008). Facilitating optimal motivation and psychological well-being across life's domains. *Canadian Psychology/Psychologie Canadienne*, 49(1), 14-23. <https://doi.org/10.1037/0708-5591.49.1.14>

**Figure 2.2** *Basic psychological needs theory* <sup>3</sup>



Internalization is a central process through which an individual integrates and reconstructs external regulation styles to achieve more intrinsically regulated motivations (Deci & Ryan, 2008a). SDT argues that psychological need satisfaction can enhance the internalization of extrinsic motivations (Deci & Ryan, 2008a). The internalization process nurtures the formation of autonomous motivations, which in turn produce predictive influence behavioral engagement and well-being (Deci & Ryan, 2008a). Such a relationship makes SDT highly relevant to health behavior interventions, as it provides a blueprint for researchers to design intervention components aimed at supporting psychological needs that can, in turn, influence the target health behavior.

The organismic viewpoint of SDT has a strong practical and translational (i.e., applied) value with its functionally focused and empirically supported framework (Ryan & Deci, 2019). SDT holds considerable appeal as a theoretical framework for understanding both initiation and persistence issues in exercise behavior (Fortier et al., 2012; Hagger & Chatzisarantis, 2008; Johnson et al., 2020; Lock et al., 2018; Teixeira et al., 2012; Wilson et al., 2008). An increasing volume of research examining the behavioral and well-being consequences associated with different exercise motives has emerged in the past two decades (Rhodes et al., 2019; Wilson et al., 2008). Studies show that more autonomous forms of exercise motivations predict the initiation and maintenance of exercise behavior (Duda et al., 2014; Gunnell et al., 2014; Jang et al., 2021; Marin et al., 2018; Sevil et al., 2016; Teixeira et al., 2015). In addition, studies have demonstrated support for links between more autonomous exercise motivations and markers of well-being such as enhanced quality of life (Buttitta et al., 2017; Farholm et al., 2017; Fortier et al., 2012; Ng et al., 2012) and psychological health experienced across study populations

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<sup>3</sup> Adapted from: Deci, E. L., & Ryan, R. M. (2008). Self-determination theory: A macrotheory of human motivation, development, and health. *Canadian Psychology/Psychologie Canadienne*, 49(3), 182-185. <https://doi.org/10.1037/a0012801>



(Gunnell et al., 2014; Johnson et al., 2020; Kazak Çetinkalp & Lochbaum, 2018; McDonough & Crocker, 2007; Ntoumanis et al., 2020).

Based on this evidence, the primary mechanism of SDT-guided health interventions involves the manipulation of intervention components to foster a psychological needs supportive climate (Ng et al., 2012; Nunes Silva et al., 2014). The best approach to improve the match between theory and intervention strategies remains a topic of ongoing investigations. In a 2019 meta-analysis of techniques to promote need satisfaction and autonomous motivation for health behavior change (Gillison et al., 2019), the authors accessed 74 SDT-guided research studies conducted over five decades. The results showed that researchers operationalized SDT principles within the intervention differently. Many needs-support techniques were employed and tested, for instance, common autonomy-support techniques such as “affirmation” and “acknowledgement,” competence-support techniques such as “developing plans” and “positive feedback,” and relatedness-support techniques such as “group co-operation” and “active listening” (Ntoumanis et al., 2020; Nunes Silva et al., 2014; Wilson et al., 2008).

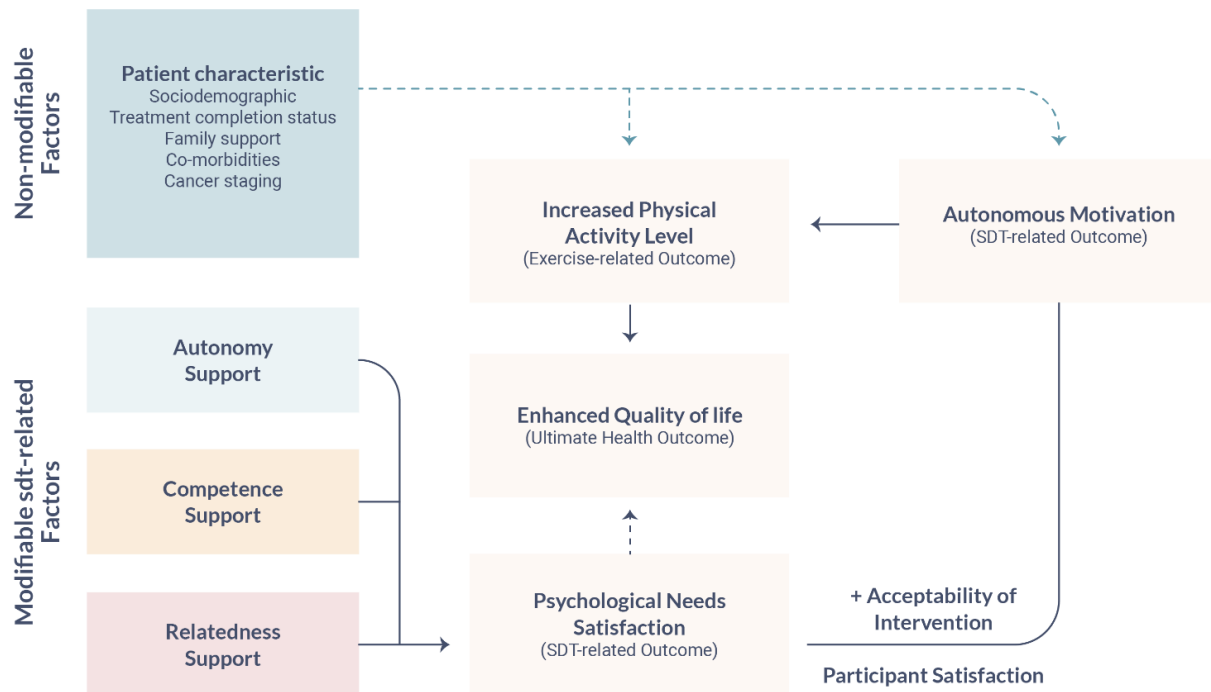
Generally, researchers argue that a need-supportive climate cannot be developed through a single technique; rather, it is achieved by a combination of techniques, actions, and interactions (Gunnell et al., 2014; Knittle et al., 2018; Ng et al., 2012). Nevertheless, the combination of strategies may not always fulfill all three basic psychological needs equally. For instance, a meta-analysis of SDT-based techniques found that interventions delivered in one-to-one settings resulted in greater competence satisfaction for adults than those delivered within groups [ $g = 0.96$  vs.  $0.28$ ] (Gillison et al., 2019). In the same meta-analysis, results showed that strategies targeting competence satisfaction, such as the provision of structure and the provision of standardized information, were both found to be associated with autonomous motivation negatively (Gillison et al., 2019). In summary, it is critical for SDT-informed interventions to manipulate both the relative balance and the intensity of the strategies with which they support the needs for autonomy, competence, and relatedness.

## **2.5 The *Lymfit* intervention**

*Lymfit* is an evidence-informed intervention theoretically guided by SDT. *Lymfit* is designed to motivate the engagement in physical activities in YAs with lymphoma through providing support in the three basic psychological needs: competence, autonomy, and

relatedness. The relationships between the intervention components and SDT's principles are displayed as a logic model in **Figure 2.3**.

**Figure 2.3** *Logic model of the Lymfit intervention*



*Lymfit* is a 12-week, virtually delivered and individualized exercise intervention. Individuals taking part in *Lymfit* are provided with an activity tracker (i.e., Fitbit), exercise stretch bands, and a personalized exercise program. The exercise program includes combinations of aerobic and resistance trainings tailored to each individual's baseline fitness level, exercise preferences and exercise tolerance. This patient-preference approach provides opportunities for participants engaged in *Lymfit* to take ownership and initiative of their exercise routine. The provision of choice is expected to support the participants' perceived autonomy. Within a 12-week timeframe, individuals taking part in the *Lymfit* intervention consult with a kinesiologist every two weeks regarding their progress, challenges, and goals. Based on individual progress and needs, the exercise program is modified as needed with the kinesiologist's guidance.

The *Lymfit* intervention is designed to provide a task-orientated climate, which is imperative to support the participants' need for feeling competent to exercise. The participants are encouraged to monitor their progress, goals, and achievements using their Fitbits and the

Fitbit smartphone application. On the interface of the Fitbit and the application, *Lymfit* participants receive constant feedback regarding their physical activity levels, allowing them to monitor their activity metrics such as daily and hourly activities, step counts, and calories burnt. When certain goals are accomplished (e.g., achieving 20,000 steps in a day), the smartphone application will display “badges and trophies” to motivate the users.

The *Lymfit* intervention delivers support for relatedness through the establishment of interdependence among the participants and between individual participants and the kinesiologists. Once participants pair their Fitbits with the smartphone application, they are connected with other participants within the “*Lymfit lounge*,” a private group created specifically for the intervention, where participants can share and compare their exercise progress and activity achievements. This intervention component provides peer support and enhances the sense of rapport and connectedness among YAs with lymphoma who are participating in the study. In addition, by showing personal involvement and supporting persistence to exercise, the kinesiologist develops a therapeutic rapport with the participants throughout the intervention. In summary, the *Lymfit* intervention incorporates strategies that are purported to satisfy the three basic psychological needs, thus potentially fostering the attainment of autonomous exercise motivation, the increase in physical activity levels, and quality of life.

***Preliminary version of Lymfit.*** The development of *Lymfit* has been an iterative process with continuous input from patient partners and experts from the field. The preliminary version of *Lymfit* was developed by a research team at the Jewish General Hospital, Lady Davis Institute (Montréal, Québec) prior to the start of the global pandemic in 2020. The preliminary version of the intervention was reviewed by long-term YAs lymphoma survivors for initial feedback. Then, a proof-of-concept study was undertaken early on in the development of the intervention (during the active pandemic-related lockdown in 2021) to allow changes to be made before more extensive testing was conducted (Angelillo et al., 2024). Using a single-armed, pre-post-test design, the purpose of this proof-of-concept study was to examine whether the intervention was suitable for further testing. Twenty YAs who were in remission from lymphoma (one to six years since chemotherapy completion) were recruited to participate in the study (Angelillo et al., 2024). Specifically, this study aimed to examine implementation feasibility (e.g., retention, technical and safety issues) of the preliminary version of *Lymfit* (Angelillo et al., 2024). The results showed that the intervention implementation had minimal technical issues and no adverse

effects. This study was published in the journal *PLoS One*, titled “*A single-armed proof-of-concept study of Lymfit: A personalized, virtual exercise intervention to improve health outcomes in lymphoma survivors in the pandemic.*” In this proof-of-concept study, I was involved as a research coordinator and contributed to participant recruitment, data collection, analysis, results interpretation, manuscript writing (initial and final drafts) and publication efforts. I was also the co-first author of the published manuscript.

I present the last piece of this chapter in the following section 2.6, which also constitutes the first published manuscript of this thesis, titled “*Motivation for health promotion in cancer survivors: An evolutionary concept analysis.*” Within the literature, the concept of “*motivation to health promotion*” lacks conceptual and operational clarity, potentially impeding its utilization in research and guiding the development of interventions to enhance health behavior change motivations among cancer survivors. Therefore, this manuscript aims to examine the concept based on the existing operationalization noted in current cancer survivorship literature. The findings of this manuscript is then used to inform the refinement of the *Lymfit* intervention.

## 2.6 Manuscript I – Concept analysis of “motivation for health promotion”

Published: *Advances in Nursing Sciences*

Title: Motivation for Health Promotion in Cancer Survivors: An Evolutionary Concept Analysis

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**Abstract**

*Motivation for health promotion* is an essential concept in healthcare research, as it pertains to an individual's ability to adapt to the adversity of chronic illnesses, including cancer. Adopting Rodgers' evolutionary method of concept analysis, the objective of this article is to clarify the concept based on its existing operationalization noted in cancer survivorship literature. Through a close examination of the construction of the concept, this article facilitates the understanding of concept as it relates to the field of cancer survivorship care, which in turns help to provide a guidance for developing health promotion intervention targeted at cancer survivors.

**Keywords:** motivation, health promotion, cancer survivorship, concept analysis

## Introduction

### Background

In the United States, roughly 2 million people were diagnosed with cancer in 2020, and this number is projected to grow in the next decades.<sup>1</sup> Fortunately, enhancements in medical treatment and early detection efforts have contributed to a substantial reduction in cancer mortality and improvement in cancer survival rates.<sup>2</sup> In 2019, individuals treated and who recovered from cancer comprise approximately five percent of the total population. As such, over 22 million individuals among the total population in the United States could live with a history of cancer diagnosis by 2030.<sup>1</sup> While the advances in oncology medicine are encouraging, it should be acknowledged that the adverse effects of cancer diagnosis and treatments can substantially impact the long-term physical and psychosocial health of this patient population.<sup>2</sup> Besides the possibility of a recurrence, cancer survivors are at greater risk for cardiovascular disease, diabetes, osteoporosis, and prolonged-fatigue compared to their age and race-matched counterpart in the general population.<sup>3,4</sup> These comorbid conditions can come from genetic predisposition and/or the toxicities of cancer therapies. Poor lifestyle management in the post-treatment period could also exacerbate existing health issues and impair physical functioning, warranting post-treatment medical therapies and symptoms management efforts to preserve physical health.<sup>5</sup>

In addition to physical symptoms management, cancer survivors need resources to address the psychosocial aspects of the illness. For instance, a substantial proportion of this patient population experiences adverse psychological effects such as fear of recurrence, anxiety, and depression.<sup>6</sup> These mental health risks, along with post-treatment symptoms and comorbid conditions, make cancer survivors one of the most complex patient populations in society.

### **Concept: *Motivation for health promotion***

*Motivation for health promotion* is an essential concept in healthcare research, as it pertains to an individual's ability to adapt to the adversity of chronic illnesses, including cancer.<sup>7</sup> Motivation is a power element mobilizing an individual to implement behavior change actions.<sup>7</sup> Health indicators such as quality of life and functional status are greatly impacted by an individual's motives to initiate and maintain health-promoting behaviors.<sup>8</sup>

Unfortunately, cancer survivors report suboptimal adherence to healthy lifestyle promotion recommendations.<sup>9</sup> Cancer treatment side effects, such as prolonged fatigue, constitute barriers in initiating, maintaining, and engaging in health promotion behaviors among survivors. This vicious cycle can further exacerbate the already compromised health of a patient.<sup>10</sup> In order to identify strategies and resources supporting successful survivorship care, a growing body of literature has analyzed the influence of motivation on behavior patterns among cancer patients and survivors.<sup>11,12</sup> Whilst considerable attention has been devoted to study the concept of *motivation for health promotion*, multiple theoretical frameworks and measurements have been adopted to study the implications surrounding motivation to promote health-related behavior among cancer survivors. The optimal mechanisms of health promotion intervention remain ambiguous due to the lack of clarity of components (i.e., attributes, antecedents, and consequences) surrounding the concept.

A clear understanding of the concept of *motivation for health promotion* is crucial in elucidating the mechanisms in which cancer survivors adopt to achieve sustainable health promotion behavior change. Clarification of the concept is necessary for its use in research and to guide the development of interventions to enhance *motivation for health promotion* among patients diagnosed with and treated for cancer. An analysis of the concept of *motivation for health promotion* in cancer survivors is presented in this paper. Rodgers' evolutionary methodology offers an inductive approach to understanding a concept.<sup>13</sup> Adopting Rodger's methodology to guide the analysis, the objectives of this paper are to a) better clarify the concept of *motivation for health promotion* as it relates to the health outcomes among cancer survivors, and b) to help provide a rational basis for making decisions regarding health promotion intervention development targeted at this patient population.

## **Method**

### **Rodgers' evolutionary concept analysis approach**

Rodgers' evolutionary concept analysis methodology was used to examine the concept of *motivation for health promotion* in the context of cancer survivorship.<sup>13</sup> This evolutionary concept analysis methodology emphasizes that concepts are dynamic in nature and are in constant changes over time.<sup>13,14</sup> Cancer survivorship research has been undergoing contextual changes over the last several decades; thus, matching with the premise of Rodgers' approach.



Furthermore, this methodological approach is suitable for analyzing concepts that could be conceptualized and operationalized differently in diverse contexts and across disciplines of practice.<sup>13,14</sup> Rodgers' model suggests that the analysis process of a concept does not lead to the identification of static or finite features. Rather, it maps current knowledge surrounding the concept and provides directions to facilitate future research endeavors.<sup>13</sup>

The evolutionary concept analysis model relies on activities that are iterative and not necessarily linear<sup>13,14</sup>. Following this iterative analysis model, the concept of interest and its related concepts known as surrogate terms were first identified; followed by the selection of an appropriate realm (i.e., the setting and sample) for data collection; after data were extracted and synthesized, the defining attributes, antecedents and consequences of the concept in the basis of interdisciplinary, sociocultural, and theoretical variations were identified. Finally, an exemplar of the concept was identified, and the implications for future research and further development of the concept were discussed.

### **Data collection: Settings and sample**

The data source for this concept analysis was published documents identified through two databases indexing health-related literature (i.e., CINAHL Plus with Full Text, and Medline - Ovid 1946 -). A literature search using the key words "motivation," "cancer survivors," "cancer survivorship," and "health promotion" was performed with consultation from a health science librarian. No year of publication restriction was placed for the searches, thus allowing for the capture of historical and contextual patterns that changed over time. Documents of various types (i.e., original research, books, and knowledge synthesis studies) and journal articles were considered for potential inclusion in this analysis. No limitations were placed on the disciplinary orientation or the types of research. Among the 630 references initially yielded, 432 remained after removal of duplicated records. Titles and abstracts were then screened to determine relevance to this review. Articles were retained if the purpose of the article was to examine the relationship between *motivation* and a *health promotion* behavior or activity (e.g., exercise, diet modification) in the context of cancer survivorship research. Commentaries, book reviews, letters to the editor, and conference proceedings were excluded from the analysis due to the limited elaboration on the concept provided. Abstracts without full-text or articles without an English full-text were also excluded from this review. A total of 44 documents remained for full-

text screening after the initial eligibility and abstract/title screening procedures. To be included in the analysis, the documents must have identified *motivation* as a factor of interest and a *health promotion behavior* as the outcome of interest, and involved adult cancer survivors above 18 years old as the target population. Nineteen documents relevant to the present concept analysis topic remained after the full-text evaluation. Reference lists of all relevant documents were hand-searched for additional relevant studies. An addition of six articles were identified in the hand-search, and a final sample of 25 documents was included as the data source of this analysis.

### **Data charting and management**

Each document was first thoroughly read, which allowed the author to gain insights on the targeted concept. Categories were then created to classify the relevant information retrieved from this first reading. Alongside standard bibliographical information (i.e., authors, primary author's disciplinary affiliation, journal, country, and year of publication), all statements/verbatim pertinent to the defining attributes, antecedents, and consequences of the concept were documented. Theoretical underpinnings, measurement tools related to the concepts, as well as surrogate terms, and related concepts were also identified during this phase. To ensure the credibility of the analysis, an audit trail of the data charting and analysis was kept. The data extraction scheme also functions to track the steps, perception and methodological judgments, and thought processes throughout the data charting and analysis procedures, thus contributing to the integrity of the analysis.<sup>13</sup>

### **Data analysis**

Thematic and inductive analytic methods were conducted to analyze the targeted concept. In the first step of the analysis, a coding system was built in which data pertaining to the defining attributes, surrogate terms, theoretical origins and measurement of the concept, and contextual information (i.e., the referents, antecedents, consequences, and related concepts) were retrieved on individual coding sheets. Each coding sheet was examined separately and repeatedly until a major recurring theme for each category of data was identified. Collected data were coded according to the emerging themes. Labels are representative descriptions generated to illuminate the nature of the data,<sup>13</sup> and they were constructed to describe the significant characteristics of each emerging themes during the analysis. Next, the coded data were then repeatedly organized and synthesized until all extracted data were grouped under a specific label subcategory. The

synthesized data were then collapsed into the synopsis presented in this paper. Although not specified in Rodgers' model, examination of the theoretical origins and measurements allow the use and application of the concept to unfold over time. They are therefore considered significant to the understanding of this concept. Throughout the analysis procedure, the concept was considered through various contextual bases, which is consistent with the principle of Rodgers' evolutionary model. For any uncertainties in the data extraction and analysis process, a nursing scholar with expertise in concept analysis and familiar with Rodgers' methodology was consulted, any concerns or disagreements emerged in the process were discussed until consensus was reached.

## Findings

A final set of 25 documents, including 24 original research published in peer-reviewed journals, and one book chapter, were included in this analysis. As shown in **Table 2.1**, year of publication, primary author's disciplinary affiliation, study designs, settings, and country of origin varied in these documents. A majority of the studies adopted theoretical models or measurement scales to operationalize *motivation for health promotion* behavior among cancer survivors. The majority of these documents were published in North America (i.e., the United States and Canada).

**Table 2.1** *Data source characteristics*

Authors, Year of Publication	Publication Type, Study Design	Disciplines of the First Author	Country of Origin
Adams et al., 2019 <sup>33</sup>	Journal, Intervention trial	Public health	Germany
Avancini et al., 2020 <sup>36</sup>	Journal, Focus group interview	Applied health sciences	Italy
Brunet et al., 2013 <sup>37</sup>	Journal, Semi-structured interview	Kinesiology/Exercise science	Canada
Clough-Gorr et al., 2009 <sup>38</sup>	Journal, Secondary data analysis	Kinesiology/Exercise science	United States
Courneya et al., 1999 <sup>39</sup>	Journal, Intervention trial	Behavioral science	Canada
Courneya et al., 2004 <sup>40</sup>	Journal, Secondary data analysis	Behavioral science	Canada
Courneya et al., 2016 <sup>11</sup>	Journal, Randomized controlled trial	Behavioral science	Canada
Courneya et al., 2012 <sup>41</sup>	Journal, Randomized controlled trial	Behavioral science	Canada

Cuevas et al., 2014 <sup>42</sup>	Journal, Intervention trial	Applied health sciences	United States
Frensham et al., 2020 <sup>24</sup>	Journal, Intervention trial	Nursing	Australia
Kim et al., 2020 <sup>35</sup>	Journal, Cross-sectional survey	Nursing	Korea
Lee et al., 2013 <sup>43</sup>	Journal, Intervention evaluation	Nursing	Korea
Martin et al., 2016 <sup>44</sup>	Journal, Randomized controlled trial	Kinesiology/Exercise science	United States
Mayer et al., 2018 <sup>20</sup>	Journal, Randomized controlled trial	Applied health sciences	United States
Mazzoni et al., 2019 <sup>45</sup>	Journal, Mixed-methods study	Behavioral science	Sweden
Midtgaard et al., 2012 <sup>30</sup>	Journal, Semi-structured interview	Nursing	Denmark
Milne et al., 2008 <sup>17</sup>	Journal, Cross-sectional survey	Kinesiology/Exercise science	Australia
Monteiro-Guerra et al., 2020 <sup>46</sup>	Journal, Semi-structured interview	Public Health	Spain
Pinto et al., 2011 <sup>47</sup>	Book Chapter	Behavioral science	Germany
Pinto et al., 2002 <sup>48</sup>	Journal, Cross-sectional survey	Behavioral science	United States
Robertson et al., 2018 <sup>49</sup>	Journal, Cross-sectional survey	Behavioral science	United States
Robinson et al., 2016 <sup>12</sup>	Journal, Focus group interview	Nursing	United States
Ryu et al., 2020 <sup>50</sup>	Journal, Cross-sectional survey	Nursing	United States
Tsai et al., 2017 <sup>51</sup>	Journal, Focus group interview	Public health	United States
Wilson et al., 2006 <sup>21</sup>	Journal, Cross-sectional survey	Applied health sciences	Canada

## Emergence of the concept

Although no year restriction was placed in the search, all of the documents meeting the inclusion criteria were published in the past two decades (i.e., 1999-2020). A majority of the publications were written on or after the year 2011 (72%,  $n = 18$ ), while only 7 publications (28%) were written in the time between 1999 to 2011. Studies examining motivation for health maintenance or promotion activities in the general population have been conducted prior to this period of time,<sup>7</sup> but it has not been applied specifically in the realm of cancer survivorship research. This finding could be attributable to the fact that the concept of *motivation for health promotion* has emerged and evolved along with the proliferation of cancer survivorship research in health literature in the past decade.<sup>5</sup>

In fact, survivorship care was not acknowledged as a specialization in the healthcare arena until 2006, when the seminal report by the Institute of Medicine explored the healthcare needs among cancer survivors, highlighting healthy lifestyle intervention as a major component in the provision of care.<sup>15</sup> During the same time period, health intervention studies aiming at improving health outcomes in the population proliferated.<sup>16</sup> As a result of all these factors combined, studies aiming at identifying the motivation and barriers in initiating and maintaining health promotion behavior have been swiftly adopted in cancer survivorship research and peaked in the past five years, with over 50% of the included documents published after 2015.

Surrogate terms are terminologies that possess the same meaning and characteristics as the terms chosen to represent the concept in a concept analysis.<sup>13</sup> The use of surrogate terms was common among the identified literature, particularly in the description of the term “motivation,” including “will power,” “drive,” and “initiative.” For the term “health promotion,” surrogate terms were often used to refer to the actual activities such as “physical activity,” “exercise,” “diet modification,” and “lifestyle modification.”

## Theoretical framework and measurements

Many theoretical frameworks have been adopted by researchers in studies investigating cancer survivors’ motivation for initiating and maintaining health promotion activities. Among the studies included in this analysis, 18 out of 24 (75%) adopted one or more theoretical frameworks have an aim to elucidate the relationship between motivation and health promotion behaviors (**Table 2.2**).

**Table 2.2** *Health behavior theories on motivation and measurement scales/ instruments*

References number	Health behavior theories	Conceptualization of motivation	Measurement scales or instruments
24, 46, 51	Social Cognitive Theory by Bandura, 2001	<b>Motivation</b> is internally comprising such processes as self-efficacy, social comparisons, goals, outcome expectations, values, and attributions. Goals and goal progress are evaluated to sustain self-efficacy and motivation.	<ul style="list-style-type: none"> <li>Physical Activity Maintenance Assessment</li> </ul>
17, 20, 21, 24, 35, 44, 45, 46, 49, 51	Self - Determination Theory by Deci & Ryan, 1985	<b>Self-motivation</b> evolves from how well a person's innate psychological or basic needs are met within their social milieu, all regulations (i.e., motives) are located adjacently along a self-determination continuum spanning a range from highly controlled to autonomously endorsed motivations.	<ul style="list-style-type: none"> <li>Behavioral Regulations of Exercise Questionnaire version 2</li> <li>Treatment Self-Regulation Questionnaire : autonomous motivation subscale, modified for physical activity behavior</li> <li>Physical Activity Maintenance Assessment</li> </ul>
11, 39, 41	Theory of Planned Behavior by Ajzen, 1991	Intention (i.e., <b>motivation</b> ) is the primary determinant of behavior. <b>Motivation</b> is also an indicator of the strength of behavioral intention.	<ul style="list-style-type: none"> <li>Not standardized, example question to access intention, "How motivated are you to exercise during the next 12 weeks?" with response options ranging from 1 (extremely unmotivated) through 4 (neutral) to 7 (extremely motivated)</li> </ul>
12, 43, 48	Transtheoretical Model by Prochaska & DiClemente, 1983	Integrating the concepts of self-efficacy and <b>motivation</b> , the model posits that the stages of change (i.e., <b>motivational readiness</b> ) are a way of viewing change on a continuum, in which individuals move from pre-contemplation, contemplation, preparation, action, to maintenance.	<ul style="list-style-type: none"> <li>Authors assessed the five stages of motivational readiness for exercising using a standardized questionnaire to assess the stage of vigorous and moderate-intensity exercise</li> </ul>
42	Reversal Theory by Apter, 2001	Adopting a phenomenological approach to understanding human <b>motivation</b> . The theory focuses on the dynamic qualities of human experience to describe how a person regularly reverses between psychological states (i.e., emotions), reflecting their motivational style.	<ul style="list-style-type: none"> <li>Apter Motivational Style Profile with a motivation subscale</li> </ul>
40	Attribution Theory by Weiner, 1985	It is postulated that how people attribute causes to events and how this cognitive perception affects their <b>motivation</b> . The causes people invoke to explain their past achievement outcomes will influence their future behavior through the mediators of expectancy of success and affective reaction.	<ul style="list-style-type: none"> <li>Each theoretical variable is measured using individual scales. e.g., Causal dimensions were measured by the revised Causal Dimension Scale</li> </ul>

For instance, in 2008, Milne et al. conceptualized motivation for physical activity among a group of breast cancer survivors using the Self-determination theory (SDT),<sup>17</sup> and operationalized the concept using the Behavioral Regulations of Exercise Questionnaire version 2 (BREQ-2) to measure exercise motivation.<sup>18</sup> SDT is a theory of human motivation and personality that concerns an individuals' inherent growth tendencies and innate psychological needs.<sup>19</sup> Alternatively, other researchers adopting SDT<sup>20,21</sup> had also aligned the motivation theory with the Treatment Self-Regulation Questionnaire autonomous motivation subscale.<sup>22</sup>

Likewise, the Social Cognitive Theory (SCT)<sup>23</sup> focuses on the intrapersonal, social, and environmental mediators in behavior change. SCT is another commonly used theoretical approach that addresses this issue of *motivation for health promotion* behaviors among cancer survivors. In a recently published study,<sup>24</sup> scholars operationalized the theoretical variables in SCT and SDT using the Physical Activity Maintenance Assessment.<sup>25</sup> Furthermore, the Theory of Planned Behavior,<sup>26</sup> the Transtheoretical Model,<sup>27</sup> the Reversal Theory,<sup>28</sup> and the Attribution Theory<sup>29</sup> have also been used by researchers in cancer survivorship health promotion studies.

As presented in **Table 2.2**, these theoretical frameworks and measurement tools offered different approaches to conceptualize and operationalize “*motivation*.” Although the theoretical underpinnings of the concept varied among the studies examined, they contained common features that informed the selection of defining attributes discussed in the next section.

### **Defining attributes**

Defining attributes refer to the characteristics that define a concept.<sup>13</sup> Rodgers proposed that attributes should exist to some extent in all instances when the concept is used. When mentioned in cancer survivorship literature, the concept “*motivation for health promotion*” exhibits explicit characteristics, and three attributes identified among the data reviewed in this analysis are displayed in **Table 2.3**.

**Table 2.3** *Motivation for health promotion: Defining attributes, antecedents, consequences, and related concepts*

Defining Attributes	Antecedents	Consequences	Related Concepts
▪ Taking ownership	▪ Moral obligation for self	▪ Attainment and maintenance of the quality of life	▪ Volition in action
▪ Multifaceted	▪ Positive outcome expectation	▪ Regaining a sense of control	▪ Self-efficacy
▪ Dynamic and in a continuum	▪ Positive affect/ emotion	▪ Conserve meaning in the illness experience	
	▪ Supportive social environment		
	▪ Perceived competence		

***Taking ownership.*** Among cancer survivors, *motivation for health promotion* represents taking ownership of one's life. Cancer diagnoses force an individual to confront with one's consciousness about death and life's finite nature.<sup>30</sup> Cancer survivors, therefore, might experience loss of security over their lives upon receiving the cancer diagnosis. *Motivation for health promotion* also signifies the experience of identifying with and owning the illness. The concept represents a proactive approach to handle one's life, illnesses, and health. The sense of self-awareness stemmed from the illness experience constitutes an important element in determining cancer survivors' wiliness to actively manage one's health, which can uncover the capacity to seek power over life's direction.

***Multifaceted.*** *Motivation for health promotion* among cancer survivors was also characterized as being multifaceted. According to Deci and Ryan (1985), motivation could have either an intrinsic or extrinsic orientation (i.e., regulated by internal or external factors).<sup>19</sup> Intrinsic motivations for health promotion behavior refers to the psychological drive and often involve internalized emotions such as the feeling of satisfaction, enjoyment, and personal accomplishment, whereas extrinsic motivations involve interactions with outside forces such as rewards, recognition among a social group, social competition, social approval, and responsibility to participate.



Further, *motivation for health promotion* could be multifaceted in terms of its relationships with personal, interpersonal (i.e., social context), environmental, and organizational factors.<sup>23</sup> Similar to intrinsic motivation, personal factors influencing an individuals' motivation can comprise enjoyment, passion, a sense of physical and mental wellness, and self-esteem. Support from individuals within the same social group and the desire to affiliate with others are considered interpersonal factors. Finally, environmental and organizational factors could include access to supportive facilities and opportunities.

***Dynamic and on a continuum.*** *Motivation for health promotion* is a dynamic concept, which could be stimulated and sustained via certain mechanisms. In the same line, the *motivation* could be restrained and weakened by certain factors.<sup>19,28</sup> Apter (2001) postulated that human motivation styles transform along with human experiences, which are dynamic.<sup>28</sup> *Motivation for health promotion* is a non-static concept, or in other words, regulated by multiple factors such as emotions, perceptions, and experiences.<sup>28</sup> According to Deci and Ryan (1985), an individual's motivation for goal-directed behavior exists on a continuum, ranging from amotivation (i.e., lack of impetus for the behavior), to controlled motivation, and finally, more self-determined motivation (i.e., able to perceive a high level of autonomy).<sup>19</sup> Furthermore, according to Prochaska & DiClemente (1983), an individual's motivational readiness can be visualized as a continuum of stages, including pre-contemplation, contemplation, preparation, action, to the maintenance stage.<sup>27</sup> In summary, cancer survivors could move within the continuum of *motivation for health promotion* reflecting the degree to which the concept has been integrated into their sense of self-ownership,' or depending on the degree to which they are influenced by factors from different sources.

### **Contextual basis**

Contextual basis illustrates the situations that precede (i.e., the antecedents) and follow the concept "*motivation for health promotion*" (i.e., the consequences), and related concepts that are distinct but often mentioned or used in publications describing *motivation for health promotion* in cancer survivorship literature. An analysis of the context basis provides knowledge on the events, situations, or phenomena to which the target concept is referenced (e.g., a specific sociocultural setting or a health care discipline).

**Referents.** The concept of *motivation for health promotion* has been situated within a diverse disciplinary landscape and sociocultural contexts. *Motivation for health promotion* was extensively studied in the field of behavioral science/behavioral medicine; eight of the included documents (32%) were written by academic scholars or practitioners in the field. Six documents (24%) included in this analysis were published by nursing scholars, while four documents (16%) were from applied health science, four (16 %) were from Kinesiology/Exercise Science, and three (12%) were from public health. While the disciplinary orientations were determined by the first authors' primary affiliation, most research team were composed of interdisciplinary members. For instance, a qualitative study investigating breast cancer survivors' motivation for participating in team exercise training intervention published in the *Journal of Clinical Nursing* was co-authored by professionals from nursing, physical therapy, and exercise science.<sup>12</sup> In terms of the country of origin, 60% (n = 15) of the documents were published in North America (i.e., United States and Canada), 24% (n = 6) in European countries, 8% (n = 2) in Australia, and 8% (n = 2) in Korea.

**Antecedents.** Antecedents are the events that precede or trigger the concept. After a thorough examination of the included literature, five antecedents for the concept of *motivation for health promotion* among the cancer survivor population have been identified (**Table 2.3**). First, “**moral obligation for self**” preceded the concept in a majority of the documents. Obligation was also described as self-responsibility, self-awareness, self-regulation, self-concordance, or self-monitoring in the literature. The motivation to initiate and maintain health promotion behaviors among cancer survivors was often triggered by a sense of awareness of the present, which signifies the responsibility to act on the behalf of oneself. Further, “**positive outcome expectation**” is also necessary to trigger the motivation among cancer survivors. A higher expectation of success can facilitate goal attainment and task engagement. Similarly, “**positive affect**” (i.e., emotions) has the potential to influence goal-orientated outcomes. For instance, perceiving a more positive life outlook, or perceptions of fulfillment and pride in tasks could also trigger or influence future behaviors. Besides, a “**supportive social environment**” could lead to a sense of relatedness and belonging. Social support is a crucial determinate of health promotion behaviors by generating the desire to affiliate with a social group. The final antecedent identified in this analysis, “**perceived competency**,” is the subjective perception of one's ability to reach the desired goal or to exhibit one's capacities. Perceived competency is

considered an essential element preceding *motivation for health promotion* among cancer survivors.

**Consequences.** Three primary results of *motivation for health promotion* were identified (Table 2.3). “**Attainment and maintenance of quality of life**” was predominately associated with the positive effects of the health promotion activities. Bettered health in general could lead to effective coping and reduced perceived vulnerability. Further, health promotion activities such as exercising could lead to a sense of self-worth, personal accomplishment, achievement, and improved physical health, all of which contributing to enhanced quality of life among cancer survivors. Additionally, *motivation for health promotion* could contribute to the “**regaining of sense of control**” for patients over their lives: being able to initiate and maintain health promotion behavior after cancer signifies control and restoration over one’s direction in life. Finally, *motivation for health promotion* helped cancer survivors to “**conserve meaning in the illness experience.**” Individuals suffering from cancer often lose the ability to make coherent sense of diagnosis. Maintaining health promotion activities represents order in daily lives, which helps the cancer survivors to find meaning in the adversity and to see the experience as a challenge worth their emotional investment.

**Related Concepts.** Related concepts are concepts that share some attributes or characteristics with the concept being analyzed.<sup>13,14</sup> *Volition in action* and *self-efficacy* were two concepts closely related to *motivation for health promotion* behavior studies in the cancer survivorship literature. **Volition** pertains to humans’ capacity for voluntary action, emphasizing an individual’s self-perceived competency and behavior control abilities.<sup>31</sup> The volition in action concept shares some characteristics with the motivation concept (e.g., action intention, goal-orientation, etc.), both of which are closely related to the concept of *motivation for health promotion*. In fact, *volition in action* and *motivation* have been adopted jointly to guide in health behavior research.<sup>32</sup> For example, in one of the studies analyzed, which was examining a physical activity intervention targeting breast cancer survivors, an integrative Motivation–Volition concept was used to provide a theoretical model to guide the intervention design.<sup>33</sup> Another related concept observed is **self-efficacy**, which is defined as the self-judgment of one’s capability to attain the desired outcome.<sup>34</sup> As an essential determinate of human behavior and actions, self-efficacy is another concept closely linked to the motivation concept in health promotion research among cancer survivors. For example, in Social Cognitive Theory and

Transtheoretical Model, the concepts of self-efficacy and motivation are integrated to help understand the process or stages of health behavior change.<sup>23,27</sup>

### **Exemplar of the concept**

Adhering to the inductive concept analysis technique, an exemplar adopted from a study conducted by Midtgaard and colleagues (2012)<sup>30</sup> was modified to provide a comprehensive description and visualization of the concept of *motivation for health promotion*.<sup>13</sup> Kaya, a 36-year-old female breast cancer survivor, was physically inactive prior to her cancer diagnosis. While she was receiving her cancer treatment at the hospital, she was recruited by her oncologist to participate in a one-year exercise rehabilitation program, which consisted of weekly supervised exercises, lectures given by exercise specialists, group-based coaching, and individualized coaching sessions. Since receiving the breast cancer diagnosis, Kaya realized how vulnerable one's health could be in the face of adversities and illnesses. She decided to prioritize her self-responsibility and take action to preserve her health and to avoid the alternative unfavorable state. After an in-depth consultation with her oncologist, intrigued by the benefits of regular physical exercise, she agreed to join the program with a positive attitude and a high expectation of success.

During the course of the rehabilitation program, the peer-support and coaching received in the sessions helped Kaya to devise a new agenda in her life. From time to time, she experienced days when she had a negative self-image and did not want to participate in the group activities. Further, Kaya also had difficulties prioritizing her time with her children while adhering to the program instructions. Nevertheless, Kaya received tremendous support from the new friends in the rehabilitation program. Within the supportive environment, Kaya was encouraged to set incremental goals and to engage in positive competition with one-self throughout the journey.

As Kaya was reintegrating her daily activities and continuing with her cancer regimes in the post-treatment period, she slowly regained a sense of control over her illness. Participating in the rehabilitation activities gave her self-worth. In her mind, the program gave her the opportunities to preserve her personal potential, therefore restoring her faith in life.

In this example, Kaya experienced the antecedents of a sense of moral obligation for herself, positive outcome expectation and attitude, and as a result she managed to preserve her

health and quality of life and regained a sense of control during her survivorship journey (i.e., consequences). As evidenced in this exemplar, the concept of *motivation for health promotion* was characterized by being on a dynamic continuum, as well as situated in the sense of ownership. This exemplar also demonstrated that the concept is multifaceted.

## Discussion

Health is multifaceted and all-encompassing; its physical, psychological, social, and spiritual aspects are all critical to cancer survivor's well-being.<sup>5</sup> Since the late 1990s, the descriptions of *health promotion* shifted from simple conversations between health providers and cancer patients to rigorous investigations describing the relationship between motivational cascades and human behavior in cancer survivorship research. The overall intention behind this evolutionary concept analysis was to map the defining attributes, antecedents, and consequences pertaining to the concept of *motivation for health promotion* among cancer survivors in the literature and across contextual circumstances. Important to the evolutionary concept analysis model is the identification of future directions pertaining to research and practice. More specifically, the identified attributes provide insights for nurses, who may reflect on their own clinical practices or research directions to understand how motivation is experienced among cancer survivors. The identified antecedents empower nurses to address personal and external factors that promote or hinder health promotion behavior among cancer survivors, in turn, guide the development of effective approaches that enhance health motivation in this population. The consequences of concept provide outcome criteria for the assessment for interventions aiming to enhance health behavior change motivation among cancer survivors.

A diverse panel of health-related disciplines has put in considerable efforts to address health promotion in cancer survivorship care. For instance, the nursing discipline addresses unmet needs at the forefront of patient-centered survivorship care, while behavioral medicine delivers sound theoretical supports to tackle issues surrounding the complex interplay of human behavior and motivation. Further, medicine, applied health sciences, exercise science, and public health offer insights into best practices regarding health promotion and lifestyle management throughout the survivorship trajectory. An interdisciplinary approach to tackle the issues surrounding *motivation for health promotion* among cancer survivors seems appropriate and should be encouraged.

This present concept analysis also depicts a complex image of theoretical models and measurements adopted by researchers to guide their research surrounding the focal variable, “motivation,” in this concept. While theories might aid in structuring the overall flow of a study, they might also create boundaries in the visualization of the full picture, depending on what complementary constructs or concepts constituted the entire framework. For instance, the Transtheoretical Model allows researchers to identify motivational readiness by categorizing individuals into distinct stages, without acknowledging the multidimensionality of the concept. The Self-Determination Theory recognized that human motivation to initiate actions could be influenced by either extrinsic or intrinsic factors, but did not take into account the factors pertaining to the maintenance of behavior over time. The Reversal Theory, on the other hand, adopted a phenomenological approach to conceive human motivation, thus viewing human motivation and behavior as inconsistent and changeable. As such, the choice of measurements corresponding to theoretical variables seems to be inconsistent across the literature. The use of such a diverse selection of theories and instruments to study a single concept might be problematic, as it suggests a lack of theoretical consensus regarding both the definition of *motivation for health promotion* and its measurement. Continual reviews and organization of motivation-related health behavior research are warranted. Meanwhile, scholars should carefully articulate the meaning and purpose of their work while matching a theoretical framework or measurements of motivation to their studies.

While most of the studies analyzed in this paper were published in North American or European countries, an analysis of sociocultural specific conceptions of *motivation for health promotion* was outside the scope of this concept analysis due to the limited diversity in the data. Nevertheless, culturally specific conceptions are essential for a comprehensive understanding of the concept. The themes of “self,” “ownership,” and “personal control” were extensively cited in the literature in most studies. In one study conducted in Korea; however, the authors specified that the collectivist culture predominating in Eastern countries values conformity to group norms and authorities over the individualistic self.<sup>35</sup> As such, the discussion of *motivation for health behavior* might revolved around group interdependence and membership, rather than individual autonomy. In sum, cultural considerations in cancer survivorship care should be taken into account in practice.

Finally, as presented in the synopsis and the exemplar case, *motivation for health promotion* is a multifaced and dynamic concept which can be perceived differently by individuals suffering from cancers based on their attitude, cognitive processes, cultural backgrounds, and personal lived experiences. Given the complexity of the illness, personalized nursing care and further theory development tailored to survivorship care are needed.

### **Limitation**

Limitations present in this concept analysis despite the adaptation of a rigorous methodology. For instance, the data extracted from qualitative (i.e., subjective data) and quantitative studies (i.e., objective data) may not be comparable across contexts. Further, given the sampling method, relevant documents published in the grey literature were excluded. Finally, publications in non-English languages were excluded in the analysis, and the results of the analysis could be Anglophone biased. As a result, this concept analysis might present an incomplete picture of the concept in terms of its cultural implications.

### **Conclusion**

This concept analysis represents the literature on the concept of *motivation for health promotion* in the field of cancer survivorship from 1999 to 2020. Adopting Rodger's evolutionary concept analysis methodology, three attributes, five antecedents, three consequences, and two related concepts were identified. Understanding how *motivation for health promotion* is applied in the context of cancer survivors is important to the practice of the nursing discipline because it will offer nurses new possibilities for providing guidance, support, and assistance in enhancing outcomes for individuals who have survived cancer. More specifically, *motivation for health promotion behavior* is a *multifaceted* and *dynamic* concept, representing a *sense of ownership* in cancer survivors' life. Antecedents including *moral obligation for self*, *positive outcome expectation*, *positive affect*, *social support*, and *self-competency* have the potential to empower cancer survivors' decision making regarding their lifestyle. The consequences, including the *attainment of quality of life*, *restoring order in life*, and *conserving meaning in the illness experience*, could be considered as the outcome criteria for the assessment of the concept in cancer survivorship care. The healthcare arena is increasingly expecting the incorporation of healthy lifestyle interventions in the standardized model of cancer survivorships care, and nursing scientists play an invaluable role in transforming the way

healthcare is delivered to the patients. An integrated and patient-centered approach must be employed throughout the cancer care trajectory. Nurses are uniquely situated to assist in the gratification of psychosocial health of cancer patients, which could be achieved by promoting adaptive coping strategies that support *motivation for health promotion* among cancer survivors.



## **Conflicts of interest**

The author has disclosed that she has no significant relationships with, or financial interest in, any commercial companies pertaining to this article.

## **Statements of significance**

**What is known or assumed to be true about this topic?** *Motivation for health promotion* is an essential ingredient in adapting to the adversity of chronic illnesses. Indeed, a substantial proportion of cancer survivors experience adverse effects such as fatigue and decreased physical functioning due to the toxicity of therapies, which can be alleviated by health promotion behaviors such as exercising. Currently, this concept lacks conceptual and operational clarity, which might hinder its use in research and to guide the development of interventions to enhance health behavior change motivations among cancer survivors.

**What this article adds:** This article adopted Rodgers' evolutionary analysis method to clarify the defining attributes, antecedents, and consequences of *motivation for health promotion* based on evidence presented in the literature. Understanding how motivation for health promotion is applied in the context of cancer survivorship is important to the practice of the nursing discipline, as it offers nurses new possibilities for providing guidance, support, and assistance in enhancing positive outcomes for individuals who have survived cancer.

## **Abbreviations**

**CINAHL:** Cumulative Index to Nursing and Allied Health Literature

**SCT:** Social cognitive theory

**SDT:** Self-determination theory

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## Bridge statement 1

In summary, *Chapter 2* offered a comprehensive overview of the pertinent literature related to the topic of this thesis. Initially, I explored the impacts of cancer treatments on YAs diagnosed with lymphoma, highlighting the physical and psychosocial challenges they encounter. Subsequently, I examined the current state of exercise intervention targeting cancer survivors, and addressed the complexities surrounding exercise engagement and the implementation of exercise interventions in this population. Further, I described the theoretical framework that underpins the *Lymfit* intervention, as well as the initial testing of the intervention.

In the first manuscript, I examined the concept of “*motivation for health promotion*” in the context of cancer survivorship utilizing the Rogers evolutionary concept analysis method. This concept analysis revealed that motivation is inherently malleable, susceptible to environmental influences, and therefore, a prime target for interventions aimed at promoting health behaviors among individuals affected by cancer. This understanding laid the groundwork for the subsequent exploration of the *Lymfit* intervention as a means to enhance exercise motivation in YAs affected by lymphoma.

Transitioning to *Chapter 3 – Methodology*, I first discuss the rationale associated with conducting a pilot feasibility study before a full trial. The intervention components, and the study procedures for the feasibility pilot RCT of *Lymfit* are then introduced. Then, I present my second manuscript, in which I discuss the complexities surrounding control condition designs in RCTs of exercise interventions for cancer survivors, emphasizing the need for robust methodologies to ensure the validity and reliability of study findings. Manuscript II was published in the *Canadian Journal of Nursing Research* and was awarded the *Canadian Journal of Nursing Research Award for Writing Excellence*, which evaluates both the rigour of academic writing, as well as the contribution to the advancement of the discipline of nursing. The insights gained from this manuscript guided the selection of the most appropriate control group design for the pilot RCT of *Lymfit*. To close this chapter, I present the methodological details of the pilot RCT of *Lymfit*, including a full description of the outcome measurements, and ethical considerations of the study.

## Chapter 3. Methodology

### 3.1 Rationales for conducting a pilot feasibility study

According to the Medical Research Council (MRC) framework for developing complex healthcare interventions, it is necessary to test the feasibility and acceptability of the study's methodological components prior to advancing to the full-scale RCT (Craig et al., 2008; O'Cathain et al., 2019). In a feasibility study, the clinical, methodological and procedural issues (e.g., participants acceptability, compliance, delivery of the intervention, recruitment, retention, and potential for biases) are identified and refined for the main trial (El-Kotob & Giangregorio, 2018; Feeley & Cossette, 2015a). Pilot studies are a subset of feasibility studies that specifically look at the design characteristics proposed for the main trial (Eldridge et al., 2016b). In a pilot study, the research team has the opportunity to model the intervention process and methodology on a smaller scale (Feeley & Cossette, 2015b).

Feasibility pilot studies are particularly crucial for the development of exercise interventions (El-Kotob & Giangregorio, 2018). In an exercise intervention study, it is impossible to create a placebo, or blind participants to group allocation, given that the participants are aware of whether they are allocated to the exercise group or not. Furthermore, biases are common in exercise interventions. For instance, contamination biases can present when participants in either group receive the intervention intended for those in the other group (Craig et al., 2008; Edmond et al., 2019). Similarly, co-intervention can occur in both the intervention group and the control group when participants receive interventions outside of the study that affect the target study outcomes (Feeley & Cossette, 2015b). Finally, drop-out rates in the post-randomization and follow-up period may be unequal if control group participants are dissatisfied with their group allocation (El-Kotob & Giangregorio, 2018; Hecksteden et al., 2018). To decipher this complexity, a methodology manuscript is presented in section 3.3, which aims to explore control group designs and the related issues in RCTs of exercise intervention, along with considerations in the selection of control groups for exercise interventions targeting cancer.

### 3.2 Refinement of the *Lymfit* intervention

Following the completion of the proof-of-concept study in 2021 (Angelillo et al., 2024), the *Lymfit* intervention underwent a refinement process informed by the insights gleaned from

the conceptual analysis presented in the first manuscript of this doctoral thesis. These insights, grounded in the self-determination theory (SDT), provided a foundation for refining intervention outcomes and strategies.

Detailed descriptions of the intervention were described in *Chapter 2* (section “2.5 *Lymfit* intervention”). The detailed study procedures of the pilot feasibility RCT of *Lymfit* are described in *Chapter 4*, manuscript III (Tock et al., 2024). In the section below, I have utilized the Template for Intervention Description and Replication (TIDieR) guideline (Hoffmann et al., 2014) to briefly summarize the intervention components and procedures of the pilot RCT (**Table 3.1**). The first box on the table, “modifications,” delineates the amendments to the preliminary version of *Lymfit* following the proof-of-concept study.

**Table 3.1** *Template for intervention description and replication (TIDieR) intervention components and procedures of the pilot RCT of Lymfit*

<b>Modifications</b>
Following the proof-of-concept study (Angelillo et al., 2024), the following modifications to the intervention were made: a) based on SDT, theoretically-supported strategies were added to the intervention: a peer-support group “ <i>Lymfit lounge</i> ” within the Fitbit smartphone application, 2) two new outcome measures, including the psychological need satisfaction in exercise scale (PNSE) and behavioral regulation in exercise questionnaire – version 3 (BREQ-3) were added as study outcomes in the pilot RCT, c) a self-reported measure to assess physical activity levels: Godin-Shephard leisure-time physical activity questionnaire (LTPA-Q), was included as a study outcome in the pilot RCT, and d) to eliminate pre-existing differences among participants which may have led to potential selection bias, we added screening procedures to select participants who are less active or engaged in more sedentary behaviors at baseline to participate in the study.
<b>Why?</b>
Guided by the principles of SDT, <i>Lymfit</i> aims to enhance exercise motivation among YAs with lymphoma through providing support in the three basic psychological needs: competence, autonomy, and relatedness.
<b>What? (materials and procedures)</b>
<i>Lymfit</i> is a 12-week, virtually delivered and individualized exercise intervention. The intervention participants are given a Fitbit activity tracker paired with a smartphone application, which provides functions such as task orientation, goal setting, progress monitoring, and feedback (support for competence). Each participant is prescribed a personalized 12-week exercise program by the kinesiologist, which is tailored to their baseline fitness level, preferences, and exercise tolerance (support for autonomy). The intervention participants are followed by the study kinesiologist for

12 weeks with bi-weekly follow-up consultations, and they are also connected with other intervention participants within the “ <i>Lymfit lounge</i> ,” a private group on the Fitbit smartphone application where participants can share and compare their exercise progress and activity achievements (support for relatedness).
<b>Who?</b>
<p><b>Participants:</b> YAs with lymphoma aged 18 to 39; English or French speaking; had a score of &lt; 14 (classified as sedentary) on the Godin-Shephard leisure-time physical activity questionnaire; receiving or have received chemotherapy with curative intent within the past six months; have been approved by their hematologist as having no contra-indications to moderate to vigorous levels of physical activity; owned a smartphone for the Fitbit application; and had an internet connection at home that supports participation in kinesiology consultation sessions via videoconferencing and to complete a consent form and questionnaires electronically.</p> <p><b>Interventionist:</b> A certified kinesiology performed the physical assessment at baseline, designed the personalized exercise prescription for each study participant, and provided bi-weekly follow-up consultations.</p>
<b>How?</b>
<p>The research coordinator mails the intervention package (Fitbit tracker, exercise stretch bands) to participants randomized to the intervention group. The study coordinator then schedules a study appointment with the participants and the study kinesiology via videoconferencing. During the appointment, the study coordinator instructs the participants on how to sync their Fitbit tracker to their smartphone application. During the same appointment, the study kinesiology meets with the participants for a baseline physical assessment. Within one week after the baseline physical assessment, the study kinesiology contacts the participants for the next study appointment meeting, where they discuss the details of the 12-week exercise program.</p> <p>For participants randomized to the wait-list control group, they are notified by the research coordinator to begin the intervention after 12 weeks.</p>
<b>Where?</b>
<p><i>Lymfit</i> is a virtually delivered and home-based intervention; there are no limits as to where the participants can complete their scheduled exercise sessions. Although the majority of exercises prescribed by the kinesiology are home-based, participants can choose to perform the exercises where they prefer. All research-related appointments (i.e., informed consent procedure, and kinesiology follow-up consultations) are conducted via videoconferencing.</p>
<b>How much?</b>
<p><b><i>Lymfit</i> intervention:</b> 12 weeks; Kinesiology follow-up consultations: bi-weekly</p> <p><b>Individualized exercise program:</b> Exercise sessions are scheduled in the format of a weekly exercise calendar, and it is adjusted or modified by the kinesiology during each follow-up as needed after consulting with the participants.</p>



<b>Tailoring</b>
<p>The kinesiologist performs the physical assessment at baseline (prior to the start of intervention), and the exercise prescription is individualized based on each participant's baseline fitness levels; it is also tailored to fit into each participant's exercise tolerance, preferences, work/school schedule, availabilities, and other. As well, the exercise program is revised and adjusted as needed during each kinesiologist bi-weekly consultation, further tailoring to study participant's progress and needs.</p>

### 3.3 Manuscript II – Review of control group designs

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Title: Considerations of Control Conditions Designs in Randomized Controlled Trials of  
Exercise Interventions for Cancer Survivors

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## **Abstract**

**Background:** Given the multifaceted complexity in the nature of randomized controlled trials, identifying an appropriate and comparable control condition is an essential step to ensure methodological rigor, which allows for researchers to draw unambiguous conclusions concerning the efficacy of the intervention being studied.

**Objectives:** The objectives of this paper are to **a)** review the current literature and analyze the control condition designs in exercise interventions targeted for cancer survivors ; **b)** provide an overview of the benefits and limitations of various types of control conditions used in exercise interventions; **c)** discuss the considerations in the design of control conditions for exercise interventions; and **d)** suggest recommendations for control condition design in future trials of behavioral interventions.

**Results:** The review of randomized controlled trials of exercise training interventions for cancer survivors revealed that the design of control conditions varied. The most commonly employed design could be classified into two major categories: a) active controls including attention control, add-on controls, and dismantling controls; and b) inactive controls including no-treatment, usual care, and wait-list control. Examples from the literature are presented. Four principal considerations concerning control condition design, including appropriateness, credibility, appeal, and comparability, are discussed. Recommendations on how to avoid some major threats to validity and potential biases are also provided.

**Conclusions:** Careful planning for the control group design is as important as for the intervention group. Researchers can use the considerations presented in the paper to assist in planning for the most appropriate control condition for their study.

**Keywords:** randomized controlled trials, methodology, control conditions, study design, exercise interventions

## **Background and objectives**

### **Background: Exercise intervention for cancer survivors**

Advances in cancer treatment and early detection efforts have yield encouraging results. The 5-year survival rate for all types of cancer has improved markedly in Canada since the early 90s (Canadian Cancer Society, 2020). The growing number of cancer survivors in the world has warranted the development of targeted health behavioral health interventions to mitigate the adverse effects of cancer diagnosis and the toxicities of treatments (Tollosa et al., 2019). While researchers have discovered a myriad of behavioral interventions that can benefit the health of cancer survivors, exercise training remains one of the options with the highest therapeutic value on both psychological and physical health (e.g., improved physical functioning and quality of life, and mitigation of anxiety) for this patient population (Liu et al., 2019; Segal et al., 2017).

The World Health Organization recommends that adults (aged 18- 64) should engage in a minimum of 150 minutes of moderate to vigorous-intensity aerobic physical activity (MVPA) per week (World Health Organization, 2020). While these guidelines were initially extended to cancer survivors, experts in the field have since reviewed the literature and recently published a series of evidence-based exercise prescriptions specifying the frequency, intensity, time, and type of exercise training for cancer survivors during and post-chemotherapy (Campbell et al., 2019). Besides the conventional aerobic or resistive exercise regimes, interventions using a variety of exercise modalities have also shown effectiveness in improving overall health status among cancer survivors (Stout et al., 2017). For the purpose of this study, exercise intervention is categorized as a sub-type of behavior interventions, of which the content comprises training that involves bodily movement aiming at increasing energy expenditure. Exercise training comprises structured, repetitive, and purposeful activities that gear towards enhancing or preserving one or more components of physical health (e.g., cardiorespiratory endurance, balance, flexibility, and musculoskeletal strength) (Campbell et al., 2019; Caspersen et al., 1985; Wolin et al., 2012).

### **Randomized controlled trials of exercise interventions**

Exercise interventions are often considered complex interventions because they typically comprise multiple components. For instance, interventionists might be required to perform a variety of complex behaviors while delivering the treatment, the intervention design might consist of personalized and tailored activities, there might be multiple levels of study outcomes,

and a large number of stakeholders can be involved at different stages of the process (Hecksteden et al., 2018; O'Cathain et al., 2019). For complex behavioral intervention studies, the phase III evaluation stage predominately relies on Randomized Controlled Trials (RCTs) as the gold standard experiment design in estimating the efficacy of the intervention, as well as the causal relationships in the study design (Hecksteden et al., 2018; Polit & Beck, 2021; Sidani, 2015). With increasing evidence supporting the relationship between exercise and physical functioning and psychological health among cancer survivors, clinical trials investigating the effectiveness of exercise intervention have been proliferated in the realm of cancer survivorship care in the past decades (Segal et al., 2017; Zhi et al., 2019). In fact, given that the methodological approach to conduct exercise training interventions is multifaceted and complex, an extension checklist of the CONSolidated Standards Of Reporting Trials (CONSORT) Statement titled the Consensus on Exercise Reporting Template (CERT) had been published in 2016 in order to provide supplementary information to report and document RCTs of exercise interventions (Slade et al., 2016).

The RCT is a robust study design most frequently used in pharmacological trials to establish safety, therapeutic efficacy, and tolerability of newly developed drugs or therapies. The gold standard design of an RCT consists of a double-blinding procedure, and placebo control, which is a pharmacologically inactive agent used to evaluate the effects of being given medications in the experimental group (U.S. Department of Health and Human Services, 2001). Choosing a proper control condition is one of the most fundamental yet critical aspects of the design in an RCT. The control is an essential element that allows the researcher to discriminate whether a treatment has an effect that is due to a hypothesized mechanism of action, and is not attributable to nonspecific effects or other confounders (e.g., sources of bias) (Sidani, 2015). In behavioral intervention studies, researchers can infer the improvements among participants receiving the intervention treatment to the salient features of the intervention itself based on the results of a well-controlled study.

### **Methodological issues**

Many nonspecific factors such as therapeutic environment, social interaction, and attention from research staff can impact the outcome of a RCT. A properly designed RCT of behavior intervention should allow for the identification of the “active ingredients” responsible

for the desired behavior (Edmond et al., 2019; Sidani, 2015). To achieve this, the control condition should not have a significant effect on the hypothesized mechanism of action that explains the effectiveness of the intervention. Unfortunately, the active and inactive components in the intervention treatment are not as well defined as those of medications in pharmacological trials, given that behavioral interventions are often complex (O'Cathain et al., 2019). Further, since behavior intervention RCTs often rely on interpersonal interactions between participants and clinicians, blinding is challenging given everyone is usually aware of the true nature of their treatment allocation. Consequently, the gold standard design for RCTs is less clear in studies investigating the effectiveness of behavioral interventions (Hecksteden et al., 2018).

In exercise science, RCTs adopting robust methodologies are required to provide valid scientific evidence on the types of exercise, training routine, and dosage appropriate for different populations (Hecksteden et al., 2018). Yet, methodological consistency of RCTs of exercise intervention targeting cancer survivors has not been established, particularly in the choice of comparable control conditions (Boutron et al., 2017; Hecksteden et al., 2018; Pinto & Floyd, 2007). Since it is not always possible to develop a deceptive/mimic intervention (i.e., the equivalent to a placebo medication) that generates solely a placebo effect in RCTs of behavioral interventions, researchers have several options for their choice of comparison conditions including inactive control (i.e., wait-list control and usual care) and active/attention control (i.e., in which the participants engage in some activities or tasks during the intervention period.) (Segal et al., 2017; Zhi et al., 2019).

### **Inactive and active/attention controls**

Using an inactive control is a common practice in RCTs of behavioral interventions due to the challenge of identifying an appropriate behavioral “placebo.” Inactive conditions allow for the researchers to detect the outcome of the experimental intervention as compared to that of an un-intervened control group (Karlsson & Bergmark, 2015; Street & Luoma, 2002). The terminologies used to describe the subtypes of inactive controls have not yet been standardized, but they generally include usual care (standard care), no treatment, and wait-list control (Locher et al., 2018; Street & Luoma, 2002). In RCTs adopting usual care as the comparator, participants in the control arm receive the care they would normally get for their clinical conditions. Depending on the nature of the study, the research interventionists might also recommend that

the participants maintain their usual habits or activity level, which applies to the context of an exercise training study (Lindquist et al., 2007). The terminology “no treatment” is less common practice in behavioral intervention RCTs; generally, the control arm not performing the intervention activities is described as usual care. Finally, in a wait-list controlled study, participants who are randomized to the control arm receive the intervention treatment upon the completion of the designated study time frame. Participants in the wait-list control arm typically receive usual care during the delay (Elliott & Brown, 2002; Lindquist et al., 2007; Street & Luoma, 2002).

Active controls are sometimes used in RCTs to account for the nonspecific effects of the intervention in a similar way that placebo medications are used to control for expectancy effects in a pharmaceutical trial (Aycock et al., 2018). Active controls are generally recognized as attention controls in behavioral intervention studies, given that participants receive an activity that is an inactive substitute of the intervention, with a similar amount of attention and contact (Aycock et al., 2018; Lindquist et al., 2007; Street & Luoma, 2002). Sub-types of attention controls include several types of component controls, where components of a pre-established intervention package are added on (i.e., additive control), or isolated from (i.e., dismantling control) the study arms in an attempt to identify the active ingredient hypothesized to contribute to the desired changes (Lindquist et al., 2007). In RCTs with multiple study arms, the experimental group is compared to two control groups, with one being a usual care/no-treatment group, and the other control group being an active attention control.

## **Objectives**

Given the multifaceted complexity in the nature of RCTs of exercise intervention and the specialized needs of cancer survivors, identifying an appropriate and comparable control condition is an essential step to ensure methodological rigor, which allows for researchers to draw unambiguous conclusions concerning the efficacy of the exercise training treatment being studied (Hecksteden et al., 2018; Karlsson & Bergmark, 2015). Because the design of control condition continues to be a challenge for researchers, the objectives of this paper were to **a)** review the current literature and analyze the control condition designs in exercise interventions targeted for cancer survivors; **b)** provide an overview of the benefits and limitations of various types of control conditions available for exercise intervention studies; **c)** provide perspectives on

considerations in the design of control conditions for exercise interventions; and **d)** suggest recommendations for control condition design in future exercise intervention RCTs in cancer survivorship research. Given the authors' specialization in oncology research, the literature reviewed in this paper are focused on the cancer survivorship studies. The motivation for writing this paper arose due to the challenges faced by the authors of this paper while undertaking an exercise intervention studies for cancer survivors. It is hoped that the cancer survivorship literature can elucidate some of the more salient issues in control condition design. While this paper primarily focuses on exercise training intervention adapted to cancer survivors, the issues and dilemmas explored here are applicable to other behavioral intervention research commonly conducted by nursing researchers such as diet modification, symptom self-management, and mindfulness intervention, etc.

## **Methods and procedures**

To examine the control condition designs in RCTs evaluating the effects of exercise interventions for cancer survivors in current literature, a comprehensive literature search was conducted. Three databases, CINAHL, Medline Ovid, and EMBASE, were searched using Boolean search strategies with truncated keywords. The search strategies for CINAHL are shown in **Table 3.2**. Criteria for inclusion were as follow: 1) RCTs of any exercise training interventions involving different training modes, such as aerobic, resistance, weight, and flexibility training were included; 2) the exercise training interventions could be conducted in different settings including home-based or community-based studies; and 3) participants involved in the RCTs had a confirmed diagnosis of any type of cancer, and had received and completed curative treatment. Studies included in the analysis were published in English since 2015.

Given the present review's focus on exercise training interventions, studies were excluded if the intervention involved mixed components combining exercise with other therapeutic approaches, such as psychotherapy, dietary modification, or cognitive-behavioral counseling. Finally, trials that compared exercise training with pharmacological and surgical treatments were excluded. When multiple publications from a single RCT were found, only the primary publication was included for this analysis in order to avoid double counting of studies using the same trial design.



## Results

### Findings

After screening procedures, 32 articles were selected for inclusion in this analysis (**Figure 3.1**). The review of RCTs of exercise training interventions for cancer survivors revealed that the design of control conditions varied. The most commonly employed design could be classified into two major categories: a) inactive controls including no-treatment, usual care, and wait-list control; and b) active controls including attention control, add-on controls, and dismantling controls, as shown in **Table 3.3**. A total of 25 of the 32 studies (78.1%) meeting the search criteria employed inactive control condition design, while seven out of the 32 studies (22.6%) employed an active control condition design. Among the 32 included studies, 5 studies had more than two arms in their design, all of which consisted of one arm receiving usual care as the control. Finally, the majority of the RCTs were conducted among breast and colorectal cancer survivors ( $n = 25$ , 78.1%). The following section provides a detailed description of the various types of control condition designs used in these studies.

#### Inactive controls: Limitations and benefits

Exercise intervention RCTs included in the analysis most frequently adopted “usual care” as the control condition design ( $n = 25$ , 78.1%). Nevertheless, the contents of the usual care activities can vary among studies (Edmond et al., 2019; Lindquist et al., 2007; Thompson & Schoenfeld, 2007). For instance, in a study of a 12-week exercise intervention for prostate cancer survivors, participants in the control arm were not referred to the exercise program. Instead, they received usual care which did not involve any physical activity recommendations (Craike et al., 2018). In another study testing the effects of a 16-week home-based exercise program among acute lymphoblastic leukemia survivors, participants in the usual care control arm received a “physical activity and usual care brochure” identical to that of the intervention group, and were instructed to continue their normal activity levels without restrictions placed on exercising throughout the study period (Manchola-Gonzalez et al., 2020). Lastly, in a study of an eight-week exercise program for lung cancer survivors, the researchers described that the usual care control arm receives general health education material, without specifying the contents of the material (Dhillon et al., 2017). This lack of standardization to quantify the contents of activities in the control condition is considered a key limitation of inactive control designs (Kinser &

Robins, 2013; Street & Luoma, 2002; Thompson & Schoenfeld, 2007). As a result, the frequency of participant contacts and the level of attention received among the study arms may vary tremendously (Street & Luoma, 2002).

Using a design that assigns participants to usual care or wait-list control will also render the blinding of participants and research interventionists impossible. Moreover, it is also observed that there is an inadequate reporting, documentation, or oversight of what activities comprise usual care conditions across study settings (Karlsson & Bergmark, 2015). For example, authors may provide limited details regarding the duration of usual care activities or the implementation of standardization of usual care activities. This non-transparency in study design reporting might further conceal the effects of certain biases and non-specific actors that impact the study outcome (Kinser & Robins, 2013; Street & Luoma, 2002; Thompson & Schoenfeld, 2007). The inability to differentiate the treatment effects and nonspecific treatment effects can eventually lead to the inability for researchers to ascertain the intervention effectiveness.

Despite their limitations, inactive control designs are still preferable in many circumstances. Studies adopting inactive control designs such as wait-list and usual care are ideal to control for threats to internal validities including regression to the mean and spontaneous improvement due to the course of illness (Locher et al., 2018). Such designs will be more likely to produce larger effect sizes than a study comparing two active interventions (Kinser & Robins, 2013; Locher et al., 2018). Furthermore, studies using an inactive control group also require smaller sample sizes and fewer resources overall (Williams et al., 2016). Three studies that adopted the wait-list control design in the literature review reported that the use of wait-list control had enhanced study participants recruitment and retention (Chang et al., 2020; Hartman et al., 2018). Wait-list control is often considered an ethical design, given that all participants will eventually receive the treatment intervention. Because the beneficial effects of exercising are well-established and well-known among the general population, this design is particularly appealing and credible to the study participants because they are guaranteed the benefits of the exercise intervention (Hecksteden et al., 2018).

### **Active controls: Limitations and benefits**

In exercise interventions, a variety of attention control designs have been implemented. Among the studies included for analysis in this paper, seven RCTs had an active control

condition, and five RCTs employed a multiple-arms design. The component control design was implemented in the study aiming to test the efficacy of weightlifting training to preserve muscle mass among a group of breast cancer survivors. In the study, both the control and intervention groups received a 13-week supervised exercise program. The hypothesized active ingredient, weight training, was added-on to the program only in the intervention group (Brown & Schmitz, 2015).

Furthermore, a different dosage of exercise (i.e., different levels of intensity) could be assigned in the intervention and control arms, respectively. For instance, in a study examining the effectiveness of a 4-week high-intensity exercise training program on cardiovascular health among colorectal cancer survivors, the participants in the attention control arm received a moderate-intensity training program of equal length to that of the experimental group (Devin et al., 2016). Likewise, the attention control arm might be assigned to receive a different modality of activity other than exercise training. For instance, Zhou and colleagues designed an RCT where ovarian cancer survivors in the intervention arm were assigned a 6-month home-based aerobic exercise program, and the attention control arm received weekly phone calls from a research team member, along with a book containing ovarian cancer survivorship-related information (Zhou et al., 2017). In multi-arm exercise intervention RCTs, multiple experimental treatment groups of different exercise dosage (Brown et al., 2018; Kampshoff et al., 2015) or different types of exercise training (Garcia-Soidan et al., 2020; Nouri et al., 2020) are compared against an inactive control condition.

Attention control is an ideal comparison condition because it omits the unique ingredients of the intervention treatment while sharing the common factors across conditions to allow for equal measure and comparison (Aycock et al., 2018). In the aforementioned attention control design, researchers aimed to control for nonspecific factors including the amount of attention, participant expectancy, treatment contact, and social support given to both study arms (Aycock et al., 2018). Attention control, therefore, allows researchers to confer an unambiguous conclusion of the hypothesized unique component of the behavioral intervention (Whitehead, 2004). Furthermore, participants in the attention control arm might benefit from the activities assigned regardless (Aycock et al., 2018; Street & Luoma, 2002). Attention control designs present many advantages over the usual care or no-treatment inactive control designs; nevertheless, they are not without limitations. Unfortunately, little guidance concerning the

design standards or the required components in an attention control arm for an exercise intervention has been established in the literature (Hecksteden et al., 2018).

Holding the important active study variables constant across study arms (e.g. intensity and timing of intervention) could be challenging (Pagoto et al., 2013). The amount of attention time participants in the control arm receive might not be equivalent to that received by the participants in the intervention arm. Since RCTs often require considerable human resources, time, infrastructure, and financial support, the resources allowance of a given study might constrain the extent to which the activities in the attention control are set up in parallel to the intervention arm (Lindquist et al., 2007). Researchers must also carefully consider the effects that the activities in the control arm might have on the study outcomes (Aycock et al., 2018; Lindquist et al., 2007). Finally, when the attention control consists of activities with completely different structure, modality, or type as compared with the intervention arm, it is also possible that the attention control activities alter the participant's behavior and through a different mechanism of action, thus becoming an alternative intervention itself. If the control arm shares too many common therapeutic qualities with the intervention arm, it renders the control condition limited in comparability with the intervention treatment (Aycock et al., 2018; Gross, 2005). As a result, it becomes difficult to infer an unambiguous cause-and-effect relationship between the active ingredient and desired outcome specified in the study hypothesis (Kinser & Robins, 2013).

### **Discussion: Considerations and recommendations**

Researchers investigating exercise interventions for cancer survivors face numerous challenges in optimal study design, which are predominantly attributed to the multi-component and multifaced nature of such interventions (Hecksteden et al., 2018; Pinto & Floyd, 2007). Based upon the brief review of current literature, it is apparent that there are numerous pitfalls surrounding control condition designs in RCTs of exercise interventions. A flawless RCT design does not exist, and the researcher must consider each option and make careful decisions by weighing the pros and cons when choosing the most appropriate approach in their studies. Researchers should focus on several considerations while designing a control condition in RCTs of exercise interventions targeting cancer survivors. Four principal considerations concerning control condition design, are discussed in this last section of the paper: appropriateness,

credibility, appeal, and comparability. Recommendations on how to avoid some major threats to validity and potential biases are also provided along with the discussion.

## **Appropriateness**

One fundamental principle in control condition design in RCTs is appropriateness. A control condition should be aligned with the overall purpose and objectives of the study, thus enabling the study outcomes to answer the research questions unequivocally (Kinser & Robins, 2013). For instance, when the primary research question is to detect the efficacy of a specific type of exercise training to lessen anxiety among cancer survivors, the intervention arm should be compared to a control condition adopting a different activity while holding the same level of attention and social contact constant (Street & Luoma, 2002). Inactive control such as usual care or wait-list control could also be used to establish the efficacy of the intervention treatment, but the researchers have to take into consideration if the inactive control allows them to adequately isolate the intervention effects from other non-specific effects such as participant expectation. In other words cautious conclusions about the intervention efficacy should be made (Karlsson & Bergmark, 2015).

Alternatively, if the research question concerns the identification of appropriate dosing (e.g., intensity, strength, length, or frequency) of a specific exercise training, the control should be an active control of the same type of exercise training, prescribed at a different dosage. In this case, inactive control conditions would not be appropriate. Finally, an exercise intervention study could aim to examine the efficacy of a specific mechanism of action (e.g., tailored regime vs. traditional exercise regime) or a theory-based variable (e.g., peer support, self-efficacy) on increasing cancer survivors' level of physical activities (Street & Luoma, 2002; Wolin et al., 2012). For instance, it is common that the exercise intervention consists of training regimes that are personalized to address individual survivors' physical abilities and specialized needs at the post-treatment transitioning period (Hecksteden et al., 2018; Slade et al., 2016). In this context, active control or wait-list control is the appropriate choice. For ethical reasons, active control or wait-list control are also superior to usual care in cancer survivorship research, considering that the benefits of exercising are well recognized. A no-treatment or usual care control denies the opportunities for the participants to receive a potentially beneficial intervention based on random

chances, which might be regarded as ethically problematic (Elliott & Brown, 2002; Street & Luoma, 2002).

### **Credibility**

The extent to which the study participants perceive the intervention as credible can affect their response to the intervention treatments (Street & Luoma, 2002). Ideally, the control condition and the intervention treatment in an RCT should be equally **credible** in terms of participant perceptions and expectations. Researchers can enhance the perceived credibility of the trial by ensuring that the control conditions contain as many common elements as the intervention treatment as possible, such as equivalent format, structure, attention, expectancy, social contact, and timing of the activities, all of which have the potential to generate the placebo effect (Lindquist et al., 2007). Having the intervention and control activities of parallel format and structure can ensure that the level of engagement among study participants are equivalent. To illustrate, the activities in both intervention and control arms should have equal numbers of sessions or modules, and the duration of involvement should also equate. Besides, the amount of attention given to the participants, quality of social contact, and timing of activities including follow-up times should not vary between groups (Aycock et al., 2018; Staudacher et al., 2017). For instance, research staff or interventionists, including instructors, counselors, educators, nurses, and data collection staff, should be engaged in an equal amount of interaction with all study participants. In situations where monitoring or follow-up are done remotely, the number of phone calls and time spent with all participants should be equivalent. All of these elements have the potential to generate expectations and relationships that influence study adherence, motivation, study completion, and self-reported outcomes by the participants (Locher et al., 2018; Street & Luoma, 2002).

### **Appeals and potential for social threats**

Relatedly, another essential consideration when designing the control condition in behavioral intervention RCTs is the participant's perceived overall appeal of the study. Both **participant recruitment and retention** could be impacted by the selection of the control condition (Lindquist et al., 2007; Schwartz et al., 1997; Street & Luoma, 2002; Whitehead, 2004). Recruiting study subjects to participate in clinical trials requires a thorough understanding of the basic structure and design of the study, which includes a random group allocation

procedure. Potential participants are aware that they will be randomly assigned into either the intervention arm or the control arm. Participant recruitment could be facilitated if both the intervention treatment and the control conditions are appealing to them. In situations where the control arm receives no treatment or a less appealing alternative treatment or activity, participants in the control arm might experience **resentful demoralization** or **compensatory rivalry**, two opposite social threats leading to the same bias in RCTs of behavioral interventions (Cook & Campbell, 1979; Horner et al., 2006). Indeed, participants in the control arm can become resentful/discouraged, or retaliatory/competitive for not obtaining the desirable intervention treatment. These issues could be magnified in exercise interventions targeted at the cancer survivor population. It is a fair assumption that cancer survivors are aware of the benefits of initiating health promotion behaviors such as exercising after treatment (Berglund et al., 1997; Pinto & Floyd, 2007). Hence, the exercise treatment assigned to the intervention arm might be favorable to the majority of the potential study participants. In the case of resentful demoralization, participants who eventually get allocated to the control arm might feel neglected and attempt to express their resentment by performing differently or inferiorly, resulting in an overestimation of the treatment efficacy (Berglund et al., 1997; Horner et al., 2006). Alternatively, participants experiencing compensatory rivalry become competitive and attempt to compensate for not receiving the desired treatment by increase efforts and seeking alternative means to achieve the same benefits as the intervention treatment, leading to co-intervention and the underestimation of the intervention efficacy (Berglund et al., 1997; Horner et al., 2006). In summary, the emotional and behavioral responses elicited by resentful demoralization and compensatory rivalry are quite the opposite, yet they both might lead to substantial systematic effects in the outcome of the control arm and threatening the construct validity of the intervention, leading to an ambiguous conclusion of study results, as well as diminishing the generalizability of the findings (Berglund et al., 1997; Schwartz et al., 1997).

Participant retention is also associated with the perceived appeal of the study. Participants who regard the control condition as unappealing could withdraw from the study, resulting in attrition, and their data not being available for the final analyses procedure (Davidson & Kaszniak, 2015; Pagoto et al., 2013; Street & Luoma, 2002). Researchers should adopt strategies to enhance the appeal of the study. Matching the control condition with the potential participants' needs and interests should be considered (Kinser & Robins, 2013; Lindquist et al., 2007). For

instance, in a study investigating the effect of a weight training exercise intervention on cancer survivors' muscle strength, offering the control arm participants a comparable alternative such as aerobic exercise could be an ideal design, since the ultimate desired outcome of the study is health promotion in the post-treatment period in both cases. Seeking a comparable yet acceptable control condition might be more challenging in the case of a novel intervention study (Street & Luoma, 2002). Given that the effect of the intervention treatment has not been previously established, an alternative control condition design such as a delay-start or wait-list control group would be ideal.

## **Comparability**

**Comparability** of the intervention treatment and control condition must be taken into consideration in the study design. Researchers need to warrant that the study outcomes are not attributable to the activities assigned in the control arm through either the same or a different mechanism as the intervention treatment (Aycock et al., 2018; Lindquist et al., 2007; Locher et al., 2018). A fundamental function of using a comparison group in an RCTs is that it provides a comparable condition (i.e., a condition able to control for the nonspecific features such as the natural course of the disease) to that of the intervention, thus allowing researchers to draw a conclusion regarding the efficacy of the hypothesized active ingredient (Aycock et al., 2018; Karlsson & Bergmark, 2015; Whitehead, 2004). Preferably, similar to the premises given to ensuring the credibility of the study, a comparable control condition should have a parallel design to that of the intervention group, with the sole difference being the active feature in the study hypothesis. Nonetheless, given the level of complexity in behavioral intervention studies, the researcher must ensure that the activity in the control condition does not unintentionally skew the study outcome. This issue can be addressed by limiting the possibility of **cross-contamination** between the control and intervention arms (Craig et al., 2008; Edmond et al., 2019). More specifically, the activities assigned in the control arm should not have the same mechanism of action that might affect, or contaminate, the study outcome (Edmond et al., 2019). For instance, the interventionists or intervention arm participants might share the intervention elements to the control arm participants unintentionally during interactions throughout the study. In a study where the control arm participants are assigned activities of the same mechanism of action as the intervention arm (e.g., unsupervised exercise versus supervised exercise), cross-contamination is highly possible.



Tackling the issue of **comparability** is challenging in behavioral intervention RCTs, particularly in exercise intervention (Hecksteden et al., 2018). Elements in exercise intervention studies such as format and the nature of engagement could be difficult to mimic. To illustrate, if the intervention involves the use of an individualized, tailored exercise prescription, the alternative activities offered in the control arm probably would not generate the same level of participants' engagement, social contact, and expectancy. Likewise, it is unrealistic to ask participants in the control arm of an exercise intervention study to stay completely inactive (Hecksteden et al., 2018).

### **Recommendation for future research**

Piloting of an RCT is necessary in order to assess for barriers to participant recruitment and to prevent a high rate of attrition (Feeley & Cossette, 2015; Feeley et al., 2009), which can provide insights concerning uncertainties of control condition design of a study. Any issues attributed to control condition designs detected in the pilot trial should be adequately addressed before proceeding to the phase III efficacy trial. In addition, scientific concerns about methodological rigor in RCTs can be overcome by transparent study reporting. It is recommended that researchers provide detailed reports of study design, recruitment, randomization, as well as rationales for choosing a specific design using the guidelines from the CONSORT Statement and the CERT extension (Karlsson & Bergmark, 2015).

### **Conclusion**

In conclusion, the state of science in exercise training is flourishing in the field of cancer survivorship research. Yet, many systematic reviews have recognized the need for more sophisticated methodological approaches and more appropriate controlled studies (Segal et al., 2017; Stout et al., 2017; Zhi et al., 2019). The gold standard RCT design involves the implementation of placebo controls, which are unfortunately not applicable in most exercise intervention studies. Researchers also need to pay special attention to the design of RCTs, especially concerning the effects of the various types of control conditions on study and participant outcomes. To further examine the challenges in developing optimal control conditions, current literature reporting RCTs of an exercise intervention targeting the cancer survivor population were reviewed in this present paper. Furthermore, to address the methodological challenges of exercise intervention studies, four key considerations were

reviewed, and recommendations to address each consideration were provided. A well-designed RCT could deliver valid conclusions about the efficacy of an intervention and can smooth the transition of evidence into clinical practice. More meticulous control condition designs are a crucial step towards making exercise intervention more readily available to cancer survivors.

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The Authors declare that there is no conflict of interest.

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## **Abbreviations**

**MVPA:** Moderate to vigorous-intensity physical activity

**RCTs:** Randomized controlled trials

**CONSORT:** CONSolidated Standards Of Reporting Trials

**CERT:** Consensus on Exercise Reporting Template

**CINAHL:** Cumulative Index to Nursing and Allied Health Literature

**EMBASE:** Excerpta Medica dataBASE

**Table 3.2** Search strategy for CINAHL

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S1 (MH "Cancer Survivors")  
S2 "cancer survivor\*"  
S3 "exercise therapy"  
S4 (MH "Physical Activity")  
S5 (MH "Physical Fitness")  
S6 (MH "Nursing Interventions")  
S7 (MH "Therapeutic Exercise")  
S8 "exercise program"  
S9 (MH "Randomized Controlled Trials")  
S10 S3 OR S4 OR S5 OR S6 OR S7 OR S8  
S11 S1 OR S2  
S12 S9 AND S10 AND S11  
Limit applied  
Published Date: 20150101-20210801

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**Table 3.3** *Comparison of control and intervention group components in exercise intervention RCTs for cancer survivors*

Authors	Year	Target population (N, C, I) *	Control condition	Intervention treatment(s)
<b>Active Control (n = 7)</b>				
Brown, & Schmitz	2015	Female breast cancer survivors (N= 294, C=146, I=148)	Maintain baseline level of physical activity; 13 weeks of supervised exercise instruction; 12 months membership to a community fitness center	Weightlifting program for 12-months; 13 weeks supervised weightlifting instructions; 12 months membership to a community fitness center
Devin et al.	2016	Colorectal cancer survivors (N= 47, C=17, I=30)	4 weeks of moderate-intensity exercise	High intensity exercise training
Knobf et al.	2016	Female breast, gynecologic or colorectal cancers or lymphoma survivors (N= 154, C=78, I=76)	Home-based health promotion program based on national guidelines for 30 minutes of moderate intensity activity most days of the week	Supervised 12-month aerobic-resistance exercise intervention at a community fitness center for 3 times per week
Pinto et al.	2015	Breast cancer survivors (N= 76, C=37, I=39)	Contact control: 12-week American Cancer Society's Reach to Recovery program	12-week Reach to Recovery program + recommendations of 30 minutes of more of moderate intensity physical activity on most days of the week
Schmitt et al.	2016	Breast cancer survivors (N= 28, C=14, I=14)	A 3-week low-to-moderate intensity exercise program	A 3-week multimodal rehabilitation program involving high intensity interval training program
Schwartz et al.	2015	Cancer survivors (N=50, C=25, I=25)	A 12-week supervised 1-on-1 exercise program (Cancer Fitness Fundamentals program)	The 12-week Cancer Fitness Fundamentals exercise program + Restwise (Recovery Science & Technology, LLC; Concord, MA) which is an online recovery assessment tool
Zhou et al.	2017	Ovarian cancer survivors (N=144, C=70, I=74)	Attention control included weekly phone calls from a staff member, along with a 26-chapter book that only contained ovarian cancer survivorship-related information	A 6-month home-based exercise program targeted at 150 minutes per week of moderate intensity aerobic exercise per week facilitated by weekly telephone calls
<b>Studies with Multiple Arms (With the control condition being an inactive design) (n = 5)</b>				
Brown et al.	2018	Colon cancer survivors (N=39, C=13, Ia=14, Ib=12)	Usual care	a) 150 min per week of aerobic exercise (low-dose) for 6 months b) 300 min per week of aerobic exercise (high-dose) for 6 months

García-Soidán et al.	2020	Breast cancer survivors (N=316, C=79, Ia=79, Ib=79, Ic=79)	The control group should not make any changes in their lifestyle, incorporating any new physical activity	2 years duration a) Strength training program b) Aqua fitness program c) Aerobic exercise program
Kampshoff et al.	2015	Breast, colon, ovarian, cervix or testis cancer, or lymphomas survivors (N=277, C=91, Ia=91, Ib=95)	Wait-list control	a) 12-week high intensity resistance exercise program b) 12-week low-to-moderate intensity resistance and endurance exercise program
Nouri et al.	2020	Breast cancer survivors (N=75, C=25, Ia=25, Ib=25)	Usual care	a) Resistance training group b) Combined training group (resistance + core stability training)
Park et al.	2015	Colorectal and breast cancer survivors (N=162, C=59, Ia=53, Ib=50)	Conventional treatment consultation (usual care)	a) Oncologist's exercise recommendation combined with an exercise motivation package b) Oncologist's exercise recommendation (exercising at least 150 minutes of moderate level physical activity and strengthening exercise twice a week.)

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#### Inactive Control (n = 20)

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Arem et al.	2016	Female breast cancer survivors (N=121, C=60, I=61)	Usual care	150 min per week of moderate-intensity aerobic exercise and twice-weekly supervised strength training
Cantarero-Villanueva et al	2016	Colon cancer survivors (N=46, C=23, I=23)	Usual care: general recommendations for a healthy lifestyle that were delivered at the start of the program in paper forma	An 8-week trunk muscle stabilization exercise program group (CO-CUIDATE) for 3 times per week
Chang et al.	2020	Breast cancer survivors (N=46, C=23, I=23)	Wait-list control: Instructed to maintain their routine occupational and leisure-time physical activity during the study period	A 12-week program with combined aerobic and resistance exercise regimen
Craike et al.	2018	Prostate cancer survivors (N= 147, C=93, I=54)	Usual care which typically does not include recommendations for physical activity	The 12-week exercise program with 150 minutes per week of home-based, supervised moderate-vigorous physical activity
Dhillon et al.	2017	Lung cancer survivors (N=112, C=55, I=56)	Usual care with general health education materials only	An 8-week physical activity program plus general health education materials
Dieli-Conwright et al.	2018	Breast cancer survivors (N=100, C=50, I=50)	Usual care (to maintain their current level of physical activity)	A 16-week program: exercise program with 150 minutes of aerobic exercise and 2 to 3 days of resistance exercise training per week

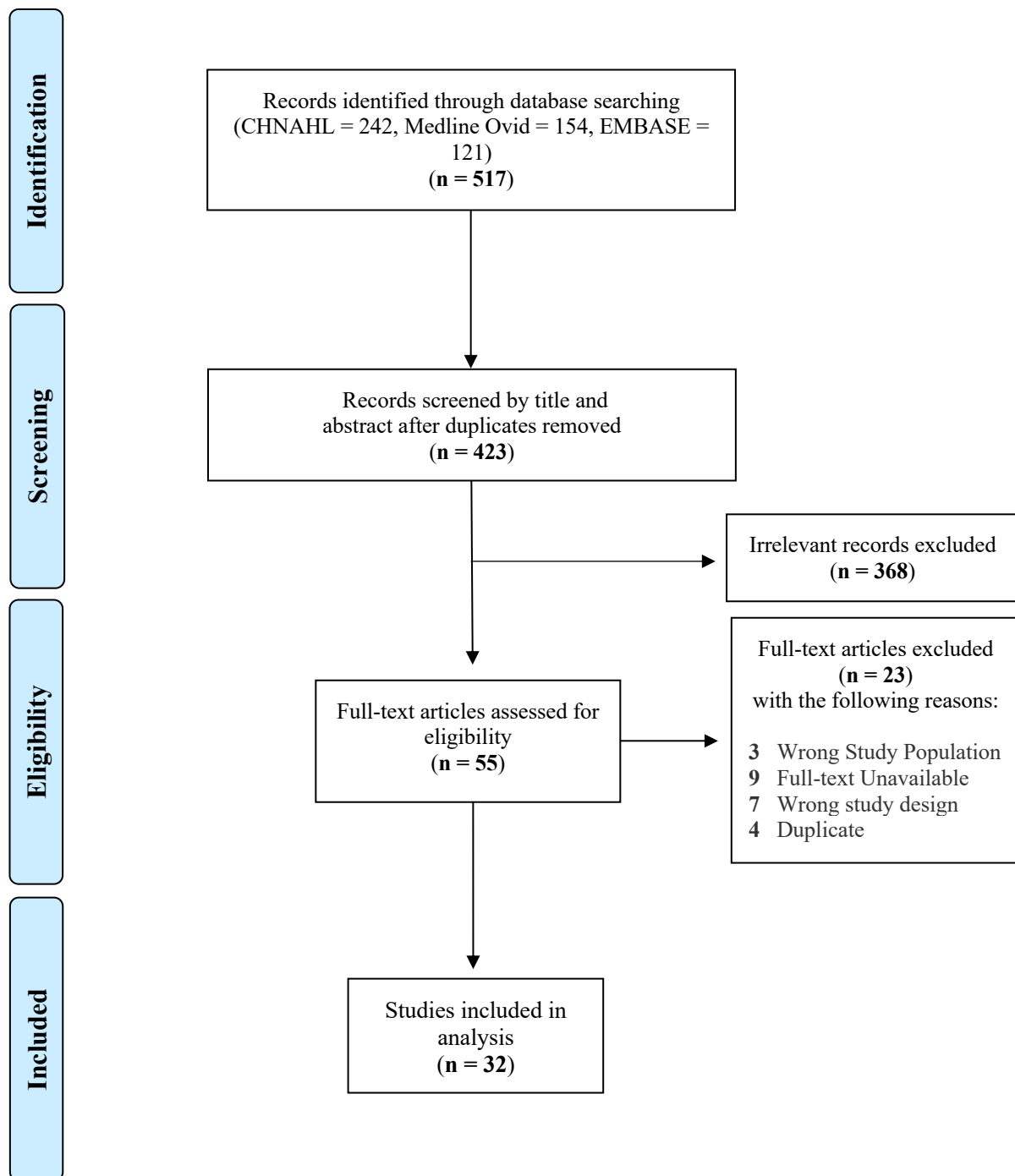
Ebrahimpour et al.	2021	Breast cancer survivors (N=30, C=15, I=15)	Usual care (participants are advised to perform their routine daily activities)	A 12-week program of concurrent yoga and Pilates training, 3 sessions per week and 75 minutes each
Galiano-Castillo et al.	2016	Breast cancer survivors (N=81, C=41, I=40)	Usual care with basic recommendations in written format for exercise	An 8-week Internet-based, tailored exercise program
Hagstrom et al.	2016	Breast cancer survivors (N=39, C=19, I=20)	Usual care	Resistance training 3 times per week for 16 weeks, sessions lasted 60 minutes each
Hartman et al.	2017	Breast cancer survivors (N=87, C=44, I=43)	Wait-list wellness-contact control (via emails)	Gradually increasing aerobic exercise over time to target at least 150 minutes of MVPA per week
Kim et al.	2019	Colorectal cancer survivors (N=71, C=34, I=37)	Usual care: participants were instructed to continue with their usual activities or exercises during the intervention	A 12-week home-based exercise program aimed to increase the level of physical activity to 18 ~ 27 metabolic equivalent of task hours per week
Lee et al.	2017	Colorectal cancer survivors (N=123, C=61, I=62)	Standard care	A 12-week home-based exercise consisting of aerobic and resistance training, with a goal of obtaining $\geq 18$ metabolic equivalent task per week
Manchola-González et al.	2019	Acute Lymphoblastic Leukemia survivors (Children and adolescents) (N=24, C=121, I=12)	Usual care: participants were advised to continue their usual activities with no restriction placed on physical activity throughout the study period	A 16-week program involving a 90-minute home visit by a trained physiotherapist, and strength, flexibility, and aerobic exercises 3 days per week
Mardani et al.	2021	Prostate cancer survivors (N=80, C=40, I=40)	Routine healthcare for the treatment of prostate cancer and instructions to maintain their customary physical activities and dietary patterns	12-week exercise program including aerobic, resistance, flexibility, and pelvic floor muscle exercises
Rogers et al.	2017	Breast cancer survivors (N=222, C=112, I=110)	Usual care included in the printed materials from the American Cancer Society	A 3-month social cognitive theory-based program including 12 supervised exercise sessions with an exercise specialist. The exercise sessions were tapered over the first 6 weeks to an exclusively unsupervised home-based program
Santos et al.	2019	Breast cancer survivors (N=25, C=13, I=12)	Requested not to change their physical activity habits	Highly supervised resistance training program (1:1 coach to patient ratio), once per week for 8 weeks
Scruggs et al.	2018	Breast cancer survivors (N=60, C=25, I=35)	Standard care	24-week, group-based program including group sessions of 90 minutes each
Tabatabai et al.	2019	Breast cancer survivors (N=206, C=103, I=103)	Usual care receiving a monthly health newsletter	12-month exercise program with a combination of resistance training and aerobic exercise administered through the Young Men's Christian Association

Winters-Stone et al.	2018	Breast cancer survivors (N= 95, C=45, I=50)	Usual care with an oncologist verbal recommendation to exercise	An oncologist verbal recommendation to exercise plus a cancer-specific yoga DVD, for a low-intensity and restorative 30-minute exercise program
Ying et al.	2019	Breast cancer survivors (N= 86, C=40, I=46)	Usual care and requested to maintain their original physical activity	Baduanjin exercise 3 days/week at hospital and another 4 days/week at home for 6 months

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\*Note: N = total number of participants in the trial; C = number of participants in the control arm; I = number of participants in the intervention arm, if more than one intervention arms were used, Ia, Ib, Ic are used to represent different arms.

**Figure 3.1** *Study selection flow diagram*



Through this manuscript, I assessed the strengths and limitations associated with different types of control groups, thereby informing the selection of an optimal design for the pilot feasibility RCT of *Lymfit*. The culmination of this methodological manuscript guided the decision to implement a wait-list control group design in the pilot RCT. This decision was predicated on the recognition of wait-list control as a superior design choice in an exercise intervention study due to its ability to:

- a) control for threats to internal validities, including regression to the mean and spontaneous improvement due to the course of cancer survivorship,
- b) enhance study participants recruitment and retention, and
- c) provide an ethical approach to participant allocation.

In the next sections of this chapter, I present the methodological details of the pilot RCT of *Lymfit* that were not explicitly described in manuscript III (*Chapter 4 – Results*). These additional details include full descriptions of the outcome measurements and ethical considerations of the study.

### **3.4 Detailed description of the outcome measurements**

The specific objectives of the pilot RCT were to a) examine the feasibility of *Lymfit*, which includes recruitment uptake, retention rate, questionnaire completion, intervention fidelity, missing data, Fitbit wear adherence, and control group design; b) assess the acceptability of *Lymfit* by assessing participants' subjective appraisal of the suitability of the intervention components and process; and c) evaluate the preliminary effects of *Lymfit* on four study outcomes: psychological need satisfaction, exercise motivation, physical activity level, and health-related quality of life. The measurement tools or instruments used to examine each of the above objectives are described below:

**Feasibility.** Based on the standards set in prior studies with similar study populations and objectives, a set of a-priori feasibility benchmarks was established to determine the feasibility of the *Lymfit* intervention. A study log was kept by the study coordinator to collect data on feasibility criteria throughout the study. For instance, data concerning recruitment and retention rates (e.g., number of patients approached, number of self-referred, number of eligible and ineligible patients, number of patients declined to participate with reasons, number of participants consented and randomized) were documented in a study log. Specifically, the a-



priori benchmarks for recruitment and retention rate were determined to be at least 50 % (Keadle et al., 2021; Sheill et al., 2019) and 70 % (Angelillo et al., 2024), respectively.

The a-priori benchmark for questionnaire completion is to have at least 95% of study participants complete the questionnaires at both baseline and post-intervention (Angelillo et al., 2024). For intervention fidelity, we aimed to have 90% of sessions delivered in accordance with the fidelity checklist (Sheill et al., 2019). A fidelity checklist tailored to the *Lymfit intervention* was used to document if the intervention milestones were met for each study participant. This checklist was completed by the study coordinator and the study kinesiologist throughout the study (**appendix 3.1**). Regarding missing data, less than 10% of missing data on the study questionnaires was considered meeting the benchmark (Wurz & Brunet, 2019).

Fitbit wear adherence is defined as the percentage of days in the 12-week intervention period that the participants logged a valid day of wear. A Fitbit wear day is considered valid if more than 1000 step counts are logged during that day (Orstad et al., 2021). The prior benchmark for adherence is at least 85% of valid days over the 12-week intervention (Hartman et al., 2022). Lastly, the control group design is considered feasible if 90% of wait-list control group participants started and remained in the intervention, which was documented at the second kinesiologist follow-up consultation meeting.

**Acceptability.** A 10-item acceptability assessment survey was developed tailored to the *Lymfit* intervention (**appendix 3.2**). The survey items were initially reviewed by potential study participants to ensure relevance and clarity. The survey development process also involved collaboration with the research team members to ensure that the survey items accurately captured the key aspects of the intervention and its delivery. The survey responses were collected at post-intervention from the intervention group participants. The participants were asked to report on the extent to which they were satisfied with each intervention component (e.g., activity tracking with a Fitbit, progress monitoring with a smartphone application, and guidance from a kinesiologist), and on the extent to which they found the intervention delivery procedures suitable (e.g., dosage, frequency, timing/scheduling, format). All items were assessed by a five-point Likert scale ranging from one to five, with a higher score indicating a more positive endorsement of the statement. In addition, a score of four or five on the Likert scale (e.g., 4 = acceptable, 5 = highly acceptable) is considered a high rating in this study.

***Self-reported Outcomes.*** In this pilot feasibility study, the preliminary effects of the *Lymfit* intervention on the four study outcomes were assessed using a set of validated questionnaires. These include: two SDT-informed outcomes, psychological need satisfaction and exercise motivation; an exercise-related outcome, physical activity level; and, a health-related outcome, quality of life. Questionnaires for the self-reported outcomes are collected from all participants at baseline before randomization, and at post-intervention. A copy of the questionnaires can be found in **appendix 3.3**.

The psychological need satisfaction in exercise (PNSE) scale (Wilson, Rodgers, & Wild, 2006) was used to assess the perception of psychological need satisfaction associated with exercise motivation. The PNSE comprises 18 items, and each item is assessed on a six-point Likert scale from false (1) to true (6). There are six items corresponding to each of the three subscales, which measure perceived support for competence, autonomy, and relatedness. Subscale scores are calculated by averaging the scores for the six items that comprise each scale. A mean score of the full scale (i.e., the mean of all 18 items) can also be calculated to represent the overall satisfaction of psychological needs. Greater perceived satisfaction of the basic psychological needs is indicated by a higher mean overall score. The scale has shown high internal consistency (Cronbach alpha  $\alpha$ : >.90) (Wilson et al., 2006).

Exercise motivation was assessed using the behavioral regulation in exercise questionnaire, version 3 (BREQ-3) (Markland & Tobin, 2004; Wilson, Rodgers, Loitz, et al., 2006). BREQ-3 comprises 24 items and six subscales; each assesses one form of behavioral regulation (i.e., amotivation, external regulation, introjection, identification, integration, and intrinsic regulation). Each question is scored on a five-point Likert scale from not true for me (0) to very true for me (4). The subscales are weighted to provide an overall estimate of behavioral regulation, the relative autonomy index (RAI), for which higher scores reflect more self-determination. The RAI is calculated by applying a weighting to each subscale, as shown in the formula:  $[\text{amotivation} \times (-3)] + [\text{external regulation} \times (-2)] + [\text{introjected regulation} \times (-1)] + (\text{identified regulation} \times 1) + (\text{integrated regulation} \times 2) + (\text{intrinsic regulation} \times 3)$ . The total weighted scores provide an index of the degree to which respondents experience autonomous motivation (i.e., self-determination). Less autonomous motivation (i.e., more controlled regulation) is indicated by lower negative scores on the RAI. Higher autonomous motivation is indicated by positive scores on the RAI (Ryan & Connell, 1989). The BREQ-3 has been shown

to have good factorial validity, reliability (Duncan et al., 2010), and acceptable internal consistency for all subscales [ $\alpha = 0.73\text{--}0.86$ ] (Markland & Tobin, 2004).

Self-reported physical activity levels were assessed using a three-item instrument, the Godin-Shephard leisure-time physical activity questionnaire (LTPA-Q) (Godin, 2011). The LTPA-Q asks individuals to recall the number of times in the past seven days they have performed any strenuous, moderate, and mild physical activity of more than 15 minutes in duration. The total physical activity score was calculated by multiplying the number of 15-minute bouts of strenuous, moderate, and mild physical activities by weights of nine, five, and three, respectively, and summing those values into an overall score. Higher scores reflect participation in a greater physical activity level. A cut-off score of  $\geq 24$  on the LTPA-Q classifies the participants as active, a score between 14 to 23 is classified as moderately active, and a score of  $< 14$  is classified as sedentary (Godin, 2011). The LTPA-Q is shown to be a valid measure to assess exercise behavior among cancer survivors (Amireault et al., 2015b). Test-retest reliability was good in previous studies (Amireault & Godin, 2015), and the questionnaire has been validated with objective physical activity measures among cancer survivors (Amireault et al., 2015a).

Quality of life was evaluated using the patient-reported outcomes measurement information system® – preference (PROPr) (Dewitt et al., 2020). The PROPr has 30 items which measure perceived health status along eight domains, with items answered on five-point Likert scales. There are four items on each of the following domains: physical function, anxiety, depressive symptoms, fatigue, sleep disturbance, ability to participate in social roles and activities, and pain interference. There are two items on the cognitive function domain. Raw scores generated for each domain are transformed into a T-score using the scoring service from the Health Measures Assessment Center ([https://www.assessmentcenter.net/ac\\_scoring-service](https://www.assessmentcenter.net/ac_scoring-service)) (Gershon et al., 2010), with higher scores indicating greater endorsement of the construct being assessed. A summary PROPr score (also called the health utility score) ranges from  $-0.022$  to  $1.0$  can also be generated using standardized code on the statistical software R (Dewitt et al., 2020). The correlations between PROPr and the other quality of life summary measures ranged from  $0.67$  to  $0.70$  (Hanmer et al., 2018). Further, its convergent validity was shown to be  $r = 0.72$  with EuroQol EQ-5D index value, and an intraclass correlation coefficient of  $0.48$  was obtained

(Klapproth et al., 2022). The construct validity of the PROPr is also supported in a previous study of patients receiving hemodialysis (Zhang et al., 2021).

### **3.5 Ethical considerations**

The study protocol was first approved by the Research Ethics Board (REB) at the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal (Jewish General Hospital) in November 2021. Four months after the initiation of the study at the first study site, a second study site (McGill University Health Centre) was added, and an additional REB approval was obtained in April 2022 (protocol code for this multi-site study: MP-05-202-2560). This study was also registered on ClinicalTrial.gov (NCT05259657). Electronic informed consent (**appendix 3.4**) was obtained after the study coordinator explained the study procedures and answered all questions from the participants. Study participants completed the consent form and all study outcome questionnaires via Qualtrics, a secure online data collection and management platform registered with McGill University – Ingram School of Nursing. Data stored on Qualtrics involved the responses to the questionnaires and the unique participant identifiers, and only research team members were authorized access to these data.

Regarding study compensation, study participants were provided with their personal Fitbit activity trackers and exercise stretch bands, which they were allowed to keep for personal use upon study completion. The intervention was conducted virtually via videoconferencing; therefore, the participants did not receive additional compensation for their time or transportation. Last, although no adverse effects or injuries were reported during the initial testing of the *Lymfit* intervention (Angelillo et al., 2024), there was the possibility of mild physical injuries related to exercising. These risks were minimized by tailored instructions based on the participant's baseline activity levels and tolerance. The increase in activity was gradual, and only safe activities were promoted during the intervention. Furthermore, YAs with lymphoma who had co-morbidities that may be at higher risk of injury were excluded based on their hematologist's recommendation.

## Bridge statement 2

A pilot RCT was conducted to examine the feasibility, acceptability, and preliminary effects of *Lymfit* on four self-reported outcomes: psychological need satisfaction, exercise motivation, physical activity level, and health-related quality of life. A total of 26 YAs with lymphoma who were undergoing chemotherapy or up to six months post-treatment were recruited at two study sites (Jewish General Hospital and McGill University Health Centre) from February 2022 to November 2022. In *Chapter 4 – Results*, I present the results of the pilot RCT of *Lymfit* in manuscript III, titled “*Pilot randomized controlled trial of Lymfit: A theory-guided exercise intervention for young adults with lymphoma.*” This manuscript first presents the study background, objectives, and methodology of the pilot RCT. Then, the results of the study and a comprehensive discussion of the study findings are also included. Manuscript III was published in *Healthcare*, special edition “Exercise Interventions and Testing for Effective Health Promotion,” and was awarded the *Canadian Journal of Nursing Research Award for Writing Excellence* 2024.

## Chapter 4. Results

### 4.1 Manuscript III – Pilot randomized controlled trial of *Lymfit*

Published: *Healthcare*

Special Issue: *Exercise Interventions and Testing for Effective Health Promotion*

Title: Pilot randomized controlled trial of *Lymfit*: A theory-guided exercise intervention for young adults with lymphoma

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## Abstract

Despite the rapidly emerging evidence on the contributions of physical activity to improving cancer-related health outcomes, adherence to physical activity among young adults with lymphoma remains suboptimal. Guided by self-determination theory (SDT), the Lymfit intervention (a 12-week individualized exercise program with bi-weekly kinesiologist support and an activity tracker) aimed to foster autonomous motivation toward physical activity. This pilot randomized controlled trial aimed to evaluate the feasibility, acceptability, and preliminary effects of Lymfit. Young adults (N = 26; mean age of 32.1 years) with lymphoma who were newly diagnosed and those up to six months after completing treatment were recruited and randomly assigned one-to-one to either the intervention group (n = 13) or a wait-list control group (n = 13). All a priori feasibility benchmarks were met, confirming the feasibility of the study in terms of recruitment uptake, retention, questionnaire completion, intervention fidelity, missing data, Fitbit wear adherence, and control group design. The intervention acceptability assessment showed high ratings, with eight out of ten items receiving >80% high ratings. At post-intervention, an analysis of covariance models showed a clinically significant increase in self-reported physical activity levels, psychological need satisfaction, and exercise motivation in the intervention group compared to controls. Lymfit also led to meaningful changes in six quality-of-life domains in the intervention group, including anxiety, depression, fatigue, sleep disturbance, social roles and activities, and pain interference. The findings support Lymfit as a promising means to meet psychological needs and increase the autonomous motivation for physical activity in this group. A fully powered efficacy trial is warranted to assess the validity of these findings.

**Keywords:** young adult cancer survivors; lymphoma; exercise motivation; exercise intervention; self-determination theory; pilot feasibility study; randomized controlled trial

## Background

Young adults (YAs) aged 18-39 are considered one of the fastest-growing segments of cancer survivors in Canada (Canadian Partnership Against Cancer, 2019). Lymphoma, cancer of the lymphatic system, is a commonly diagnosed cancer affecting YAs (Canadian Cancer Society et al., 2022; National Cancer Institute, 2023). Lymphoma can be highly curable with chemotherapy and/or radiotherapy; however, these treatments can have potentially serious short and long-term toxicities (Lo et al., 2021). Consequently, cancer diagnoses and their treatment can significantly hamper the productive years of YAs (Darbà & Marsà, 2021). Despite this, the long-term supportive needs among YA with lymphoma remain understudied (Colabroy, 2021).

Physical activity is a promising means to reduce the intensity and frequency of toxicities resulting from cancer treatment agents, along with enhancing both physical and psychosocial health among cancer survivors (Adams et al., 2021; Campbell et al., 2019). Evidence suggests that post-diagnosis physical activity reduces all-cause and cancer-specific mortality among survivors of breast, prostate and colorectal cancers (Kang et al., 2022). Physical activity among individuals with lymphoma is also shown to significantly modulate psychological distress and illness-related anxiety (Zhi et al., 2019), improve quality of life (Vlooswijk et al., 2021), alleviate fatigue (Liu et al., 2019), prolong survival (Boyle et al., 2017a; Pophali et al., 2018), in addition to promoting cardiovascular health and muscle strength (Zucchetti et al., 2018).

Despite a substantial body of evidence demonstrating the positive impact of physical activities on cancer-related health outcomes, adherence to recommended physical activity guidelines among cancer survivors remains sub-optimal (Tollosa et al., 2019). Notably, lack of motivation is a frequently reported psychological barrier to physical activity engagement in this population (Elshahat et al., 2021). The literature suggests that focusing on modifying motivational factors in health behavior interventions can yield multiple positive effects on cancer survivors, such as improved quality of life, the restoration of order in life, and the preservation of meaning to life in the face of illness and health challenges (Tock, 2022).

Self-determination theory (SDT) is a macro theory of human motivation (Deci & Ryan, 1985, 2008b). SDT is relevant to understanding the mechanisms of health behavior change, including the maintenance of exercise (Fortier et al., 2012; Hagger & Chatzisarantis, 2008; Ntoumanis et al., 2020). SDT provides a framework for intervention development by proposing

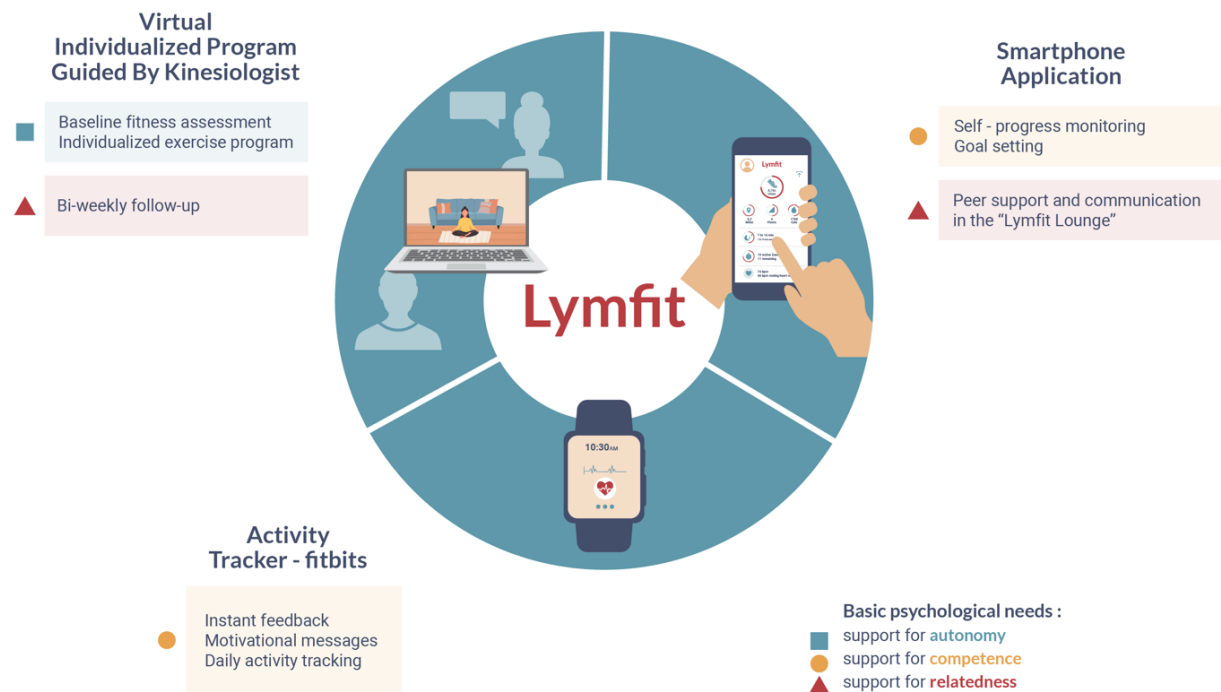


that three basic psychological needs (i.e., autonomy, competence, and relatedness) must be supported to foster autonomous forms of motivation (or intrinsic motivation) (Ryan & Deci, 2002), which in turn are associated with important health outcomes including psychological health, well-being, and improved quality of life (Deci & Ryan, 2008a). Accordingly, exercise interventions based on or informed by SDT have grown considerably in recent years (Rhodes et al., 2019). Yet, limitations of these SDT-informed interventions exist, for example, (a) the physical activity program is predetermined or standardized and not tailored to cancer survivors' needs (lack autonomy support), (b) key components of competence support (e.g., goal setting) are neglected, and/or (c) measurement and interpretation of results are not in relation to the theory (Gillison et al., 2019; Rodrigues et al., 2023). To address these limitations, we developed, and pilot-tested *Lymfit* – an individualized, virtually delivered, and SDT-guided intervention aiming to promote exercise motivation in YAs diagnosed and treated for lymphoma.

### ***Lymfit* Intervention**

*Lymfit* is a 12-week, virtually delivered and individualized exercise intervention. Theoretically guided by SDT, *Lymfit* is designed to enhance the motivation for exercise engagement in YA with lymphoma through providing support in the three basic psychological needs (**Figure 4.1**). The intervention participants are given a Fitbit, which provides functions such as task orientation, goals setting, progress monitoring, and feedback (**support for competence**). Participants are prescribed a personalized 12-week exercise program by the kinesiologist, which is tailored to their baseline fitness level and exercise tolerance (**support for autonomy**). The intervention participants are followed by the study kinesiologist for 12 weeks (with bi-weekly follow-up consultations), and they are also connected with other intervention participants within the “*Lymfit lounge*,” a private group on the Fitbit smartphone application where participants can share and compare their exercise progress and activity achievements (**support for relatedness**).

**Figure 4.1** *Lymfit* intervention components



The development of *Lymfit* has been an iterative process. The preliminary version of *Lymfit* was reviewed with YA lymphoma survivors for initial feedback. Then, we recently undertook a proof-of-concept study early on in the development of the intervention, in which 20 long-term YA lymphoma survivors participated in a single-armed pilot study that aimed to examine implementation feasibility (e.g., technical and safety issues) of the preliminary version of *Lymfit* (Angelillo et al., 2024).

## Objectives

This present study aimed to pilot-test *Lymfit* through a randomized controlled trial (RCT). Specifically, the objectives of this pilot RCT were to assess *Lymfit*'s (a) feasibility through predetermined a-priori benchmarks; (b) acceptability; and (c) its preliminary effects on four study outcomes: psychological need satisfaction, exercise motivation, physical activity level, and health-related quality of life.

## Methods

### Design

This study was a 1:1, parallel, two-group (intervention and wait-list control group) pilot RCT (trial registration: NCT05259657). The design and reporting of this study were guided by the Consolidated Standards of Reporting Trials (CONSORT) 2010 guideline for randomized pilot and feasibility trials (Eldridge et al., 2016) (**appendix 4.1**) and the Template for Intervention Description and Replication (TIDieR) guideline (Hoffmann et al., 2014) (**appendix 4.2**). This study was approved by the Research Ethics Boards from the two recruiting sites in Montreal, Quebec.

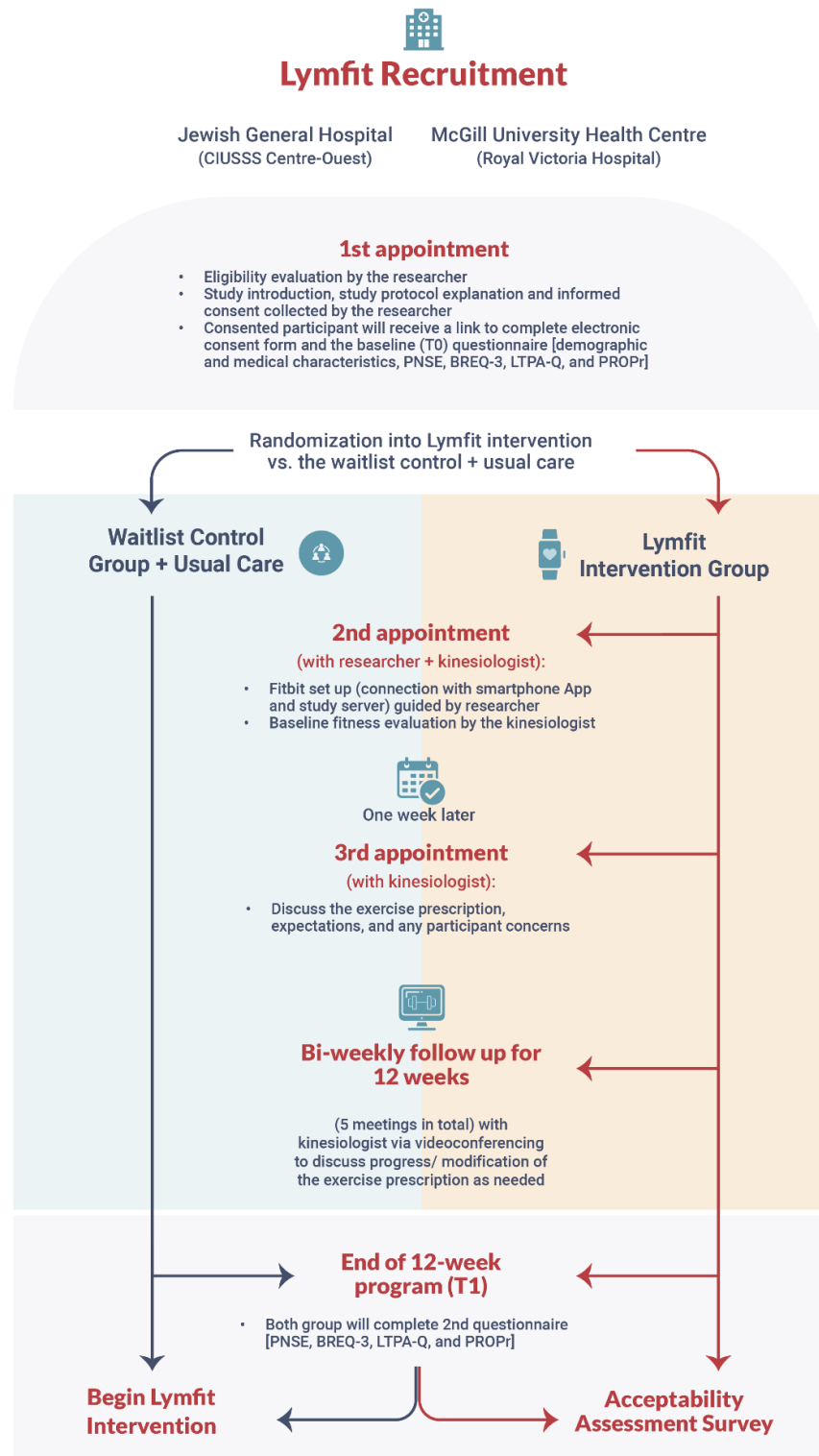
### **Setting, recruitment, participants, and sample size**

Study participants were recruited from two university-affiliated hospitals in Montréal, Canada, by hematologists and by self-referral via flyers in the oncology clinic from February to November 2022. Newly diagnosed YAs with lymphoma aged 18 to 39 who had a score of < 14 (classified as sedentary) on the Godin-Shephard leisure-time physical activity questionnaire (LTPA-Q) (Godin, 2011) were considered eligible. Participants also had to be receiving or completed chemotherapy within the past six months; own a smartphone; and had an internet connection at home. Power calculation for sample size was not performed for this study. Instead, based on the recommendations for pilot RCTs, a target sample size of at least 12 per group was set (Hertzog, 2008; Julious, 2005).

### **Randomization and blinding**

The study coordinator scheduled the first study appointment with eligible participants via videoconferencing (study procedures are shown on **Figure 4.2**). During this meeting, the participants completed an electronic consent form and baseline measures (i.e., T0) comprising questions on demographics and medical characteristics and a set self-reported questionnaire. The study coordinator then registered participants' pre-assigned Fitbit (Charge V model, Fitbit Inc., San Francisco, CA) on the *Lymfit* platform (study web database), which randomized participants to the intervention or the control group using a computer-generated randomization schedule stratified on chemotherapy completion status (i.e., completed chemotherapy vs. undergoing chemotherapy). To ensure allocation concealment and avoid selection bias, the *Lymfit* platform was programmed by a statistician not involved in the study, and research team members did not have access to the randomization schedule.

**Figure 4.2** *Lymfit study procedures*



## Study groups

**Intervention group.** All study appointments were conducted via videoconferencing. First, the study package consisted of a pre-assigned Fitbit and exercise stretch bands were mailed to the participants. At the second study appointment, the study coordinator guided the participants to set up the Fitbit and to pair with their smartphone application. Participants were then added to a virtual “*Lymfit lounge*,” acting as a peer-support group, within the Fitbit application. During the same appointment, the study kinesiologist conducted a baseline physical assessment [details previously published in the proof-of-concept study of *Lymfit* (Angelillo et al., 2024)]. In the following week, the kinesiologist evaluated the data collected from the assessment. Using the baseline data, the kinesiologist established an individualized exercise program for the participant. One week after the second appointment, the study kinesiologist met with the participant to discuss the exercise program, expectations, and any participant concerns (third study appointment). Each individualized exercise program is designed based on the evidence-based exercise guidelines targeting cancer survivors published by the American College of Sports Medicine (Campbell et al., 2019), while taking into consideration the results from the baseline assessment for each participant. Further detail about the individualized exercise program is shown in **appendix 4.3**.

Thereafter, follow-up appointments with the study kinesiologist were conducted every two weeks for a duration of 12 weeks. During these sessions, participants engaged in discussions with the kinesiologist to review their progress and make necessary modifications or advancements to their exercise programs. At the end of the 12-week intervention (i.e., T1), participants completed outcome measures and an acceptability assessment survey. Participants were instructed to complete measures within one week of intervention completion.

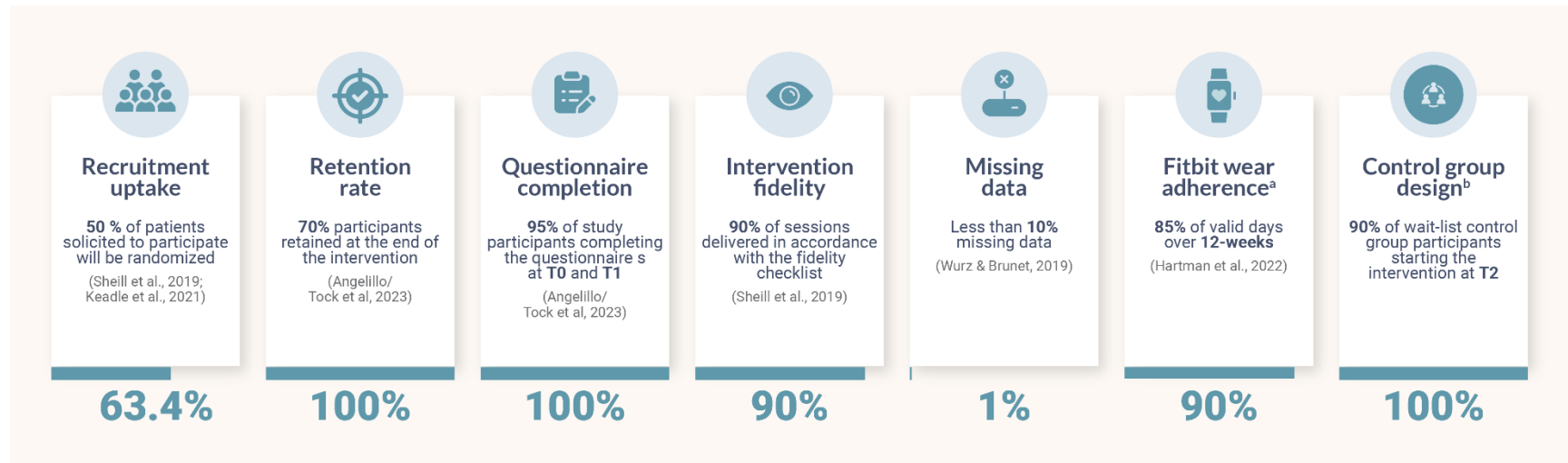
**Wait-list control group.** Control group participants continued usual care as per the recruiting sites’ protocol. Once the outcome measures were completed at T1, the study kinesiologist contacted the participants on the wait-list control group to begin the *Lymfit* intervention. The study coordinator documented if control group participants remained in the study at the second kinesiologist follow-up meeting (i.e., T2).

## Data collection

***Demographic and clinical characteristics.*** Questions on demographic and clinical characteristics were part of the baseline assessment questionnaire completed by all participants before randomization at T0.

***Feasibility.*** As illustrated in **Figure 4.3**, a set of a-priori benchmarks were established to determine the feasibility of the *Lymfit* intervention. A study log was kept by the study coordinator to collect data on feasibility criteria throughout the study. For instance, data concerning recruitment and retention rates (e.g., number of patients approached, number of self-referred, number of eligible and ineligible patients, number of patients who decline to participate with reasons, number of participants consented and randomized) were documented in the study log.

**Figure 4.3** *A-priori feasibility benchmarks and results*



**Note:**

<sup>a</sup> data collected in intervention group only (n=13)

<sup>b</sup> data collected in control group only (n=13)

**Acceptability.** An acceptability assessment survey comprising 10 items tailored to *Lymfit*, was collected at T1 from the intervention group (**Table 4.1**). Participants rated their satisfaction with each intervention component and the suitability of delivery procedures on a five-point Likert scale, with higher score indicating more positive endorsement of the statement.

**Table 4.1** *Acceptability assessment survey results*

Questionnaire items	Respondents endorsing a score of 4/5 in each question <sup>a</sup>	
	n	%
1. How helpful was the personalized exercise program from the kinesiologist in motivating you to exercise?	11	84.6
2. Are you satisfied with the remote format of the exercise program?	11	84.6
3. Was the frequency of the kinesiologist follow-up acceptable?	10	76.9
4. How helpful was wearing the Fitbit tracker and receiving alerts in motivating you to exercise?	12	92.3
5. How much did you enjoy using the peer-support group on the App?	7	53.8
6. How helpful was the progress monitoring function on the App in motivating you to exercise?	11	84.6
7. Was the amount of time it took to complete this program (12 weeks) acceptable?	13	100.0
8. Was the exercise program prescribed by the kinesiologist tailored to your personal needs?	12	92.3
9. Was starting this exercise program close to completing your cancer treatment acceptable?	11	84.6
10. How would you rate your overall satisfaction with the <i>Lymfit</i> program?	12	92.3
<b>Note:</b> <sup>a</sup> Items were assessed by 5-point Likert scale ranging from 1 to 5, with higher score indicating more positive endorsement of the statement. A score of 4 or 5 is considered a high rating.		

**Self-reported outcomes.** The preliminary effects of the *Lymfit* intervention on the four self-reported study outcomes were assessed through questionnaires collected from all participants at baseline before randomization (T0), and at post-intervention (T1). A detailed description and the psychometric properties of the instruments can be found on **appendix 4.4**.

The Psychological Need Satisfaction in Exercise (PNSE) scale (Wilson, Rodgers, & Wild, 2006) was used to assess the perception of psychological need satisfaction associated with exercise motivation (18 items in total). The overall satisfaction scores and the three subscales



(perceived support for competence, autonomy, and relatedness) scores can be calculated, with higher scores indicating higher needs satisfaction.

Exercise motivation (i.e., self-determination) was assessed using the Behavioral Regulation in Exercise Questionnaire (BREQ-3) (Markland & Tobin, 2004; Wilson, Rodgers, Loitz, et al., 2006). The BREQ-3 comprises 24 items and six subscales, measuring the six types of motivations (i.e., amotivation, external regulation, introjection, identification, integration, and intrinsic regulation). The subscale scores were weighted to provide an overall estimate of self-determination, the relative autonomy index (RAI), for which higher scores reflect more self-determination (more exercise motivation).

Self-reported physical activity level was assessed using the three-item Godin-Shephard leisure-time physical activity questionnaire (LTPA-Q) (Godin, 2011). The LTPA-Q asks individuals to recall the number of times in the past seven days they have performed any strenuous, moderate, or mild/ light physical activity of more than 15 minutes in duration. A total physical activity score can be calculated.

The Patient-Reported Outcomes Measurement Information System® – Preference (PROPr) (Dewitt et al., 2020) was used to measure perceived quality of life along eight domains (i.e., physical function, anxiety, depressive symptoms, fatigue, sleep disturbance, ability to participate in social roles and activities, pain interference, and cognitive function; 30 items in total). A T-score was generated from each subscale, with higher scores indicating greater endorsement of the construct being assessed (Gershon et al., 2010). A PROPr utility score (representing overall quality of life) was also calculated (Dewitt et al., 2020).

## **Data analysis**

***Demographics, feasibility and acceptability data.*** Participant characteristics, feasibility and acceptability data were summarized using descriptive statistics. Baseline group equivalence was assessed using appropriate statistical tests. For feasibility data, percentages pertaining to the criteria (e.g., recruitment uptake, retention rate, questionnaire completion, etc.) were calculated and compared to the priori benchmarks. For the acceptability survey items, a score of four or five on a 5 point-Likert scale (i.e., 4 = acceptable, 5 = highly acceptable) is considered a high rating. The percentage of high ratings for each question were reported.

**Preliminary effects.** All data analyses were conducted on R Studio (v. 2023.09.1+494). Independent t-tests were used to compare the mean values of all self-reported study outcomes at baseline between intervention and control groups. Analysis of covariance (ANCOVA) models were used to compare post-intervention group differences for the study outcomes between the two groups, where the post-intervention values of the study outcomes were the dependent variables, the baseline (pre-intervention) values served as covariates, and the grouping variable identified the two study groups. Assumption checks for all data on the self-reported outcomes were first checked using appropriate statistical tests and plots. Univariate models were used to examine the homogeneity of regression assumption on each dependent variable. Full-factor ANCOVA models were then fitted to evaluate the group differences on the post-intervention scores adjusted for the baseline scores. For this pilot investigation, an effect size of at least 0.2 for each study outcome was considered acceptable (Page, 2014). Additionally, the minimal important change (MIC) was calculated for quality of life domains (measured by PROPr), striving for a threshold of four T-score points change to be considered meaningful within-group change and between-group comparison (Terwee et al., 2021; Yost et al., 2011).

## **Results**

### **Participant characteristics**

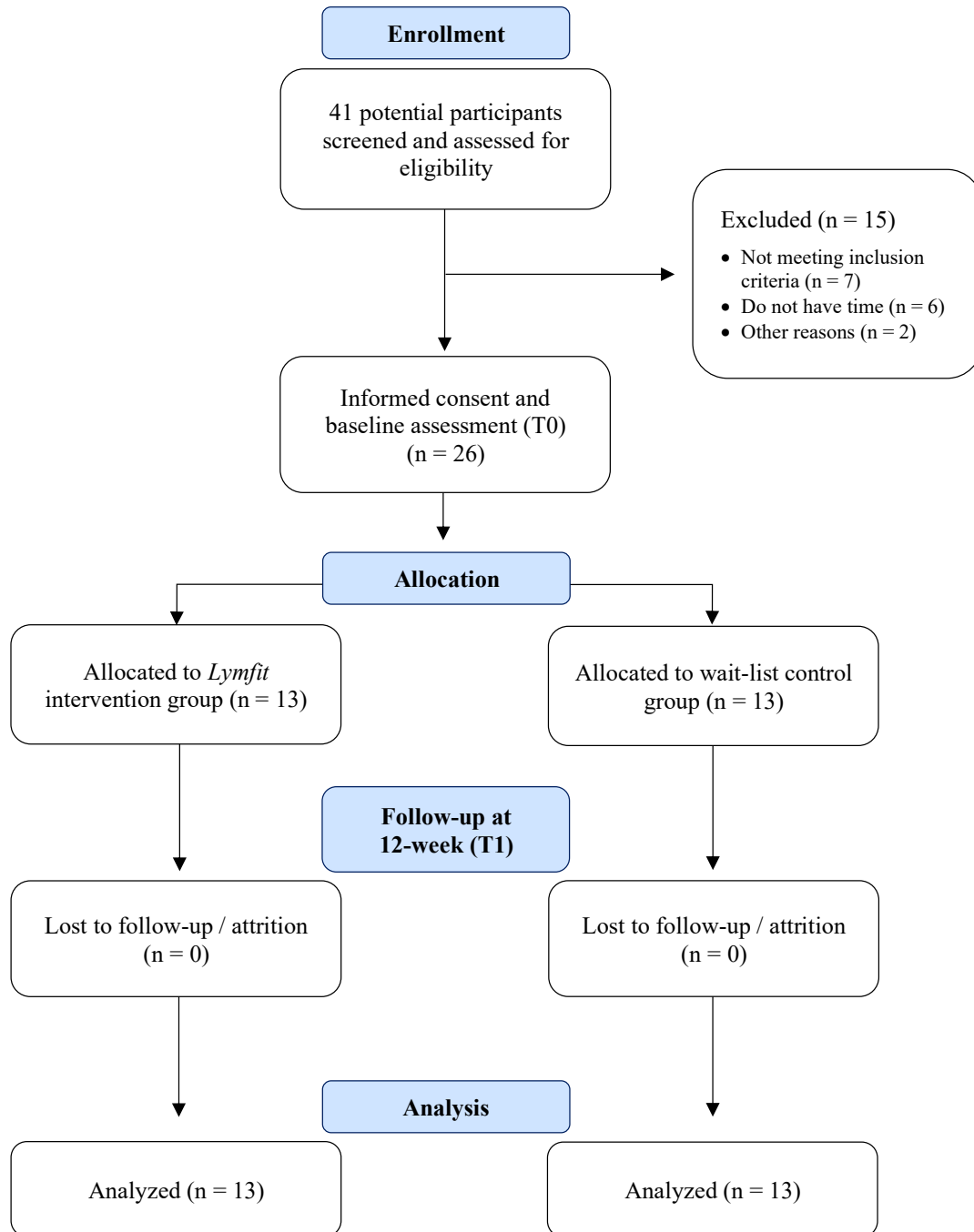
A total of 26 YAs with lymphomas were randomized. The mean age of the participants was 32.4 years old (SD = 5.82, range = 20 – 39). A majority of the study participants were female (84.6%), white (92.3%), and more than half had some university or college education (57.7%). Approximately half of the participants were married (53.8%) and did not have dependent children (57.7%). One-third were employed or going to school full-time. Mean body mass index (BMI) was 24.93 kg/m<sup>2</sup> (SD = 4.35, range = 16.86 – 34.87), which is considered within the healthy weight range (Centers for Disease Control and Prevention, 2022). Nearly one-third were undergoing chemotherapy. Equal numbers of participants were diagnosed with Hodgkin's Lymphoma and non-Hodgkin's Lymphoma and were receiving chemotherapy in the frontline setting with curative intent (**Table 4.2**). **Figure 4.4** CONSORT flow diagram details participants' flow through the study.

**Table 4.2** *Participant demographic and clinical characteristics*

	Intervention (n=13)		Control (n=13)		Overall (N=26)		Statistical comparison between groups <sup>a</sup>
	Mean (range) / n	SD / (%)	Mean (range) / n	SD / (%)	Mean (range) / n	SD / (%)	
<b>Age (years)</b>	30.69 (24 – 39)	5.78	34.0 (20 – 39)	5.58	32.35 (20 – 39)	5.82	W = 111.5; p = 0.172
<b>BMI</b>	25.11 (18.29 – 32.85)	4.56	24.76 (16.86 – 34.87)	4.32	24.93 (16.86 – 34.87)	4.35	W = 83; p = 0.959
<b>BMI categories</b>							$\chi^2 = 0.28$ ; p = 0.964
< 18.5	1	7.7	1	7.7	2	7.7	
18.5 – 24.9	6	46.2	7	53.8	13	50.0	
25.0 – 29.9	3	23.1	3	23.1	6	23.1	
≥ 30.0	3	23.1	2	15.4	5	19.2	
<b>Gender</b>							$\chi^2 = 0$ ; p = 1.0
Female	11	84.6	11	84.6	22	84.6	
Male	2	15.4	2	15.4	4	15.4	
<b>Ethnicity / Racial identity</b>							$\chi^2 = 2.0$ ; p = 0.368
White	12	92.3	12	92.3	24	92.3	
Black	0	0.0	1	7.7	1	3.8	
Asian	1	7.7	0	0.0	1	3.8	
<b>Education</b>							$\chi^2 = 2.75$ ; p = 0.432
High school or less	0	0.0	1	7.7	1	3.8	
High school graduate	0	0.0	0	0.0	0	0.0	
Some CEGEP	0	0.0	0	0.0	0	0.0	
Some university/ college	7	53.8	8	61.5	15	57.7	
College / technician school degree	0	0.0	0	0.0	0	0.0	
University degree	5	38.5	4	30.8	9	34.6	
Graduate degree	1	7.7	0	0.0	1	3.8	
<b>Marital status</b>							$\chi^2 = 2.4$ ; p = 0.494
Married / Common law	7	53.8	7	53.8	14	53.8	
Divorced / Separated	0	0.0	1	7.7	1	3.8	

Single	6	46.2	4	30.8	10	38.5	
In partnership	0	0.0	1	7.7	1	3.8	
<b>Household income</b>							$\chi^2 = 1.21$ ; p = 0.546
\$30 000 - \$60 000	3	23.1	4	30.8	7	26.9	
\$60 001 - \$ 90 000	7	53.8	8	61.5	15	57.7	
\$90 001 - \$120 000	3	23.1	1	7.7	4	15.4	
<b>Employment/ Education</b>							$\chi^2 = 4.1$ ; p = 0.251
Full-time	6	46.2	4	30.8	10	38.5	
Part-time	2	15.4	3	23.1	5	19.2	
Full time homemaker	0	0.0	3	23.1	3	11.5	
On leave	5	38.5	3	23.1	8	30.8	
<b>Number of dependent children</b>							
0	8	61.5	7	53.8	15	57.7	$\chi^2 = 1.4$ ; p = 0.706
1	1	7.7	3	23.1	4	15.4	
2	2	15.4	2	15.4	4	15.4	
3 or more	2	15.4	1	7.7	3	11.5	
<b>Chemo status</b>							$\chi^2 = 0$ ; p = 1.0
Not yet completed	4	30.8	5	38.5	9	34.6	
Completed	9	69.2	8	61.5	17	65.4	
<b>Diagnosis</b>							$\chi^2 = 1.38$ ; p = 0.239
Hodgkin's Lymphoma	5	38.5	8	61.5	13	50.0	
Non-Hodgkin's Lymphoma	8	61.5	5	38.5	13	50.0	
<b>Notes:</b> <sup>a</sup> W = Mann Whitney U test (Wilcoxon Rank Sum Test); $\chi^2$ = Chi-squared test. There were no significant differences between the two groups at baseline.							

**Figure 4.4** Consolidated standards of reporting trials (CONSORT) flow diagram



## Feasibility

All predetermined feasibility benchmarks were achieved (**Figure 4.3**). Of the 41 potential participants screened for eligibility, 26 were enrolled and randomized into the two study groups, representing a 63.4% recruitment uptake rate. The retention and questionnaire completion rates were both 100%, with minimal (<1%) data missing. For Fitbit wear adherence (n = 13), valid wear days over the 12-week intervention period were 90% (982 of 1092 total days). Further, no protocol infringements occurred during the study, and 90% of the sessions were delivered in accordance with the fidelity checklist. Reasons for missed follow-up appointments included: participants going on vacation, sickness, unable to schedule a meeting time due to school or work obligations, etc. For most of the missed follow-up appointments, the study kinesiologist was able to connect with the participants via email or phone calls to discuss program progress and to address any concerns from the participants. Last, all participants randomized to the wait-list control group were successfully retained in the study at T2.

## Acceptability

The thirteen participants from the intervention group completed the acceptability assessment survey at T1. Item number five, which assessed participant enjoyment of using the peer-support group on the smartphone application, received the least number of high ratings (53.8%). This represents a low acceptability of the peer support group component. Additionally, 23% rated item number three (was the frequency of the kinesiologist follow-up acceptable?) a score of three or below. The rest of the items received >80% high ratings (i.e., 4 or 5 on a 5-point scale). Item #10 assessed the participant's overall satisfaction with the *Lymfit* intervention and received 92.3% high ratings (**Table 4.1**).

## Preliminary effects on study outcomes

**Table 4.3** presents the ANCOVA results of the four self-reported outcome measures. The T0 values, T1 adjusted values, and the effect size (ES) with 95% CI, and p-values are presented. The benchmark for effect size of at least 0.2 were mostly met on the self-reported study outcomes. As hypothesized, intervention group participants reported improvements in all four main study outcomes (ES of overall PNSE = 0.498, ES of overall BREQ-3 = 0.598, ES of LTPA-Q = 0.348, and ES of overall PROPr = 0.332).

**Table 4.3** *Analysis of covariance results*

Instruments and Outcomes <sup>a</sup>	Baseline		Post-intervention (Adjusted)		Effect size	p-value <sup>c</sup>
	Intervention (n=13)	Control (n=13)	Intervention (n=13)	Control (n=13)		
	mean ± SD <sup>b</sup>	mean ± SD	mean ± SE (95% CI) <sup>c</sup>	mean ± SE (95% CI)	( $\eta_p^2$ ) <sup>d</sup> (95% CI)	
<b>PNSE</b>						
Overall needs satisfaction	3.62 ± 0.47	3.44 ± 0.38	3.96 ± 0.06 (3.82, 4.09)	3.52 ± 0.06 (3.38, 3.65)	0.498 (0.181 – 0.671)	<0.001**
Competence	3.20 ± 0.80	3.21 ± 0.73	3.62 ± 0.09 (3.42, 3.82)	3.24 ± 0.09 (3.05, 3.42)	0.255 (0.016 – 0.489)	0.01*
Autonomy	4.05 ± 0.61	4.00 ± 0.63	4.32 ± 0.11 (4.08, 4.55)	4.01 ± 0.20 (3.57, 4.04)	0.311 (0.040 – 0.535)	0.004*
Relatedness	3.62 ± 0.65	3.11 ± 0.80	3.94 ± 0.16 (3.60, 4.28)	3.49 ± 0.16 (3.15, 3.84)	0.128 (0 – 0.372)	0.079
<b>BREQ – 3</b>						
Overall self-determination	1.40 ± 5.03	-3.10 ± 5.28	4.50 ± 0.63 (3.20, 5.80)	-0.85 ± 0.63 (-2.15, 0.46)	0.589 (0.283 – 0.732)	<0.001**
Amotivation	1.50 ± 0.69	1.87 ± 0.93	0.84 ± 0.10 (0.63, 1.05)	1.77 ± 0.10 (1.56, 1.98)	0.636 (0.344 – 0.763)	<0.001**
External regulation	1.17 ± 0.70	1.10 ± 0.68	0.85 ± 0.15 (0.55, 1.16)	1.15 ± 0.15 (0.84, 1.45)	0.077 (0 – 0.313)	0.178
Introjected regulation	1.54 ± 0.95	2.08 ± 0.87	1.89 ± 0.13 (1.62, 2.15)	2.21 ± 0.13 (1.94, 2.48)	0.114 (0 – 0.357)	0.098
Identified regulation	1.71 ± 0.66	1.58 ± 0.92	2.12 ± 0.13 (1.85, 2.39)	1.80 ± 0.13 (1.53, 2.07)	0.115 (0 – 0.357)	0.098
Integrated regulation	1.56 ± 0.69	1.10 ± 0.83	2.03 ± 0.13 (1.75, 2.30)	1.57 ± 0.13 (1.30, 1.84)	0.199 (0 – 0.441)	0.025 *
Intrinsic regulation	1.65 ± 0.76	1.00 ± 0.68	1.53 ± 0.07 (1.38, 1.67)	1.30 ± 0.07 (1.16, 1.44)	0.176 (0 – 0.420)	0.037 *
<b>LTPA – Q</b>	12.92 ± 5.01	11.04 ± 7.91	40.36 ± 3.67 (32.77, 47.95)	22.06 ± 3.67 (14.47, 29.66)	0.348 (0.061 – 0.563)	0.002*

<b>PROPr</b>						
Overall quality of life <sup>f</sup>	0.28 ± 0.12	0.26 ± 0.10	0.53 ± 0.05 (0.43, 0.63)	0.29 ± 0.05 (0.19, 0.39)	0.332 (0.051 – 0.551)	0.003*
Physical function <sup>g</sup>	48.79 ± 7.57	50.15 ± 12.04	52.14 ± 1.62 (48.79, 55.50)	43.57 ± 1.62 (40.22, 46.93)	0.385 (0.084 – 0.590)	<0.001**
Anxiety	60.59 ± 10.22	60.88 ± 5.19	55.09 ± 2.05 (50.72, 59.43)	60.21 ± 2.05 (55.74, 64.80)	0.119 (0 – 0.362)	0.091
Depression	56.62 ± 10.25	54.57 ± 8.86	50.79 ± 1.71 (47.26, 54.33)	56.54 ± 1.71 (53.01, 60.08)	0.196 (0 – 0.439)	0.027*
Fatigue	56.84 ± 8.03	58.66 ± 5.93	50.05 ± 2.06 (45.80, 54.30)	60.25 ± 2.06 (56.00, 64.50)	0.346 (0.060 – 0.562)	0.002*
Sleep disturbance	55.87 ± 4.40	56.77 ± 5.49	46.11 ± 2.06 (41.85, 50.37)	52.76 ± 2.06 (48.50, 57.02)	0.184 (0 – 0.428)	0.032*
Social roles and activities	48.56 ± 5.75	43.76 ± 5.15	53.68 ± 1.77 (50.02, 57.34)	45.64 ± 1.77 (41.99, 49.30)	0.291 (0.031 – 0.519)	0.005*
Pain interference	48.79 ± 7.57	50.99 ± 11.77	43.77 ± 1.76 (40.13, 47.40)	52.64 ± 1.76 (49.01, 56.27)	0.355 (0.065 – 0.569)	0.002*
Cognitive abilities	47.47 ± 7.10	44.52 ± 8.24	49.13 ± 1.70 (45.62, 52.64)	47.54 ± 1.70 (44.03, 51.05)	0.018 (0 – 0.214)	0.518
<b>Notes:</b> <sup>a</sup> PNSE = Psychological Need Satisfaction in Exercise; BREQ – 3 Behavioral Regulation in Exercise Questionnaire; LTPA – Q = Godin-Shephard leisure-time physical activity questionnaire; PROPr = Patient-Reported Outcomes Measurement Information System® – Preference <sup>b</sup> SD = standard deviation; SE = standard error <sup>c</sup> CI = confidence interval <sup>d</sup> Partial eta-squared <sup>e</sup> * p = <0.05; ** p = <0.001 <sup>f</sup> Overall quality of life score is the PROMIS-Preference (PROPr) score, which provides a preference-based summary score for health states defined by 7 PROMIS domains. It ranges from -0.022 to 1.00 <sup>g</sup> PROPr sub-scale values are reported as T-scores with a mean of 50						



The ANCOVA model showed a group effect on overall psychological need satisfaction at post-intervention after adjusting for baseline score differences (overall PNSE:  $p < 0.001$ , intervention:  $M = 3.96$ ,  $SE = 0.06$ , vs. Control:  $M = 3.52$ ,  $SE = 0.06$ ). Among the three PNSE subscales, competency and autonomy subscales had met the ES threshold of 0.2 ( $ES = 0.255$ ;  $0.311$ ), while the relatedness subscale did not meet the ES threshold ( $ES = 0.128$ ).

For self-determination (exercise motivation, measured by BREQ – 3), the ANCOVA model showed a significant group effect on overall self-determination at post-intervention after adjusting for baseline score differences (overall BREQ–3:  $p < 0.001$ , intervention:  $M = 4.50$ ,  $SE = 0.63$ , vs. Control:  $M = -0.85$ ,  $SE = 0.63$ ). Among the six subscales, amotivation was the only one meeting the ES threshold of 0.2 ( $ES = 0.636$ ). Next, the result of ANCOVA showed that there was a significant group effect on self-reported physical activity levels at post-intervention (LTPA–Q:  $p = 0.002$ , intervention:  $M = 40.36$ ,  $SE = 3.67$ , vs. Control:  $M = 22.06$ ,  $SE = 3.67$ ) after controlling for participants score at baseline. Lastly, the ANCOVA model showed a significant group effect on overall quality of life at post-intervention after adjusting for baseline score differences (PROPr:  $p = 0.003$ , intervention:  $M = 0.53$ ,  $SE = 0.05$ , vs. Control:  $M = 0.29$ ,  $SE = 0.05$ ). The ES threshold was also met for four out of the eight PROPr subscales, including physical function ( $ES = 0.385$ ), fatigue ( $ES = 0.346$ ), ability to participate in social roles and activities ( $ES = 0.291$ ), and pain interference ( $ES = 0.355$ ).

In terms of PROPr domains (**Table 4.4**), six subscales out of eight exhibited beneficial changes in T-scores that met the MIC threshold of a minimum of four T-score points overtime in the intervention group (i.e., anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, and pain interference). Further, seven subscales out of eight met the MIC threshold for between group comparisons (i.e., physical function, anxiety, depression, fatigue, and sleep disturbance, ability to participate in social roles and activities, and pain interference).

**Table 4.4** *Quality of life domains – Minimal important changes (MIC)*

PROPr domains <sup>a</sup>	Baseline (T0)		Post-intervention (T1) (Adjusted)		Change in T-score	
	Intervention (n=13)	Control (n=13)	Intervention (n=13)	Control (n=13)	Intervention (n=13)	Control (n=13)
	mean ± SD	mean ± SD	mean ± SD	mean ± SD	T-score change from T0 to T1	T-score change from T0 to T1
<b>Physical function</b>	48.79 ± 7.57	50.15 ± 12.04	52.18 ± 5.68	43.53 ± 5.82	+3.39	- 6.62
<b>Anxiety</b>	60.59 ± 10.22	60.88 ± 5.19	55.02 ± 10.34	60.28 ± 5.69	- 5.57	- 0.60
<b>Depression</b>	56.62 ± 10.25	54.57 ± 8.86	51.12 ± 6.94	56.22 ± 6.56	- 5.50	+ 1.65
<b>Fatigue</b>	56.84 ± 8.03	58.66 ± 5.93	49.48 ± 8.53	60.82 ± 8.44	- 7.36	+ 2.16
<b>Sleep disturbance</b>	55.87 ± 4.40	56.77 ± 5.49	45.73 ± 8.50	53.14 ± 8.26	- 10.14	- 3.63
<b>Social roles and activities</b>	48.56 ± 5.75	43.76 ± 5.15	55.48 ± 7.01	43.84 ± 7.41	+ 6.92	+ 0.08
<b>Pain interference</b>	48.79 ± 7.57	50.99 ± 11.77	43.48 ± 4.84	52.92 ± 8.12	- 5.31	+ 1.93
<b>Cognitive abilities</b>	47.47 ± 7.10	44.52 ± 8.24	49.98 ± 9.11	46.69 ± 5.15	+ 2.51	+ 2.17
<b>Notes</b> <sup>a</sup> PROPr sub-scales (domains) values are reported as T-scores with a mean of 50 Green = beneficial change; Red = detrimental change						

## Discussion

Overall, this pilot RCT garnered promising findings. The *Lymfit* intervention addresses the needs to promote exercise motivation among YAs undergoing lymphoma treatment or immediately post-treatment. The study documented key benchmarks for feasibility, acceptability, and preliminary effects of the intervention in preparation for a larger trial.

Several key findings are worth noting. First, this pilot study tested *Lymfit* using a rigorous design and demonstrated the feasibility and acceptability of the intervention. All a-priori feasibility benchmarks were met. Results provide a strong foundation for future testing on a larger scale. Particularly, the wait-list control design is highly feasible; a 100% retention rate in the control group was achieved. These findings are consistent with the literature, suggesting that a wait-list control group can improve retention as compared to usual care/ no-treatment control groups in exercise interventions (Tock et al., 2022).

Another main significance of this study is that it demonstrated the acceptability of a virtual exercise intervention delivery during treatment and immediately post-treatment. This finding suggests that rehabilitation could be implemented in conjunction with cancer therapy to enhance the quality of life in YAs affected by lymphoma (Sleight et al., 2022).

Further, promising trends were found for all main outcome variables, including overall psychological needs satisfaction, overall exercise motivation, physical activity levels, and overall quality of life. Among all self-reported outcomes, the largest effect size of 0.636 was observed for the amotivation subscale (measured using the BREQ-3), the least desirable type of motivation as posited by the SDT. These preliminary results suggest that *Lymfit* has a significant effect on moving the intervention group participants up the relative autonomy continuum from amotivation. In addition, the MIC threshold was met for multiple domains in the PROPr for both within-group changes and between-group differences at post-intervention, demonstrating the positive effects of the intervention on participants' quality of life. The above findings are in line with SDT, reflecting the significance of providing a favorable environment for performing exercise during and immediately after cancer treatment, supporting autonomy, competence and relatedness required for health behavior change (Ntoumanis et al., 2020).

With regards to psychological needs satisfaction (measured with the PNSE), our preliminary findings show that the intervention had significant effects on competence and

autonomy, but not on relatedness. This is concordant with another study's findings, which show a low acceptability of the use of peer-support groups. The low utilization of the peer-support group may be driven by the fact that participation in the in-App *Lymfit lounge* was not mandatory. Further modification to support relatedness needs is required. For instance, social support from family and friends likely was another essential aspect of cancer rehabilitation interventions highlighted in the literature that may be added to future interventions (Mazzoni et al., 2019).

*Lymfit* provided flexible, individualized programs tailored to YA cancer survivors' unique needs. Compared to standardized or group-formatted interventions, individually tailored interventions can better provide autonomy support (Slemp et al., 2021). In accordance with the literature, physical activity interventions should be tailored for personal facilitators, barriers, and motivations to maximize survivorship adaptations (Moraitis et al., 2021). A recent systematic review of physical activity interventions in pediatric, adolescent, and YA cancer survivor populations reported that the majority of the studies were focused on pediatric and adolescent populations, missing the opportunity to examine the effects of exercise in the YAs (Crowder et al., 2022). Further, none of the interventions in this review offered individualized programs or comprehensive content to address psychological needs. Of note, the recruitment rate and retention rate in the present pilot study exceeded those intervention studies included in this review, which might endorse the more flexible intervention design taken by *Lymfit*.

This study has some limitations. First, more women than men agreed to participate in the study. Although this is commonly reported in exercise intervention studies (Doré et al., 2022), more inclusive recruitment strategies are warranted for a more diverse sample in future trials. We also acknowledge a potential bias related to eligible patients who declined to participate in the study because of time constraints is acknowledged, and it indicates that recruitment strategies need to be developed in future trials to address potential participants' concerns. For instance, we should reinforce the notion that this exercise program is tailored to participant's availability and needs; therefore, participation in the study should not conflict with their daily routine.

## **Conclusion**

This pilot RCT was considered successful, given that feasibility, acceptability, and promising preliminary effects of the intervention were supported. In summary, the generally positive outcomes can be attributable to several factors. First, the development of *Lymfit* has

been an iterative process, with continuous input from YAs with lymphoma. Second, *Lymfit* guides YAs through the behavior change process supported by a powerful theoretical framework, setting it apart from many other exercise interventions. Third, an individualized exercise program delivered during cancer treatment and immediately after cancer treatment might be practical for patients with low motivation and limited experience in exercising.

The evidence from this pilot RCT can guide the selection of main outcome and secondary outcomes for larger trials and identify areas in need of improvement for a larger trial as mentioned above, such as the format of relatedness support. Even if the results of this pilot study are promising, a larger trial needs to be conducted prior to concluding that *Lymfit* is effective.

## **Impact statement**

We certify that this work consists of recent novel clinical research. Our study highlights the development and testing of an intervention, *Lymfit*, guided by self-determination theory. *Lymfit* is aimed at promoting motivation to engage in physical activity among young adults affected by lymphoma. Through this pilot randomized controlled trial, the feasibility, acceptability, and preliminary effects of *Lymfit* were established. *Lymfit* addresses the fundamental importance of motivational support in physical activity interventions by focusing on satisfying basic psychological needs guided by an evidence-based theory. If further corroborated, self-determination theory-guided interventions may be more broadly implemented to promote exercise engagement and quality of life among cancer survivors.

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## **Conflict of interest statement**

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

## **Data availability**

Data of this study are available at the OSF data depository:

Tock, W. L. (2024, January 8). Pilot evaluation of a theory-guided exercise intervention for young adult survivors of lymphoma. Retrieved from [osf.io/n5abk](https://osf.io/n5abk)

## **Abbreviations**

**ANCOVA:** Analysis of covariance

**App:** Application

**BMI:** Body mass index

**BREQ – 3** Behavioral regulation in exercise questionnaire

**CONSORT:** CONSolidated Standards Of Reporting Trials

**ES:** Effect size

**LTPA – Q:** Godin-Shephard leisure-time physical activity questionnaire

**MIC:** Minimal important change

**PNSE:** Psychological Need Satisfaction in Exercise

**PROPr:** Patient-reported outcomes measurement information system® – Preference

**RCT:** Randomized controlled trial

**SD:** Standard deviation

**SDT:** Self-determination theory

**SE:** Standard error

**TIDieR:** Template for Intervention Description and Replication

**YAs:** Young adults

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## Chapter 5. Discussion and conclusions

### 5.1 Main outcomes and implications

In this doctoral thesis, a pilot study was conducted to examine the feasibility, acceptability, and preliminary effects of a theory-guided exercise intervention, *Lymfit*. Further, I reviewed the conceptualization of health promotion motivation and methodological considerations of exercise intervention within the context of cancer survivorship research. The first manuscript presented in *Chapter 2* lays the conceptual foundation of the intervention by clarifying the concept of *motivation for health promotion* in the context of cancer survivorship. This conceptual clarity provides a framework for understanding the underlying motivations driving the adaptation of health behaviors in individuals affected by cancer. The results of the concept analysis depict a complex image of theoretical frameworks and measurements adopted by researchers to guide their research surrounding the focal variable, “*motivation*.” SDT was selected as the guiding theoretical framework for *Lymfit* due to its strong practicality and translational value in health behavior research (Gillison et al., 2019; Wilson et al., 2008), as well as its close alignment with the conceptualization of health promotion motivation postulated in the concept analysis.

Notably, attributes of the concept of *motivation for health promotion*, such as “taking ownership” (**Table 2.3**), align with SDT’s notion of autonomy support. The concept’s antecedents identified in the first manuscript emphasize both personal factors (e.g., moral obligation for oneself, perceived competence) and external factors (e.g., supportive social environment) that either facilitate or impede health promotion behavior among cancer survivors, mirroring the principles of SDT (Tock, 2021). Moreover, the consequences of the concept outlined in the manuscript provide outcome criteria for evaluating interventions aimed at enhancing health behavior change motivation among cancer survivors, with one such consequence, “attainment of quality of life,” as an outcome assessed in my pilot study of the *Lymfit* intervention. In summary, the conceptual insights gained from this work validate the use of SDT in guiding the development of *Lymfit* and in the outcome assessment selection in the pilot evaluation of the intervention.

A pilot RCT (*Chapter 4*) was then conducted to evaluate the feasibility, acceptability, and preliminary effects of *Lymfit* on four self-reported study outcomes: psychological need

satisfaction, exercise motivation, physical activity level, and quality of life. The findings of my pilot study showed that the intervention was feasible and acceptable among YAs with lymphoma. Encouraging observation was also seen in terms of the intervention's preliminary effect, where the benchmark of effect size was met in most self-reported study outcomes.

Several significant findings emerged from the pilot RCT of *Lymfit*, with the first focusing on intervention design. To ensure a robust evaluation of the *Lymfit* intervention, a thorough review of methodological designs for exercise interventions was conducted (*Chapter 3*). A wait-list control group was implemented in the pilot evaluation of *Lymfit*. This control group design was demonstrated to be feasible in the study, as evidenced by the 100% retention rate in the control group. The decision to use a wait-list control group aligns with existing literature, which indicates that implementing a wait-list control group can enhance retention rates and minimize participant dropout in exercise interventions, in contrast to usual care or no-treatment control groups (Kinser & Robins, 2013; Tock et al., 2022). Additionally, utilizing a wait-list control group has been proposed as a means to address ethical concerns associated with withholding a potentially beneficial intervention (in this case, an exercise intervention) from control group participants (Tock et al., 2022). However, recent research cautions against the use of wait-list control groups due to potential adverse effects, including participant disappointment (Gunnarsson et al., 2023). In our study, we did not observe these adverse consequences, which may be attributed to several factors. Firstly, participants in our wait-list control group only faced a relatively short waiting period of 12 weeks, contrasting with other studies where participants waited for the intervention for up to six months or more (Nissen et al., 2020). Furthermore, clear information regarding group allocation was provided during the informed consent process in our study. Participants were also reassured of our intent to provide them with the intervention following the 12-week waiting period, which may have helped alleviate any negative experiences or perceptions associated with group assignments.

Another notable finding from the pilot study is the demonstration that *Lymfit* is both feasible and well-received among YAs undergoing active lymphoma treatments (34.6% of study participants were undergoing active treatment). Engaging in exercise during chemotherapy has been shown to be safe and beneficial, providing improvements in muscular and aerobic fitness as well as enhancing quality of life (Campbell et al., 2019). However, despite these benefits, exercise is not routinely prescribed during chemotherapy, as medical treatment and the

management of immediate side effects from treatment agents typically take precedence (Alderman et al., 2020; Murray et al., 2023). Additionally, individuals experiencing treatment-related side effects may lack the physical strength or motivation to engage in exercise during active treatment, therefore further diminishing the engagement in physical activities among individuals undergoing cancer treatments (Elshahat et al., 2021). A tailored and individualized exercise intervention, such as *Lymfit*, might be able to meet the unique needs and challenges faced by this population. Further, the observation that my study demonstrated feasibility and acceptability of *Lymfit* among YAs in active treatment suggests that the treating hematologists should be more forthright in encouraging their patients to exercise during treatment.

Not only did our pilot study of *Lymfit* establish the feasibility and acceptability of an individualized exercise program among YAs undergoing chemotherapy, but our results also demonstrated the psychological benefits of the intervention, as evidenced by improvements in quality of life domains among participants in the intervention group at post-intervention. Specifically, we observed that six out of eight PROPr (Patient-reported outcomes measurement information system® – Preference) quality of life domains met the MIC threshold (a four T-score point change within group from baseline to post-intervention). These domains include anxiety, depression, fatigue, ability to participate in social roles and activities, sleep disturbance and pain interference. Consistent with the hypothesis outlined in the *Lymfit* logic model (**Figure 2.3**), our results suggest that *Lymfit* has the potential to enhance both psychological well-being (e.g., reducing anxiety and depression) and physiological aspects of quality of life (e.g., mitigating fatigue and sleep disturbances) based on participants' self-reported outcomes. These findings align with existing literature, which consistently demonstrates the positive impact of exercise interventions on the overall quality of life in individuals affected by cancer (AlJohi et al., 2022; Lee & Lee, 2020).

The largely positive feasibility and acceptability outcomes observed in our study could be attributable to the flexibility of the intervention, which was virtually delivered and individualized. Such flexibility may be particularly beneficial for YAs undergoing active lymphoma treatment (Moraitis et al., 2021). In fact, a recent systematic review of nine exercise intervention trials among pediatric, adolescent, and YA cancer survivors revealed that the majority of studies used an in-person format, and none offered individualized programs to address each patient's unique needs (Crowder et al., 2022). Across the studies evaluated in this

review, only two reported improvements in physical activity levels. These findings underscore the importance of individualization, an emerging approach aiming to maximize intervention efficiency by accounting for interindividual heterogeneity (Gronwald et al., 2020).

*Lymfit* offered a flexible and individualized program tailored to participants' unique needs and exercise tolerance, potentially supporting autonomy more effectively than structured or group-format interventions (Gillison et al., 2019). Additionally, the recruitment and retention rates in our pilot study exceeded those of recently published exercise intervention studies (Koutoukidis et al., 2020; Sabahat et al., 2023), possibly indicating the benefits of the more flexible intervention design employed by *Lymfit*. In conclusion, the favorable outcomes observed in the pilot study suggest the potential efficacy of implementing individualized and virtually delivered exercise interventions among YAs affected by lymphoma, with anticipated benefits for enhancing exercise motivation, increasing physical activity levels, and improving both psychological and physiological quality of life.

Despite the generally positive feasibility and acceptability outcomes identified in our study, there was a notable lack of acceptance among participants regarding the frequency of kinesiologist follow-up appointments. Approximately 23% of participants rated item number three on the acceptability survey – pertaining to the acceptability of kinesiologist follow-up frequency – a score of three or below on a five-point scale. Several factors may account for this observation. For instance, participants undergoing chemotherapy and experiencing side effects might perceive bi-weekly follow-up appointments as too frequent, leading them to potentially miss or reschedule appointments. Additionally, some participants might express a preference for more frequent or longer sessions, underscoring the highly personalized nature of such preferences.

Indeed, the frequency of professional consultations in exercise interventions has exhibited considerable variability across studies. For instance, a systematic review of exercise intervention trials by Batalik et al. (2021) reported a range of consultation frequencies from once a week to once every four weeks, and the effects of consultation frequencies on study outcomes have not been investigated (Batalik et al., 2021). Therefore, future studies should aim to investigate the ideal frequency of consultations, potentially considering different frequencies for participants undergoing chemotherapy and those who have completed treatment. Such

investigations are crucial for tailoring intervention delivery to the specific needs and circumstances of cancer survivors, ultimately optimizing the effectiveness and acceptability of exercise interventions in this population.

In terms of the preliminary effects of *Lymfit* on study outcomes, our results indicated adequate effects (as evidenced by an effect size of above 0.2) on overall PNSE (psychological need satisfaction in exercise), as well as on the competence and autonomy sub-scales, albeit not on the relatedness sub-scale. While our study results demonstrated adequate effects on overall PNSE, the lack of effects in the relatedness sub-scale suggests that the intervention may have provided strong support for competency and autonomy but insufficient support to foster a sense of social belonging and connectedness.

Current literature indicates that digital social support in a virtual intervention may provide the needed relatedness support similar to that of an in-person intervention, but the digital component must create accountability, generate opportunities for tailored feedback, and create social connectedness to successfully promote the desired health behavior change (Santarossa et al., 2018). Indeed, the virtual peer-support group utilized in our intervention was not a mandatory feature, and although initial engagement was high, it gradually declined over time, potentially explaining the lack of effect on the relatedness sub-scale as shown in our results. In addition, a low level of acceptance was noted for the virtual peer-support group feature, as approximately 46% of participants rated item number five on the acceptability survey — assessing the enjoyment of using the peer-support group on the App — a score of three or below on a five-point scale. This finding concerning the low acceptability of the use of digital social support in our exercise intervention indicates that our intervention necessitates further modifications to address relatedness needs. As such, alternative strategies should be explored to enhance support for relatedness in future interventions. For instance, previous studies have shown that support from family members or other significant others can enhance feelings of social connectedness, while serving as predictors of exercise participation and adherence (Carmack et al., 2021; Ormel et al., 2018). Incorporating such additional strategies into future interventions holds promise for optimizing relatedness support.

As posited by the organismic viewpoint of SDT, all three psychological needs (i.e., autonomy, competence, and relatedness) play equally pivotal roles in fostering motivation (Deci



& Ryan, 2008a; Ryan & Deci, 2000). It is plausible that with enhanced support for relatedness, the overall effect size on overall PNSE could have been further augmented in our study. Additionally, it is plausible that the PNSE relatedness sub-scale, which assesses participants' relationships with their "exercise companion" (example questions: "I feel a sense of camaraderie with my exercise companions because we exercise for the same reasons," "I feel connected to the people who I interact with while we exercise together") (Wilson, Rodgers, & Wild, 2006), may be more relevant to in-person interventions and less applicable to virtual peer support groups such as the one implemented in our study. Thus, the development of novel measurement instruments may be warranted to adequately assess virtual or online social support, particularly in light of the growing reliance on virtually delivered health interventions in cancer survivors (Gonzalo-Encabo et al., 2022).

As postulated by SDT, the satisfaction of the three psychological needs can enhance the internalization process, through which an individual integrates external regulation styles to achieve more intrinsically regulated motivations (Deci & Ryan, 2008a). The effects of *Lymfit* on exercise motivation, as measured by the Behavioral Regulation in Exercise Questionnaire-3, were also investigated in our pilot study. While we only observed an adequate effect size on the amotivation subscale, the overall exercise motivation (as represented by the relative autonomy index) and physical activity level achieved adequate effect sizes. This suggests that *Lymfit* successfully enhanced overall exercise motivation (defined as the degree to which respondents feel self-determined to exercise) and increased engagement in physical activities within the intervention group compared to the control group. Among the six regulation styles assessed, we also noted increases in the integrated (ES=0.19) and intrinsic regulation (ES=0.18) subscales, both of which had effect sizes close to 0.2.

SDT suggests that integrated regulation represents the most internalized form of extrinsic motivation, characterized by behaviors aligned with personal goals and values (Deci & Ryan, 2000). Consistent with findings from previous studies, integrated regulation has been identified as the strongest predictor of initial uptake of exercise and habit formation (Patrick & Williams, 2012; Teixeira et al., 2012). The increase in integration regulation levels may help elucidate the improvement observed in the physical activity levels among intervention group participants in our study. Moreover, the increase in intrinsic regulation style suggests that participants in the intervention group experienced feelings of enjoyment and personal accomplishment from

engaging in exercise. Markedly, intrinsic motivation is predictive of the longer-term maintenance and adherence to health behaviors, including exercising (Phillips & More, 2022). However, it is important to acknowledge that our pilot RCT only collected data immediately post-intervention, limiting our ability to determine the sustainability of the observed increase in physical activity levels over the long term. Therefore, future studies should aim to examine which regulation style, or whether external or internal motivation, predicts long-term maintenance and adherence to exercise behaviors. This exploration will be crucial for informing the development of effective interventions aimed at promoting sustained engagement in physical activity among YAs with lymphoma.

## **5.2 Strengths and limitations**

The main contribution of this doctoral thesis lies in the use of a robust theoretical framework throughout the conceptualization and evaluation of *Lymfit*. SDT posits that psychological need satisfaction can nurture the formation of autonomous motivations, which in turn produce a predictive influence on behavioral engagement and well-being (Reis et al., 2000; Ryan & Deci, 2018). Our study results showed that the psychological need-supportive approach employed in *Lymfit* has positive impacts on exercise behavior and psychological well-being. Hence, we could advocate for the broader adoption of SDT-guided interventions in various domains of health behavior promotion research, particularly among YAs affected by cancer.

The use of a rigorous methodology in the testing of the intervention further highlights the strength of this thesis. By elucidating the multifaceted nature of motivation, the concept analysis (manuscript I) offered conceptual clarity and practical applicability of motivation concepts in cancer survivorship research. Moreover, the methodological considerations elucidated in manuscript II regarding trial design and selection of control group conditions in exercise intervention testing can be extrapolated to behavior change interventions across diverse patient populations. Consequently, the conceptualization and methodological approaches explored within this thesis hold promise for their application in corresponding contexts involving other patient cohorts.

Another methodological strength concerns the use of predetermined a-prior benchmarks to examine intervention feasibility in the pilot RCT (manuscript III). Particularly, we referred to standards set in our proof-of-concept study and other prior studies in the literature with similar

populations and objectives to determine the benchmarks. Feasibility benchmarks derived from empirical evidence from the existing literature are more likely to be contextually relevant to the specific characteristics and needs of the target population, intervention, and research setting. This enhances the applicability and validity of the benchmarks for guiding decision-making in the pilot RCT. Leveraging the existing body of research to identify benchmarks and performance indicators can also facilitate the interpretation of feasibility outcomes and allow us to assess how our pilot RCT measures up against established benchmarks. Finally, our pilot study successfully met all a-priori feasibility benchmarks, signaling the methodological soundness and feasibility of the intervention. The identification of areas requiring improvement for future larger-scale trials further solidifies the groundwork laid for subsequent testing of the intervention on a broader scale.

Among the limitations of this thesis is the limited generalizability of the results. The pilot study of *Lymfit* (manuscript III) involved a homogenous sample. Despite concerted efforts by the research team to promote inclusive recruitment, the majority of study participants, both self-referrals and those recruited by hematologists, were White (92.3%) and females (84.6%). While lymphoma can affect individuals of all genders and ethnicities, the study's lack of diversity highlights the need for future recruitment efforts to ensure representation across diverse demographic groups. Promoting inclusivity in research is crucial to better understand the potential benefits of exercise during and after treatment for individuals of all ethnic groups and genders.

Further, the concept analysis (manuscript I) elucidated culturally specific conceptions crucial for a comprehensive understanding of the concept of “*motivation for health promotion*” in cancer survivorship research. For instance, while themes such as “self,” “ownership,” and “personal control” were prevalent across the literature published in North American and European countries, studies from other cultural groups (e.g., east Asians) highlighted the influence of collectivist cultural norms, which prioritize conformity to group norms and authorities over individualistic self-expression (Kim et al., 2020). Consequently, the concept analysis may present an inadequate portrayal of the concept, particularly concerning its cultural implications.

Another limitation concerns the possible Hawthorne effect that likely took place in the study, considering the control group participants exhibited an increase in physical activity levels, as evidenced by the increase in mean score from 11.04 to 22.06 on the Godin-Shephard leisure-time physical activity questionnaire. The Hawthorne effect refers to a phenomenon in which study participants alter or modify their behavior in response to their awareness of being observed (McCambridge et al., 2014). In fact, this effect is not uncommon in exercise intervention studies. A systematic review by Kettle et al. in 2022 noted that control group participants in exercise interventions tend to become aware of, or anticipate involvement in an exercise program, leading to heightened physical activity levels despite not being in the intervention group (Kettle et al., 2022). Consequently, our study findings may underestimate the true effects of the intervention.

The potential for co-intervention bias poses an additional limitation. This bias could arise from additional interventions received by participants outside the study intervention (e.g. attending gym class, or hiring a private trainer), which might potentially confound the outcome of interest (Armijo-Olivo et al., 2021). In the pilot RCT, we did not assess for co-intervention or limit the use of outside resources by participants due to the fact that our study was conducted during the global pandemic, where recourses for physical activities for individuals affected by cancer were considerably limited (Gonzalo-Encabo et al., 2022). It would have been unethical to ask participants to refrain from opportunities to exercise outside our intervention. Future trials should monitor the use of additional resources and any exercise engagements (e.g., ask participants to self-report recourses used at each data collection time point). Such monitoring would facilitate the identification of co-intervention effects, enable appropriate adjustments during the analysis, and provide for a more unbiased interpretation of study results.

### **5.3 Future directions**

Future studies should consider employing a fully powered trial with a longitudinal design to assess the effectiveness of *Lymfit* over time. Such investigations can incorporate additional exploratory analyses to identify mediating and moderating factors for physical activities. Regression analyses can further elucidate specific factors, such as psychological needs or behavior regulation styles, that may predict the maintenance of physical activity levels and quality of life outcomes (Nogg et al., 2021).

Future studies could rely on a mixed-method approach, which may offer valuable insights into the barriers and facilitators associated with participation in exercise interventions among YAs with lymphoma. This approach can also address gaps identified in our pilot RCT, including the identification of strategies to enhance social connectedness and to determine the optimal frequency of kinesiologist consultations for patients undergoing chemotherapy and those who have completed treatment. Such information can be invaluable for clinicians and researchers to tailor exercise programs that better meet the unique needs of this patient population.

As a next step, our research team is currently conducting a full trial RCT, supported by a two-year funding grant from the Rossy Cancer Network. This trial will further validate the efficacy of *Lymfit* as an exercise intervention for YAs with lymphoma, contributing to the advancement of evidence-based practices in YA survivorship care.

#### **5.4 Overall conclusion**

The mounting evidence supporting the beneficial effects of physical activity on the health outcomes of cancer survivors underscores its significance. However, lack of motivation remains a persistent barrier to exercise engagement among YAs with lymphoma. Fortunately, this barrier is amenable to modification using behavioral change techniques and health interventions. Not only does motivation directly influence health behaviors, but it also exerts a profound impact on overall well-being and quality of life among individuals affected by cancer. Consequently, there is a pressing need for interventions grounded in sound theoretical frameworks to address the challenge of how best to motivate YAs with lymphoma to engage in physical activity.

Recognizing the gaps in exercise intervention development, this thesis introduced *Lymfit*, an evidence-based and individualized exercise intervention guided by SDT. Subsequently, a pilot RCT was conducted to assess the feasibility, acceptability, and preliminary effects of *Lymfit*, which aims to bolster essential psychological needs to enhance exercise motivation and quality of life among YAs with lymphoma.

The *Lymfit* intervention was demonstrated to be highly acceptable among YAs undergoing chemotherapy and up to six months post-treatment. All predetermined a-priori benchmarks for feasibility were successfully met in the pilot RCT. Additionally, the study results demonstrated that the intervention had adequate effects on self-reported study outcomes, including psychological needs satisfaction, exercise motivation, self-reported physical activity

levels, and quality of life domains. This pilot study not only served as a foundation for selecting outcomes but also identified areas for refinement for a larger trial, thus informing future research endeavors.

In summary, the culmination of this doctoral thesis marks a significant contribution to the understanding of intervention design aimed at promoting exercise engagement among YAs affected by lymphoma. Through conducting a concept analysis and contributing to a discussion paper on exercise intervention trial methodological considerations, the thesis reinforced the theoretical foundation and methodological rigor underpinning the pilot RCT of *Lymfit*. The results of this rigorously designed and implemented pilot RCT demonstrate the promise of *Lymfit* as an adjunct to routine cancer survivorship care, potentially enhancing exercise engagement and motivation in YAs with lymphoma.

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## List of appendices

<i>Appendix 3.1 Intervention fidelity checklist .....</i>	<i>147</i>
<i>Appendix 3.2 Acceptability assessment survey .....</i>	<i>148</i>
<i>Appendix 3.3 Study outcome questionnaires .....</i>	<i>149</i>
<i>Appendix 3.4 Information and consent form .....</i>	<i>154</i>
<i>Appendix 4.1 CONSORT 2010 Checklist of information to include when reporting a pilot for feasibility trial .....</i>	<i>159</i>
<i>Appendix 4.2 The template for intervention description and replication (TIDieR) checklist ..</i>	<i>161</i>
<i>Appendix 4.3 Detailed description of the individualized exercise program .....</i>	<i>162</i>
<i>Appendix 4.4 Description of study outcome measures and their psychometric properties .....</i>	<i>163</i>

### Appendix 3.1 Intervention fidelity checklist

Rater: \_\_\_\_\_

Participant' Research Identifier: \_\_\_\_\_

Date: \_\_\_\_\_

#### Intervention Fidelity Checklist

Pre-intervention				
	Actions	Rating		Date
1.	The participant receives the study package in the mail (i.e., Fitbit tracker, resistance training bands, measurement tapes)	YES	NO	
2.	The research team member schedules a meeting with the participant	YES	NO	
3.	The research team member helps the participant to download the Fitbit App to their smartphone	YES	NO	
4.	The research team member helps the participant to sync their Fitbit to their smartphone App	YES	NO	
5.	The research team member demonstrates the interface and functions of the Fitbit App	YES	NO	
6.	The research team member demonstrates how the Fitbit is charged	YES	NO	
7.	The research team member demonstrates how data is synced from the tracker to the App	YES	NO	
8.	The research team member demonstrates functions of the Fitbit tracker	YES	NO	
9.	The research team member adds the participant to the <i>Lymfit lounge</i>	YES	NO	
10.	The research team member explains the purposes of the <i>Lymfit lounge</i> and demonstrates the various functions within the App	YES	NO	
11.	The research team member asks if the participant has any questions regarding the Fitbit and the App, and answer all questions raised	YES	NO	
14.	The kinesiologist provides the baseline physical assessment	YES	NO	
15.	The kinesiologist asks if the participant has any questions regarding the assessment questionnaire, and answer all questions raised	YES	NO	
16.	The kinesiologist notifies the participant of the expected date they will receive their exercise program	YES	NO	
17.	The kinesiologist explains to the participant regarding the expectations, frequency, and procedures of the follow-up consultation appointments	YES	NO	
Intervention				
	Actions	Rating		Date
1.	1 <sup>st</sup> kinesiologist follow-up	YES	NO	
2.	2 <sup>nd</sup> kinesiologist follow-up	YES	NO	
3.	3 <sup>rd</sup> kinesiologist follow-up	YES	NO	
4.	4 <sup>th</sup> kinesiologist follow-up	YES	NO	
5.	5 <sup>th</sup> kinesiologist follow-up	YES	NO	
6.	6 <sup>th</sup> kinesiologist follow-up	YES	NO	

### Appendix 3.2 Acceptability assessment survey

This survey intends to assess your satisfaction with various aspects of the program and how they are delivered.

1. How helpful was the personalized exercise program in motivating you to exercise?  
“very unhelpful” 1 2 3 4 “very helpful” 5
2. Are you satisfied with the remote format of the exercise program?  
“very dissatisfied” 1 2 3 4 “very satisfied” 5
3. Was the frequency of the kinesiologist follow-up acceptable?  
“very unacceptable” 1 2 3 4 “very acceptable” 5
4. How helpful was wearing the Fitbit tracker and receiving alerts in motivating you to exercise?  
“very unhelpful” 1 2 3 4 “very helpful” 5
5. How much did you enjoy using the peer-support group on the App?  
“not at all” 1 2 3 4 “very much” 5
6. How helpful was the progress monitoring functions on the App in motivating you to exercise?  
“very unhelpful” 1 2 3 4 “very helpful” 5
7. Was the amount of time it took to complete this program (12 weeks) acceptable?  
“very unacceptable” 1 2 3 4 “very acceptable” 5
8. Was the exercise program prescribed by the kinesiologist tailored to your personal needs?  
“not at all” 1 2 3 4 “very much” 5
9. Was starting this exercise program close to completing your cancer treatment acceptable?  
“very unacceptable” 1 2 3 4 “very acceptable” 5
10. How would you rate your overall satisfaction with the *Lymfit* program?  
“very dissatisfied” 1 2 3 4 “very satisfied” 5

### Appendix 3.3 Study outcome questionnaires

#### I. The Psychological Need Satisfaction in Exercise Scale (PNSE)

The following statements represent different experiences people have when they exercise. Please answer the following questions by considering how **you typically** feel while you are exercising. Each PNSE item is presented along with a 6-point Likert scale with verbal anchors affixed to each numerical response option:

	False	Mostly false	More false than true	More true than false	Mostly true	True
1. I feel that I am able to complete exercises that are personally challenging	1	2	3	4	5	6
2. I feel attached to my exercise companions because they accept me for who I am	1	2	3	4	5	6
3. I feel like I share a common bond with people who are important to me when we exercise together	1	2	3	4	5	6
4. I feel confident I can do even the most challenging exercises	1	2	3	4	5	6
5. I feel a sense of camaraderie with my exercise companions because we exercise for the same reasons	1	2	3	4	5	6
6. I feel confident in my ability to perform exercises that personally challenge me	1	2	3	4	5	6
7. I feel close to my exercise companions who appreciate how difficult exercise can be	1	2	3	4	5	6
8. I feel free to exercise in my own way	1	2	3	4	5	6
9. I feel free to make my own exercise program decisions	1	2	3	4	5	6
10. I feel capable of completing exercises that are challenging to me	1	2	3	4	5	6
11. I feel like I am in charge of my exercise program decisions	1	2	3	4	5	6
12. I feel like I am capable of doing even the most challenging exercises	1	2	3	4	5	6
13. I feel like I have a say in choosing the exercises that I do	1	2	3	4	5	6
14. I feel connected to the people who I interact with while we exercise together	1	2	3	4	5	6
15. I feel good about the way I am able to complete challenging exercises	1	2	3	4	5	6
16. I feel like I get along well with other people who I interact with while we exercise together	1	2	3	4	5	6
17. I feel free to choose which exercises I participate in	1	2	3	4	5	6
18. I feel like I am the one who decides what exercises I do	1	2	3	4	5	6



## II. The Behavioral Regulation in Exercise Questionnaire (BREQ-3)

Why do you engage in exercise?

We are interested in the reasons underlying peoples' decisions to engage or not engage in physical exercise. Using the scale below, please indicate to what extent each of the following items is true for you. Please note that there are no right or wrong answers and no trick questions. We simply want to know how you personally feel about exercise. Your responses will be held in confidence and only used for our research purposes.

	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
1. It's important to me to exercise regularly	1	2	3	4	5
2. I don't see why I should have to exercise	1	2	3	4	5
3. I exercise because it's fun	1	2	3	4	5
4. I feel guilty when I don't exercise	1	2	3	4	5
5. I exercise because it is consistent with my life goals	1	2	3	4	5
6. I exercise because other people say I should	1	2	3	4	5
7. I value the benefits of exercise	1	2	3	4	5
8. I can't see why I should bother exercising	1	2	3	4	5
9. I enjoy my exercise sessions	1	2	3	4	5
10. I feel ashamed when I miss an exercise session	1	2	3	4	5
11. I consider exercise part of my identity	1	2	3	4	5
12. I take part in exercise because my friends/family/partner say I should	1	2	3	4	5
13. I think it is important to make the effort to exercise regularly	1	2	3	4	5
14. I don't see the point in exercising	1	2	3	4	5
15. I find exercise a pleasurable activity	1	2	3	4	5
16. I feel like a failure when I haven't exercised in a while	1	2	3	4	5
17. I consider exercise a fundamental part of who I am	1	2	3	4	5
18. I exercise because others will not be pleased with me if I don't	1	2	3	4	5
19. I get restless if I don't exercise regularly	1	2	3	4	5
20. I think exercising is a waste of time	1	2	3	4	5
21. I get pleasure and satisfaction from participating in exercise	1	2	3	4	5
22. I would feel bad about myself if I was not making time to exercise	1	2	3	4	5
23. I consider exercise consistent with my values	1	2	3	4	5
24. I feel under pressure from my friends/family to exercise	1	2	3	4	5

### **III. Godin-Shephard leisure-time physical activity questionnaire (LTPA-Q)**

During a typical 7-Day period (in the past week), how many times on the average do you do the following kinds of exercise for more than 15 minutes?

**A.** Strenuous exercise (heart beats rapidly) (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long-distance bicycling).

\_\_\_\_\_ times

**B.** moderate exercise (not exhausting) (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing).

\_\_\_\_\_ times

**C.** Mild/light exercise (minimal effort) (e.g., yoga, archery, fishing from riverbank, bowling, horseshoes, golf, snow-mobiling, easy walking).

\_\_\_\_\_ times

#### IV. Patient-Reported Outcomes Measurement Information System (PROMIS®) – Preference (PROPr)

**Direction:** Please respond to each question or statement by marking one box per row.

<b>Physical Functioning</b>					
	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
1. Are you able to do chores such as vacuuming or yard work?	1	2	3	4	5
2. Are you able to go up and down stairs at a normal pace?	1	2	3	4	5
3. Are you able to go for a walk of at least 15 minutes?	1	2	3	4	5
4. Are you able to run errands and shop?	1	2	3	4	5
<b>Anxiety:</b> In the past 7 days...					
	Never	Rarely	Sometimes	Often	Always
5. I felt fearful	1	2	3	4	5
6. I found it hard to focus on anything other than my anxiety	1	2	3	4	5
7. My worries overwhelmed me	1	2	3	4	5
8. I felt uneasy	1	2	3	4	5
<b>Depression:</b> In the past 7 days...					
	Never	Rarely	Sometimes	Often	Always
9. I felt worthless	1	2	3	4	5
10. I felt helpless	1	2	3	4	5
11. I felt depressed	1	2	3	4	5
12. I felt hopeless	1	2	3	4	5
<b>Fatigue:</b> In the past 7 days...					
	Not at all	A little bit	Somewhat	Quite a bit	Very much
13. I feel fatigued	1	2	3	4	5
14. I have trouble starting things because I am tired	1	2	3	4	5
15. How run-down did you feel on average?	1	2	3	4	5
16. How fatigued were you on average?	1	2	3	4	5

<b>Sleep Disturbance: In the past 7 days...</b>					
	Very poor	Poor	Fair	Good	Very good
17. My sleep quality was	1	2	3	4	5
<b>Sleep Quality: In the past 7 days...</b>					
	Not at all	A little bit	Somewhat	Quite a bit	Very much
18. My sleep was refreshing	1	2	3	4	5
19. I had a problem with my sleep	1	2	3	4	5
20. I had difficulty falling asleep	1	2	3	4	5
<b>Ability to Participate in Social Roles and Activities</b>					
	Never	Rarely	Sometimes	Usually	Always
21. I have trouble doing all of my regular leisure activities with others	1	2	3	4	5
22. I have trouble doing all of the family activities that I want to do	1	2	3	4	5
23. I have trouble doing all of my usual work (include work at home)	1	2	3	4	5
24. I have trouble doing all of the activities with friends that I want to do	1	2	3	4	5
<b>Pain Interference: In the past 7 days...</b>					
	Not at all	A little bit	Somewhat	Quite a bit	Very much
25. How much did pain interfere with your day-to-day activities?	1	2	3	4	5
26. How much did pain interfere with work around the home?	1	2	3	4	5
27. How much did pain interfere with your ability to participate in social activities?	1	2	3	4	5
28. How much did pain interfere with your household chores?	1	2	3	4	5
<b>Cognitive Function – Abilities: In the past 7 days...</b>					
	Not at all	A little bit	Somewhat	Quite a bit	Very much
29. I have been able to concentrate	1	2	3	4	5
30. I have been able to remember to do things, like take medicine or buy something I needed	1	2	3	4	5

### **Appendix 3.4** *Information and consent form*

#### **Information and Consent Form**

##### **Research Study Title**

Feasibility, acceptability, and preliminary effects of *Lymfit*: A pilot randomized controlled trial among young adults with lymphoma

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Ride to Conquer Cancer 2018-2019 rides & Le week-end pour combattre le cancer 2021

##### **Introduction of the Study**

This research is designed to look at the effectiveness of a personalized exercise program to improve exercise engagement among young adults diagnosed and treated for lymphoma. You are invited to participate in this study because you are completing or have recently completed treatment for lymphoma. You have the right to know about the purpose and procedures that are to be used in this research study, and to be informed about the potential benefits, risks, compensation, and discomfort of this research. Before you agree to take part in this study, it is important that you read the information in this consent form. You should ask as many questions as you need to in order to understand what you will be asked to do. You should take as much time as you need to make your decision. You should ask the study staff to clarify anything that you do not understand and make sure your concerns are being addressed completely before signing this consent form. Participation is completely voluntary, and you do not have to take part in this study if you do not want to. Whether you choose to participate or not, your decision will not result in any loss of benefit to your care to which you are otherwise entitled at the hospital.

##### **Objectives of the Study**

**Background:** The treatment of lymphoma can be associated with many side effects, such as compromised immune system, fatigue and anxiety, all of which can significantly impair the

individual's health-related quality of life. Regular exercise is well-accepted to reduce these side effects in cancer survivors. It can be challenging to become physically active without the help of an exercise expert among individuals affected by cancer treatments. Fortunately, research shows that mobile health interventions utilizing activity trackers, such as Fitbit, can motivate individuals to increase their exercise engagement and encourage a less sedentary lifestyle.

**Aims:** Our study team has developed an exercise intervention for young adults affected by lymphoma. The aim of this study is to determine if this intervention can increase their exercise engagement and quality of life.

**Responsibility:** For the duration of the study, you will be asked to complete online questionnaires. Also, you will be following up with the kinesiologist via videoconferencing every two weeks for 12 weeks months. Therefore, it is important that you have a device (smartphone or laptop) that allows you to do access study questionnaires and to conduct video calls.

## Study Procedures

**Registration and group assignment:** Once you have consented, the research coordinator will register you on the *Lympfit* server. You will then be randomly assigned (like the flipping of a coin) to either **Group A) an immediate intervention group**, where you will begin the exercise program within 1 week of signing the consent form, or you will be allocated to **B) a delayed intervention group**, where the personalized exercise program will begin 12 weeks after you consent to participate.

You will be asked to answer a set study questionnaire after you sign the consent form, and 12 weeks after you sign the consent form.

**Here is a summary table showing the tasks you are responsible to complete during the study:**

Tasks	Approximate time required	Content of the tasks	Timepoint - Group A	Timepoint - Group B
<b>Baseline questionnaires</b>	10 – 15 minutes	A set of online questionnaires asking about your life quality and motivation to exercise, plus your personal information such as age, marital status, number of young children at home, cancer types, stage, and treatment.	Before the start of the study, after you sign the consent form	Before the start of the study, after you sign the consent form
<b>Physical assessment</b>	10 – 15 minutes	Weight, height, waist circumference, flexibility, strength, coordination, endurance, and your baseline activity level, etc.	After you sign the consent form, during your first videoconference meeting with the research team	During your first videoconference meeting with the research team
<b>Follow-up questionnaires</b>	10 – 15 minutes	A set of online questionnaires asking about your life quality and motivation to exercise.	At the end of the 12-week exercise program	At the end of the 12-week exercise program
<b>Acceptability Assessment</b>	5 minutes	A short survey asking if you are satisfied with this study.	At the end of the 12-week exercise program	At the end of the 12-week exercise program

### **Here is a detailed description of the two study groups:**

**Group A. Immediate intervention group:** If you are assigned to this group, we will mail you a Fitbit charge V activity tracker, which you will wear for the duration of the study (12 weeks) and keep afterwards. The research coordinator will get in touch with you and schedule a videoconference with you. During the meeting, the research coordinator will register your Fitbit in the *Lymfit* server with a unique research identification number (e.g., lymfit 001). The coordinator will help you to install the Fitbit App on your phone, and show you how to use it and log-in to the App using a pre-registered username (e.g., lymfit001@ladydavis.ca). The coordinator will also add you to a private peer-support group within the App. This group involves only the participants of this study, you will have the opportunities to interact with other study participants, you can share your progress/activities with the group. You will not have to share your identity, other participants will only see your research identification number when you share/post something, and participation in the group is not mandatory.

During the same meeting, the kinesiologist will perform a baseline physical assessment. You will be asked to answer questions pertaining to your activity levels before and after treatment, your exercise preferences, and your exercise habits. After this initial meeting, you will be contacted within 1 week to schedule a videoconferencing session with the kinesiologist to discuss the personalized exercise program. Every two weeks, the kinesiologist will follow up with you via videoconference to assess your progress. You may discuss any concerns regarding the exercise program, the kinesiologist will adjust and modify the program based on your progress and needs. The goal of the exercise program is to increase your activity level, as tolerated, in order to meet the fitness recommendations in the guidelines for individuals affected by cancer (30 active min x 3 or 90 active minutes per week). This will be done gradually, by increasing the number of active minutes by 10%/week, but this is flexible. If you are deriving benefits and agree to increase the intensity and duration of exercise activity, the kinesiologist will help you reach the recommended guidelines for the general population (50 active minutes x 3/week or 150 min/week).

**Group B. Delayed exercise program:** If you are in this group, you will be provided instructions regarding healthy lifestyles and current exercise guidelines. After 12 weeks, you will be contacted by the research coordinator to begin the intervention (same procedures as Group A).

### **Risks, Inconvenience and Disadvantages**

There is a theoretical risk of injury when you will be performing moderate to vigorous physical activity (e.g., fall or injury if running outside). The risk is minimized by only including participants who don't have medical issues that would prevent them from undertaking physical activities. There is an increased risk of having sore muscles 24-48 hours after performing exercises, especially if you haven't performed exercise in some time. Mild discomfort is normal and should subside over time. If the discomfort is more severe and persists, you should discuss it with your hematologist.

### **Potential Benefits of Research Participation**

It is possible that you may benefit personally as a result of participating in this research study because of the well-established benefits of physical activity in improving cancer patients' health outcomes. Further, your participation will allow the researchers to better understand the best approach to promote exercise engagement in young adults affected by lymphoma. This is expected to benefit future patients, such as contributing to the development of exercise interventions for patients who are undergoing or have completed treatment for lymphoma.

## **Compensation**

You will not receive any financial compensation for your time. You will receive a Fitbit tracker and exercise stretch bands for the exercise program, which you will get to keep at the end of the study. There is no extra travel time that will be required in the context of this research.

## **Confidentiality**

To keep your information private, you will be identified only by a research identifier (e.g., lymfit 001). The documentation that links your name to your research identifier will be kept on the *Lymfit* server at the Jewish General Hospital. Only the investigators involved in this study will have access to the server through a personal username and password. Your personal information will be kept on the *Lymfit* platform (a secured site where we will keep track of your personal information) (e.g., phone number, email); all of your personal information will be available only to the study coordinators and investigators. With your personal contact information, we can email you reminders to sync your phone or complete the study questionnaires, as well as contact you to schedule your appointments with the kinesiologist.

After the study is completed, we will disconnect the research identifier that is linked to your Fitbit. We will follow the Fitbit protocol for erasing data associated with the research identifier and its email address. This step will be performed by the research team. If you want to use their Fitbit tracker after the study is over, you can simply create a new account with your own personal email address and your personal information. Once you pair your new personal account with the Fitbit tracker, it will be ready for use, and you will be considered a new user. No one but only you will have access to the information in your personal account.

**Storage, retention and destruction of documents:** All information that may allow you to be identified will be kept on the *Lymfit* server until the end of the study. After which, the electronic data will be stored on a hard drive that will be kept in a locked cabinet in a locked office that is only accessible to researchers at the Lady Davis Institute. The information collected from you will be kept for 10 years, then it will be permanently destroyed. The results of this study will not be added to your medical record.

## **Volunteer Participation and the Right to Withdraw**

Your participation in this research study is voluntary and ongoing. You are free to refuse to participate. You may withdraw from this research study at any time without having to give a reason and without any consequence. You may withdraw at any time from this research study and your decision will not affect the quality of care and services that you have the right to receive or your relationship with your care providers in any way. If you withdraw from this research study before it ends, the information we have already collected from you will be kept, unless you ask us to destroy it before data analysis has started.

## **Questions and contact information:**

If you have any questions regarding this research study, you can the student researcher, Wing Lam Tock, by email: [wing.tock@mail.mcgill.ca](mailto:wing.tock@mail.mcgill.ca) For all questions concerning your rights during your participation in this study, or if you have any complaints or comments regarding your experience in taking part in this research study, you can contact the Local Commissioner of Complaints and Quality of Service of the CIUSSS Centre-Ouest-de-l'Île-de-Montréal or the ombudsman of the institution at (514) 340-8222, ex. 24222.



## Statement of Consent

### Research study title:

Feasibility, acceptability, and preliminary effects of *Lymfit*: A pilot randomized controlled trial among young adults with lymphoma

### Participant statement:

I understand the information that was explained to me as contained in this consent form. All my questions were answered to my satisfaction. I will receive a copy of this signed consent form. My participation is voluntary, and I can withdraw from the research study at any time without any consequences and without having to give a reason. Withdrawing from this research study, at any time, will not affect my medical care now, or later, in any way (where applicable). By signing this consent form, I do not give up any of my legal rights.

### I agree to participate in this research study.

Yes ☐ No ☐

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

### Researcher statement:

I, as the person obtaining consent, certify that I have explained to the participant or his/her legal representative (where applicable) the research study information contained in this consent form and have answered all questions. I have clearly explained to the participant that s/he is free to withdraw at any time without providing a reason, and without any consequences. I commit, together with the members of the research team to respect all conditions described in this consent form and to give a signed copy of the consent form to the participant.

### Name and signature of the **researcher or person delegated to obtain consent**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

### Name and signature of **translator/witness**, if applicable:

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Appendix 4.1** *CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*



Section/ Topic	Item No	Checklist item	Reported on page No/ section *
<b>Title and abstract</b>			
	1a	Identification as a pilot or feasibility randomised trial in the title	Study title
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	Abstract
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	p 85-87
	2b	Specific objectives or research questions for pilot trial	p 87
<b>Methods</b>			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	p 88
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Table 3.1
Participants	4a	Eligibility criteria for participants	p 88
	4b	Settings and locations where the data were collected	p 88
	4c	How participants were identified and consented	p 88
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	p 89-90 & Figure 4.2
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	p 91-94
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	Table 3.1
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	p 91-92
Sample size	7a	Rationale for numbers in the pilot trial	p 88
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	p 88
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	p 88
Allocation, concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	p 88
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	p 88
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	p 88
	11b	If relevant, description of the similarity of interventions	N/A

Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	p 94-95
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 4.4 CONSORT flow diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 4.4
Recruitment	14a	Dates defining the periods of recruitment and follow-up	p 88
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 4.2
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 4.4
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Table 4.3
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	p 99
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
	19a	If relevant, other important unintended consequences	N/A
<b>Discussion</b>			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	p 105
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	p 105
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	p 104-106
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	p 105
<b>Other information</b>			
Registration	23	Registration number for pilot trial and name of trial registry	p 88
Protocol	24	Where the pilot trial protocol can be accessed, if available	p 108
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	p 107
Ethical approval	26	Ethical approval or approval by research review committee, confirmed with reference number	p 88

(\*The page numbers on this checklist correspond to those in this thesis.)

**Reference:** Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355. This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 3.0) license (<http://creativecommons.org/licenses/by/3.0/>), which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited.

## Appendix 4.2 The template for intervention description and replication (TIDieR) checklist



Item	Item	Where located *	
		Primary paper	Other † (details)
	<b>BRIEF NAME</b>		
1.	Provide the name or a phrase that describes the intervention.	Title	
	<b>WHY</b>		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Page 85-877	
	<b>WHAT</b>		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).		Data depository, appendices
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Page 89-90	Figure 4.2
	<b>WHO PROVIDED</b>		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Page 86	
	<b>HOW</b>		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Page 90	
	<b>WHERE</b>		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Page 90	
	<b>WHEN and HOW MUCH</b>		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Page 88-90	Figure 4.2
	<b>TAILORING</b>		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Page 86	Appendix 4.3
	<b>MODIFICATIONS</b>		
10.†	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).		Table 3.1
	<b>HOW WELL</b>		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Page 91	Figure 4.3
12.†	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Page 99	Figure 4.3

(\*The page numbers on this checklist correspond to those in this thesis.)

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

### Appendix 4.3 Detailed description of the individualized exercise program

The exercise program in this study incorporates individualized and incremental aspects of goal setting. These operate upon two main assumptions: firstly, by individualizing the goals, the goals are more specific to an individual's lifestyle and thus more achievable for them, enhancing their autonomy. Secondly, incrementally introducing the exercise program over the course of 12 weeks would make it less difficult for participants to adjust to their goals as it would be less cognitively demanding and impactful on participants' lifestyles, especially considering that these are individuals undergoing or just completed cancer treatments.

The exercise program is developed guided by the **FITT principles**: a minimum of 3 times per week (**F**requency); at a moderate-to-vigorous level (**I**ntensity); for 30 minutes each session, for at least 8 to 12 weeks (**T**ime); and with aerobic activity favored over resistance training (**T**ype) (Campbell et al., 2019). While the programs should be specific to cancer types, treatments, and/or outcomes, the FITT Principles have been widely adopted in exercise interventions for cancer patients and survivors. Based on the data collected in the baseline physical assessment (e.g., participants' baseline activity levels and preferences), the kinesiologist will motivate participants to increase their minutes of MVPA gradually each week until they reach the guidelines set for cancer survivors (90 min/week) (Campbell et al., 2019). For sedentary or symptomatic participants who lack any motivation to exercise, the initial goal would be to increase the step count and decrease sedentary time. The kinesiologist and participants can explore opportunities during the follow-up meeting based on the progress within the past two weeks. As these small milestones are achieved, the goal would be to increase the duration of the activity (increase step counts) and to increase the intensity of the activity (i.e., increase the heart rate to be considered "active" minutes by increasing the pace of walking or by walking on an incline). In participants who can tolerate increased activity levels, the exercise program will be tailored accordingly. In motivated participants who have successfully achieved 90 min of MVPA/week, the kinesiologist will encourage them to gradually increase their activity to 50 min x 3 times/week to meet the Canadian general population guidelines (Canadian Society for Exercise Physiology, 2021).

### References

- Campbell, K. L., Winters-Stone, K. M., Wiskemann, J., May, A. M., Schwartz, A. L., Courneya, K. S., ... Schmitz, K. H. (2019). Exercise guidelines for cancer survivors: consensus statement from international multidisciplinary roundtable. *Medicine & Science in Sports & Exercise*, 51(11), 2375-2390. <https://doi.org/10.1249/mss.00000000000002116>
- Canadian Society for Exercise Physiology. (2021). *Canadian 24-Hour Movement Guidelines for Adults aged 18-64 years: An Integration of Physical Activity, Sedentary Behaviour, and Sleep*. <https://csepguidelines.ca/guidelines/adults-18-64/>

#### Appendix 4.4 Description of study outcome measures and their psychometric properties

Outcome variables	Instruments	Description (Number of items, subscales)	Scoring	Psychometric properties	Cronbach's alpha (study data)
<b>Psychological need satisfaction</b>	The Psychological Need Satisfaction in Exercise (PNSE) scale (Wilson et al., 2006a)	<ul style="list-style-type: none"> <li>- 18 items, 3 sub-scales</li> <li>- 6-point Likert scales</li> <li>- 6-items in each of the sub-scales: competence, autonomy, and relatedness</li> </ul>	Sub-scale score = mean of the 6 items (range = 1- 6) Total score = mean of the 18 items (range = 1- 6)	$\alpha > .90$ (Wilson et al., 2006)	pre-test data: 0.871 post-test data: 0.898 combined: 0.929
<b>Exercise motivation</b>	Behavioral Regulation in Exercise Questionnaire (BREQ-3) (Markland & Tobin, 2004; Wilson et al., 2006b)	<ul style="list-style-type: none"> <li>- 24 items, 6 subscales</li> <li>- 5-point Likert scales</li> <li>- 4 items in each of the sub-scales: amotivation, external regulation, introjected regulation, identified regulation, integrated regulation, intrinsic regulation</li> </ul>	Sub-scale score = mean of the 4 items Relative autonomy index: (amotivation $\times$ (-3)) + (external regulation $\times$ (-2)) + (introjected regulation $\times$ (-1)) + (identified regulation $\times$ 1) + (integrated regulation $\times$ 2) + (intrinsic regulation $\times$ 3). Higher score = higher autonomous motivation (range: -24 to 24)	Good factorial validity, reliability (Duncan et al., 2010) Subscale $\alpha = 0.73$ – $0.86$ (Markland & Tobin, 2004)	pre-test data: 0.636 post-test data: 0.870 combined: 0.879
<b>Physical activity level</b>	Godin-Shephard leisure-time physical activity questionnaire (LTPA-Q) (Godin, 2011)	<ul style="list-style-type: none"> <li>- 3 items: the number of times in the past 7 days they have performed any strenuous, moderate, and mild physical activity of more than 15 minutes in duration</li> </ul>	Item weights: Strenuous $\times$ 9; Moderate $\times$ 5; Mild $\times$ 3  A total score $\geq 24$ = Active 14 – 23 = moderately active $< 14$ = sedentary	Percentage agreement between LTPA-Q & accelerometer classification coding: 70.8 %. Sensitivity: 75.3% Specificity: 58.5 % (Amireault et al, 2015)	combined: 0.634
<b>Quality of life</b>	Patient-Reported Outcomes Measurement Information	<ul style="list-style-type: none"> <li>- 31 items, 8 domains</li> <li>- 5-point Likert scales</li> <li>- 4 items each: physical function, anxiety, depressive symptoms,</li> </ul>	Raw scores generated for each domain will be transformed into a T-score (mean = 50).	Correlations between PROPr and the other quality of life summary measures ranged from 0.67	pre-test data: 0.833 post-test data: 0.741 combined:

	System® – Preference (PROPr) (Dewitt et al., 2020)	<p>fatigue, sleep disturbance, ability to participate in social roles and activities, and pain interference</p> <ul style="list-style-type: none"> <li>- 2 items: cognitive function</li> <li>- 1 item: pain intensity (from 0 to 10)</li> </ul>	<p>A utility PROPr score range can also be generated (range: –0.022 to 1.0)</p> <p>Higher score = greater endorsement of the construct being assessed</p>	<p>to 0.70 (Hanmer et al., 2018)</p> <p>Convergent validity: r = 0.72 with EuroQol EQ-5D index value (EQ-5D) and Intraclass Correlation Coefficient (ICC) of 0.48 (Klapproth et al., 2022)</p> <p>Construct validity supported in a previous study of patients in hemodialysis (Zhang et al., 2021).</p>	0.852
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