
Theses

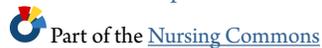
2018

Effect of a nurse-led lymphoma survivorship model of care: A pragmatic phase II pilot randomised controlled trial

Karen Taylor

The University of Notre Dame Australia

Follow this and additional works at: <https://researchonline.nd.edu.au/theses>



COMMONWEALTH OF AUSTRALIA
Copyright Regulations 1969

WARNING

The material in this communication may be subject to copyright under the Act. Any further copying or communication of this material by you may be the subject of copyright protection under the Act.

Do not remove this notice.

Publication Details

Taylor, K. (2018). Effect of a nurse-led lymphoma survivorship model of care: A pragmatic phase II pilot randomised controlled trial (Doctor of Philosophy (College of Nursing)). University of Notre Dame Australia. <https://researchonline.nd.edu.au/theses/206>

This dissertation/thesis is brought to you by ResearchOnline@ND. It has been accepted for inclusion in Theses by an authorized administrator of ResearchOnline@ND. For more information, please contact researchonline@nd.edu.au.



Chapter One — Introduction

“When I finished treatment, it was a bit like an anti-climax, it was – okay you have finished treatment, see you later. I felt like I had just been forgotten”
Female_NHL

1.0 Introduction

This thesis consists of six related papers that provide a comprehensive account of the development and testing of a pilot nurse-led lymphoma survivorship model of care.

This chapter provides a brief background to lymphoma cancer, the issues survivors face and the need to develop better models of follow-up care for lymphoma patients who finish curative-intent treatment. An overview of the purpose of this study, the research questions that guided all aspects of this study are then presented. The chapter concludes with an overview of the structure of the thesis and a glossary of terms.

The Problem

Lymphoma is a blood cancer originating from B and T cells in the lymphatic system which undergo a malignant change. Although there are around 30 different types, they can be categorised into two main types; non-Hodgkin lymphoma (NHL) or Hodgkin lymphoma (HL) (Cancer Australia, 2018).

In Australia, HL is considered a rarer cancer, accounting for only 0.5% of all cancer diagnosed. It is estimated about 683 cases will be diagnosed, with mortality around 30 cases in 2018 (Australian Institute of Health and Welfare, 2017). Five-year relative survival at diagnosis is 87.5% (Australian Institute of Health and Welfare, 2017). It is the most common cancer of the adolescent and young adult population, with over a third of all incidences in the 15–30-year age group. Unlike other types of lymphoma, HL is diagnosed when the presence of what are termed Reed-Sternberg cells are seen in the biopsy material (Kuppers & Hansmann, 2005).

The majority (80%) of NHL arises from B cells and is the most common type of lymphoma, especially in those over 50 years of age where incidence increase with age (Australian Institute of Health and Welfare, 2017). An estimated 5,720 cases will be diagnosed, and an estimated 1,443 deaths in 2018. Five-year relative survival at diagnosis is approximately 74% (Australian Institute of Health and Welfare, 2017).

Combined, lymphomas represent the sixth most common cancer diagnosis in Australia and worldwide (Cancer Australia, 2018; Howlader et al., 2016) and tend to occur more frequently in men (Australian Institute of Health and Welfare, 2017). Incidence and survival in Australia are increasing. An estimated 6,232 cases were diagnosed in 2017, equating to 4.6% of all cancer cases (Australian Institute of Health and Welfare, 2017). Conversely, an estimated 1,481 people will have died from lymphoma, equating to 3.1% of all cancer deaths in 2017. Improved survival rates have been attributed predominantly to developments in treatment and supportive care options. These include chemotherapy and/or radiotherapy and may involve haematopoietic stem cell transplantation or immunotherapy or targeted therapies (Carey et al., 2012). An estimated 76% of those diagnosed survive at least five years; this is a marked increase from 52% in the mid-1980s.

With increased remission and survival rates, many survivors are living with issues and concerns, called unmet needs, due to the aggressive nature of the cancer and the intensity of treatment (Carey et al., 2012; Sant et al., 2014). These long-term and late effects may have an ongoing impact on health and quality of life (QoL) (Leeuwen & Ng, 2017; Oerlemans, Mols, Nijziel, Lybeert, & van de Poll-Franse, 2011; Sarker et al., 2017). Difficulties faced by lymphoma survivors may relate to: fatigue; poor nutritional intake; decreased exercise capacity; cognition impairment; fear of recurrence;

depression and anxiety; fertility issues; relationship stress; financial concerns; employment issues; and difficulty in obtaining particular types of insurance, for example health and/or travel insurance (Arboe et al., 2017; Bryant et al., 2015; Daniels, Oerlemans, Krol, Creutzberg, & van de Poll-Franse, 2014; Daniels, Oerlemans, Krol, van de Poll-Franse, & Creutzberg, 2013; de Lima et al., 2017; Hall et al., 2016; Jones et al., 2015; Kreissl et al., 2016; Krolak, Collins, Weiss, Harris, & Van der Jagt, 2017; Leeuwen & Ng, 2017; Linendoll et al., 2016; Magyari et al., 2017; Mojs, Warchol-Biedermann, & Samborski, 2017; Oerlemans et al., 2014; van de Wal, van de Poll-Franse, Prins, & Gielissen, 2016; Zimmer et al., 2015). Furthermore, health can be compromised by an increased risk of developing other diseases such as cardiovascular disease and second cancers (Leeuwen & Ng, 2017; Schaapveld et al., 2015). These are often experienced earlier than the general population (Panek-Hudson, 2013), an escalating problem in those diagnosed at a younger age (Grinyer, 2010; Hemminki, Lenner, Sundquist, & Bermejo, 2008), which is further elevated if treatment involves radiotherapy (Ng, LaCasce, & Travis, 2011; Travis et al., 2012). Survivor lifestyle behaviours, such as smoking, can likewise have an effect on secondary disease development (Ng et al., 2011). It is important that health care providers, survivors and their families have an awareness of potential late effects, to ensure timely and appropriate follow-up (Ng et al., 2011).

Regardless of what is currently known about the issues faced by lymphoma survivors, compared with other more common cancers such as breast, prostate and colorectal, this cancer remains understudied in survivorship literature. This gap in the published literature is important to address as inadequate service provision at treatment completion may be leading to unmet needs along the survivorship continuum (De Leeuw & Larsson, 2013). When this research was proposed in 2014, no RCTs were identified that

related to adult lymphoma survivor cohorts. Since that time there has been one published RCT reporting a 12-week exercise intervention in haematological cancer survivors (mainly lymphoma $n=33$, 89%), assessing cancer-related fatigue (Furzer et al., 2016).

The lack of published evidence-based guidelines for the ongoing management of cancer survivors has previously been acknowledged in the cancer literature (Phillips & Currow, 2010; Rechis, Arvey, & Beckjord, 2013). Current follow-up care for lymphoma patients has traditionally been led by the haematologist (Taylor, Chan, & Monterosso, 2015), with a focus largely on recurrence surveillance (Molassiotis et al., 2017) that overlooks needs-based tailored support and information (Earle & Ganz, 2012; Jefford et al., 2008). Likewise, no consensus exists on whether other health care providers, such as nurses or GPs could deliver holistic care to transition survivors into the survivorship phase upon treatment completion.

Cancer nurses have established expertise in the areas of health promotion, information, support and resource provision (Jackson, Scheid, & Rolnick, 2013). Findings from recent studies have supported nurse-led models of survivorship care that utilised the existing skills of experienced cancer nurses (Beaver et al., 2012; Gates, Seymour, & Krishnasamy, 2015; Howell et al., 2012; Jefford et al., 2016; John & Armes, 2013; Maly, Liang, Liu, Griggs, & Ganz, 2017). An important aspect of these models was the administration of survivor-specific and patient-centred assessment measures to accurately ascertain and address concerns or issues that are important to the survivor. Equally it is proposed these measures may empower survivors to seek out information and support to manage their concerns and ongoing symptoms, and to adopt healthy lifestyle behaviours (Fitch, 2008; Ganz, Casillas, &

Hahn, 2008; McDowell, Occhipinti, Ferguson, Dunn, & Chambers, 2010; Stricker et al., 2011).

Patient empowerment or activation (Klemanski, Browning, & Kue, 2016) in this context, indicates the degree to which an individual comprehends that he or she has a role in managing health and health care. It likewise includes the extent to which the individual feels capable of fulfilling that role (Hibbard, Mahoney, Stock, & Tusler, 2007). It could be argued that self-efficacy is an important indicator of a successful transition into survivorship (Rosenberg et al., 2016).

National and international professional cancer organisations have recommended the use of survivorship care plans and treatment summaries (SCPTS) as an important aspect in the facilitation of holistic survivorship follow-up care (Clinical Oncology Society of Australia, 2016; MacMillan Cancer Support & NHS Improvement, 2010; McCabe, Bhatia, et al., 2013). The provision of a written, individualised SCPTS should increase the amount of information that is communicated to the survivor and other health professionals such as the GP who may be responsible for future ongoing care of survivors. A treatment summary succinctly documents an individual's disease and treatment information, along with potential late effects and recommended management. The survivorship care plan is then individualised to each patient and should guide personalised follow-up care with recommendations, screening guidelines, information and healthy lifestyle promotion and support (Alfano, Ganz, Rowland, & Hahn, 2012; Grant & Economou, 2008; Hausman, Ganz, Sellers, & Rosenquist, 2011; Hewitt, Greenfield, & Stovall, 2005; Jabson & Bowen, 2013; Panek-Hudson, 2013; Taylor & Monterosso, 2015).

Aim and Objectives

The purpose of this research was to develop and empirically test an evidence-based nurse-led lymphoma survivorship model of care to transition lymphoma survivors into the survivorship phase, using a pilot pragmatic randomised controlled trial (RCT). This research aimed to facilitate the participant randomised to the intervention group to normal functioning sooner and to produce a reduction in perceived unmet informational, practical and emotional needs or concerns and an increase in participant self-management compared with those randomly assigned to the current standard of care (usual care). This research will furthermore provide baseline data to support hypothesis development, and the calculation of sample sizes for future multisite randomised controlled trials. It thereby fills a gap in lymphoma survivorship care where evidence-based research and outcome evaluation of models of care is lacking (Irwin, Klemp, Glennon, & Frazier, 2011).

Design

The thesis comprised a four-phase prospective study that incorporated quantitative and qualitative research methodology (Figure 1.1). The main focus of this thesis was the phase II pilot pragmatic randomised controlled trial (RCT). Pragmatic RCTs are customarily conducted in the “real-world” setting where patients receive their usual care (Thorpe et al., 2009). In this case, participants were recruited from the haematology department of a large tertiary cancer centre in Perth, Western Australia. As is the case with pragmatic RCTs, recruitment is offered to potentially all eligible patients receiving care in the participating location. Intervention delivery and participant follow-up are closely aligned to usual care to understand the real-world implications of the intervention and to determine the effects of the

intervention in conditions where it would normally be applied (Thorpe et al., 2009). Qualitative research was undertaken to complement the quantitative findings of this study and occurred concurrently with the pragmatic RCT. The qualitative interviews were undertaken with a subset of intervention participants at the completion of all study measures to explore participant perceptions of the nurse-led lymphoma survivorship clinic (NLSC) intervention, assessment measures and SCPTS. Feedback was also sought from intervention participants' GPs to determine the usefulness and utility of the SCPTS to inform practice. As there was no published test-retest reliability data for one of the chosen assessment measures (Short-Form Survivor Unmet Needs Survey), this process was also undertaken as part of this thesis.

Research Questions

A number of questions guided each of the four phases.

Phase One: Systematic/Integrative Literature Reviews

1. Models of survivorship care
 - a. What are the common attributes of survivorship models of care developed generally for cancer patients and specifically for haematology cancer patients?
 - b. What resources are required to support these models?
 - c. What are the potential benefits and shortfalls of these models?
 - d. What outcome measures have been used to evaluate these models and what are the findings?

2. Survivorship care plans and treatment summaries (SCPTS)
 - a. What are the common attributes of SCPTS developed for haematological cancer patients?
 - b. What resources are required to develop SCPTS?
 - c. What are the potential benefits and limitations of SCPTS?
 - d. What outcome measures have been used to evaluate SCPTS and what are the findings?
3. Needs assessment measures
 - a. What reliable and valid measurement tools are currently available to measure the informational and practical needs of lymphoma cancer survivors?
 - b. What are the implications of the findings from the review for future research and clinical practice?

Phase Two: Intervention Development

1. What assessment instruments will be chosen to measure: survivor-specific informational, practical and emotional needs; depression, anxiety and stress; mental adjustment; and patient empowerment?
2. What components are required for an SCPTS designed for lymphoma survivors?
 - a. How will these be tested for content validity (apparent internal consistency, clarity and reliability)?
3. What information and resources will be required to develop a tailored resource pack, including health promotion strategies?

Phase Three: Pilot Pragmatic Randomised Controlled Trial (RCT)

1. Do participants assigned to the nurse-led lymphoma survivorship clinic intervention demonstrate a reduction in perceived unmet informational,

practical and emotional needs compared with those randomly assigned to usual care?

2. Do participants assigned to the nurse-led lymphoma survivorship clinic demonstrate a reduction in self-reported anxiety, depression and stress and an increase in patient self-management behaviours compared with participants randomly assigned to usual care?
3. Does the SF-SUNS demonstrate test–retest stability and reliability over time?

Phase Four: Qualitative Interviews / General Practitioner Evaluation

1. What questions will best elicit participant perceptions of the assessment measures, the nurse-led survivorship model of care and the SCPTS?
 - a. Who should assist with the interview schedule development and who should undertake the interviews to reduce bias?
2. What questions and format will work best to elicit general practitioner (GP) perceptions of the utility and usefulness of the SCPTS.
 - a. Who is best suited to provide advice and suggestions regarding the development of an evaluation survey and cover letter that will maximise response rates from GPs?

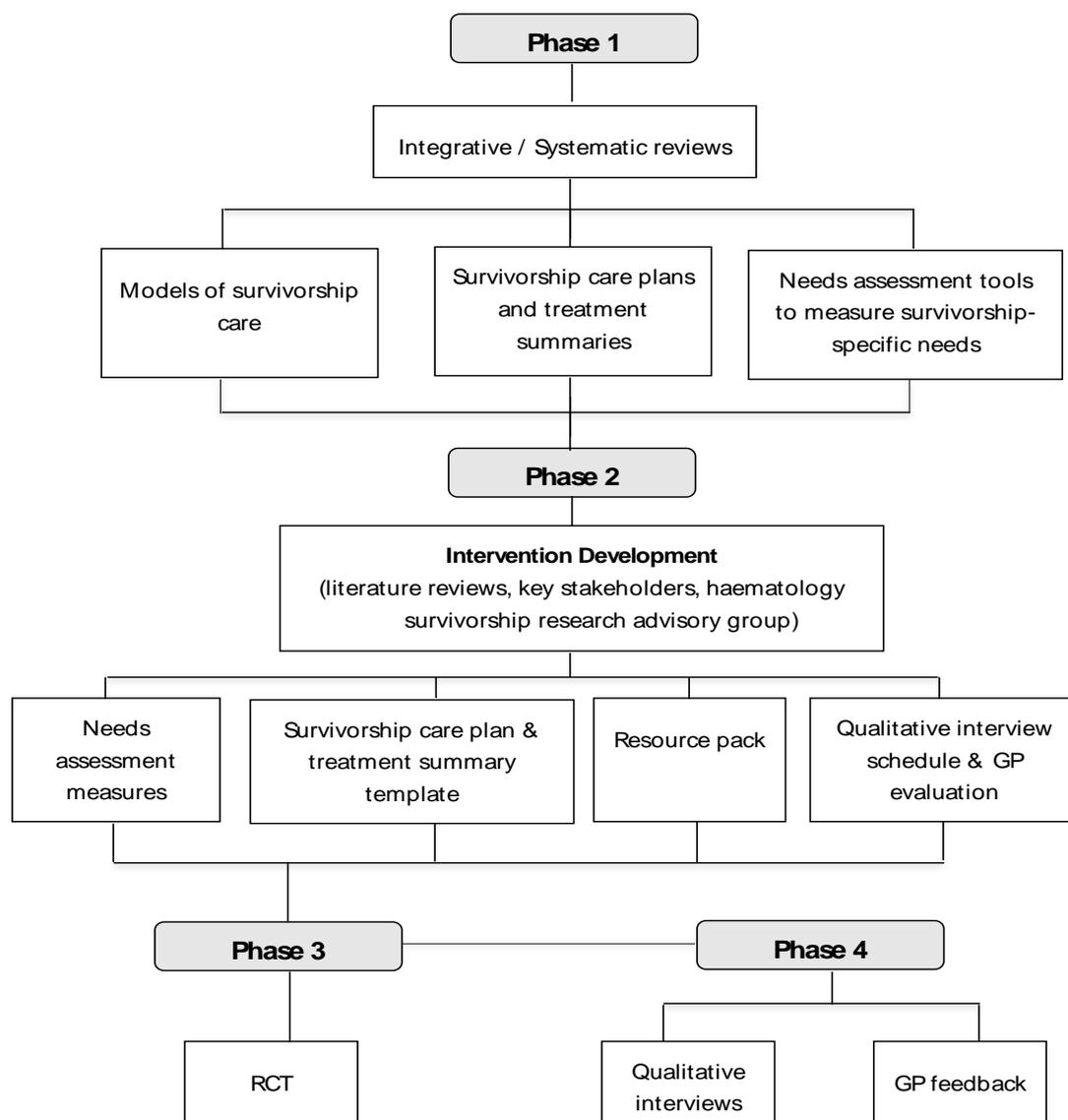


Figure 1.1. Overall study design.

Components of the RCT

The main focus of this thesis has been the pragmatic RCT to test the nurse-led model of lymphoma survivorship care intervention. This intervention comprised three core components:

1. The administration of four self-reporting assessment measures over three time periods
 - a. Baseline (Time 1), Three months' post-treatment completion
 - b. Three months' post-baseline (Time 2), Six months' post-treatment completion
 - c. Six months' post-baseline (Time 3), Nine months' post-treatment completion
2. Provision of an individualised SCPTS consisting of
 - a. Diagnosis and treatment information
 - b. A tailored list of potential late effects with recommendations for the GP to follow-up
 - c. Participant-derived concerns, health goals and proposed actions
 - d. General health information, screening recommendations and healthy lifestyle behaviour support
3. Provision of tailored evidence-based education, information and resources to address participant-reported needs, likely post-treatment physical and emotional concerns and maximising participant involvement in healthy lifestyle behaviours.

Overview of the Thesis

The very nature of a thesis by publication will involve some repetition of information, necessary to ensure the readers of the published papers can understand the wider context. As each paper was published from 2015 to 2018, the background and literature have been constantly updated; however, the intent of the research remains unchanged. An introduction and summary of content are given for each chapter.

Chapter Two is the literature review section of the thesis and comprises three published papers. The integrative review of lymphoma models of survivorship care was published in the internationally peer-reviewed journal *Supportive Care in Cancer*. The integrative review of haematological cancer survivorship care plans and treatment summaries was published in the internationally peer-reviewed journal *Oncology Nursing Forum*. The final paper in this chapter is a systematic review of needs assessment measures used with lymphoma survivors and was published in the peer-reviewed journal *The Australian Journal of Cancer Nursing*. Although some papers included other haematology cancers to ensure a wide range of literature was gathered, the primary focus has always been lymphoma. Included after each paper is an updated literature review of current published research on the three topics previously described.

Chapter Three describes the conceptual framework that guided the development of the nurse-led lymphoma survivorship model of care.

Chapter Four describes the development of the essential elements of the nurse-led lymphoma survivorship model of care: the advisory committee; the unique survivorship care plan and treatment summary (SCPTS); the assessment measures; and the resource pack. In addition, it provides further details on the GP evaluations that were used in Phase Four. Where possible, repetitive information contained in the methodology section (Chapter Five) has been reduced in this chapter.

Chapter Five provides an account of the methodology of this thesis. This consists of a protocol paper published in the prestigious and internationally peer-reviewed journal *British Medical Journal Open*. It also includes the ethical considerations of this study.

Chapter Six is the results of the Phase Three pragmatic RCT, GP evaluations and qualitative interviews undertaken in Phase Four and the test–retest reliability analysis of one of the chosen assessment measures; the Short-Form Survivor Unmet Needs Survey (SF-SUNS). This chapter provides a reporting of the results of the pragmatic RCT and GP evaluations and is followed by two published papers. Qualitative interviews were conducted with a subset of intervention participants when they completed all aspects of the study. These results have been published in the internationally peer-reviewed journal *European Journal of Oncology Nursing*. Test–retest reliability of the SF-SUNS was conducted during the pragmatic RCT, results of this analysis have been published in the internationally peer-reviewed journal *Asia-Pacific Journal of Oncology Nursing*.

Chapter Seven presents a discussion of Phase One literature reviews, Phase Three pragmatic RCT and Phase Four GP evaluations and qualitative interviews. Additionally, a summary of the test–retest analysis is presented. This chapter includes the limitations and strengths of this thesis research.

Chapter Eight concludes the thesis and discusses the implications of the study findings and makes recommendations relevant to nursing research and practice, education and future research directions.

References throughout the thesis, including published papers, have been combined into a final reference list. All published papers are included in the appendix in their published form. Several supplementary elements of this thesis are included in the appendix and are listed throughout the thesis.

Glossary of Terms

The following terms have been used in the thesis and are defined here.

Active Treatment: Treatment that is used just after diagnosis until remission of the cancer is achieved.

Assessment Measure: A questionnaire, scale or tool to assist in gathering information to identify and evaluate a range of issues or functional ability of the responder.

Autologous Transplant: A stem cell transplant using the patient's own stem cells that are given back as a "rescue" for high-dose, myeloablative chemotherapy.

Cancer Nurse Coordinator: A registered nurse who is highly experienced and knowledgeable. A specialist in cancer nursing, cancer care and cancer treatments.

Chemotherapy: Chemical drug agents used to treat cancer.

De Novo: New diagnosis of a cancer that is not related to a previous cancer.

GP: General Practitioner.

HL: Hodgkin Lymphoma. One of two main types of lymphoma characterised by the presence of Reed-Sternberg cells. Cancer cells originate in the lymphatic system. Overall term given to several sub-types.

Immunotherapy: Treatment of cancer using drugs that enhance, induce or suppress an immune response in the person to fight cancer. They are thought to work by slowing the growth and spread of cancer cells and by helping the immune system to recognise and kill existing cancer cells.

Informational Needs: Information to assist in decision making and the acquisition of skills to decrease fear, anxiety and misperception.

Late Effects: Absent or subclinical toxicities of treatment that can manifest years later.

Long-Term Effects: Toxicities or issues that appear during treatment and persist.

MOC: Models of Care.

Motivational Interviewing: A directive, patient-centred counselling style for eliciting behaviour change, by assisting patients to explore and resolve ambivalence.

Myeloablative: High-dose chemotherapy that kills cells in the bone marrow spaces, including cancer cells and normal blood-forming cells. This treatment will cause death if untreated by a stem cell transplant.

NHL: Non-Hodgkin Lymphoma. One of two main types of lymphoma, with cancer cells originating in both lymphoid tissue and other organs. Overall term given to several sub-types.

NLSC: Nurse-led Lymphoma Survivorship Clinic.

PET: Positron emission tomography. An imagining scan that detects cancer tumours. Routinely used to assess for disease status. HL patients with a clear mid-treatment PET no longer have routine post-treatment scans.

PCP: Primary Care Provider.

Practical Needs: Direct interventions that support the survivor to complete a task or meet a concern.

QoL: Quality of Life.

RCT: Randomised Controlled Trial.

SCPTS: Survivorship Care Plan and Treatment Summary. The care plan is a personalised document that guides and coordinates follow-up care after treatment has finished. It includes recommendations, information and resources for surveillance of the diagnosed disease, screening for potential long-term and late effects from treatment and health-promoting behaviours. The treatment summary section is a comprehensive summary on the disease and treatment and may include provider contact details.

Self-efficacy: a belief in your ability to achieve a task or succeed in a specific situation.

Self-empowerment: a belief that you know what is best for yourself, and therefore you can take control of your life through strength of mind, goal setting and positive choices.

Survivorship: The experience of living with, through and beyond a diagnosis of cancer. Including the impact on family and friends.

Targeted Therapy: Used to treat cancer by blocking the growth of cancer cells by interfering with specific target molecules.

Unmet Need: Concerns or issues where a lack of support or services is perceived by a person, thereby making it difficult to receive the help they feel they require.