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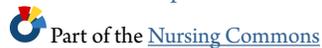
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Effect of a nurse-led lymphoma survivorship model of care: A pragmatic phase II pilot randomised controlled trial

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Chapter Four — Phase Two

*“Because you do feel a bit sometimes like you are just treated like a number.
Having things individualised helped a lot” Female_NHL*

4.0 Intervention Development

The purpose of this chapter is to describe in detail the processes related to the development of a nurse-led lymphoma survivorship model of care. While the following information has been presented using separate headings for clarity, it does not necessarily reflect that development occurred linearly. Development of some components occurred concurrently where necessary. The rationale for concurrent development was to progress the proposed research as expeditiously as possible to meet candidacy and Human Research Ethics Committee (HREC) submission requirements promptly since the estimated time frames required for approval were somewhat lengthy.

This chapter begins with a brief section that describes the haematology survivorship research advisory committee that was initiated to guide the nurse-led lymphoma survivorship model of care. The model of care comprised the following essential components: development of a lymphoma survivorship care plan and treatment summary (SCPTS); assessment measures; and development of a resource pack. These components are described briefly in Chapter Five of this thesis, with more detail given in this chapter to provide clarity on development. Likewise, the final section of the chapter provides detail on the development of the GP evaluation (Phase Four), which is briefly discussed in Chapter Five.

Haematology Survivorship Research Advisory Committee (HSRAC)

This committee was convened in 2014, at the beginning of the research process and comprised academic and clinical health professionals (doctors, nurses and psychologists), a community support group executive and two

consumers who met monthly at the study site for the duration of the study. The committee was guided by Terms of Reference, with the primary aim to provide insight, feedback and guidance on the development of the intervention components for the pragmatic RCT, including inclusion/exclusion criteria, timeframes and recruitment strategies. The opinions of all members were valued, especially those of the consumers who had a unique insight into lymphoma post-treatment follow-up at the study site.

Survivorship Care Plan and Treatment Summary

The unique lymphoma-specific survivorship care plan and treatment summary (SCPTS) developed for this RCT is described in Chapter Five, in the form of a published protocol article (Taylor, Joske, Bulsara, Bulsara, & Monterosso, 2016). However, detail is provided in this chapter regarding how the SCPTS was created.

At the completion of the integrative review on SCPTS, no Australian or international SCPTS were perceived as appropriate for use in the study centre. Therefore, an SCPTS was developed that was more patient-centred and unique to this study cohort. The first full draft comprised two pages of diagnosis and treatment information including chemotherapy drug names and information on administration, dosing, protocol changes and potential long-term and late effects which included recommended follow-up by the GP. This was followed by a page that allowed lymphoma survivors an opportunity to document their health concerns and health goals. Two further pages listed general health screening and healthy lifestyle behaviour information. This draft was presented to the SCGH Haematology Department for review prior to content validation. The draft SCPTS was sent

to health professionals including GPs and consumers to ascertain apparent internal consistency, clarity and reliability. Appendix F.2 contains the validation document that was sent with the SCPTS. All reviewers received the same document to review.

Each item was assessed for:

- Content clarity—whether each item was clearly defined (Yes/No)
- Apparent internal consistency
 - a) whether each item belonged in the SCPTS (Yes/No)
 - b) the general fit with other items (Yes/No)
- Content validity—level of relevance of each item
 - 4-point Likert-type rating scale (1=not relevant to 4=highly relevant).

The content validity index (CVI) (Polit & Beck, 2006) score was generated for each item. “Yes” scores (content, clarity and apparent internal consistency) and scores of 3 or 4 (content validity) were added. The intent of the evaluation was to remove low scoring items and to assess for agreement of greater than 80% per item. A comments section was provided for each item to gain further feedback.

Six consumers completed an evaluation. Results indicated consumers were unsure what late effects meant or what was meant by extra-nodal disease. There was however, overwhelming consensus on the clarity (CVI: .98), the apparent internal consistency (CVI: 100) and relevancy (CVI: .95) of the items. Consumer comments related to the meaning of late effects and made suggestions on the wording of elements of the SCPTS, i.e. ‘could it say main aims, not goals?’. Two consumers felt the general lifestyle information should already be known to patients.

Six clinicians completed the evaluation; these included haematology nurses (n=4) and GPs (n=2). Consensus was achieved on clarity (CVI: .99). Apparent internal consistency was slightly lower (CVI: .91), this result was evident from GPs who did not find all the treatment summary information was required, although the result of whether each item generally belonged within the SCPTS was high (CVI of .99). Relevancy of items generated a low result (CVI: .84). This was again attributed to the GPs who indicated all the detailed drug information and disease information was not relevant. Comments reflected that a long treatment summary with information thought more relevant to the haematologist should be removed. One GP commented that it would be inappropriate to ask a patient what their main health concerns would be, this should be specified by the doctor.

One of the evaluated GPs sent the document to other GPs (n=6) for comment. Feedback was emailed to the researcher; however, no evaluation forms were completed. It was unclear what information had been provided on the intent of the SCPTS. All feedback was considered, however not all comments were relevant. Suggestions for inclusion on the SCPTS that were not deemed relevant by the HSRAC were: listing all past medical history; all allergies and adverse reactions not related to treatment; travel immunisation schedules; information on sexually transmitted diseases; contraception advice; stratification of recurrence risk; male and female versions; and doctor-derived concerns not patient-derived. Comments that were relevant included: reducing the treatment summary section and removing the chemotherapy drug lists; giving the general health information to the survivor only (GPs indicated they know this information); and moving the potential late effects section to after the treatment summary section.

A section for haematologists to sign the TS and late effects section was added as research had indicated nurse-led SCPTS might not be valued by GPs (Mor Shalom et al., 2011). Once consensus was reached from HSRAC on changes to the treatment section and the wording of a few items, the final document was a TS (half a page in length) and SCP (one and a half pages in length), with the general health information in a two-page document for survivors (Appendix F.1). The final SCPTS was reviewed and approved by the haematologists at the study site for provision to patients recruited to the trial.

A search of the literature was undertaken for potential late effects that can affect lymphoma survivors. Two documents in chart form were created for NHL and HL late effects, including recommendations for follow-up. These documents were circulated to the SCGH haematologists and radiation oncologists for review and comment. Once approved, they were used when completing potential late effect information on the SCPTS.

Measures

At the completion of the needs assessment systematic review (Taylor & Monterosso, 2016) and in consultation with the HSRAC, four assessment measures were chosen for the pragmatic RCT. These measures were required to ascertain: survivor-specific informational, practical and emotional needs; anxiety, depression and stress; mental adjustment to cancer; and patient empowerment. Copies of the assessment measures are located in Appendix E.2 to E.5.

The needs assessment systematic review (Chapter 2.3) identified the importance of a survivor-specific measure that had been developed with a cohort of survivors including lymphoma survivors. The measure chosen was

the *Short-Form Survivor Unmet Needs Survey (SF-SUNS)*(Campbell et al., 2014). Further information on this measure is found throughout the thesis and particularly in Chapter 6.3.

The prevalence of the symptoms of distress are often overlooked in survivorship research (Holland et al., 2010). Therefore, it was imperative that a measure be found that would allow participants an opportunity to self-report items that encompass distress such as depression, anxiety and stress. Thus, the *Depression Anxiety Stress Scale (DASS21)*(Antony, Bieling, Cox, Enns, & Swinson, 1998; Lovibond & Lovibond, 1995) was chosen for this study. Distress has been defined as a multifactorial disagreeable emotional experience that may interfere with the ability to cope effectively with cancer, and can be psychological, social and/or spiritual in nature (Holland et al., 2010). To improve the identification and management of distress, screening in survivors is essential as many aspects of distress, such as fear of cancer recurrence, uncertainty about the future, loss of health, anger and preoccupation with thoughts around cancer may continue after treatment completion (McCarter et al., 2018). Patient outcomes are improved when distress screening is implemented and interventions provided (Mitchell, 2013), however many research studies that report a lack of benefit with screening are more likely due to a lack of appropriate follow-up for those identified with distress (Meijer et al., 2013). During this study, as items of distress were identified, the appropriate support and resources were offered to the intervention group participants during the study period. For those in the control group, support was offered after they had completed all elements of the study.

Leading on from the selection of the DASS21 to measure components of distress, an assessment measure that has items that are similarly related to

aspects of distress and coping was considered appropriate to gauge a wider view on patient-reported concerns and issues in this area. Therefore the *Mini Mental Adjustment to Cancer Scale (Mini-MAC)* (Watson, Law, & dos Santos, 1994) was selected.

The fourth measure chosen was the *Patient Empowerment Scale (PES)* (Bulsara & Styles, 2013) as it was important to measure the self-reported level of a patient's coping ability and self-efficacy in managing their illness and making decisions about support strategies. Empowerment can be seen as a proactive strategy in acknowledging what an individual feels they can control, and equally importantly, what lies outside of their control (Bulsara & Styles, 2013). This was meaningful for the study as the SCPTS involved participant-derived aspects. Consequently, it was important to assess the level of a participant's empowerment, especially when they would be encouraged to seek out support and information for themselves as required.

Assessment measures would be posted to those randomised to the control group after baseline; therefore, a letter was created to remind them about the study and to encourage them to complete and return the assessment measures. (Appendix G).

Resource Pack

A resource pack was developed after consideration of the evidence (reported haematology survivor unmet needs and concerns) from the integrative reviews undertaken in Phase One. The information assembled for dissemination to the intervention group participants needed to address anticipated participant-identified unmet needs, likely post-treatment physical and emotional concerns, and to encourage optimal participant

involvement in healthy lifestyle behaviours. Information currently in use by established cancer support sources such as the Cancer Council Australia and the various state-based Cancer Council websites were assessed. Standardised Australian Government information (as referenced below) was likewise obtained. Where information was insufficient or not targeted to the lymphoma cohort, the researcher adapted the information using a variety of credible cancer sources including Australian, North American and United Kingdom oncology websites.

All participants were offered the following booklets and information sheets:

- *Living Well After Cancer* (Bell & Fagan, 2015)
- *Exercise for People Living with Cancer* (Bruce, 2016)
- New insurance policies (Cancer Council Western Australia, 2016)
- Australian Guide to Healthy Eating (Australian Government, 2015)
- Coping with fear of recurrence (American Society of Clinical Oncology, 2015)
- Coping with cancer fatigue (Cancer Council Victoria, 2015)
- Coping with memory and concentration impairment (developed by the researcher)
- Cancer survivor exercise program (Edith Cowan University, 2015)
- Cancer Council WA “Life Now” information and dates (Cancer Council Western Australia, 2015–2017)
 - A programme of supportive care activities such as exercise, yoga, meditation for any person who has or had cancer

Targeted information was offered based on responses to the baseline measures or requested from the participant at the first NLSC appointment. This could include the following booklets and/or information sheets:

- “*Cancer and Your Finances*” (Bruce, 2015)

- *“Sexuality, Intimacy and Cancer”* (Bruce, 2016)
- Rekindle study information, University of Sydney, Australia
 - This was a study to test an online resource to promote sexual well-being for patients and partners. Once recruitment closed in 2016 this information was no longer offered.
- Cancer Council Pro Bono programs (legal, financial and workplace advisory) (Cancer Council Australia, 2015)
- Information on insurance and countries with reciprocal health care agreements with Australia (developed by the researcher)
- Quit smoking (Cancer Council, 2016)
- Motivational chart (developed by the researcher)
- Mental Health Plan information (Australian Government, 2015)
- Canteen (CanTeen, 2015)
 - A support group to help young people (12–25 years) cope with cancer in their family, or their own cancer
- Centrelink (Australian Government, 2015)
 - An Australian Government department delivering social and health payments and services.

A checklist was created of resources and information given to the intervention participants throughout the study period (Appendix J.1).

General Practitioner (GP) Evaluation

The completed SCPTS was given to all intervention participants and sent to GPs. Participants were encouraged to share this document with future health professionals and discuss with their GP during the trial. It was important therefore to gain an understanding of the thoughts and perceptions of GPs who received the SCPTS. This was to gauge the use and usefulness of the document.

An evaluation based on the proposed SCPTS was developed. Advice on the document was sought from the GP on the HSRAC to make the evaluation targeted and succinct and to ensure that the cover letters to accompany the evaluation and SCPTS similarly were clear and concise. The final evaluation was one and a half pages in length and was checked by a GP researcher from the University of Melbourne, not involved in the research. His comments indicated the size and content was appropriate to gain the information required.

The evaluation collected a small amount of demographic information: years working as a GP; gender; and if the intervention participant had been seen in the last six months. The first section of the evaluation comprised 'yes/no/not applicable' questions related to the SCPTS, receipt and discussions (7 items). The next section rated elements of the SCPTS and used a Likert-type scale: 1=very poor; 2=poor; 3=adequate; 4=good; 5=very good (4 items). Five open questions followed and ascertained if: further information was required; information did not belong on the SCPTS; any general comments; further haematology education required; and the preferred format for education. The final evaluation form is found in Appendix H.

The GP cover letters were each one page in length. The introductory cover letter was attached to the initial posting of the SCPTS after the intervention participant had completed the first NLSC intervention appointment. The content gave a brief overview of their patient's involvement in the RCT and the intent of the SCPTS. Any urgent clinic concerns were directed to the haematology department at the study site (SCGH). As previously described GP input had indicated a listing of chemotherapy drug names was not required, therefore a link to EviQ (an Australian evidence-based cancer treatment protocols and information website for health professionals) with

username and password were included if GPs wanted to look drug information up for themselves. The subsequent cover letter was attached with the evaluation and a further copy of the SCPTS to remind the GP their patient had participated in an RCT and to ask if they would complete an evaluation. Both cover letters are found in Appendix H.

Chapter Summary

In summary, a number of important elements were developed that guided the thesis and the components that would be tested in the pragmatic RCT. A unique lymphoma-specific SCPTS was developed. However, it was important to ensure the content validity of the SCPTS items prior to use in the pragmatic RCT. Likewise, it was important the haematologists were confident that evidence-based late effects information and recommendations were going to be given to their patients. In addition, this chapter discussed the assessment measures chosen and the resource pack that was developed. Furthermore, the creation of an evaluation of the SCPTS by GPs has been detailed in this chapter as only condensed detail was provided in Chapter Five, methodology and Chapter Six, pragmatic RCT results.

The following methodology chapter of this thesis is in the format of the protocol journal article that was published in the *British Medical Journal Open*, and which provides a complete overview of the pragmatic RCT.