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Title

Is self-management feasible and acceptable for addressing nutrition and physical activity needs of cancer survivors?

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Abstract

Background: Self-management is recommended for patients with chronic conditions but its use with cancer survivors is underexplored. Optimal strategies for achieving lifestyle changes in cancer survivors are not known.

Objective: We aimed to determine feasibility, acceptability and preliminary efficacy of self-management based nutrition and physical activity interventions for cancer survivors.

Design, Setting and Participants: Adult survivors (n=25) during (Group1, n=11) or post (Group2, n=14) curative chemotherapy for solid tumours, most (n=20, 80%) with breast cancer, were recruited prospectively from a single clinical centre.

Intervention: The Flinders Living Well Self-Management Program™, a generic self-management care planning program, was utilised to establish patient-led nutrition and exercise goals within a tailored 12-week intervention. Fortnightly progress reviews occurred with assessments at baseline, 6 and 12 weeks.

Results: Most participants (84%) found the intervention acceptable/very acceptable. Both groups showed a trend towards significant improvement in the self-management capability 'knowledge about changing risk factors' (p=0.047); and Group2 showed a trend towards significantly improved 'psychological impacts' (p=0.007). Goal ratings improved for both groups (p=0.001). Quality of life improved for both groups for emotional functioning (p=0.03). Physical functioning improved for Group2 (p=0.05); however, most symptom domains worsened for Group1, as expected given their treatment stage.

Discussion and Conclusions: Self-management interventions are feasible for this population. In particular, building self-management capacity during the active phase of patients' cancer treatment provides health and psychosocial benefits. Larger randomised controlled trials are required to further determine efficacy. Further translational research is also needed to determine acceptability, feasibility, enablers and barriers for clinicians embedding this approach into routine cancer survivorship care.

Key Words: Cancer; Exercise; Nutrition; Prevention (Risk Factors); Self-Management (Self-care); Survivor.

Introduction

With improved cancer survival, more people are living with long-term consequences of cancer and its treatment. In Australia, there are approximately 700,000 cancer survivors and this figure is increasing by 2.5 % each year.¹ Cancer is associated with increased risk of chronic diseases.² Lifestyle factors associated with diet and exercise are important contributors to this risk³ and to cancer recurrence and reduced cancer specific survival.^{4,5} The

cause of this health burden is multifactorial, including effects of cancer itself and long-term adverse impacts (late effects) of cancer and its treatment including musculoskeletal pain, fatigue, depression and cognitive impairment, which can have significant impacts on the person's capacity to self-manage their health.^{2,6-8}

Current approaches to cancer care do not adequately engage cancer survivors to self-manage their long-term needs, non-cancer issues such as health lifestyle management or management of comorbidity.⁹⁻¹¹ A US survey of cancer survivors¹² showed that up to 29% had unmet physical needs and up to 45% had unmet emotional needs; both needs which are important to successful self-management of health.¹³ Various approaches to provision of treatment summaries and survivorship care plans have been explored among cancer survivors.^{14,15} Notably, the focus of these survivorship care plans has been on cancer specific management, rather than patient-led identification of self-management needs, strengths and barriers which may influence their lifestyle behaviour and engagement in care plans.¹⁶ Service user involvement in cancer care has been found to benefit their capacity to live well with cancer, refocusing their lives, "in a positive, purposeful and productive way".¹⁷

Little is known about how cancer survivors manage lifestyle risk factors for ill-health once primary cancer treatment is complete, and how they can be supported to do this. The assumption held by the community is that life will somehow get back to normal.^{11,18} During the active phase of treatment, many cancer patients lose physical strength and condition. Many attempt to adopt more healthy lifestyles by paying particular attention to their diet, exercise levels, alcohol use, smoking and stress management; however, many put such considerations on hold.^{19,20}

Promoting each person's capacity to self-manage their health within a more collaborative framework of provision of care and self-management support is a priority focus of healthcare systems in Australia and internationally. This is particularly important as healthcare burden continues to grow.^{13,21,22} Self-management support provided through a partnership between the patient and support providers reverses the focus on telling patients what they 'should do' to one where the patient is supported in addressing their own agenda.^{23,24} It is integral in delivering more person-centred care which promotes greater patient autonomy and control, and patient/health professional collaboration, and re-establishing patients' personal ownership of health. People with high self-efficacy are also more likely to engage in self-management behaviours.^{25,26} This may be especially important for people who have experienced cancer and survived, particularly because many cancer patients report heightened feelings of fear and powerlessness in the face of a cancer diagnosis and the threat of its recurrence.^{27,28}

Self-management approaches have been shown to be effective for many chronic conditions and risk factors^{29,30} and preliminary research suggests superior outcomes when incorporating self-management models into health care delivery for cancer.^{15,18,31} The aim of this paper is to report the feasibility, acceptability and preliminary efficacy of the Flinders Program™, a well-established approach to self-management of a range of non-cancer conditions, in different contexts and populations.³²⁻³⁴ Our hypothesis was that this patient-led self-management approach would be feasible and acceptable to cancer survivors and would improve their nutrition and exercise behaviours and quality of life regardless of stage of treatment. Effectiveness measures of the study, including anthropometric, strength, body composition and functional exercise capacity, are reported elsewhere.³⁵

Methods

Sample

Participants were men and women diagnosed with solid tumours, treated with curative intent, assigned to two patient groups: Group1) those currently receiving chemotherapy (within 4 weeks of commencing treatment); and Group2) patients following active treatment (within 8 weeks of treatment completion which included chemotherapy +/- radiotherapy or surgery). All participants were aged 18 years and over, with an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1.³⁶ Patients were excluded if they were pregnant or planned to become pregnant during the study period, and if their treating clinical oncologist assessed them as possessing a level of cognitive impairment, mental illness and/or physical disability that would impair their capacity to provide consent and participate in the intervention.

Recruitment Procedure

The study received ethics approval from the Southern Adelaide Clinical Human Research Ethics Committee. Eligible patients were identified between August 2012 and March 2013 and invited to participate by medical oncologists and cancer care coordinators, as well as using flyers and by mailed letters of invitation containing opt-in forms and reply paid envelopes. Once eligibility was confirmed, signed consent was obtained and a mutually acceptable time for baseline assessments and intervention was arranged.

Intervention

The Flinders Living Well Self-Management Program™ (FLW Program) was utilised. It is an evidence-based, structured interview process, using cognitive behavioural and motivational processes that allow for assessment

of self-management behaviours, enablers and barriers to change, and collaborative identification of problems and goals, leading to the development of an individualised person-centred self-management care plan.³⁷⁻³⁹ This is the first time that these tools have been tested in a cancer population. They include the following steps:

- 1) The Living Well Scale (LWS): A patient Likert-rated questionnaire adapted (for prevention and risk factors) from the Partners in Health Scale.⁴⁰ It is a validated tool within the Flinders Program™ which is based on the WHO and Australian National Chronic Disease Strategy principles of self-management.⁴¹ It enables measurement of perceived change over time where 0= more favourable and 8= less favourable self-management capacity. Self-management rated capacities include knowledge of risk factors, actions taken, access to services and ability to discuss health concerns, general health, and social and psychological impacts of managing risk factors.
- 2) The Cue and Response Interview (C&R): An adjunct to the LWS using open-ended questions or cues to explore the patient's responses to the LWS in more depth, with the patient and worker comparing their Likert-ratings to identify agreed good self-management and agreed issues that need to be addressed as part of a self-management care plan. It enables the strengths and barriers to self-management to be explored, and checks assumptions that either the worker or patient may have, as part of a motivational process.
- 3) The Problems and Goals (P&G) Assessment: Defines a problem statement from the patient's perspective (the problem, its impact and how it makes them feel) and identifies specific, measurable, achievable, realistic and timely (SMART) goals that they can work towards. It is Likert-rated, allowing measurement of progress over time where 0=not a problem and 8=a significant problem; and goal statements: 0=no progress towards achievement and 8=achieved.
- 4) Living Well Care Plan: Self-management issues, aims, steps to achieve them, who is responsible and date for review.

The research officer (SZ-a qualified dietician) received training in the use of the tools from a Flinders Program accredited trainer (SL). Fidelity during the intervention was assured by the research officer delivering all Flinders Program interventions and by meeting with the accredited trainer following their first three care planning interventions and being assessed as demonstrating competence in use of the tools. The research officer worked with participants to develop tailored nutrition and physical activity goals, with interventions of their choice to support goal attainment, delivered over a 12-week period. All participants could choose from a range of nutrition and physical activity supports in addition to personalised actions outlined on their care plan.

Nutrition and physical activity services included home exercise programs, supervised exercise classes, supermarket tours, and 1-on-1 dietary counselling. These were delivered by the various healthcare providers; and settings, formats and number of sessions varied. Reviews of progress with actions on their care plans and progress towards these goals occurred fortnightly at 2,4,8 and 10 weeks via telephone (by the project's dietetics honours student), with Flinders Program assessments at baseline, 6 and 12 weeks (performed by SZ). Participants were also asked to complete a brief survey at the completion of the study, asking about their experience of using the FLW Program and other interventions. This survey asked about their perceptions of the intervention, including its content, format and delivery, location, and the acceptability of review periods and mechanisms of assessment. Several objective and exploratory measures of nutrition and physical activity status were used in addition to the FLW Program. The results of these are reported in detail elsewhere.³⁵ Quality of life was assessed using the EORTC-QLQ-c30, chosen because of its rigor and applicability to cancer survivors to measure global quality of life, physical, social and emotional role functions and individual cancer specific symptom domains.⁴² See Appendix 1 for further details of all assessment and evaluation measures and their delivery.

Data Analysis

Mixed effects models were used to assess the changes in nutrition, physical activity and other goal scores over the 12 weeks of the intervention. We also used mixed effects models to assess the changes in each of the 10 LWS domain scores over the 12 weeks. In each model, we included time, group and a time x group interaction term. Subject was included as a random intercept and time was entered as a categorical variable. A global p-value was obtained for time to assess the overall change over time and a global p-value for the time x group interaction term was used to assess whether there was any overall difference in scores between the two groups across time. Within group differences across time were also compared using the mixed model estimates. All analyses were performed in Stata (version 13, StataCorp, Texas, USA). To adjust for the multiple comparisons performed within the same instrument, we used $p < 0.005$ ($0.05/10$) and $p < 0.0033$ ($0.05/15$) as our two-sided Type 1 error rates for the LWS score domains and the Quality of Life scores respectively. Data in figures are displayed as mean and 95% confidence interval. Data in tables are displayed as mean \pm SD unless otherwise stated.

Results

Sample, Recruitment and Retention

Twenty-five cancer survivors participated in the study (Group1=11; Group2=14). Most were women with breast cancer (80%). Other cancer types were ovarian, colorectal, lung and brain cancer. Average age of the total cohort was 49.9 (± 9.9) years, with Group1 participants being generally older than Group2 participants (53.1(± 8.7) and 47.4(± 10.4) respectively). Group2 participants were more likely to be in couple relationships than Group1 participants. Educational attainment was mixed across both groups, with Group2 having more participants with higher educational attainment. Only one participant in Group1 had a comorbid chronic condition; whereas, more Group2 participants had comorbid chronic conditions. Body mass index was similar across the groups with the average being 25.8(± 6.6) for the total sample. (See Table 1)

Table 1: Characteristics of the study sample (N=25)

	Group 1 (N=11)	Group 2 (N=14)	Total Survivors (N=25)
Gender			
Female	10 (91)	13 (93)	23 (92)
Age	53.1 \pm 8.7	47.4 \pm 10.4	49.9 \pm 9.9
< 65 years	9 (82)	12 (86)	21 (84)
\geq 65 years	2 (18)	2 (14)	4 (16)
Body Mass Index (BMI) #	25.9 \pm 3.3	25.7 \pm 8.5	25.8 \pm 6.6
Marital Status			
Married/ De facto	7 (64)	13 (93)	20 (80)
Divorced	1 (9)	1 (7)	2 (8)
Single	3 (27)	0 (0)	3 (12)
Ethnicity			
Caucasian	10 (91)	13 (93)	23 (92)
Asian	0 (0)	1 (7)	1 (4)
Other	1 (9)	0 (0)	1 (4)
Education			
Did not complete secondary school *	4 (36)	1 (7)	5 (20)
Completed secondary school	4 (36)	4 (29)	8 (32)
TAFE *	1 (9)	3 (21)	4 (16)
Tertiary education	2 (18)	6 (43)	8 (32)
Cancer			
Breast	10 (91)	10 (71)	20 (80)
Ovarian	0 (0)	2 (14)	2 (8)
Colorectal	0 (0)	1 (7)	1 (4)
Lung	1 (9)	0 (0)	1 (4)
Brain	0 (0)	1 (7)	1 (4)
Chemotherapy	11 (100)	14 (100)	25 (100)
Surgery	11 (100)	14 (100)	25 (100)
Radiotherapy	6 (55)	9 (64)	15 (60)
Most Common Comorbid Conditions			
Overweight or obese (as above)	5 (45)	10 (71)	15 (60)
Chronic Obstructive Pulmonary Disease	1 (9)	4 (29)	5 (20)
Hypertension	0 (0)	3 (21)	3 (12)
Impaired Glucose Tolerance	0 (0)	3 (21)	3 (12)

Data presented as N (%) or mean \pm SD.

World Health Organisation BMI definitions: Acceptable weight (18.5 – 24.9 kg/m²) Overweight (25 – 29.9 kg/m²) Obese (30 – 39.9 kg/m²)

* In Australia, students usually turn 18 years of age in their final year of secondary schooling. TAFE students are those who have finished secondary schooling/or left prior to completion who undertake vocational courses.

Seventy-two patients were identified as being potentially eligible, and were approached to participate between August and November 2012. Of these, 25 were confirmed eligible and agreed to participate (35% recruitment rate). No major demographic differences were observed between those who consented versus declined. The main reason for declining was lifestyle changes not being considered a priority. Twenty-two of the initial 25 participants (91%) completed the FLW Program and other assessments at 6 weeks, and 20 participants (80%) completed them (Group1=9; Group2=11) at 12 weeks. All missing assessments are accounted for by withdrawals (n=4). These withdrawals were due to cancer recurrence (n=1), coping issues (n=2), and chemotherapy related complications (n=1). For the EORTC-QLQ-c30, one (4%) participant's forms were incomplete and unable to be utilised.

Living Well Self-Management Capabilities

There were no significant changes across time for any of the domains. See Table 2 and Figure 1A-1J. However, there was a trend towards a significant increase over time for “knowledge about changing risk factors” scores (p=0.047) and a trend towards differences between groups in changes in scores for “psychological impact” (p=0.05) and “ability to discuss health with health professionals” (p=0.06):

- For “psychological impact”, scores for Group1 did not change across time (p=0.29 and p=0.54 at 6 and 12 weeks respectively) but there was a trend for scores in Group 2 to be improved at week 12 compared to baseline (p=0.007) (Figure 1).
- For “ability to discuss health”, scores for Group1 did not change across time (p=0.49 and p=0.19 compared to baseline at 6 and 12 weeks respectively). Scores for Group2 increased non-significantly (p=0.49 and p=0.09 compared to baseline at weeks 6 and 12 respectively).

Table 2: The Living Well Scale Scores by Domain at Baseline, 6 and 12 weeks

	Baseline		6-weeks		12 weeks		p-value for time ¹	p-value for time x group ¹
	n	Mean(±SD)	n	Mean(±SD)	n	Mean(±SD)		
Knowledge About Risk Factors								
Total Survivors	25	6.3±1.6	21	7.0±1.4	22	7.4±0.7	0.37	
Group1	11	6.5±1.4	9	7.1±1.4	9	7.2±0.8		
Group2	14	6.1±1.7	12	6.8±1.5	13	7.5±0.7		0.54
Knowledge About Changing Risk Factors								
Total Survivors	25	25±5.6	21	7.0±1.2	22	7.3±0.6	0.047	
Group1	11	5.8±2.2	9	7.0±1.7	9	7.2±0.7		
Group2	14	5.4±1.9	12	6.9±0.8	13	7.3±0.6		0.83
Taking Action								
Total Survivors	25	5.2±1.5	21	6.0±1.3	22	6.3±1.2	0.24	
Group1	11	5.4±1.5	9	5.8±6.2	9	5.8±6.6		
Group2	14	5.1±1.6	12	6.2±0.9	13	6.6±0.9		0.26
General Health Impact								
Total Survivors	25	5.2±2.2	21	5.8±2.0	22	5.9±1.7	0.88	
Group1	11	5.2±2.5	9	5.3±2.1	9	5.0±2.2		
Group2	14	5.3±2.0	12	6.2±1.9	13	6.5±0.9		0.21
Social Impact								
Total Survivors	25	6.2±2.2	21	6.1±1.3	22	6.7±1.3	0.98	
Group1	11	6.4±2.2	9	6.2±1.1	9	6.2±1.4		
Group2	14	6.1±2.3	12	6.1±1.5	13	7.0±1.2		0.45
Living Situation Impact								
Total Survivors	25	6.0±2.0	21	5.9±1.8	22	6.0±2.2	0.93	
Group1	11	6.2±1.7	9	6±1.9	9	5.9±2.0		
Group2	14	5.9±2.2	12	5.8±1.8	13	6.2±2.4		0.84
Psychological Impact								
Total Survivors	25	5.1±2.0	21	5.1±2.2	22	5.6±1.9	0.56	
Group1	11	4.9±1.9	9	4.2±2.5	9	4.4±2.2		
Group2	14	5.2±2.2	12	5.8±1.7	13	6.5±1.1		0.05
Accessibility To Services								
Total Survivors	25	5.8±1.8	21	5.2±2.2	22	6.0±1.9	0.43	
Group1	11	5.9±1.9	9	5.1±2.6	9	5.2±2.4		
Group2	14	5.7±1.8	12	5.3±1.9	13	6.5±1.2		0.31
Ability To Discuss Health								
Total Survivors	25	5.7±2.1	21	5.0±2.1	22	5.8±2.5	0.42	
Group1	11	5.8±1.7	9	5.1±2.0	9	4.7±2.9		
Group2	14	5.6±2.4	12	5.0±2.3	13	6.6±1.9		0.06
Staying Healthy								
Total Survivors	25	4.9±1.9	21	4.6±2.1	22	5.7±1.9	0.43	
Group1	11	5.7±1.7	9	5.1±2.4	9	5.9±1.9		
Group2	14	4.2±1.8	12	4.3±2.0	13	5.5±1.9		0.38

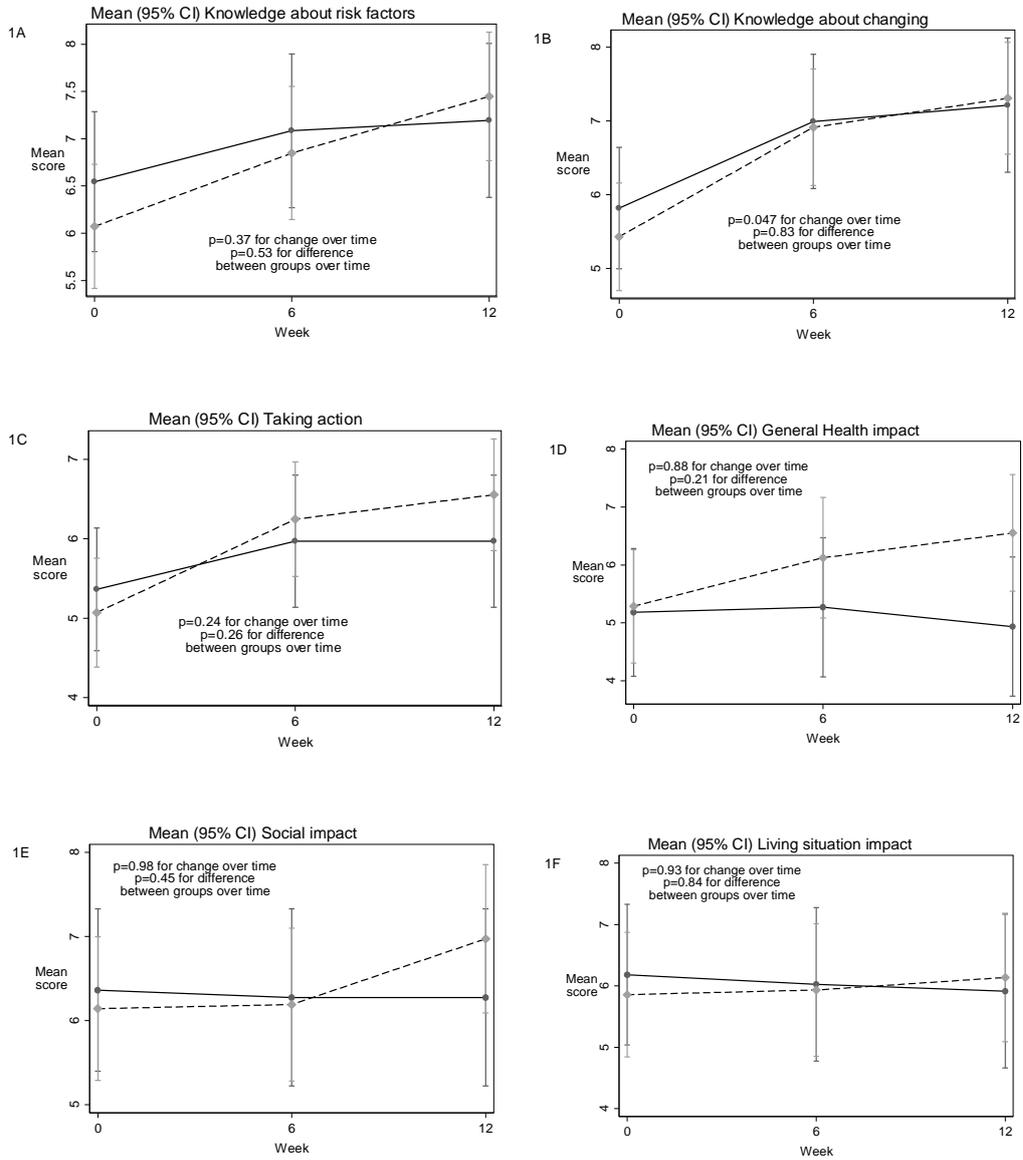
Note: The Living Well Scale is a self-rated Likert scale which measures a person's skill and ability to self-manage.

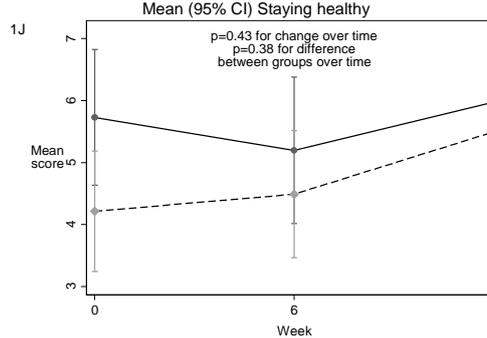
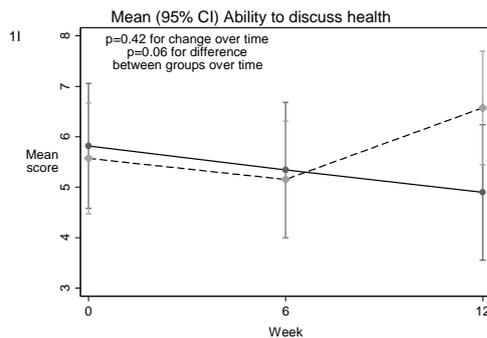
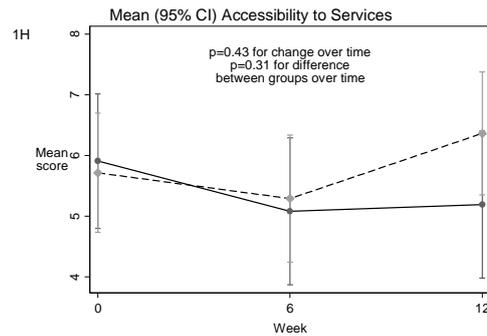
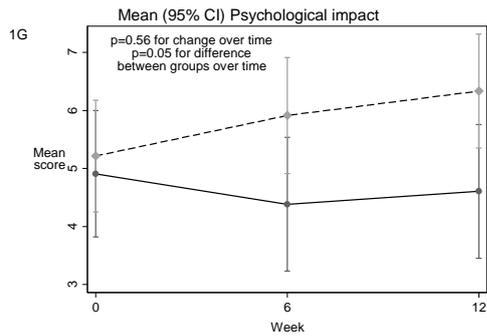
¹Using a mixed effects model with time and time x Group as fixed effects and the subject as a random effect

Figure 1A-1J: Changes in Living Well Scale Scores over the 12 week Intervention

Figure Legend: Mean (95% CI) changes in scores over the 12 week intervention for each of the 10 LWS domains

—●— Group 1 - -◆- - Group 2





Problems and Goals

Sixty-eight percent of participants (n=17) set problem statements (Group1 n=7; Group2 n=10). For participants who did not set problem statements, their predominant reported reason for this was that they did not want to dwell on the negatives present in their lives as a result of the presence of cancer. These participants expressed a strong desire to set goals. Group1 and Group2 participants were just as likely / unlikely to set a problem statement. There were trends in decreasing problem ratings with mean (\pm SD) baseline rating at 5.76 (\pm 1.75) and mean 12-weeks rating at 3.17 (\pm 1.44), where 0=no problem and 8=a significant problem. Although problem ratings improved, statistical significance was not achieved (0.12) due to the small sample. Of the participants who identified problem statements, 36% (n=9) identified weight (either gain or loss) as their biggest problem, followed by body image 8% (n=2), cancer (for example, diagnosis, fear of recurrence) 8% (n=2), weight and fitness 4% (n=1), smoking 4% (n=1), motivation 4% (n=1), work-life commitments 4% (n=1) and physical ability 4% (n=1). Thirty-two percent of participants with problem statements (n=8) had complete fortnightly problem ratings data across the intervention period. Missing data on problem ratings was due to this aspect being overlooked during follow-up with the research assistant or receiving less priority by participants as part of interactions at these follow-up sessions. Examples of problem statements and their ratings over the study period are displayed below:

Examples of Problem Statements							
Group1 Problem Statement: I see my main problem as gaining weight, which might lead me to be less active which makes me sad, disappointed and angry. (50 female, breast cancer)							
Ratings	baseline	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
	6	5	5	4	2	0	0
Group2 Problem Statement: My biggest problem is getting going (motivation)/started. I have become lazy, unmotivated and I sleep in and just lose days. I feel frustrated. (67 female, breast cancer)							
Ratings	baseline	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
	4	3	3	1	1	1	1
Likert 9-point scale where 0=no problem and 8=a significant problem							

Thirty-seven physical activity goals were set by the 25 participants over the 12-week intervention period. Continuous data (i.e. each goal rated at baseline, 2, 4, 6, 8, 10 and 12 weeks) is available on 17 goals (46%). This percent does not reflect dropouts or participants not achieving their goals but was because we allowed participants flexibility with their goals and making changes over the intervention, as part of the FLW Program process. For example, if they set a goal to perform supervised exercise three times per week and found it too difficult to attend on-site exercise at week 6, they may have changed to home exercise and hence set a new goal. Therefore, that participant had 2 incomplete rating of goals sets due to the revaluation they did at week 6. Another example was if their goal was achieved by week 6 and the participant wished to add another goal. There was a significant increase in physical activity goal scores across the 12 weeks ($p < 0.001$). There was no significant difference between Group1 and Group2 ($p = 0.50$).

Seventy-four nutrition goals were set by the 25 participants (on average setting three goals each). Complete data (as per above) was available on 53 goals (72%). The three most commonly set nutrition goals were increasing vegetable consumption, decreasing extras (includes foods that provide excess calories, salt and were of low nutrient value) and increasing consumption of reduced fat dairy. Participants were more likely to re-evaluate their physical activity goals changing one for another whereas nutrition goals remained more constant with additional ones added. There was a significant increase in nutrition goal scores across the 12 weeks ($p < 0.001$). There was no significant difference between Group1 and Group2 ($p = 0.36$).

Sixteen other goals were set by 16 participants at baseline. Complete data was available on 11 goals (69%). Fifteen (94%) of the other goals set were related to weight management. This included weight maintenance, loss and, in one circumstance, gain. One person set a goal around attending social activities. There was a significant increase in other goal scores across the 12 weeks ($p < 0.001$). There was no significant difference between Group1 and Group2 ($p = 0.24$).

Goal achievement significantly improved ($p=0.001$) across the total sample, from 0.9 (± 2.1) at baseline to 6.9 (± 1.9) at 12 weeks for physical activity goals, and 2.4 (± 2.2) at baseline and 7.1 (± 1.2) at 12 weeks for nutrition goals. There was no significant difference between Group1 and Group2 for goal achievement. (See Table 3 and Figure 2A-2C)

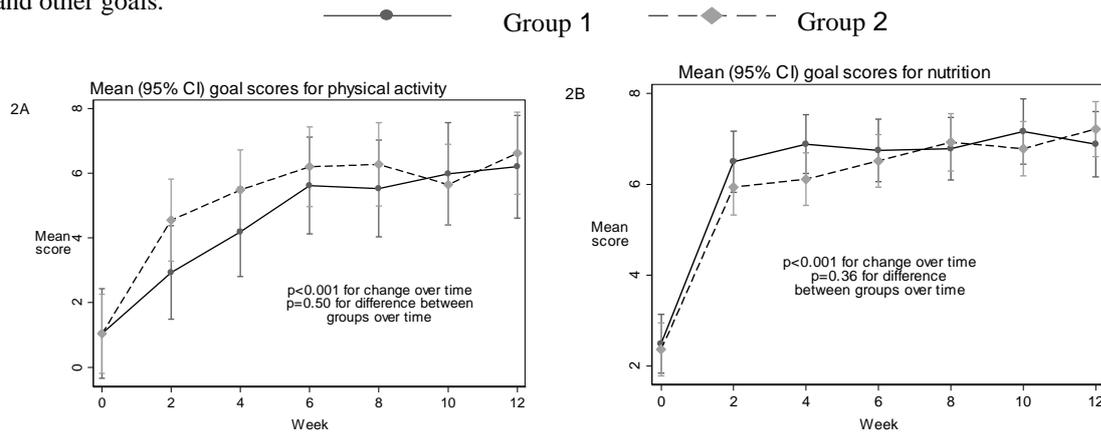
Table 3: Self-rated Physical Activity, Nutrition and Other Goals Scores at Baseline, 6 and 12 weeks

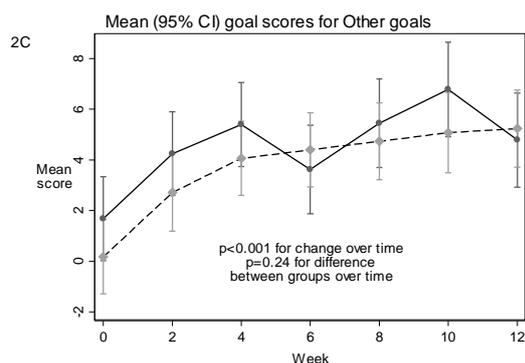
	Baseline		Week 6		Week 12		p-value for time ¹	Time x Group ¹
	n	Mean (\pm SD)	n	Mean (\pm SD)	n	Mean (\pm SD)		
Physical Activity Goals								
Total Survivor Goals	32	0.9 \pm 2.1	29	5.8 \pm 3.0	25	6.9 \pm 1.9	<0.001	
Group1 Goals	14	0.8 \pm 1.8	11	5.5 \pm 3.3	9	6.4 \pm 2.2		0.50
Group2 Goals	18	0.9 \pm 2.3	18	6 \pm 2.9	16	7.2 \pm 1.8		
Nutrition Goals								
Total Survivor Goals	73	2.4 \pm 2.2	68	6.6 \pm 1.7	61	7.1 \pm 1.2	<0.001	
Group1 Goals	33	2.5 \pm 2.4	28	6.8 \pm 1.5	25	6.9 \pm 1.3		0.37
Group2 Goals	40	2.4 \pm 2.2	40	6.5 \pm 1.9	36	7.3 \pm 1.0		
Other Goals (e.g. weight management, improving social activities)								
Total Survivor Goals	16	0.8 \pm 2.2	15	4.2 \pm 2.8	13	5.2 \pm 3.2	<0.001	
Group1 Goals	7	1.9 \pm 3.2	6	4.2 \pm 3.4	5	5.2 \pm 3.6		0.24
Group2 Goals	9	0.0 \pm 0.0	9	4.2 \pm 2.4	8	5.1 \pm 3.2		

Note: Self rated goals are measured on a likert scale from 0- 8, where 0 is no success and 8 is complete success.
¹Using a mixed effects model with time and time x Group as fixed effects and the subject as a random effect

Figure 2A-2C: Changes in Self-rated Physical Activity, Nutrition and Other Goal Scores over the 12 week Intervention

Figure Legend: Mean (95% CI) changes in scores over the 12 week intervention for physical activity, nutrition and other goals.





Quality of Life

For functioning domains of the EORTC QLC c30 scale, where higher scores equal better functioning, changes in QOL measures of emotional functioning showed a non-statistically significant improvement ($p=0.031$) for the total sample, and global health, physical functioning and social functioning also showed non-statistically significant improvements for Group2. Group2's global health status increased clinically from a mean (\pm SD) of 71.53 (\pm 17.57) at baseline to 83.33 (\pm 11.24) at 12 weeks ($p=0.023$). Group1 showed clinically significant physical functioning decline between baseline and 6 weeks, and baseline and 12 weeks (87.41, 77.04 and 75.56 respectively). For symptom domains, where higher scores equal worse symptoms, Group1 had clinically significant increases for dyspnoea, with more variable patterns in global, functional and other symptom scores observed. Unfavourable trends in physical and social functioning and fatigue, insomnia and diarrhoea symptoms were witnessed, although not significant. Within these symptom domains, Group1 showed clinically significant worsening of insomnia between week 6 and week 12 (40.74 and 55.56 respectively) and worsening of fatigue between baseline and 12 weeks (39.51 and 51.85 respectively) (See Table 4).

Table 4: Descriptive Statistics for Quality of Life Scores at Baseline, 6 and 12 weeks

	N	Baseline Mean	SD	N	6 Weeks Mean	SD	N	12 Weeks Mean	SD	p Value
Global health status										
Total Survivors	21	66.67	21.89	21	65.87	25.8	21	72.62	21.43	0.059
Group1	9	60.19 ^a	26.28	9	50 ^a	229.17	9	58.33	23.94	0.374
Group2	12	71.53 ^a	17.57	12	77.78	15.21	12	83.33 ^a	11.24	0.023
Physical Functioning										
Total Survivors	21	88.89	10.61	21	86.98	15.27	21	86.67	17.51	0.778
Group1	9	87.41 ^{ab}	9.69	9	77.04 ^{ax}	17.67	9	75.56 ^{bz}	21.34	0.164
Group2	12	90 [†]	11.54	12	94.44 ^x	7.43	12	95 ^{tz}	7.03	0.050
Role Functioning										
Total Survivors	21	74.6	28.68	21	74.6	31.01	21	77.78	22.57	0.827
Group1	9	62.96	29.79	9	53.7 [€]	35.14	9	59.26 [£]	16.9	0.626
Group2	12	83.33	25.62	12	90.28 [€]	15.01	12	91.67 [£]	15.08	0.531

Emotional Functioning										
Total Survivors	21	79.31	21.81	21	71.11 ^{af}	25.97	21	82.62 ^{af}	13.73	0.031
Group1	9	76.55 ^a	16.79	9	62.04 ^{ab}	31.21	9	76.85 ^b	13.68	0.241
Group2	12	81.39	25.47	12	77.92	20	12	86.94	12.61	0.149
Cognitive functioning										
Total Survivors	21	79.37	18.93	21	76.19	23.9	21	79.37	20.35	0.617
Group1	9	70.37 ^a	20.03	9	59.26 ^{ab}	25.15	9	66.67 ^b	22.05	0.508
Group2	12	86.11	15.62	12	88.89 ^b	12.97	12	88.89 ^b	12.97	0.751
Social Functioning										
Total Survivors	21	70.64	23.51	21	74.6	29.16	21	76.98	28.61	0.602
Group1	9	62.96	23.24	9	53.7 ^p	27.36	9	55.56 ^o	27.64	0.802
Group2	12	76.39 ^{ab}	22.98	12	90.28 ^{ab}	19.41	12	93.06 ^{bo}	16.6	0.037
Fatigue										
Total Survivors	21	32.27	20.46	21	30.68	21.35	21	33.32	24.35	0.282
Group1	9	39.51 ^a	15.82	9	44.44 ^y	15.71	9	51.85 ^{ah}	22.22	0.237
Group2	12	26.84	22.46	12	20.36 ^y	19.44	12	19.43 ^{hu}	15.07	0.222
Nausea and Vomiting										
Total Survivors	21	6.35	11.15	21	7.14	9.96	21	3.97	7.27	0.386
Group1	9	12.96 ^λ	13.89	9	12.96 ^τ	11.11	9	7.4	8.78	0.571
Group2	12	1.39 ^λ	4.81	12	2.78 ^τ	6.49	12	1.39	4.81	0.647
Pain										
Total Survivors	21	21.43	24.23	21	18.25	16.59	21	15.08	18.18	0.272
Group1	9	31.48	28.19	9	27.78 ^ξ	14.43	9	29.63 ^φ	18.22	0.927
Group2	12	13.89	18.58	12	11.11 ^ξ	14.79	12	4.17 ^φ	7.54	0.353
Dyspnoea										
Total Survivors	21	12.7 ^a	19.65	21	22.22	32.2	21	25.4 ^a	25.61	0.131
Group1	9	14.81 ^{ab}	17.57	9	44.44 ^{ay}	33.33	9	44.44 ^{bt}	23.57	0.026
Group2	12	11.11	21.71	12	5.56 ^λ	19.25	12	11.11 ^{tz}	16.41	0.348
Insomnia										
Total Survivors	21	33.33	36.51	21	28.57	28.45	21	36.51	33.17	0.259
Group1	9	48.15	44.44	9	40.74 ^a	32.39	9	55.56 ^{aA}	33.33	0.407
Group2	12	22.22	25.95	12	19.44	22.29	12	22.22 ^A	25.94	0.606
Appetite Loss										
Total Survivors	21	14.29	16.9	21	14.29	19.92	21	11.11	19.24	0.609
Group1	9	22.22	16.67	9	18.52	24.22	9	18.52	24.22	0.853
Group2	12	8.33	15.08	12	11.11	16.41	12	5.56	12.97	0.237
Constipation										
Total Survivors	21	17.46	20.05	21	12.7	24.67	21	15.87	29.1	0.650
Group1	9	25.93	22.22	9	22.22	33.33	9	22.22	37.27	0.962
Group2	12	11.11	16.41	12	5.56	12.97	12	11.11	21.71	0.402
Diarrhoea										
Total Survivors	21	6.35	13.41	21	9.52	18.69	21	7.94	17.97	0.736
Group1	9	14.81 ^y	17.57	9	22.22 ^z	23.57	9	18.52 ^ξ	24.22	0.764
Group2	0	0 ^y	0	0	0 ^z	0	0	0 ^ξ	0	-
Financial difficulties										
Total Survivors	21	28.57	33.81	21	25.4	36.37	21	25.4	34.81	0.629
Group1	9	37.04	38.89	9	37.04	42.31	9	37.04	42.31	1.000
Group2	12	22.22	29.59	12	16.67	30.15	12	16.67	26.6	0.402

Matched symbols (e.g., #) indicate statistically significant difference between pairs and matched letters (e.g. aa) indicate a clinically significance difference as defined as a 10 point difference in functioning scores (Osaba et al 1998).

Acceptability and Feasibility

On average, 21 (84%) participants who completed the final survey found the FLW Program acceptable or totally acceptable. Twenty-one participants (84%) found the P&G acceptable or very acceptable, stating that they could tailor it to their needs. Of those that did not find these tools acceptable, three participants (12%) had withdrawn from the trial and one participant's data (4%) was incomplete. Participants' levels of engagement with each of the FLW Program tools suggests that goal setting was particularly feasible for cancer survivors, particularly nutrition goals. Their full participation in completing the FLW scale (which assessed their self-management capabilities) across all intervention time points also suggests that this tool is convenient and feasible for use with this population. Further survey outcomes are not reported here.

Discussion

Our study demonstrated that cancer survivors, in the active phase of treatment or later in their cancer treatment trajectory, found the FLW Program acceptable as a means of helping them to develop and achieve their nutrition and physical activity goals. High levels of acceptability of the Flinders ProgramTM tools have been found in other studies.³²⁻³⁴

Many participants rated their baseline risk factor self-management capacity as relatively good across the LWS domains. This differs from baseline ratings of self-management capacity commonly observed in studies of populations with existing chronic diseases.³²⁻³⁴ In those studies, physical and psychosocial impacts are particularly challenging and often rated poorly. This is likely because of the longstanding nature of chronic disease and its insidious capacity to impact negatively on the individual's resources and supports over time, and also because multiple comorbidities can make self-management challenging.⁴³ Cancer, on the other hand, may affect those with no other chronic conditions prior to the cancer diagnosis. The support networks of cancer sufferers may even improve as a result of the cancer diagnosis, and they have been shown as important for survivorship.⁴⁴

Many participants did not want to set problems, and our findings showed that, for participants with complete data on their problem rating, their problem did not change over time. Likely reasons for this are the short 12-week time period, the nature of the population and the context of their cancer treatment stage in which we would not expect problems related to nutrition and physical activity to improve. However, they appeared more motivated to talk about goals. This may be related to the journey many cancer survivors take as part of discovering they have cancer and fortifying themselves to fight it⁴⁵ Unlike chronic conditions, which require

accommodations⁴⁶ and 'living with' and addressing problems as they arise as part of long-term self-management,^{31,47} cancer is something we are socialised to see as 'fighting' and 'surviving'. This is an important distinction, with significant implications for how cancer as a chronic disease is perceived.⁴⁸

As confirmed in the results, participants found goal setting acceptable because it remained flexible to their real world experience and needs, and was not rigid or with artificially imposed timeframes for achievement (i.e. participants were able to achieve their goals at their own pace). Participants were also more inclined to set nutrition goals than physical activity goals, suggesting that they felt more able or willing to work towards nutrition goals at these stages of their cancer treatment. In addition, more nutrition goals were worked on continuously over the total intervention period than physical activity goals (72% and 46% respectively). Reasons for this are unclear and require further investigation.

When considering differences between groups, the post chemotherapy group (Group2) did better generally and reported better quality of life. Worsening physical functioning related to problems with dyspnoea, insomnia and fatigue in Group1 would be expected, given participants in this group were in the active phase of chemotherapy treatment. Despite this, those currently receiving chemotherapy appeared to benefit also from early intervention to promote healthy lifestyle self-management. The results indicate that there is value in starting self-management support during the active phase of treatment with curative intent. Davies and Bateup⁴⁹ argue that conversations with patients about self-management need to begin at point of diagnosis, as part of a collaborative, empowering and interactive relationship between patient & healthcare provider. They also argue that there needs to be a shift in perception by clinicians from expert to enabler, and by patients from passive recipients to active participants in their care. This is similarly argued in the chronic disease area.⁴⁷ However, self-management is more than just knowledge acquisition. Supporting patients' self-efficacy or confidence to self-manage is one of the most important roles that clinicians can play because it is one of the most significant personal attributes affected after cancer diagnosis, treatment and survivorship.^{26,49} Self-management support tools such as the FLW Program appear to be acceptable and feasible for use with this population.

This study involved a small sample. Most participants were women with breast cancer. We cannot be certain whether this was due to recruitment bias, their greater motivation or willingness to participate compared to people with other cancer types, or some other reason. Oncologists and cancer care coordinators at the centre from which participants were recruited serve patients with a wide range of cancer diagnoses. Further research is needed to investigate potential gender differences and acceptability and feasibility for patients with different

cancer types. People with more comorbidity might have chosen not to participate, due to issues related to health literacy, but also potential burden of tasks that the cancer patient is facing where these issues may take a lower priority. Also, the study involved an intervention tailored to the needs of the individual and thus was delivered in diverse settings by a diverse range of providers. This approach introduces the variability of the delivery of interventions which may impact on efficacy but at the same time facilitates adaptation to different settings and is fundamental to the tailored approach. Participants were specifically encouraged to set physical activity and nutrition goals; whereas, the spirit of self-management within chronic condition management is for the patient to freely determine their goals. Further research using an RCT design, with a larger sample, with intervention occurring over a longer time period and more rigorous protocols for data collection is needed. Further translational research is also needed to determine acceptability, feasibility, enablers and barriers for clinicians embedding this approach into routine cancer survivorship care.

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Appendix 1: Study Interventions and Measures

Assessments
<p>Dietary assessment: pPerformed by qualified dietitian (SZ), based on nationally recognised guidelines, involving anthropomorphic, biochemical, clinical, dietary and social measures. Taken at baseline, including a dietary history, then at 6 and 12 weeks:</p> <ul style="list-style-type: none">- 24 hour dietary recall- Body measures (including height, weight and, waist circumference)- DEXA Scan <p>Physical assessment: b Based on the Nutrition and Exercise Guidelines for Cancer Survivors, performed by a qualified dietitian (SZ) with support from a dietetics honours student. Taken at baseline, then at 6 and 12 weeks:</p> <ul style="list-style-type: none">- Sub-maximal exercise test (6 minute walk test on the treadmills)- Hand grip strength test <p>Self-Management Capabilities: pPerformed by a qualified dietitian (SZ); andwith collection of follow-up measures with support from a dietetics honours student. The Flinders Living Well Scale (LWS)</p> <ul style="list-style-type: none">- Baseline then at 6 and 12 weeks <p>Problems and Goals: The Problem and Goal Assessment (P&G)</p> <ul style="list-style-type: none">- Baseline then fortnightly telephone review of Likert-rated scores <p>Self-Management Care Plan Issues: The Cue and Response Interview (C&R) to determine priority issues for care plan The Living Well Care Plan</p> <p>Quality of Life: pPerformed by a qualified dietitian (SZ), with support from a dietetics honours student The EORTC-QLQ-c30⁴²</p> <ul style="list-style-type: none">- Baseline then at 6 and 12 weeks
Interventions to Support Goal Attainment
<p>Nutrition Goals: Ongoing counselling for all participants by a qualified dietitian (SZ), plus choice of 1 or more of the following strategies, also delivered by them:</p> <ul style="list-style-type: none">- Nutrition DVD tailored to each group. Group 1: those currently receiving chemotherapy. Group 2: patients following active treatment.- One-off group education session- Supermarket tour in the community <p>Physical Activity Goals: Exercise options designed by a qualified physiologist and tailored to the individual, based on assessment of physical assessment,. Ffacilitated by a qualified exercise scientist with additional cancer specific training. Options included a choice of 1 or more of the following strategies:</p> <ul style="list-style-type: none">- Supervised (hospital on-site gym 'Lift for Life Program' up to 3 times per week)- or Hhome-based aerobic and resistance (enabling safe repeat of the exercises in their own home or community-based gym of their choice)- Graded walking program- Rehabilitation yoga (available on-site once per week, by a qualified yoga instructor)- Plus provision of therabands (elastic exercise bands) to all participants to safely perform upper and lower body resistance exercises.
Post-Study Survey
<p>Acceptability of the trial assessments: p Performed by a qualified dietitian, with support from a dietetics honours student. (Likert-rated, where 1=totally unacceptable and 5=totally acceptable):</p> <ol style="list-style-type: none">1. Self-management

- Living Well ScalePartners in Health Survey
- Rating your pProblems and gGoals Assessment
- 2. Nutrition
 - Body measures (including height, weight, waist circumference)
 - DEXA Scan
 - 24 hour dietary recall
- 3. Physical Activity
 - Sub-maximal exercise test (6 minute walk test on the treadmills)
 - Hand grip strength test
 - Writing daily entries in ‘mMy personal goals and physical activity diary’
- 4. Overall
 - Time taken to attend all assessments
 - Any suggestions about how to improve the trial assessments

Level of agreement regarding the following statements on the self-management intervention (Likert-rated where 1=strongly agree and 5=strongly disagree):

1. The Flinders Living Well Self-Management Program helped me to identify factors that impact on me leading a healthy lifestyle.
2. The Flinders Living Well Self-Management Program gave me the opportunity to discuss identified issues relating to my risk factors and brainstorm strategies.
3. I felt my priorities were listened to as part of the completing the Flinders Living Well Self-Management Program.
4. I found the Flinders Living Well Self-Management Program useful in helping to identify my nutrition goals.
5. I found the Flinders Living Well Self-Management Program useful in helping to identify my physical activity goals.

Nutrition Interventions:

1. Resources used to help achieve nutrition goals
2. Acceptability of DVD – use, length, pace, content, educational value, perceived benefit (Likert-rated where 1=strongly agree and 5=strongly disagree)
3. Acceptability of dietary counselling and perceived benefit, perceived benefit of fortnightly telephone calls, and perceived benefit of 6 and 12 week nutrition assessment advice (Likert-rated where 1=strongly agree and 5=strongly disagree)
4. Potential barriers impacting on ability to achieve nutrition goals: – family commitments, work commitments, physical symptoms, mental health, lack of time, access to facilities, knowledge, cost (Likert-rated where 0=not applicable, 1=no effect and 5=very significant effect)
5. Suggestions for improvement of nutrition interventions

Physical Activity Interventions:

1. Resources used to help achieve physical activity goals
2. Acceptability of level of guidance to confidently and safely undertake exercise routine, perceived benefit of fortnightly telephone calls, and perceived benefit of 6 and 12 week assessments in helping to support physical activity goals (Likert-rated where 1=strongly agree and 5=strongly disagree)
3. Potential barriers impacting on ability to achieve physical activity goals: – family commitments, work commitments, physical symptoms, mental health, lack of time, access to facilities, knowledge, cost (Likert-rated where 0=not applicable, 1=no effect and 5=very significant effect)
4. Suggestions for improvement of physical activity interventions

Level of agreement regarding the following statements regarding the trial overall (Likert-rating scales 1-5 where 1=strongly agree and 5=strongly disagree):

1. Overall, I was satisfied with the Nutrition and Physical Activity trial.
2. The trial provided me with additional support throughout my treatment/recovery.
3. Participating in the trial was beneficial to my health and wellbeing.