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Health status and needs of cancer survivors and their caregivers: Routine evaluation of attendees at Sydney Survivorship Centre clinics and programmes

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Abstract:

Introduction:

The care of cancer survivors after primary adjuvant treatment is recognised as a distinct phase of the cancer journey. Recent research highlights the importance of lifestyle factors in treating symptoms, potentially decreasing the risk of a cancer recurrence, and modifying the risk of developing other chronic illnesses that are increased in the cancer population. Survivorship services aim to deliver care that addresses these issues.

Methods:

An observational, single centre study evaluating the physical and psychological health, symptoms, quality of life, and lifestyle (physical activity and nutrition) of early-stage cancer survivors attending the multidisciplinary Sydney Survivorship Clinic and of survivors (at any stage of the cancer journey) and caregivers participating in Sydney Survivorship Centre courses. Evaluation of patient satisfaction is also included.

Discussion:

This study will provide important information regarding the health status and needs of Australian cancer survivors, and the ability of the Survivorship Centre to address these needs. These data will shape the future direction of survivorship care in Australia and facilitate the design of interventions or measures to provide better quality of care to this patient population.

Strengths and Limitations:

Strengths:

-large, longitudinal follow up with comprehensive assessment of health and well-being of cancer survivors attending a multi-disciplinary Survivorship Centre post primary adjuvant treatment

Weaknesses:

- observational cohort study

- sample size determined by number of patients attending programme

Introduction

Until relatively recently the focus of cancer treatment and research was on the acute treatment of cancer and monitoring for disease recurrence. In 2005 the ground-breaking Institute of Medicine (IOM) Report "Lost in Transition" identified the substantial failure of current follow-up care to comprehensively address the needs of adult cancer survivors.[1] Through the IOM the distinct needs of adult cancer survivors have been recognised along with the importance of helping survivors live with the longer term physical, psychological, and practical effects of cancer and its treatment.[1]

By the broadest definition a person becomes a cancer survivor the moment they are diagnosed with cancer, a state that continues throughout the remainder of their life.[1] There are estimated to be more than 25 million cancer survivors worldwide, a number that is projected to increase rapidly due to our ageing population, improved screening leading to earlier detection of cancer, and improvements in cancer treatments.

Even cancer survivors with no evidence of disease recurrence, experience greater ongoing health problems than the general population. Cancer survivors are known to be at increased risk of cardiovascular disease, type II diabetes, metabolic syndrome, and osteoporosis, in addition to the risk of a cancer recurrence or a second primary cancer. [1-5] There are a number of identified lifestyle risk factors associated with cancer risk and recurrence, and the chronic diseases that accompany them. These lifestyle risk factors are modifiable and include obesity, physical inactivity, smoking, and inadequate fruit and vegetable intake.[6]

In an attempt to better address the needs of adult cancer survivors some cancer centres have established Survivorship Services, Centres, or Clinics. These services are designed to help survivors and their caregivers better manage their disease and any lasting effects of treatment, beyond the period of acute diagnosis and treatment.[5] In addition, many try to facilitate survivors enacting lifestyle changes to increase their physical activity and maintain a healthy weight, in order to aid recovery, improve health related quality of life (QOL), and possibly long-term survival.[7] Psychological support is an important feature of most programmes.

The IOM recommended, with support of a number of peak bodies including the American Society of Clinical Oncology (ASCO), that all cancer survivors transitioning from active to the post treatment phase should receive an individualised Treatment and Survivorship Care Plan (SCP).[1] This should include a summary of cancer treatment received, and recommendations regarding future clinical care and coordination, including the frequency and nature of surveillance based on the best available evidence. A number of SCP templates are freely available, including generic and disease specific templates from ASCO and Livestrong, which include information on potential late and long-term effects from the cancer and/or treatment(s). Despite recommendations from oncology organisations that SCP should be used, there is limited evidence that they improve long term outcomes for cancer survivors although survivor satisfaction with the SCP is generally high.[8]

The Sydney Survivorship Centre was established in September 2013 at the Concord Cancer Centre, in Sydney. It includes: i) a multi-disciplinary survivorship clinic for patients with localised cancer who have completed primary treatment with curative intent (e.g. surgery, chemotherapy, and radiation therapy) without evidence of cancer recurrence; and, ii) a range of programmes to support lifestyle change. At the initial

visit patients see a multi-disciplinary team (MDT) comprising a medical oncologist or haematologist, cancer nurse specialist, dietitian, clinical psychologist, and accredited exercise physiologist (AEP). Prior to attendance at each clinic, patients complete a number of questionnaires assessing symptoms, physical activity, diet, QOL and well-being, and are asked to fill in an evaluation after each clinic. Education regarding healthy lifestyle and encouragement to maintain a healthy weight are an important focus of every clinic. An individualised SCP is developed for each oncology patient. Approximately two thirds of survivors attend the clinic once and then return to their regular medical team for ongoing follow up. The remainder continue follow up through the Survivorship Clinic. On subsequent visits they see the medical oncologist and cancer nurse specialist specific to their tumour type, with referral to other health professionals as required.

In response to the high proportion of survivors who were overweight or obese, and the increasing evidence supporting obesity as a risk factor for cancer recurrence, [9] we established a weight management clinic focused on dietary modification, exercise and behavioural change for those with early stage solid tumours. The intervention was based on a recent systematic review that reported dietary modification involving restrictions of energy and fat intake, and promotion of exercise and behavioural changes were the key components for successful weight loss and maintenance.[10]

The Sydney Survivorship Centre opened the Survivorship Cottage in May 2014. The cottage is located in the grounds of the hospital, away from the main buildings, and surrounded by gardens and furnished in a homely manner. This is where the majority of the courses are held for cancer survivors at any stage of their cancer journey, and their caregivers, with a focus on healthy lifestyle and well-being. The Exercise and

Nutrition Routine Improving Cancer Health (ENRICH)[11] programme is a 6-week exercise and healthy eating course offered in collaboration with the Cancer Council New South Wales (NSW) and held regularly throughout the year. Other courses include: Mindfulness Meditation, Medical QiGong, yoga, acupuncture, music and art therapy, as well as scrap-booking, card making and individual one-off workshops. In addition we provide support groups and public fora on topics of interest to cancer patients and their caregivers and families.

Research is an integral component of the Survivorship Centre. Our major research aims to: (i) determine the health status, needs, symptoms, QOL and lifestyle characteristics of cancer survivors attending the Sydney Survivorship Clinic or participating in courses; (ii) evaluate changes over time in these variables, (iii) determine risk factors that may affect cancer survivors' clinical outcomes (e.g. metabolic syndrome, obesity, inactivity); (iv) evaluate patients' and/or their caregivers/family members' experience with services offered by the Sydney Survivorship Centre; and (v) evaluate the impact of the multidisciplinary team (MDT) approach in addressing cancer survivors' needs.

Methods and Patient Population

This is a single site, longitudinal study led by the Survivorship Research Group (SuRG), University of Sydney and the Sydney Survivorship Centre, Concord Cancer Centre. Ethics approval has been obtained from Concord Repatriation General Hospital Human Research Ethics Committee (HREC/14/CRGH/23). Patient reported outcome data are collected as part of standard care and for quality assurance. Patients attending clinics and courses at the Sydney Survivorship Centre are given the option of a tick box to "opt of out" if they do not wish their de-identified data to be used for

research purposes.

The Sydney Survivorship Centre (SSC) clinic commenced in September 2013 and courses were introduced gradually from this time.

Eligibility:

Medical oncology or haematology patients who have completed primary adjuvant treatment for early stage cancer and have no evidence of a cancer recurrence are eligible to attend the Survivorship Clinic. Breast cancer patients may be receiving hormonal treatment and/or targeted therapy such as trastuzumab. Figure 1 depicts the referral pathway.

Procedure:

Prior to attending the Survivorship clinic patients are sent a package containing printed Patient Reported Outcome (PRO) Questionnaires assessing symptoms, psychological well-being, distress, QOL, physical activity, dietary intake and performance status. They are asked to bring the completed questionnaires to their appointment. Those with incomplete questionnaires are asked to finalise them during the clinic visit. Patients with insufficient English or poor literacy skills can have assistance from a health translator, family members, or clinic staff during the clinic appointment.

Medical information and weight history are obtained from the medical record. Anthropometry (height and weight) is obtained at the initial visit by clinic staff. A SCP is prepared for oncology patients prior to their initial visit, by either the medical oncologist or registrar. This plan is refined with the patient after consultation with the

MDT members, and a copy posted to them after the clinic. Haematology patients receive a detailed letter from the haematologist with recommendations rather than a formal Survivorship care plan.

Patients are asked to complete an evaluation form after each clinic visit. In addition, those who have given verbal permission to be contacted subsequently will be asked to complete a satisfaction survey over the phone or in person to provide feedback on how useful the Survivorship Care Plan has been, how they used it, and if it has been revised. This will be approximately 6 months after their initial visit. A subset of patients will be invited to participate in a qualitative interview aimed to explore their experience of the survivorship service.

All patients and their caregivers attending the Survivorship Centre (SSC) courses are asked to complete questionnaires prior to commencing, and at the conclusion, of courses requiring more than one visit.

Measures:

Outcome measures used in this study are comprehensive assessments of patient self-report symptoms, QOL, distress, and lifestyle factors. The schedule of assessments and details of measures are outlined in Table 1.

Endpoints:

The global aim of this multi-faceted project is to evaluate the impact of the Sydney Survivorship Centre Clinic and Programmes on patients attending the clinic, and survivors and/or their caregivers participating in programmes. We aim to assess changes in the endpoints, stated below, over time:

Survivorship Clinic

- incidence and severity of symptoms that may be associated with cancer and/or treatment – as assessed by the Patient's Disease and Treatment Assessment Form[12]
- distress - as assessed by the Distress thermometer [13]
- quality of life as assessed by the FACT-G [14]
- physical activity and sedentary behaviour- as assessed by the Active Australia Exercise Questionnaire [15] and the Sitting Questionnaire [16] and AEP consultation.
- dietary intake and behaviour – as assessed by an in-house 3-day food diary and Food Questionnaire and dietitian consultation
- Eastern Co-operative Oncology Group Performance Status (ECOG Performance Status) [17]- as assessed by both clinician and participant
- Clinical assessments: medical and physical assessment by doctor and nurse; fear of cancer recurrence assessed by Clinical Psychologist, anthropometric assessment.
- Effectiveness of MDT in addressing survivors' needs measured by change in outcomes, e.g., QOL, sedentary behaviour, etc
- Use and effectiveness of Treatment and Survivorship Care Plan (SCP). To determine the incidence of patients attending the Survivorship Clinic who: receive a survivorship plan; are referred to other health professionals from clinic; use the SCP (e.g. show other health professionals, carry out the clinic recommendations). Whether patients found the SCP helpful, did it contain new information and suggestions for improvement.

- Clinical progress as determined by results of clinical examination, blood tests and/or imaging ordered as part of standard of care.
- Effectiveness of surveillance system: Total number of cases of recurrence of cancer
- Patients' experience with Sydney Survivorship Clinic

Specific SSC programmes:

Weight management programme:

- Facilitated and supervised by AEP and Dietitian
- attendance (number of enrolees, proportion completing programmes, reasons for non-attendance)
- QOL, symptoms, food intake, exercise behaviour, knowledge/practice and changes compared to baseline assessment
- Lifestyle outcomes: anthropometry measurements, vital signs, aerobic capacity and muscular strength - Week 0, 12, 26 and then 6 monthly until 2 years.
- blood results collected as part of standard of care
- patient experience as measured by a satisfaction survey and interview

See Appendix Table 1 for full details.

Mindfulness, QiGong, Yoga, Music therapy, Art therapy or similar courses:

- Attendance (number of enrolees, proportion completing programmes, reasons for non-attendance)
- Clinical outcomes: demographics, cancer diagnosis and treatment,
- Symptoms: assessed by the Patient's Disease and Treatment Assessment Form[12]
- Psychosocial outcomes (completed pre and post intervention):

QOL and fatigue assessed by the FACT-General (G) [14] and Fatigue (F) subscale [18]

Spiritual well-being assessed by the FACT-Spiritual [19] (for mindfulness, yoga medical Qigong, acupuncture and medical well-being courses)

Symptoms of anxiety and depression –assessed by the Hospital Anxiety and Depression Scale (HADS)[20]

Distress – assessed by the Distress Thermometer [13]

- ECOG performance status (patient rated) [17]
- Participant satisfaction questionnaire – at end of programme only

In-depth Qualitative exploration of patient experience:

Cancer survivors and/or caregivers/family members will be invited to participate in focus group(s) and/or interviews to provide in-depth feedback about their experience of SSC services, and information about unmet needs to guide the direction of the SSC clinic or programmes. Consenting individuals will attend a focus group meeting, a face-to-face interview, or a telephone interview with staff of the University of Sydney who are not involved in their clinical care.

Data analysis and statistical issues

The sample size will be determined by attendance of consenting patients at clinics and courses.

Data are entered into a specifically designed REDCap™ database. Simple descriptive methods will be used to report incidence and, where appropriate, severity of patient reported outcomes, physical activity, and dietary behaviour for cancer survivors. A comparison of change over time in symptoms and behaviours will be performed. Wherever comparisons are made 95% confidence intervals will be reported to enable readers to interpret the precision of the results reported.

Discussion:

Survivorship concerns are increasingly recognised as poorly addressed in many standard follow-up appointments. There is considerable debate and a lack of evidence regarding how best to follow up cancer survivors. Multi-disciplinary clinics have the capacity to provide holistic care with a focus on education concerning lifestyle issues, prevention of long term side effects and psychological well being; but they are resource intensive for staff.

A physically active lifestyle and healthy weight have been shown in observational studies to decrease the risk of common cancers and cancer recurrence. Studies have also shown that physical activity and healthy nutrition can improve symptoms associated with cancer treatment, and decrease the risk of chronic diseases that are commonly found in cancer survivors; including metabolic syndrome, obesity, type II diabetes, cardiovascular disease and osteoporosis.[21] Although a number of cancer organisations have published recommendations regarding exercise and weight, the majority of cancer patients are overweight or obese, and most do not meet the guidelines of 150 minutes/week of moderate intensity physical activity, two sessions of resistance exercise/week and minimising sedentary activities, despite the increasing evidence for benefit.[21 22] This suggests that cancer survivors require additional support and education to facilitate their instituting important lifestyle changes.

The Sydney Survivorship Centre has the potential to improve physical and psychological well-being and QOL for cancer survivors. This study will obtain unique data regarding the impact of a multi-disciplinary team Survivorship clinic for cancer patients who have completed primary adjuvant treatment, and evaluation of the courses offered by the Sydney Survivorship Centre for patients at any stage of the

cancer journey and their caregivers/family. This will help determine whether assessing health status, providing education and lifestyle programmes facilitates adoption and adherence to a healthy lifestyle, and whether this can lead to improvement in well-being. Further, it will evaluate the Survivorship care plans through usage in routine clinical practice, as well as gaining information about who uses the Sydney Survivorship Centre programmes, and patient (and caregiver) satisfaction with the clinic and courses.

Conclusions:

Survivorship services are expanding in Australia and globally. The Sydney Survivorship Centre is the only multidisciplinary clinic of its kind in Australia. This study will provide important information about the health status of Australian cancer survivors, and enable us to better understand the symptoms, lifestyle and risk factors of our patient population. This will facilitate the design of supportive measures or interventions to better address these issues.

Author Contributions:

J. Vardy: study concept and design, and writing of the protocol and manuscript.
C. Tan: study concept and design, and writing of the protocol and manuscript.
J. Turner: study concept and design, and writing of the protocol and manuscript.
H. Dhillon: study concept and design, and writing of the protocol and manuscript.

Competing Interests:
None of the authors have any conflicts of interest to declare.

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Data Sharing:
This is a protocol for a longitudinal study so unpublished data is not available for sharing.

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Data entry: Erika Jungfer and Loraine Fong.

Figure Legend

Figure 1 Referral pathway through the Sydney Survivorship Clinic, centre and courses

Table 1 Schedule of assessments for patients attending the Sydney Survivorship Clinic or participating in Sydney Survivorship Centre courses:

a) Sydney Survivorship Clinic

	Assessment	Initial visit	Follow Up*
	Demographics and cancer/ cancer treatment characteristics	X	
	Clinical examination	X	X
	Anthropometry • Weight • Weight history	 X X	 X
	Blood tests: As per standard of care e.g. colorectal cancer survivors: CEA every 3 months Other blood tests only as clinically indicated	X	X
	Imaging/Procedures: As per ASCO guidelines Breast cancer: Mammogram and/or breast ultrasound annually. Colorectal cancer: CT chest/abdomen/pelvis annually for 5 years. Colonoscopy: 1 year after diagnosis then 1-2 yearly dependent on result Results of other procedures as ordered by oncology team as part of standard of care.	X	X
Patient Reported Outcomes	Distress (Distress Thermometer) [13]	X	X
	Symptoms (Patient's Disease and Treatment Assessment Form)[12]	X	X
	Sedentary time (Sitting Questionnaire) [16]	X	X*
	Physical activity (Active Australia Questionnaire) [15]	X	X*
	3-day food diary and food questionnaire	X	X*
	Quality of Life questionnaire (FACT-G) [14]	X	X*
	ECOG performance status [17]	X	X
Evaluation	SSC Feedback Questionnaire	X	
	SSC Satisfaction survey		X
	Treatment and Survivorship Plan evaluation		X*

*Follow up will be individualised depending on tumour type and stage of disease but will generally be every 3-6 months. With the exception of the distress thermometer, Patients Disease and Treatment assessment form and the self-rated performance status, questionnaires will not be completed more frequently than every 6 months.

b) Courses for Sydney Survivorship Centre

Assessment	**Initial Visit**	**Conclusion of Programme**
Baseline demographics and disease characteristics	X	
Questionnaires:		
• FACT-G [14]	X	X
• FACT-fatigue (F) subscale [18]	X	X
• FACT Spirituality (Sp) subscale* [19]	X	X
• Patient's Disease and Treatment Assessment Form[12]	X	X
• Distress Thermometer [13]	X	X
• Hospital Anxiety and Depression Scale (HADs) [20]	X	X
Participant evaluation	X	X

* Only for Medical Qigong, yoga, mindfulness, acupuncture and music and well-being

SSC = Sydney Survivorship Centre
CEA = Carcinoembryonic Antigen; ASCO= American Society of Clinical Oncology; FACT = Functional Assessment of Cancer Therapy (G= general; F= Fatigue; Sp = spirituality)

Appendix Table 1 - Schedule of assessments for patients attending the Sydney Survivorship "Weight Management Course"

Assessment	Baseline	3 Month	6 Month	12 Month
Baseline demographics and disease characteristics, weight history	X			
Clinical examination (accredited exercise physiologist, dietitian, physician)	X	X	X	X
Body Composition Bioimpedance analysis, skinfold measures, girth measures, BMI	X	X		
DEXA scan (where appropriate)	X			X
Fasting blood tests FBC, EUC, LFT, glucose, lipids, iron studies, sex hormones, vitamin D, vitamin B12, TSH, IGF-1, CRP, albumin Other bloods as appropriate when ordered as standard of care	X	X	X	X
Physical Function 6MWT and/or Graded Sub-maximal Exercise Test; Maximal 1-RM leg press; Hand grip dynamometry	X	X	X	X
Nutritional Status 3-day weighed food diary	X	X	X	X
Patient Reported Outcomes • IPAQ-sf [15] • EORTC-QLQ-C30 [23] • FACT-F 13-item subscale [18] • Patient's Disease and Treatment Assessment Form [12] • Distress Thermometer [13] • Hunger Visual Analogue Scale [24]	X	X	X	X
Physical Activity Behaviour 7-day Actigraph GT1M accelerometers	X		X	X
Participant program evaluation; semi-structured interviews			X	
Adverse Events (CTCAE V4) [25]		X	X	X

BMI= Body mass index
EORTC-QLQC30 = The European Organisation for Research and Treatment of Cancer

FBC = full blood count; EUC = electrolytes, urea, creatinine; LFT = liver function tests ; TSH = Thyroid stimulating hormone; IGF-1 = Insulin-like growth factor -1; CRP = C-reactive protein
6MWT= six-minute walk test; 1-RM=one repetition maximum
IPAQ-sf=International Physical Activity Questionnaire – short form
EORTC QLQ-C30= The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire
FACT-F = Functional Assessment of Cancer Therapy (F= Fatigue)
CTCAE= common terminology criteria for adverse event

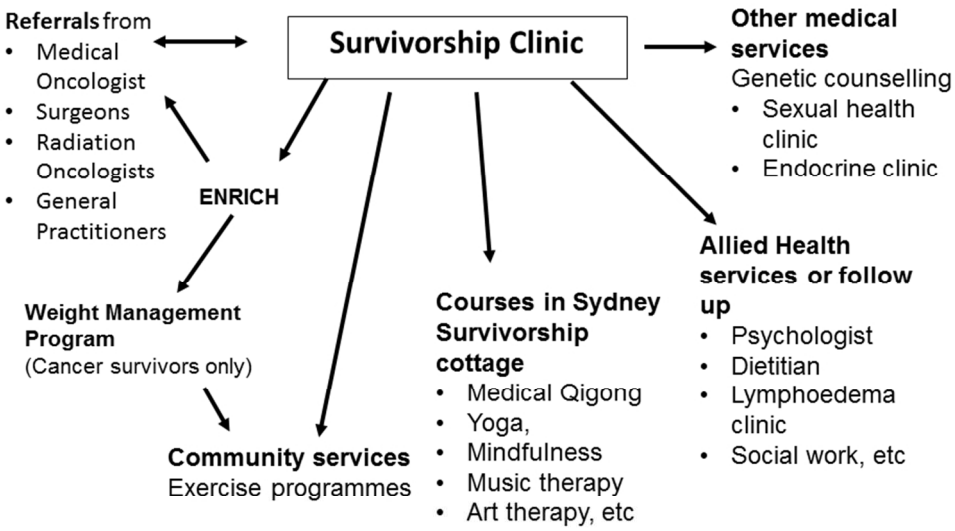

Figure 1 Referral pathway
Figure 1 Referral pathway
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The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	___Survivorship Clinic p_5-6, 8-_____ Courses p.6-7	____Protocol paper_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	p._4-7__	_____
	WHAT		
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).	Questionnaires_ p.10___	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_p. 4-9	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	p.5-6__	_____
	HOW		
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.	____p.8____	_____

	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	p. 7-8	_____
	WHEN and HOW MUCH		
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.	_p.7-12__	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	__p.7-12_	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_N/A_____ ___	_____
	HOW WELL		
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.	____N/A_____ ___	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	__N/A_____	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† 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.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the

TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist

BMJ Open

Health status and needs of cancer survivors attending the Sydney Survivorship Centre clinics and programmes: A protocol of a longitudinal study

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Health status and needs of cancer survivors attending the Sydney Survivorship Centre clinics and programmes: A protocol of a longitudinal study

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Abstract:

Introduction:

The care of cancer survivors after primary adjuvant treatment is recognised as a distinct phase of the cancer journey. Recent research highlights the importance of lifestyle factors in treating symptoms, potentially decreasing risk of a cancer recurrence, and modifying the risk of developing other chronic illnesses that are increased in the cancer population. Survivorship services aim to deliver care that addresses these issues. The overall aims are to determine the health status of cancer survivors and evaluate the services offered by the Sydney Survivorship Centre.

Methods and analysis:

An observational, single centre study evaluating the longitudinal physical and psychological health, symptoms, quality of life, and lifestyle (physical activity and nutrition) of early-stage cancer survivors attending the multidisciplinary Sydney Survivorship Clinic and of survivors (at any stage of the cancer journey) and caregivers participating in Sydney Survivorship Centre courses. Evaluation of patient satisfaction is included. Patient reported outcomes and patient characteristics will be summarised using descriptive statistics with Spearman rank sum correlation coefficients to determine associations between patient-reported outcomes. Regression modelling may be used to further evaluate associations and to investigate risk factors and predictors of health outcomes. Qualitative data will be analysed using thematic analysis to identify themes. Sample size will be determined by attendance of consenting patients at clinics and courses.

Ethics and dissemination:

The study has received ethics approval from the Concord Repatriation General Hospital Human Research Ethics Committee (HREC/14/CRGH/23). The results will be published and presented at appropriate conferences.

This study will provide important information regarding the health status and needs of Australian cancer survivors, and the ability of the Survivorship Centre to address these needs. These data will shape the future direction of survivorship care in Australia and facilitate the design of interventions or measures to provide better quality of care to this patient population.

Introduction

Until relatively recently the focus of cancer treatment and research was on the acute treatment of cancer and monitoring for disease recurrence. In 2005 the ground-breaking Institute of Medicine (IOM) Report "Lost in Transition" identified the substantial failure of current follow-up care to comprehensively address the needs of adult cancer survivors.[1] Through the IOM the distinct needs of adult cancer survivors have been recognised along with the importance of helping survivors live with the longer term physical, psychological, and practical effects of cancer and its treatment.[1]

By the broadest definition a person becomes a cancer survivor when they are diagnosed with cancer, a state that continues throughout the remainder of their life.[1] There are estimated to be more than 25 million cancer survivors worldwide, a number that is projected to increase rapidly due to our ageing population, improved screening leading to earlier detection of cancer, and improvements in cancer treatments.

Even cancer survivors with no evidence of disease recurrence experience greater ongoing health problems than the general population. Cancer survivors are known to be at increased risk of cardiovascular disease, type II diabetes, metabolic syndrome, and osteoporosis, in addition to the risk of a cancer recurrence or a second primary cancer. [1-5] There are a number of identified lifestyle risk factors associated with cancer risk and recurrence, and the chronic diseases that accompany them. These lifestyle risk factors are modifiable and include obesity, physical inactivity, smoking, and inadequate fruit and vegetable intake.[6]

In an attempt to better address the needs of adult cancer survivors some cancer centres have established Survivorship Services, Centres, or Clinics. These services are

designed to help survivors and their caregivers better manage their disease and any lasting effects of treatment, beyond the period of acute diagnosis and treatment.[5] In addition, many try to facilitate survivors enacting lifestyle changes to increase their physical activity and maintain a healthy weight, in order to aid recovery, improve health related quality of life (QOL), and possibly long-term survival.[7] Psychological support is an important feature of most programmes, and may include psycho-oncology consultations with a clinical psychologist to manage specific concerns such as fear of cancer recurrence, anxiety, or depression, general or disease specific support groups, or counselling support from allied health professionals.[8 9]

The IOM recommended, with support of a number of peak bodies including the American Society of Clinical Oncology (ASCO), that all cancer survivors transitioning from active to the post treatment phase should receive an individualised Treatment and Survivorship Care Plan (SCP).[1] This should include a summary of cancer treatment received, and recommendations regarding future clinical care and coordination, including the frequency and nature of surveillance based on the best available evidence. A number of SCP templates are freely available, including generic and disease specific templates from ASCO and Livestrong, which include information on potential late and long-term effects from the cancer and/or treatment(s). Despite recommendations from oncology organisations that SCP should be used, there is limited evidence that they improve long term outcomes for cancer survivors although survivor satisfaction with the SCP is generally high.[10]

The Sydney Survivorship Centre was established in September 2013 at the Concord Cancer Centre, in Sydney. It includes: i) a multi-disciplinary survivorship clinic for patients with localised cancer who have completed primary treatment with curative intent (e.g. surgery, chemotherapy, and radiation therapy) without evidence of cancer

recurrence; and, ii) a range of programmes to support lifestyle change. At the initial clinic visit patients see a multi-disciplinary team (MDT) comprising a medical oncologist or haematologist, cancer nurse specialist, dietitian, clinical psychologist, and accredited exercise physiologist (AEP). Prior to attendance at each clinic, patients complete a number of questionnaires assessing symptoms, physical activity, diet, QOL and well-being, and are asked to fill in an evaluation after each clinic. Education regarding healthy lifestyle and encouragement to maintain a healthy weight are an important focus of every clinic. An individualised SCP is developed for each oncology patient.

Approximately two thirds of survivors attend the clinic once and then return to their regular medical team for ongoing follow up. At the request of the caring team, the remainder continue follow up through the Survivorship Clinic. On subsequent visits they see the medical oncologist and tumour specific nurse specialist, with referral to other health professionals and/or programmes as required.

In response to the high proportion of survivors who were overweight or obese, and the increasing evidence supporting obesity as a risk factor for cancer recurrence, [11] we established a weight management clinic focused on dietary modification, exercise and behavioural change for those with early stage solid tumours, who have a body mass index (BMI) >25. The intervention was based on a recent systematic review that reported dietary modification involving restrictions of energy and fat intake, and promotion of exercise and behavioural changes were the key components for successful weight loss and maintenance.[12]

The Sydney Survivorship Centre opened the Survivorship Cottage in May 2014. The cottage is located in the grounds of the hospital, away from the main buildings, and

surrounded by gardens and furnished in a homely manner. This is where the majority of the courses are held for cancer survivors at any stage of their cancer journey, and their caregivers, with a focus on healthy lifestyle and well-being. The Exercise and Nutrition Routine Improving Cancer Health (ENRICH)[13] programme is a 6-week exercise and healthy eating course offered in collaboration with the Cancer Council New South Wales (NSW) and held regularly throughout the year. Other courses include: Mindfulness Meditation, Medical QiGong, yoga, acupuncture, music and art therapy, including scrap-booking, card making, floral design as well as individual one-off workshops. Courses are selected based on some level of evidence for their efficacy in cancer survivors.[14-20] The courses are offered weekly for 10 weeks coinciding with school terms, with 4 terms each year. Commitment to a full term is required. In addition we provide support groups and public fora on topics of interest to cancer patients and their caregivers and families.

In keeping with the ASCO guidelines,[5] research is an integral component of the Survivorship Centre. The major research aims of the centre are to: (i) determine the health status, needs, symptoms, QOL and lifestyle characteristics of cancer survivors attending the Sydney Survivorship Clinic or participating in courses; (ii) evaluate changes over time in these variables; (iii) determine risk factors that may affect cancer survivors' clinical outcomes (e.g. metabolic syndrome, obesity, inactivity); (iv) evaluate patients' and/or their caregivers/family members' experience with services offered by the Sydney Survivorship Centre; and (v) evaluate the multidisciplinary team (MDT) approach in addressing cancer survivors' needs.

Methods and Analysis

This is a single site, longitudinal study led by the Survivorship Research Group

(SuRG), University of Sydney and the Sydney Survivorship Centre, Concord Cancer Centre. Patient reported outcome data are collected as part of standard care and for quality assurance.

Sydney Survivorship Clinic:

The Sydney Survivorship Centre (SSC) clinic commenced in September 2013.

Eligibility:

Medical oncology or haematology patients who have completed primary adjuvant treatment for early stage cancer and have no evidence of a cancer recurrence are eligible to attend the Survivorship Clinic. Breast cancer patients may be receiving hormonal treatment and/or targeted therapy such as trastuzumab. Figure 1 depicts the referral pathway.

Procedure:

Prior to attending the Survivorship clinic patients are sent a package containing printed Patient Reported Outcome (PRO) Questionnaires assessing symptoms, psychological well-being, distress, QOL, physical activity, dietary intake and performance status. They are asked to bring the completed questionnaires to their appointment. Those with incomplete questionnaires are asked to finalise them during the clinic visit. Patients with insufficient English or poor literacy skills can have assistance from a health translator, family members, or clinic staff during the clinic appointment.

Medical information and weight history are obtained from the medical record. Anthropometry (height and weight) is obtained at the initial visit by clinic staff. A

SCP is prepared for oncology patients prior to their initial visit, by either the medical oncologist or registrar. This plan is refined with the patient after consultation with the MDT members, and a copy posted to them after the clinic. Haematology patients may receive a detailed letter from the haematologist with recommendations rather than a formal Survivorship care plan.

Patients are asked to complete an evaluation form after each clinic visit. In addition, those who have given verbal permission to be contacted subsequently will be asked to complete a satisfaction survey over the phone or in person to provide feedback on how useful the Survivorship Care Plan has been, how they used it, and if it has been revised. This will be approximately 6 months after their initial visit. A subset of patients will be invited to participate in a qualitative interview to explore, in depth, their experience of the survivorship service.

Sydney Survivorship Courses:

The courses were gradually introduced from 2014.

Eligibility:

Posters advertising the programmes are displayed in the Concord Cancer Centre waiting areas. Patients with any stage cancer are able to self-refer to participate in Survivorship courses. Concord Cancer Centre patients receive priority for courses, but patients from surrounding hospitals are able to attend if space permits. Carers can accompany a patient and participate if space permits.

Measures used for Survivorship Clinic and Courses:

Outcome measures used in this study are comprehensive assessments of patient self-report symptoms, QOL, distress, and lifestyle factors. The schedule of assessments and details of measures are outlined in Table 1.

Endpoints:

The global aim of this multi-faceted project is to evaluate the Sydney Survivorship Centre Clinic and Programmes. We aim to assess changes in the endpoints, stated below, over time:

Survivorship Clinic

- incidence and severity of symptoms that may be associated with cancer and/or treatment – as assessed by the Patient's Disease and Treatment Assessment Form.[21] This is a 48 item questionnaire assessing symptoms with responses ranging from 0 – 10 (no trouble at all to worst I can imagine) over the previous month.
- distress - as assessed by the Distress thermometer. [22] This asks participants to rate their level of distress over the previous week from 0 – 10 (no distress to extreme distress).
- quality of life as assessed by the FACT-G. [23] This 27-item questionnaire assesses physical, social, emotional and functional well-being over the previous week, with ratings from 0 – 4 (not at all to very much).
- physical activity and sedentary behaviour- as assessed by the Active Australia Exercise Questionnaire [24] and the Sitting Questionnaire [25] and AEP consultation. Active Australia is a 4-item questionnaire evaluating the time spent performing physical activity and the intensity of the activity in the

previous week. The Sitting questionnaire is a 2-item questionnaire assessing the time usually spent sitting, on a weekday and on a weekend.

- dietary intake and behaviour – as assessed by an in-house 3-day food diary and Food Questionnaire, and dietitian consultation. The 4-item Food Questionnaire assesses changes made to diet since a cancer diagnosis/treatment, average number of serves of fruit, vegetables, dairy and soft drinks daily, and alcohol intake.
- Eastern Co-operative Oncology Group Performance Status (ECOG Performance Status) [26]- as assessed by both clinician and participant.
- Clinical assessments: medical and physical assessment by doctor and nurse; fear of cancer recurrence assessed by Clinical Psychologist, anthropometric assessment.
- Effectiveness of MDT in addressing survivors' needs measured by change in outcomes, e.g., QOL, sedentary behaviour, etc
- Use and effectiveness of Treatment and Survivorship Care Plan (SCP). To determine the incidence of patients attending the Survivorship Clinic who: receive a survivorship plan; are referred to other health professionals from clinic; use the SCP (e.g. show other health professionals, carry out the clinic recommendations). Whether patients found the SCP helpful, did it contain new information and suggestions for improvement.
- Clinical progress as determined by results of clinical examination, blood tests and/or imaging ordered as part of standard of care.
- Effectiveness of surveillance system: Total number of cases of cancer recurrence and disease-free survival.

- Patients' experience with Sydney Survivorship Clinic, developed by the authors, asking patients to rate how useful the session with each member of the multidisciplinary team was, and how well their questions were answered. They also rate how worthwhile it was attending the clinic and give reasons for their answer, and comment on the length and timing of the clinic in their cancer journey. Finally they are asked whether they would recommend the clinic to others and any additional information or services they would have liked to receive.

Specific SSC programmes:

Weight management programme:

- Facilitated and supervised by AEP and Dietitian.
- Eligibility: BMI >25; attendance at Sydney Survivorship Clinic, completion of the ENRICH 6 week lifestyle programme.
- attendance (number of enrolees, proportion completing programmes, reasons for non-attendance).
- QOL, symptoms, food intake, exercise behaviour, knowledge/practice and changes compared to baseline assessment.
- Lifestyle outcomes: anthropometry measurements, vital signs, aerobic capacity and muscular strength - Week 0, 12, 26 and then 6 monthly until 2 years.
- blood results collected as part of standard of care.
- patient experience as measured by a satisfaction survey and interview.

See Appendix Table 1 for full details.

Mindfulness, QiGong, Yoga, Music therapy, Art therapy or similar courses:

- Attendance (number of enrolees, proportion completing programmes, reasons for non-attendance)

- Clinical outcomes: demographics, cancer diagnosis and treatment,
- Symptoms: assessed by the Patient's Disease and Treatment Assessment Form[21]
- Psychosocial outcomes (completed pre and post intervention):

  QOL and fatigue assessed by the FACT-General (G) [23] and 13-item Fatigue (F) subscale [27]

  Spiritual well-being assessed by the 12-item FACT-Spiritual [28] (for mindfulness, yoga medical Qigong, acupuncture and medical well-being courses)

  Symptoms of anxiety and depression –assessed by the Hospital Anxiety and Depression Scale (HADS)[29]

  Distress – assessed by the Distress Thermometer [22]
- ECOG performance status (patient rated) [26]
- Participant satisfaction questionnaire – at end of programme only

<u>In-depth Qualitative exploration of patient experience:</u>

Cancer survivors and/or caregivers/family members will be invited to participate in focus group(s) and/or interviews to provide in-depth feedback about their experience of SSC services, and information about unmet needs to guide the direction of the SSC clinic or programmes. Both focus groups and telephone interviews are offered to ensure maximum access for individual participants via these flexible options. Consenting individuals will attend a focus group meeting, a face-to-face interview, or a telephone interview with staff of the University of Sydney who are not involved in their clinical care. All interviews are semi-structured, following an ethics approved interview guide developed for the clinic and each programme.

To monitor changing experiences of the clinic over time, groups of attendees will be purposively sampled periodically on the basis of their disease group, side effect profile, and the programmes attended.

Qualitative data will be transcribed verbatim and analysed using thematic analysis.

Data analysis and statistical issues

This protocol describes a data collection process that is ongoing as part of service evaluation. The sample included in each analysis will be dependent on the specific questions asked, with specific hypotheses developed prior to analyses, and the sample size determined for each proposed analysis. The sample size will be determined by attendance of consenting patients at clinics and courses. It is estimated that the Survivorship clinic will see 100 new patients per year, of whom 90% will consent to the use of their de-identified data. The first evaluation of initial clinic visits will be performed after 3 years, with an estimated sample size of 300 new patients. This would be considered of clinical significance for determining health status, Approximately 25% of the medical oncology patients receive their follow up at the Survivorship Clinic. We will perform a longitudinal analysis once we have three year follow up for 150 patients. Three year disease free survival is considered a surrogate marker for overall survival for some common tumour types,[30] and this time frame would provide important information on longitudinal health status of survivors.

Outcomes and patient characteristics will be summarised using standard descriptive statistics for each group. Missing data on the PRO will be handled according to the guidelines for each questionnaire. Comparison of results between groups (for example comparing PRO between tumour types) will be performed using Kruskal-Wallis test for continuous variables, Cochran-Armitage test for trend for ordinal variables, and

exact χ^2 tests for categorical variables. Spearman rank sum correlation coefficients will be used to determine associations between patient-reported outcomes. Regression modelling may be used to further evaluate associations and to investigate risk factors and predictors of health outcomes.

For longitudinal changes in patient reported outcomes a 10% change in the scale from baseline will be considered a clinically meaningful change.[31] A comparison of change over time in symptoms and behaviours will be performed. Changes in PRO at each time point will be analysed and regression analyses may be subsequently performed for major health status outcomes, to adjust for variables such as time since treatment completion and tumour site.

Qualitative data analysis: Interview data will be analysed using thematic analysis with at least two people involved in the analysis. Data coding will occur within a framework using MS office Excel.[32] Rigour will be ensured through multiple readings of the data, multiple coders, cross-coding, and member checking of themes with attendees of the clinic.

Discussion:

Survivorship concerns are increasingly recognised as poorly addressed in many standard follow-up appointments. There is considerable debate and a lack of evidence regarding how best to follow up cancer survivors. Multi-disciplinary clinics have the capacity to provide holistic care with a focus on education for lifestyle issues, prevention of long term side effects and psychological well being; but they are resource intensive for staff.

A physically active lifestyle and healthy weight have been shown in observational studies to decrease the risk of common cancers and cancer recurrence. Studies have also shown that physical activity and healthy nutrition can improve symptoms associated with cancer treatment, and decrease the risk of chronic diseases that are commonly found in cancer survivors; including metabolic syndrome, obesity, type II diabetes, cardiovascular disease and osteoporosis.[33] Although a number of cancer organisations have published recommendations regarding exercise and weight, the majority of cancer patients are overweight or obese, and most do not meet the guidelines of 150 minutes/week of moderate intensity physical activity, two sessions of resistance exercise/week and minimising sedentary activities, despite the increasing evidence for benefit.[33 34] This suggests that cancer survivors require additional support and education to facilitate their instituting important lifestyle changes.

The Sydney Survivorship Centre has the potential to improve physical and psychological well-being and QOL for cancer survivors. This study will obtain unique data regarding the benefits of a multi-disciplinary team Survivorship clinic for cancer patients who have completed primary adjuvant treatment, and evaluation of the courses offered by the Sydney Survivorship Centre for patients at any stage of the cancer journey and their caregivers/family. This will help determine whether assessing health status, providing education and lifestyle programmes facilitates adoption and adherence to a healthy lifestyle, and whether this can lead to improvement in well-being. Further, it will evaluate the Survivorship care plans through usage in routine clinical practice, as well as gaining information about who uses the Sydney Survivorship Centre programmes, and patient (and caregiver) satisfaction with the clinic and courses.

The strengths of the study are that it will provide a large sample size with longitudinal follow up with comprehensive assessment of health and well-being of cancer survivors attending a multi-disciplinary Survivorship Centre post primary adjuvant treatment. Limitations of the study include that it is an uncontrolled, observational cohort study, with the sample size dependent on the number of patients attending the clinic and programmes who consent to their deidentified data being used.

Ethics Approval:

Ethics approval has been obtained from Concord Repatriation General Hospital Human Research Ethics Committee (HREC/14/CRGH/23). Patients attending clinics and courses at the Sydney Survivorship Centre are given the option of a tick box to "opt out" if they do not wish their de-identified data to be used for research purposes.

Dissemination Plan:

Study results will be disseminated through a series of peer-reviewed publications and conference presentations.

Data storage and security:

Questionnaires are part of standard medical care and are kept in patient's oncology subfile. Data are entered into a specifically designed REDCap™ database, that is password protected and kept on a secure University of Sydney website. Records are identified by a study ID number, and a master list with names is kept separately. Data can only be accessed by authorised research team members. Data will be retained in perpetuity after conclusion of the study, and after each patient is discharged from the Survivorship Service either through completion of follow-up, disease recurrence, or

death their data will be fully anonymised by destruction of their details from the master list.

Conclusions:

Survivorship services are expanding in Australia and globally. The Sydney Survivorship Centre is the only multidisciplinary clinic of its kind in Australia. This study will provide important information about the health status of Australian cancer survivors, and enable us to better understand the symptoms, lifestyle and risk factors of our patient population. This will facilitate the design of supportive measures or interventions to better address these issues.

Author Contributions:

J. Vardy: study concept and design, and writing of the protocol and manuscript.
C. Tan: study concept and design, and writing of the protocol and manuscript.
J. Turner: study concept and design, and writing of the protocol and manuscript.
H. Dhillon: study concept and design, and writing of the protocol and manuscript.

Competing Interests:
None of the authors have any conflicts of interest to declare.

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Data Sharing:
This is a protocol for a longitudinal study so unpublished data are not available for sharing.

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Figure Legend

Figure 1 Referral pathway through the Sydney Survivorship Clinic, centre and courses

Table 1 Schedule of assessments for patients attending the Sydney Survivorship Clinic or participating in Sydney Survivorship Centre courses:

a) Sydney Survivorship Clinic

	Assessment	Initial visit	Follow Up*
	Demographics and cancer/ cancer treatment characteristics	X	
	Clinical examination	X	X
	Anthropometry • Weight • Weight history	 X X	 X
	Blood tests: As per standard of care e.g. colorectal cancer survivors: CEA every 3 months Other blood tests only as clinically indicated	X	X
	Imaging/Procedures: As per ASCO guidelines Breast cancer: Mammogram and/or breast ultrasound annually. Colorectal cancer: CT chest/abdomen/pelvis annually for 5 years. Colonoscopy: 1 year after diagnosis then 1-2 yearly dependent on result Results of other procedures as ordered by oncology team as part of standard of care.	X	X
Patient Reported Outcomes	Distress (Distress Thermometer) [22]	X	X
	Symptoms (Patient's Disease and Treatment Assessment Form)[21]	X	X
	Sedentary time (Sitting Questionnaire) [25]	X	X*
	Physical activity (Active Australia Questionnaire) [24]	X	X*
	3-day food diary and food questionnaire	X	X*
	Quality of Life questionnaire (FACT-G) [23]	X	X*
	ECOG performance status [26]	X	X
Evaluation	SSC Feedback Questionnaire	X	
	SSC Satisfaction survey		X
	Treatment and Survivorship Plan evaluation		X*

*Follow up will be individualised depending on tumour type and stage of disease but will generally be every 3-6 months. With the exception of the distress thermometer, Patients Disease and Treatment assessment form and the self-rated performance status, questionnaires will not be completed more frequently than every 6 months.

b) Courses for Sydney Survivorship Centre

Assessment	**Initial Visit**	**Conclusion of Programme**
Baseline demographics and disease characteristics	X	
Questionnaires:		
• FACT-G [23]	X	X
• FACT-fatigue (F) subscale [27]	X	X
• FACT Spirituality (Sp) subscale* [28]	X	X
• Patient's Disease and Treatment Assessment Form[21]	X	X
• Distress Thermometer [22]	X	X
• Hospital Anxiety and Depression Scale (HADs) [29]	X	X
Participant evaluation	X	X

* Only for Medical Qigong, yoga, mindfulness, acupuncture and music and well-being

SSC = Sydney Survivorship Centre
CEA = Carcinoembryonic Antigen; ASCO= American Society of Clinical Oncology; FACT = Functional Assessment of Cancer Therapy (G= general; F= Fatigue; Sp = spirituality)

Appendix Table 1 - Schedule of assessments for patients attending the Sydney Survivorship "Weight Management Course"

Assessment	Baseline	3 Month	6 Month	12 Month
Baseline demographics and disease characteristics, weight history	X			
Clinical examination (accredited exercise physiologist, dietitian, physician)	X	X	X	X
Body Composition Bioimpedance analysis, skinfold measures, girth measures, BMI	X	X		
DEXA scan (where appropriate)	X			X
Fasting blood tests FBC, EUC, LFT, glucose, lipids, iron studies, sex hormones, vitamin D, vitamin B12, TSH, IGF-1, CRP, albumin Other bloods as appropriate when ordered as standard of care	X	X	X	X
Physical Function 6MWT and/or Graded Sub-maximal Exercise Test; Maximal 1-RM leg press; Hand grip dynamometry	X	X	X	X
Nutritional Status 3-day weighed food diary	X	X	X	X
Patient Reported Outcomes • IPAQ-sf [24] • EORTC-QLQ-C30 [35] • FACT-F 13-item subscale [27] • Patient's Disease and Treatment Assessment Form [21] • Distress Thermometer [22] • Hunger Visual Analogue Scale [36]	X	X	X	X
Physical Activity Behaviour 7-day Actigraph GT1M accelerometers	X		X	X
Participant program evaluation; semi-structured interviews			X	
Adverse Events (CTCAE V4) [37]		X	X	X

BMI= Body mass index
EORTC-QLQC30 = The European Organisation for Research and Treatment of Cancer

FBC = full blood count; EUC = electrolytes, urea, creatinine; LFT = liver function tests ; TSH = Thyroid stimulating hormone; IGF-1 = Insulin-like growth factor -1; CRP = C-reactive protein
6MWT= six-minute walk test; 1-RM=one repetition maximum
IPAQ-sf=International Physical Activity Questionnaire – short form
EORTC QLQ-C30= The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire
FACT-F = Functional Assessment of Cancer Therapy (F= Fatigue)
CTCAE= common terminology criteria for adverse event

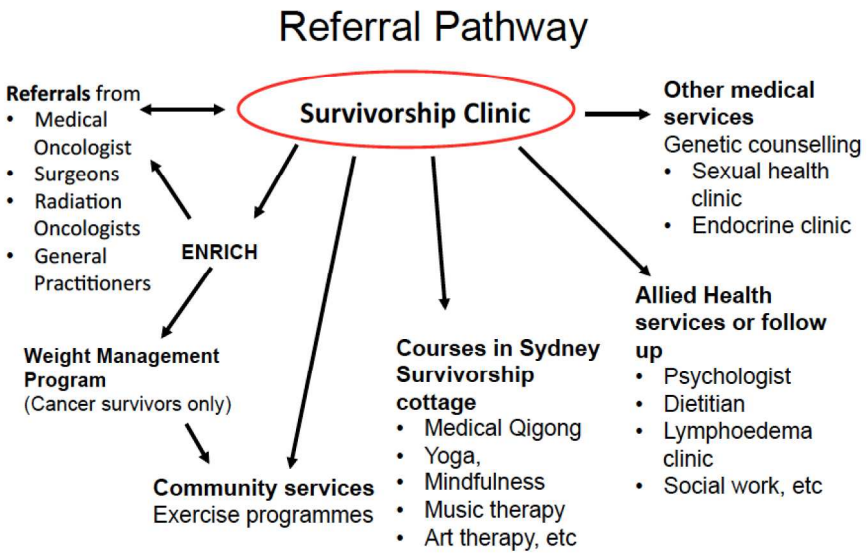

Figure 1 Referral pathway
Figure 1 Referral pathway
357x209mm (144 x 144 DPI)

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	___Survivorship Clinic p_5-6, 8-_____ Courses p.6-7	____Protocol paper_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	p._4-7__	_____
	WHAT		
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).	Questionnaires_ p.10___	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_p. 4-9	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	p.5-6__	_____
	HOW		
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.	____p.8____	_____

	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	p. 7-8	_____
	WHEN and HOW MUCH		
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.	_p.7-12__	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	__p.7-12_	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_N/A_____ ___	_____
	HOW WELL		
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.	____N/A_____ ___	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	__N/A_____	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† 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.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the

TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist

BMJ Open

Health status and needs of cancer survivors attending the Sydney Survivorship Centre clinics and programmes: A protocol for longitudinal evaluation of the Centre's services

Journal:	*BMJ Open*
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Health status and needs of cancer survivors attending the Sydney Survivorship Centre clinics and programmes: A protocol for longitudinal evaluation of the Centre's services

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Abstract:

Introduction:

The care of cancer survivors after primary adjuvant treatment is recognised as a distinct phase of the cancer journey. Recent research highlights the importance of lifestyle factors in treating symptoms, potentially decreasing risk of a cancer recurrence, and modifying the risk of developing other chronic illnesses that are increased in the cancer population. Survivorship services aim to deliver care that addresses these issues. The overall aims are to determine the health status of cancer survivors and evaluate the services offered by the Sydney Survivorship Centre.

Methods and analysis:

An observational, single centre study evaluating the longitudinal physical and psychological health, symptoms, quality of life, and lifestyle (physical activity and nutrition) of early-stage cancer survivors attending the multidisciplinary Sydney Survivorship Clinic and of survivors (at any stage of the cancer journey) and caregivers participating in Sydney Survivorship Centre courses. Evaluation of patient satisfaction is included. Patient reported outcomes and patient characteristics will be summarised using descriptive statistics with Spearman rank sum correlation coefficients to determine associations between patient-reported outcomes. Regression modelling may be used to further evaluate associations and to investigate risk factors and predictors of health outcomes. Qualitative data will be analysed using thematic analysis to identify themes. Sample size will be determined by attendance of consenting patients at clinics and courses.

Ethics and dissemination:

The study has received ethics approval from the Concord Repatriation General Hospital Human Research Ethics Committee (HREC/14/CRGH/23). The results will be published and presented at appropriate conferences.

This study will provide important information regarding the health status and needs of Australian cancer survivors, and the ability of the Survivorship Centre to address these needs. These data will shape the future direction of survivorship care in Australia and facilitate the design of interventions or measures to provide better quality of care to this patient population.

Strengths and Limitations:

Strengths:

-large, longitudinal follow up with comprehensive assessment of health and well-being of cancer survivors attending a multi-disciplinary Survivorship Centre post primary adjuvant treatment

Weaknesses:

- observational cohort study

- sample size determined by number of patients attending programme, and giving consent to deidentified data being used.

Introduction

Until relatively recently the focus of cancer treatment and research was on the acute treatment of cancer and monitoring for disease recurrence. In 2005 the ground-breaking Institute of Medicine (IOM) Report "Lost in Transition" identified the substantial failure of current follow-up care to comprehensively address the needs of adult cancer survivors.[1] Through the IOM the distinct needs of adult cancer survivors have been recognised along with the importance of helping survivors live with the longer term physical, psychological, and practical effects of cancer and its treatment.[1]

By the broadest definition a person becomes a cancer survivor when they are diagnosed with cancer, a state that continues throughout the remainder of their life.[1] There are estimated to be more than 25 million cancer survivors worldwide, a number that is projected to increase rapidly due to our ageing population, improved screening leading to earlier detection of cancer, and improvements in cancer treatments.

Even cancer survivors with no evidence of disease recurrence experience greater ongoing health problems than the general population. Cancer survivors are known to be at increased risk of cardiovascular disease, type II diabetes, metabolic syndrome, and osteoporosis, in addition to the risk of a cancer recurrence or a second primary cancer. [1-5] There are a number of identified lifestyle risk factors associated with cancer risk and recurrence, and the chronic diseases that accompany them. These lifestyle risk factors are modifiable and include obesity, physical inactivity, smoking, and inadequate fruit and vegetable intake.[6]

In an attempt to better address the needs of adult cancer survivors some cancer centres have established Survivorship Services, Centres, or Clinics. These services are

designed to help survivors and their caregivers better manage their disease and any lasting effects of treatment, beyond the period of acute diagnosis and treatment.[5] In addition, many try to facilitate survivors enacting lifestyle changes to increase their physical activity and maintain a healthy weight, in order to aid recovery, improve health related quality of life (QOL), and possibly long-term survival.[7] Psychological support is an important feature of most programmes, and may include psycho-oncology consultations with a clinical psychologist to manage specific concerns such as fear of cancer recurrence, anxiety, or depression, general or disease specific support groups, or counselling support from allied health professionals.[8 9]

The IOM recommended, with support of a number of peak bodies including the American Society of Clinical Oncology (ASCO), that all cancer survivors transitioning from active to the post treatment phase should receive an individualised Treatment and Survivorship Care Plan (SCP).[1] This should include a summary of cancer treatment received, and recommendations regarding future clinical care and coordination, including the frequency and nature of surveillance based on the best available evidence. A number of SCP templates are freely available, including generic and disease specific templates from ASCO and Livestrong, which include information on potential late and long-term effects from the cancer and/or treatment(s). Despite recommendations from oncology organisations that SCP should be used, there is limited evidence that they improve long term outcomes for cancer survivors although survivor satisfaction with the SCP is generally high.[10]

The Sydney Survivorship Centre was established in September 2013 at the Concord Cancer Centre, in Sydney. It includes: i) a multi-disciplinary survivorship clinic for patients with localised cancer who have completed primary treatment with curative intent (e.g. surgery, chemotherapy, and radiation therapy) without evidence of cancer

recurrence; and, ii) a range of programmes to support lifestyle change. At the initial clinic visit patients see a multi-disciplinary team (MDT) comprising a medical oncologist or haematologist, cancer nurse specialist, dietitian, clinical psychologist, and accredited exercise physiologist (AEP). Prior to attendance at each clinic, patients complete a number of questionnaires assessing symptoms, physical activity, diet, QOL and well-being, and are asked to fill in an evaluation after each clinic. Education regarding healthy lifestyle and encouragement to maintain a healthy weight are an important focus of every clinic. An individualised SCP is developed for each oncology patient.

Approximately two thirds of survivors attend the clinic once and then return to their regular medical team for ongoing follow up. At the request of the caring team, the remainder continue follow up through the Survivorship Clinic. On subsequent visits they see the medical oncologist and tumour specific nurse specialist, with referral to other health professionals and/or programmes as required.

In response to the high proportion of survivors who were overweight or obese, and the increasing evidence supporting obesity as a risk factor for cancer recurrence, [11] we established a weight management clinic focused on dietary modification, exercise and behavioural change for those with early stage solid tumours, who have a body mass index (BMI) >25. The intervention was based on a recent systematic review that reported dietary modification involving restrictions of energy and fat intake, and promotion of exercise and behavioural changes were the key components for successful weight loss and maintenance.[12]

The Sydney Survivorship Centre opened the Survivorship Cottage in May 2014. The cottage is located in the grounds of the hospital, away from the main buildings, and

surrounded by gardens and furnished in a homely manner. This is where the majority of the courses are held for cancer survivors at any stage of their cancer journey, and their caregivers, with a focus on healthy lifestyle and well-being. The Exercise and Nutrition Routine Improving Cancer Health (ENRICH)[13] programme is a 6-week exercise and healthy eating course offered in collaboration with the Cancer Council New South Wales (NSW) and held regularly throughout the year. Other courses include: Mindfulness Meditation, Medical QiGong, yoga, acupuncture, music and art therapy, including scrap-booking, card making, floral design as well as individual one-off workshops. Courses are selected based on some level of evidence for their efficacy in cancer survivors.[14-20] The courses are offered weekly for 10 weeks coinciding with school terms, with 4 terms each year. Commitment to a full term is required. In addition we provide support groups and public fora on topics of interest to cancer patients and their caregivers and families.

In keeping with the ASCO guidelines,[5] research is an integral component of the Survivorship Centre. The major research aims of the centre are to: (i) determine the health status, needs, symptoms, QOL and lifestyle characteristics of cancer survivors attending the Sydney Survivorship Clinic or participating in courses; (ii) evaluate changes over time in these variables; (iii) determine risk factors that may affect cancer survivors' clinical outcomes (e.g. metabolic syndrome, obesity, inactivity); (iv) evaluate patients' and/or their caregivers/family members' experience with services offered by the Sydney Survivorship Centre; and (v) evaluate the multidisciplinary team (MDT) approach in addressing cancer survivors' needs.

Methods and Analysis

This is a single site, longitudinal study led by the Survivorship Research Group

(SuRG), University of Sydney and the Sydney Survivorship Centre, Concord Cancer Centre. Patient reported outcome data are collected as part of standard care and for quality assurance.

Sydney Survivorship Clinic:

The Sydney Survivorship Centre (SSC) clinic commenced in September 2013.

Eligibility:

Medical oncology or haematology patients who have completed primary adjuvant treatment for early stage cancer and have no evidence of a cancer recurrence are eligible to attend the Survivorship Clinic. Breast cancer patients may be receiving hormonal treatment and/or targeted therapy such as trastuzumab. Figure 1 depicts the referral pathway.

Procedure:

Prior to attending the Survivorship clinic patients are sent a package containing printed Patient Reported Outcome (PRO) Questionnaires assessing symptoms, psychological well-being, distress, QOL, physical activity, dietary intake and performance status. They are asked to bring the completed questionnaires to their appointment. Those with incomplete questionnaires are asked to finalise them during the clinic visit. Patients with insufficient English or poor literacy skills can have assistance from a health translator, family members, or clinic staff during the clinic appointment.

Medical information and weight history are obtained from the medical record. Anthropometry (height and weight) is obtained at the initial visit by clinic staff. A

SCP is prepared for oncology patients prior to their initial visit, by either the medical oncologist or registrar. This plan is refined with the patient after consultation with the MDT members, and a copy posted to them after the clinic. Haematology patients may receive a detailed letter from the haematologist with recommendations rather than a formal Survivorship care plan.

Patients are asked to complete an evaluation form after each clinic visit. In addition, those who have given verbal permission to be contacted subsequently will be asked to complete a satisfaction survey over the phone or in person to provide feedback on how useful the Survivorship Care Plan has been, how they used it, and if it has been revised. This will be approximately 6 months after their initial visit. A subset of patients will be invited to participate in a qualitative interview to explore, in depth, their experience of the survivorship service.

Sydney Survivorship Courses:

The courses were gradually introduced from 2014.

Eligibility:

Posters advertising the programmes are displayed in the Concord Cancer Centre waiting areas. Patients with any stage cancer are able to self-refer to participate in Survivorship courses. Concord Cancer Centre patients receive priority for courses, but patients from surrounding hospitals are able to attend if space permits. Carers can accompany a patient and participate if space permits.

Measures used for Survivorship Clinic and Courses:

Outcome measures used in this study are comprehensive assessments of patient self-report symptoms, QOL, distress, and lifestyle factors. The schedule of assessments and details of measures are outlined in Table 1.

Endpoints:

The global aim of this multi-faceted project is to evaluate the Sydney Survivorship Centre Clinic and Programmes. We aim to assess changes in the endpoints, stated below, over time:

Survivorship Clinic

- incidence and severity of symptoms that may be associated with cancer and/or treatment – as assessed by the Patient's Disease and Treatment Assessment Form.[21] This is a 48 item questionnaire assessing symptoms with responses ranging from 0 – 10 (no trouble at all to worst I can imagine) over the previous month.
- distress - as assessed by the Distress thermometer. [22] This asks participants to rate their level of distress over the previous week from 0 – 10 (no distress to extreme distress).
- quality of life as assessed by the FACT-G. [23] This 27-item questionnaire assesses physical, social, emotional and functional well-being over the previous week, with ratings from 0 – 4 (not at all to very much).
- physical activity and sedentary behaviour- as assessed by the Active Australia Exercise Questionnaire [24] and the Sitting Questionnaire [25] and AEP consultation. Active Australia is a 4-item questionnaire evaluating the time spent performing physical activity and the intensity of the activity in the

previous week. The Sitting questionnaire is a 2-item questionnaire assessing the time usually spent sitting, on a weekday and on a weekend.

- dietary intake and behaviour – as assessed by an in-house 3-day food diary and Food Questionnaire, and dietitian consultation. The 4-item Food Questionnaire assesses changes made to diet since a cancer diagnosis/treatment, average number of serves of fruit, vegetables, dairy and soft drinks daily, and alcohol intake.
- Eastern Co-operative Oncology Group Performance Status (ECOG Performance Status) [26]- as assessed by both clinician and participant.
- Clinical assessments: medical and physical assessment by doctor and nurse; fear of cancer recurrence assessed by Clinical Psychologist, anthropometric assessment.
- Effectiveness of MDT in addressing survivors' needs measured by change in outcomes, e.g., QOL, sedentary behaviour, etc
- Use and effectiveness of Treatment and Survivorship Care Plan (SCP). To determine the incidence of patients attending the Survivorship Clinic who: receive a survivorship plan; are referred to other health professionals from clinic; use the SCP (e.g. show other health professionals, carry out the clinic recommendations). Whether patients found the SCP helpful, did it contain new information and suggestions for improvement.
- Clinical progress as determined by results of clinical examination, blood tests and/or imaging ordered as part of standard of care.
- Effectiveness of surveillance system: Total number of cases of cancer recurrence and disease-free survival.

- Patients' experience with Sydney Survivorship Clinic, developed by the authors, asking patients to rate how useful the session with each member of the multidisciplinary team was, and how well their questions were answered. They also rate how worthwhile it was attending the clinic and give reasons for their answer, and comment on the length and timing of the clinic in their cancer journey. Finally they are asked whether they would recommend the clinic to others and any additional information or services they would have liked to receive.

Specific SSC programmes:

Weight management programme:

- Facilitated and supervised by AEP and Dietitian.
- Eligibility: BMI >25; attendance at Sydney Survivorship Clinic, completion of the ENRICH 6 week lifestyle programme.
- attendance (number of enrolees, proportion completing programmes, reasons for non-attendance).
- QOL, symptoms, food intake, exercise behaviour, knowledge/practice and changes compared to baseline assessment.
- Lifestyle outcomes: anthropometry measurements, vital signs, aerobic capacity and muscular strength - Week 0, 12, 26 and then 6 monthly until 2 years.
- blood results collected as part of standard of care.
- patient experience as measured by a satisfaction survey and interview.

See Appendix Table 1 for full details.

Mindfulness, QiGong, Yoga, Music therapy, Art therapy or similar courses:

- Attendance (number of enrolees, proportion completing programmes, reasons for non-attendance)

- Clinical outcomes: demographics, cancer diagnosis and treatment,
- Symptoms: assessed by the Patient's Disease and Treatment Assessment Form[21]
- Psychosocial outcomes (completed pre and post intervention):

  QOL and fatigue assessed by the FACT-General (G) [23] and 13-item Fatigue (F) subscale [27]

  Spiritual well-being assessed by the 12-item FACT-Spiritual [28] (for mindfulness, yoga medical Qigong, acupuncture and medical well-being courses)

  Symptoms of anxiety and depression –assessed by the Hospital Anxiety and Depression Scale (HADS)[29]

  Distress – assessed by the Distress Thermometer [22]
- ECOG performance status (patient rated) [26]
- Participant satisfaction questionnaire – at end of programme only

<u>In-depth Qualitative exploration of patient experience:</u>

Cancer survivors and/or caregivers/family members will be invited to participate in focus group(s) and/or interviews to provide in-depth feedback about their experience of SSC services, and information about unmet needs to guide the direction of the SSC clinic or programmes. Both focus groups and telephone interviews are offered to ensure maximum access for individual participants via these flexible options. Consenting individuals will attend a focus group meeting, a face-to-face interview, or a telephone interview with staff of the University of Sydney who are not involved in their clinical care. All interviews are semi-structured, following an ethics approved interview guide developed for the clinic and each programme.

To monitor changing experiences of the clinic over time, groups of attendees will be purposively sampled periodically on the basis of their disease group, side effect profile, and the programmes attended.

Qualitative data will be transcribed verbatim and analysed using thematic analysis.

Data analysis and statistical issues

This protocol describes a data collection process that is ongoing as part of service evaluation. The sample included in each analysis will be dependent on the specific questions asked, with specific hypotheses developed prior to analyses, and the sample size determined for each proposed analysis. The sample size will be determined by attendance of consenting patients at clinics and courses. It is estimated that the Survivorship clinic will see 100 new patients per year, of whom 90% will consent to the use of their de-identified data. The first evaluation of initial clinic visits will be performed after 3 years, with an estimated sample size of 300 new patients. This would be considered of clinical significance for determining health status. Approximately 25% of the medical oncology patients receive their follow up at the Survivorship Clinic. We will perform a longitudinal analysis once we have three year follow up for 150 patients. Three year disease free survival is considered a surrogate marker for overall survival for some common tumour types,[30] and this time frame would provide important information on longitudinal health status of survivors.

Outcomes and patient characteristics will be summarised using standard descriptive statistics for each group. Missing data on the PRO will be handled according to the guidelines for each questionnaire. Comparison of results between groups (for example comparing PRO between tumour types) will be performed using Kruskal-Wallis test for continuous variables, Cochran-Armitage test for trend for ordinal variables, and

exact χ^2 tests for categorical variables. Spearman rank sum correlation coefficients will be used to determine associations between patient-reported outcomes. Regression modelling may be used to further evaluate associations and to investigate risk factors and predictors of health outcomes.

For longitudinal changes in patient reported outcomes a 10% change in the scale from baseline will be considered a clinically meaningful change.[31] A comparison of change over time in symptoms and behaviours will be performed. Changes in PRO at each time point will be analysed and regression analyses may be subsequently performed for major health status outcomes, to adjust for variables such as time since treatment completion and tumour site.

Qualitative data analysis: Interview data will be analysed using thematic analysis with at least two people involved in the analysis. Data coding will occur within a framework using MS office Excel.[32] Rigour will be ensured through multiple readings of the data, multiple coders, cross-coding, and member checking of themes with attendees of the clinic.

Discussion:

Survivorship concerns are increasingly recognised as poorly addressed in many standard follow-up appointments. There is considerable debate and a lack of evidence regarding how best to follow up cancer survivors. Multi-disciplinary clinics have the capacity to provide holistic care with a focus on education for lifestyle issues, prevention of long term side effects and psychological well being; but they are resource intensive for staff.

A physically active lifestyle and healthy weight have been shown in observational studies to decrease the risk of common cancers and cancer recurrence. Studies have also shown that physical activity and healthy nutrition can improve symptoms associated with cancer treatment, and decrease the risk of chronic diseases that are commonly found in cancer survivors; including metabolic syndrome, obesity, type II diabetes, cardiovascular disease and osteoporosis.[33] Although a number of cancer organisations have published recommendations regarding exercise and weight, the majority of cancer patients are overweight or obese, and most do not meet the guidelines of 150 minutes/week of moderate intensity physical activity, two sessions of resistance exercise/week and minimising sedentary activities, despite the increasing evidence for benefit.[33 34] This suggests that cancer survivors require additional support and education to facilitate their instituting important lifestyle changes.

The Sydney Survivorship Centre has the potential to improve physical and psychological well-being and QOL for cancer survivors. This study will obtain unique data regarding the benefits of a multi-disciplinary team Survivorship clinic for cancer patients who have completed primary adjuvant treatment, and evaluation of the courses offered by the Sydney Survivorship Centre for patients at any stage of the cancer journey and their caregivers/family. This will help determine whether assessing health status, providing education and lifestyle programmes facilitates adoption and adherence to a healthy lifestyle, and whether this can lead to improvement in well-being. Further, it will evaluate the Survivorship care plans through usage in routine clinical practice, as well as gaining information about who uses the Sydney Survivorship Centre programmes, and patient (and caregiver) satisfaction with the clinic and courses.

The strengths of the study are that it will provide a large sample size with longitudinal follow up with comprehensive assessment of health and well-being of cancer survivors attending a multi-disciplinary Survivorship Centre post primary adjuvant treatment. Limitations of the study include that it is an uncontrolled, observational cohort study, with the sample size dependent on the number of patients attending the clinic and programmes who consent to their deidentified data being used.

Ethics Approval:

Ethics approval has been obtained from Concord Repatriation General Hospital Human Research Ethics Committee (HREC/14/CRGH/23). Patients attending clinics and courses at the Sydney Survivorship Centre are given the option of a tick box to "opt out" if they do not wish their de-identified data to be used for research purposes.

Dissemination Plan:

Study results will be disseminated through a series of peer-reviewed publications and conference presentations.

Data storage and security:

Questionnaires are part of standard medical care and are kept in patient's oncology subfile. Data are entered into a specifically designed REDCap™ database, that is password protected and kept on a secure University of Sydney website. Records are identified by a study ID number, and a master list with names is kept separately. Data can only be accessed by authorised research team members. Data will be retained in perpetuity after conclusion of the study, and after each patient is discharged from the Survivorship Service either through completion of follow-up, disease recurrence, or

death their data will be fully anonymised by destruction of their details from the master list.

Conclusions:

Survivorship services are expanding in Australia and globally. The Sydney Survivorship Centre is the only multidisciplinary clinic of its kind in Australia. This study will provide important information about the health status of Australian cancer survivors, and enable us to better understand the symptoms, lifestyle and risk factors of our patient population. This will facilitate the design of supportive measures or interventions to better address these issues.

Author Contributions:

J. Vardy: study concept and design, and writing of the protocol and manuscript.
C. Tan: study concept and design, and writing of the protocol and manuscript.
J. Turner: study concept and design, and writing of the protocol and manuscript.
H. Dhillon: study concept and design, and writing of the protocol and manuscript.

Competing Interests:
None of the authors have any conflicts of interest to declare.

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Data Sharing:
This is a protocol for a longitudinal study so unpublished data are not available for sharing.

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Data entry: Erika Jungfer, Loraine Fong and Christopher Mo.

Figure Legend

Figure 1 Referral pathway through the Sydney Survivorship Clinic, centre and courses

Table 1 Schedule of assessments for patients attending the Sydney Survivorship Clinic or participating in Sydney Survivorship Centre courses:

a) Sydney Survivorship Clinic

	Assessment	Initial visit	Follow Up*
	Demographics and cancer/ cancer treatment characteristics	X	
	Clinical examination	X	X
	Anthropometry • Weight • Weight history	 X X	 X
	Blood tests: As per standard of care e.g. colorectal cancer survivors: CEA every 3 months Other blood tests only as clinically indicated	X	X
	Imaging/Procedures: As per ASCO guidelines Breast cancer: Mammogram and/or breast ultrasound annually. Colorectal cancer: CT chest/abdomen/pelvis annually for 5 years. Colonoscopy: 1 year after diagnosis then 1-2 yearly dependent on result Results of other procedures as ordered by oncology team as part of standard of care.	X	X
Patient Reported Outcomes	Distress (Distress Thermometer) [22]	X	X
	Symptoms (Patient's Disease and Treatment Assessment Form)[21]	X	X
	Sedentary time (Sitting Questionnaire) [25]	X	X*
	Physical activity (Active Australia Questionnaire) [24]	X	X*
	3-day food diary and food questionnaire	X	X*
	Quality of Life questionnaire (FACT-G) [23]	X	X*
	ECOG performance status [26]	X	X
Evaluation	SSC Feedback Questionnaire	X	
	SSC Satisfaction survey		X
	Treatment and Survivorship Plan evaluation		X*

*Follow up will be individualised depending on tumour type and stage of disease but will generally be every 3-6 months. With the exception of the distress thermometer, Patients Disease and Treatment assessment form and the self-rated performance status, questionnaires will not be completed more frequently than every 6 months.

b) Courses for Sydney Survivorship Centre

Assessment	**Initial Visit**	**Conclusion of Programme**
Baseline demographics and disease characteristics	X	
Questionnaires:		
• FACT-G [23]	X	X
• FACT-fatigue (F) subscale [27]	X	X
• FACT Spirituality (Sp) subscale* [28]	X	X
• Patient's Disease and Treatment Assessment Form[21]	X	X
• Distress Thermometer [22]	X	X
• Hospital Anxiety and Depression Scale (HADs) [29]	X	X
Participant evaluation	X	X

* Only for Medical Qigong, yoga, mindfulness, acupuncture and music and well-being

SSC = Sydney Survivorship Centre
CEA = Carcinoembryonic Antigen; ASCO= American Society of Clinical Oncology; FACT = Functional Assessment of Cancer Therapy (G= general; F= Fatigue; Sp = spirituality)

Appendix Table 1 - Schedule of assessments for patients attending the Sydney Survivorship "Weight Management Course"

Assessment	Baseline	3 Month	6 Month	12 Month
Baseline demographics and disease characteristics, weight history	X			
Clinical examination (accredited exercise physiologist, dietitian, physician)	X	X	X	X
Body Composition Bioimpedance analysis, skinfold measures, girth measures, BMI	X	X		
DEXA scan (where appropriate)	X			X
Fasting blood tests FBC, EUC, LFT, glucose, lipids, iron studies, sex hormones, vitamin D, vitamin B12, TSH, IGF-1, CRP, albumin Other bloods as appropriate when ordered as standard of care	X	X	X	X
Physical Function 6MWT and/or Graded Sub-maximal Exercise Test; Maximal 1-RM leg press; Hand grip dynamometry	X	X	X	X
Nutritional Status 3-day weighed food diary	X	X	X	X
Patient Reported Outcomes • IPAQ-sf [24] • EORTC-QLQ-C30 [35] • FACT-F 13-item subscale [27] • Patient's Disease and Treatment Assessment Form [21] • Distress Thermometer [22] • Hunger Visual Analogue Scale [36]	X	X	X	X
Physical Activity Behaviour 7-day Actigraph GT1M accelerometers	X		X	X
Participant program evaluation; semi-structured interviews			X	
Adverse Events (CTCAE V4) [37]		X	X	X

BMI= Body mass index
EORTC-QLQC30 = The European Organisation for Research and Treatment of Cancer

FBC = full blood count; EUC = electrolytes, urea, creatinine; LFT = liver function tests ; TSH = Thyroid stimulating hormone; IGF-1 = Insulin-like growth factor -1; CRP = C-reactive protein
6MWT= six-minute walk test; 1-RM=one repetition maximum
IPAQ-sf=International Physical Activity Questionnaire – short form
EORTC QLQ-C30= The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire
FACT-F = Functional Assessment of Cancer Therapy (F= Fatigue)
CTCAE= common terminology criteria for adverse event

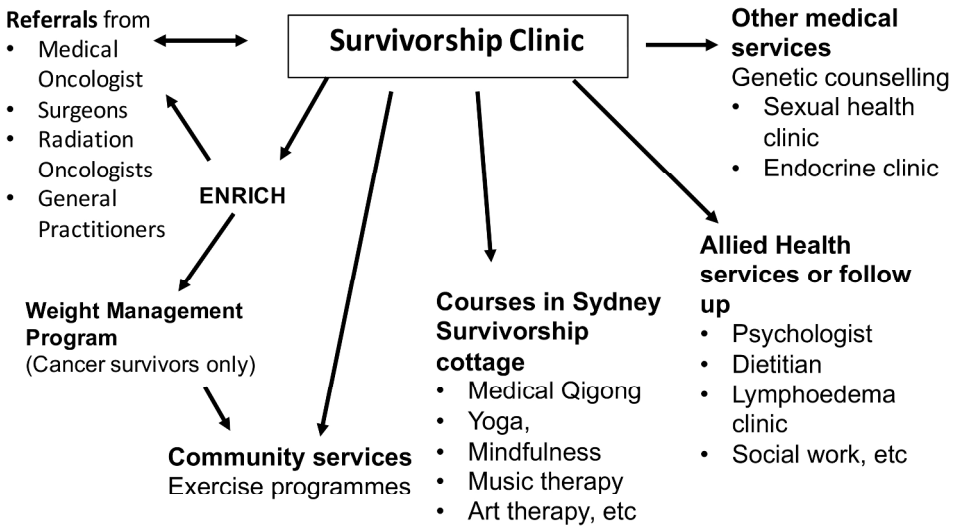

Figure 1 Referral pathway
Figure 1 Referral pathway
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The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	___Survivorship Clinic p_5-6, 8-_____ Courses p.6-7	____Protocol paper_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	p._4-7__	_____
	WHAT		
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).	Questionnaires_ p.10___	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_p. 4-9	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	p.5-6__	_____
	HOW		
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.	____p.8____	_____

	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	p. 7-8	_____
	WHEN and HOW MUCH		
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.	_p.7-12__	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	__p.7-12_	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_N/A_____ ___	_____
	HOW WELL		
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.	____N/A_____ ___	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	__N/A_____	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† 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.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the

TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist