|  |
| --- |
| **Instructions for using this project description / protocol template**   1. The protocol should provide the scientific and academic background and context of a project. 2. A protocol is a mandatory component of an ethics submission and must follow the format below. If headings or sub-headings are not relevant to a project (e.g. drugs and devices), they may be deleted. 3. There is no need to duplicate information in the HREA if the question asks for information that is specifically outlined in the protocol –when referring to the protocol in the HREA, please reference specific section numbers. 4. Lay language should be used as reviewers may not be academics or have knowledge of the field of study. Dot points may be used. On average a good protocol can be done in 3-10 pages. 5. Where a project involves multiple data collection methods and/or participant groups, please complete the table provided at the end of this document to provide reviewers with a snapshot of the project. This table does not negate the need to provide a complete description. |

**Project Description / Protocol**

## Assessing parkrun for walking rehabilitation for cancer survivors: acceptability, adherence, social support and physical function

* Version 1

## Project Team Roles & Responsibilities

**Lead Investigator:**

Associate Professor Suzanne Broadbent, Clinical Exercise Physiology

School of Health & Behavioural Sciences, University of the Sunshine Coast

Ph: 61 7 54594545 Email: sbroadbe@usc.edu.au

**Co-Investigators:**

Dr Sonja Coetzee

Dr Rob Buhmann

Dr Yuri Kriel

Professor Christian Jones

Dr Michelle Morris

## Resources

* Resources necessary for the project to be conducted:
* Parkrun ID barcode (participation, timing, distance). Participant smart phones and watches can also be used for a step-counter app.
* Wellness app (to be downloaded to mobile phone or smart watch), to record wellness and participant’s mood.
* Exercise science laboratory for participant screening and data collection at baseline and other timepoints.
* Funding for payment of participant parking fees at USC for pre-project screening and baseline data gathering will be sought from internal and external grants.
* Funding for a Research Assistant to assist with project organization will be sought from internal and external grants.
* The Lead Investigator has some discretionary funds which can be used for project advertising for recruitment.
* Funding/support being sought or secured:
* USC SPARK Grant preliminary internal funding was gained to develop the project application for larger external grants in 2023-24
* We will submit external grant applications to Exercise and Sports Science Australia (ESSA Research grant up to $50,000), Medibank (up to $100,000) and the Cancer Council rounds for 2023.

## Background

* SYNOPSIS

Parkrun is an established global, free community walk or run event. Adults can join a Saturday 5km walk/run in local parks where there is no set time limit and where volunteers monitor the participants to make sure all are safe and finish the course. There are also 2 km events for children aged 4 to 14 years. Regular physical activity (PA) is currently recommended for survivors of most types of cancers to maintain physical function, reduce some treatment side effects and to improve wellness and quality of life (QoL) [1]. However, compliance and adherence to physical activity is often challenging for patients due to the nature of their treatments, symptoms and psychosocial issues [1-3]. The structure of parkrun lends itself to group support and to potential rehabilitation clients who would benefit from the group setting and social aspects of participation. It might be a more appealing exercise modality compared to a clinical rehab setting, therefore promoting greater adherence. In fact, the Royal Australian College of General Practitioners has recently received publicity for endorsing GPs to refer patients to parkrun as a way of preventing and managing some lifestyle diseases and mental health symptoms, colloquially referred to as ‘social prescription” [4]. There is a growing body of evidence that parkrun improves physical fitness, BMI, mood and personal and social wellbeing [5] in individuals ranging from recreational athletes to those with health issues (e.g. obesity, sedentary behaviour, mental health). However, parkrun has not yet been suggested as a mode of exercise for cancer survivors. This study will assess the feasibility of parkrun to provide physical, functional and psychosocial benefits for cancer survivors, contributing to the current evidence for physical activity and cancer rehabilitation.

* LITERATURE REVIEW including reference list

There is substantial evidence that exercise is a beneficial adjuvant treatment modality for cancer survivors [1-3,]. The Clinical Oncology Society of Australia (COSA) Position Statement on Exercise in Cancer Care [1-2] includes recommendations that individuals should aim towards, and maintain, participation in at least 150 minutes of regular moderate-intensity aerobic exercise each week, or potentially up to 75 minutes of more vigorous higher-intensity aerobic exercise weekly. The modes of exercise could include walking, jogging, swimming, cycling or similar. Strength training is also recommended two to three times per week [1,2]. The bulk of evidence in support of regular exercise has been gathered for breast, prostate and colorectal cancers but there is emerging evidence that exercise can benefit people with blood and other cancers [1-3]. Physical function, symptom attenuation (especially fatigue), quality of life (QoL), risk of new or reoccurring cancers and co-morbidities can all be improved by participation in regular exercise [1-3,6].

What are less clear are the reasons why cancer survivors, on the whole, are not meeting these physical activity levels [1,5]. Between 60-70% of cancer survivors do not participate in enough aerobic exercise and closer to 90% do not meet strength training recommendations [3,6,7]. It is clear that regular exercise can reduce the severity of adverse treatment side effects, new cancer onset and cancer-specific/all-cause mortality. There is recent evidence that provides some insight into the poor physical activity participation rates [7,8] but useful strategies for improving adherence have not been robustly investigated. To develop, and make use of existing, effective exercise interventions, we need to understand the factors that influence exercise adherence, acceptance and enjoyment and to identify potential barriers to exercise participation.

A recent umbrella review of exercise adherence in chronic diseases and with older adults [9] identified the following factors as being directly relevant to exercise adherence and compliance: the type of exercise program and its integration into daily living; inter-disciplinary care; appropriate exercise supervision; usable technology; an understanding of the participant’s characteristics, barriers, enablers and education; adequate expectations and knowledge about the exercise risks and benefits; enjoyment and absence of unpleasant experiences; social support; communication and feedback; available progress information and monitoring; self-efficacy and competence; participant’s active role; and achievable goal setting. The majority of these factors can be applied to cancer survivors, according to the most recent evidence. Cancer patients often have the added burden of muscle weakness, weight loss and sub-optimal nutrition, which affects their ability to be physically active [10-12].

Clinical factors associated with poor adherence to aerobic and resistance exercise guidelines, among various types of cancer patients, included being overweight or obese, cancer treatments [6,13], disease symptoms (fatigue, pain) [14] and poor motivation or lack of interest [14]. The issues with multi-modal cancer treatments included side-effects, financial distress and lack of understanding of the benefits of physical activity whilst undergoing treatments [13]. Kirkham et al., (2018) also reported that breast cancer patients had lower adherence to both aerobic and resistance exercise during chemotherapy compared to radiation therapy [14], with common barriers including disease symptoms and medical appointments. Other studies of cancer survivors (predominantly prostate and breast cancer) [14,15] have reported that unmet supportive needs, global distress and symptom-related anxiety contributed to poor exercise program adherence whilst improved QoL, fatigue, sexual activity, hormonal symptoms and education were significantly associated with better adherence to exercise [15,16]. Individuals who had a more positive perception of their ability to perform daily tasks and leisure activities had greater adherence to their exercise program [16]. The same study also reported that 80% of participants felt that their clinician’s referral influenced their participation and adherence, irrespective of their improvements in physical function during the intervention [16]. Adherence also seems to improve with individualized, one-on-one sessions and home-based programs which promote ongoing, maintenance exercise participation [16-18], although the psychosocial aspects of group exercise can be beneficial [18]. Other studies have reported that the flexibility and simplicity of exercise interventions can promote participation, whether they be individualized or in group settings [17,19,20]. Furthermore, the use of fitness trackers, apps and wearable technology that provide participant feedback may also contribute to better compliance and adherence [21].

There has been increased emphasis on using physical activity to prevent and manage chronic diseases. In fact, general practitioners and primary healthcare clinicians are being encouraged to “socially prescribe” exercise participation to patients who are sedentary and/or have lifestyle diseases [4,22]. There is growing evidence that community-based physical activity programs, such as parkrun, are effective, inclusive and attractive to individuals who are inactive or who have health issues such as obesity, heart disease and limiting disabilities [22-24]. A recent systematic review of the outcomes of, and factors influencing, parkrun [5] reported that the event participation improved physical fitness, body weight, mental health, social interaction and social wellbeing. However, most participants were either runners or relatively healthy, if unfit, adults with 34% to 43% of participants being overweight or obese. There is less evidence of the benefits of parkrun for people with chronic diseases, despite the potential benefits. Quirk and Haake [24] published a qualitative study, encompassing people with diabetes, asthma, cardiac conditions, arthritis, depression and dementia, that investigated the benefits of individuals with disabilities being parkrun participants or volunteers, but it was unclear if any participants were cancer survivors.

There is growing evidence that parkrun has substantial health benefits, physical and mental, with a broad range of contributing factors such as exercise in green spaces; its informal social nature, interaction and connectivity; the automatic event timing; volunteer event support; inclusivity; providing self-efficacy and feelings of being valued [5,24-26]. Barriers to parkrun included access and distance to travel [5], inconvenient start times, feeling too unfit to participate, injuries and other health concerns, being time-poor and childcare obligations, with more women than men reporting psychological barriers [27-31]. Interestingly, most of the parkrun studies have been conducted in the UK and authors have noted that UK population subgroups with high levels of social deprivation and ethnicity were under-represented at parkrun [5].

For parkrun to be a viable, enjoyable and acceptable mode of exercise rehabilitation for cancer survivors, we need to consider participant preferences, inclusivity, social support and “connection”, event access, health status and willingness to try something “new”. Disease-specific barriers may include medical treatment side-effects, symptoms, muscle weakness and sarcopenia [8-12] and participant perception of social isolation and disconnection [27]. This study aims to investigate the feasibility and acceptability of parkrun as an effective form of exercise to maintain or improve physical function, and prevent a decline in health and QoL.

**References**

1. Clinical Oncology Association of Australia. COSA Position Statement on Exercise in Cancer Care. COSA 2018. Retrieved from [www.cosa.org.au](http://www.cosa.org.au) August 4 2022.
2. Hayes, S.C., et al. The Exercise and Sports Science Australia position statement: exercise medicine in cancer management. *J Sci Med Sport*, 2019 22:1172-1199.
3. Fuller J.T., et al,.Therapeutic effects of aerobic and resistance exercises for cancer survivors: a systematic review of meta-analyses of clinical trials. *Br J Sports Med,* 2018 52**:**1311.
4. Cassidy, C. Not in the script: doctors turn to parkrun and social activities to treat chronic conditions. The Guardian, 2022, May 29th. Retrieved from: <https://www.theguardian.com/australia-news/2022/may/29/not-in-the-script-doctors-turn-to-parkrun-and-social-activities-to-treat-chronic-conditions>
5. Peterson, B., et al. Outcomes of participation in parkrun, and factors influencing why and how often individuals participate: a systematic review of quantitative studies. *J Sports Sci*, 2022 doi.org/10.1080/02640414.2022.2086522
6. Cormie, P., et al. The impact of exercise on cancer mortality, recurrence, and treatment-related adverse effects, *Epidemiologic Reviews*, 2017 39(1):71–92, <https://doi.org/10.1093/epirev/mxx007>
7. Eakin, E.G., et al. Health behaviors of cancer survivors: data from an Australian population-based survey. *Cancer Causes Control*, 2007 18(8):881-94.
8. Ng, A et al. Exercise barriers and adherence to recommendations in patients with cancer. *J Oncol* *Pract*, 2021 17:e972-e981.
9. Collado-Mateo, D., et al. Key factors associated with adherence to physical exercise in patients with chronic diseases and older adults: an umbrella review. *IJERPH*, 2021 18:2023 doi.org/10.3390/ijerph1804202
10. Inglis, J et al. Nutritional interventions for treating cancer-related fatigue: a qualitative review. *Nutr Cancer*, 2019. 71(1):21-40
11. Cao, A., et al. Effect of exercise on sarcopenia among cancer survivors: a systematic review. *Cancers,* 2022 14:786-802 doi.org/10.3390/cancers14030786
12. Arends, J et al. ESPEN expert group recommendations for action against cancer-related malnutrition. *Clin Nutr*, 2017 36(5):1187-1196 doi: 10.1016/j.clnu.2017.06.017
13. Coletta, A et al. Clinical factors associated with adherence to aerobic and resistance physical activity guidelines among cancer prevention patients and survivors. *PLoS ONE*, 2019 14(8):e0220814 Doi.org/10.1371/journal.pone.0220814
14. Kirkham, A et al. Exercise prescription and adherence for breast cancer: one size does not FITT all. *Med Sci Sport Exerc*, 2018 50(2):177-186
15. Galvao, D.A., et al. Compliance to exercise-oncology guidelines in prostate cancer survivors and associations with psychological distress, unmet supportive care needs, and quality of life. *Psychooncology*, 2015 24(10):1241-1249
16. Craike, M., et al. Predictors of adherence to a 12-week exercise program among men treated for prostate cancer: ENGAGE study. *Cancer Medicine*, 2016 5(5):787-794.
17. Livingstone, P., et al. Effects of a clinician referral and exercise program for men who have completed active treatment for prostate cancer: a multicenter cluster randomized controlled trial (ENGAGE). *Cancer*, 2015. Doi.org/10.1002/cncr.29385
18. Delrieu, L., et al. Feasibility and health benefits of an individualized physical activity intervention in women with metastatic breast cancer: intervention study. *JMIR MHealth UHealth*, 2020 8(1): e12306.
19. Santa Mina, D., et al. Effects of the community-based Wellspring Cancer Exercise Program on functional and psychosocial outcomes in cancer survivors. *Current Oncology*, 2017 24(5):284-294.
20. Rajotte, E., et al. Community-based exercise program effectiveness and safety for cancer survivors. *J Cancer Surviv*, 2012 6(2):219-228.
21. Phillips S.M., et al. Breast cancer survivors' preferences for technology-supported exercise interventions. *Support Care Cancer*, 2017 25(10):3243-3252
22. Fleming, J. Parkrun: increasing physical activity in primary care. *Br J Gen Practice*, 2019 483-484 doi.org/10.3399/bjgp19X705641
23. Stevenson, C and Hickson, M. Exploring the public health potential of a mass community participation event. *J Public Health(Oxf)*, 2014 36(2):268-274.
24. Quirk, H and Haake, S. How can we get more people with long-term health conditions involved in parkrun? A qualitative study evaluating parkrun’s PROVE project. *BMC Sports Sci Med Rehabil* 2019 11:22-31
25. Quirk, H., et al. Exploring the benefits of participation in community-based running and walking events: a cross-sectional survey of parkrun participants. *BMC Public Health*, 2021 21:1978-1993 doi.org/10.1186/s12889-021-11986-0
26. Grunseit, A et al. Evidence on the reach and impact of the social physical activity phenomenon parkrun: a scoping review. *Prev Med Rep*, 2020 20:101231 doi.org/10.1016/j.pmedr.2020.101231.
27. Bowness, J., et al. Understanding the parkrun community; sacred Saturdays and organic solidarity of parkrunners. *Eur J Sport Soc*, 2021 18(1):44-63.
28. Stevens, M., et al. Social identification, exercise participation, and positive exercise experiences: evidence from parkrun. *J Sports Sci*, 2019 37(2):221-228.
29. Cleland, V., et al. Exploring the health-promoting potential of the “parkrun” phenomenon: what factors are associated with higher levels of participation? *Am J Health Promotion*, 2019 33(1):13-23.
30. Dunne, A., et al. Motivation to improve mental wellbeing via community physical activity initiatives and the associated impacts – a cross-sectional survey of UK parkrun participants. *IJERPH*, 2021 18(24) doi.org/10.3390/ijerph182413072
31. Reece, L., et al. Barriers to initiating and maintaining participation in parkrun. *BMC Public Health* 2022 22:83-92
32. Cochrane Library, 2022. [https://childhoodcancer.cochrane.org/non-randomised-controlled-study-nrs-designs Retrieved 15th August 2022](https://childhoodcancer.cochrane.org/non-randomised-controlled-study-nrs-designs%20Retrieved%2015th%20August%202022)
33. Exercise and Sports Science Australia. Adult Pre-exercise Screening System (APSS V2), 2019.
34. BORG scale of perceived exertion
35. Fayers, PM et al, on behalf of the EORTC Quality of Life Group. The EORTC QLQ-C30 Scoring Manual (3rd Edition).
36. Zigmond, A and Snaith, R. The hospital anxiety and depression scale. *Acta Psychiatr Scand*, 1983 67(6):361-70 d[oi.org/10.1111/j.1600-0447.1983.tb09716.x](https://doi.org/10.1111/j.1600-0447.1983.tb09716.x)
37. Lee, P. Validity of the international physical activity questionnaire short form (IPAQ-SF): A systematic review. *Int J Behav Nutr Phys Act*, 2011 8:115-126 doi: 10.1186/1479-5868-8-115
38. Dietitians of Canada Ontario Primary Health Care Action Group Mediterranean Diet Toolkit. Adapted from tools produced by Alison Hornby and Katherine Paterson, 2013
39. Estruch et al. Primary Prevention of Cardiovascular Disease with a Mediterranean Diet Supplemented with Extra Virgin Olive Oil and Nuts. *N Engl J Med* 2018; 379;1387-1389. Doi: 10. 1056/NEJMc1809971
40. Braun, V., and Clarke, V. Using thematic analysis in psychology. *Qual Res in Psych*, 2006 *3*(2):77–101. <https://doi>. org/10.1191/14780 88706 qp063oa

* RATIONALE and JUSTIFICATION (how the research will fill any gaps, contribute to the field of research or contribute to existing or improved practice)

Regular exercise for cancer survivors is strongly recommended yet the majority of individuals do not meet the recommended levels of physical activity. Common reasons for low participation rates include access issues, poor levels of baseline fitness, fitting exercise around medical appointments and treatments, disease symptoms and treatment side effects. Growing evidence from group exercise programs and parkrun itself suggest that it is a mode of physical activity that appeals to people with low fitness levels, and it provides a framework and social support that can be beneficial for people with chronic diseases and disabilities. Parkrun can be a walk or run event, and is self-paced and well-monitored, therefore has the potential to be a manageable, safe mode of exercise for individuals with low functional capacity.

This project will investigate the feasibility of parkrun as a mode of physical activity for cancer survivors, with regard to acceptability, enjoyment and social identification for participants, and efficacy in maintaining or improving physical and functional status, and QoL. There is very little published data on the use of parkrun for people with chronic diseases and disabilities, so this study will provide much-needed evidence that parkrun is accessible, inclusive, supportive, safe and effective, and that it can provide real benefits for patients that can be translated to clinical practice.

* RESEARCH QUESTIONS

1. Do cancer survivors find parkrun an enjoyable and manageable form of physical activity?
2. Are cancer survivors able to adhere to regular parkrun participation over a 6-month period?
3. What are specific barriers to parkrun participation for cancer survivors?
4. Does parkrun participation maintain or improve physical capacity or function?
5. Does parkrun improve QoL, anxiety and depression in cancer survivors?
6. Does parkrun improve disease symptoms and treatment side effects (fatigue, sarcopenia, weight gain, nausea, pain)?
7. Does participation in parkrun affect the diet quality and eating behaviour of participants?
8. What are the levels of physical activity and sedentary behaviour (sitting) in cancer survivors before and after the parkrun intervention?

* AIMS and OBJECTIVES

1. To evaluate the feasibility and acceptability of parkrun as a physical activity intervention for cancer survivor rehabilitation
2. To assess the efficacy of parkrun for preventing physical and functional decline, and improving general health and QoL
3. To assess general physical activity levels and sedentary behaviour across a range of cancer survivors, before and after parkrun participation

* HYPOTHESES

1. Consistent parkrun participation will improve cancer survivor engagement in physical activity, social interaction and social identity with parkrun event groups.
2. Cancer survivors will enjoy doing parkrun events
3. Cancer survivors participating in parkrun will have improved physical function and mental health, compared to baseline measures, after the 6 months intervention
4. Parkrun participation will reduce the severity of disease symptoms and treatment side effects
5. Parkrun participation will improve the diet quality and eating behaviour of participants
6. Parkrun participation will increase general levels of physical activity and reduce sedentary behaviour (sitting) in participants

* EXPECTED OUTCOMES

**Outcome Measures**

1. Demographics and participant information including: age and gender, type and stage of cancer, time since diagnosis, type of treatment(s), symptoms
2. Physical function (anthropometry, resting heart rate and blood pressure, 6MWT [speed and distance], parkrun session step count and walk distance], 30 s Sit to Stand [lower leg strength]), Perceived Exertion ([RPE] Borg Rate of Perceived Exertion 6-20 scale)
3. Wellness and Quality of Life (European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire [QLQ-C30])
4. Mental Health (Hospital Anxiety and Depression Scale, HADS)
5. IPAQ Short Form physical activity questionnaire
6. Mediterranean Diet Score Tool
7. Adherence (sessions attended, attrition %, participant feedback)

**Expected Study Outcomes**

We have hypothesized that regular parkrun participation will improve physical capacity and function in cancer survivors, in addition to improved QoL, mental health, social interaction and identity. Recent studies of parkrun have provided evidence of these sorts of outcomes with recreational athletes and sedentary individuals, and we hope to see similar results with cancer survivors. Event adherence and sustained participation for 6 months is also a focus of this study, and identifying factors that contribute to adherence, enjoyment, improved mood and acceptability of parkrun as a form of exercise rehabilitation. Another important study outcome will be if there are positive changes in dietary intake, nutrition and eating behaviours, given the risk of sarcopenia and muscular weakness with many types of cancers.

## Project Design

|  |  |
| --- | --- |
|  | **Intervention/ Tests** |
| **Research Activity** | 9-month prospective, controlled cohort study. Mixed methods. |
| **Setting** | Community-dwelling, out-patients.  Parkrun events held at Sunshine Coast parks - Mujimba, Brightwater, Baringa Sports Ground/Aura, Kawana, Golden Beach, Nambour, Maleny, Glasshouse Mountains |
| **Participants** | Cancer survivors diagnosed with any type of cancer and aged 18+. Participants may be undergoing treatment or in remission |
| **Identifiability during data collection** | Identifiable – participant name and contact details for initial screening, baseline and post-intervention data; participants can be assigned their numerical parkrun ID number for data analysis purposes. Parkrun ID number for attendance, distance and mood (app) metrics. |
| **Identifiablity – data storage** | Re-identifiable |
| **Identifiability – publications etc.** | Non-identifiable |
| **Recruiting methods and/or considerations** | Social media  Flyers  Radio  USC website  Project awareness from local cancer care nurses, oncologists and general practitioners  Cancer support groups and networks  Cancer care nurses who can advise patients of the project  Bloomhill cancer wellness centre  Parkrun advertising  Email to potential participants |
| **Consent**  **-Written/Verbal/ /Waiver/ Opt Out**  **-Specific / Extended / Unspecified**  **-Other considerations** | Written |
| **Risks and Benefits** | RISKS  Dizziness, nausea – researchers and parkrun volunteers are first-aid trained  Muscular stiffness or soreness if unused to exercise (participants will be advised to self-pace their walking or jogging, take rests and stretch if necessary and wear comfortable, appropriate non-slip footwear with adequate arch support and some shock absorption)  Sunburn and dehydration (participants will be advised to wear hats and sunscreen and carry a water bottle)  Asthma (participants with diagnosed asthma should bring inhalers with them)  A cardiovascular event is possible but extremely unlikely and each parkrun event has trained CPR/1st aid volunteers along the routes. All participants will have been screened for CVD risk and any person who has a serious, uncontrolled cardiac condition will have been excluded from the study  BENEFITS  Potential improvements or maintenance of health status, physical capacity, strength, cancer symptoms and treatment side effects  Potential weight loss  Potential gain in muscle mass or reduced risk of sarcopenia  Potential positive changes in appetite, dietary intake and eating behaviours  Improved mental health, mood and QoL  Improved social interaction, identity, connection and support  General increase in incidental physical activity and reduced sedentary time/sitting during and after the 6-month intervention  Summary report of de-identified study findings plus a personal summary report of each individual’s pre- and post-study data  Reimbursement of USC parking paid (if LAUNCH successful) |
| **Data Storage/ Considerations** | Secure USC laptop  R drive during and upon project completion |
| **Results/ Outcomes/ Future plans** | Peer-reviewed publications  Conference presentations  Future related projects by this team in collaboration with cancer wellness centres, oncologists and cancer support groups |

* Research project settings
* Free-living/outpatient adults recruited from the general community
* Sunshine Coast parkrun events (Mujimba, Brightwater, Baringa Sports Ground/Aura, Kawana, Golden Beach, Nambour, Maleny, Glasshouse Mountains)
* University of the Sunshine Coast: Sippy Downs campus exercise science laboratories (participant screenings, baseline, pre- and post-intervention assessments)

### Methodological approach

* Prospective 9-month cohort study with data collection at 1 month pre-intervention, 1 week pre-intervention, post-6-month intervention and at 3 months follow-up [32].

|  |  |  |  |
| --- | --- | --- | --- |
| **Timepoint 1**  1-month pre. Screening and baseline measures | **Timepoint 2**  Week before start of 6-month parkrun participation | **Timepoint 3**  Post-6-month intervention.  All measures + participant survey | **Timepoint 4**  3-month follow-up.  EORTC QLQ-30  HADS IPAQ-SF  MEDAS  Survey |

* Mixed-method study (qualitative and quantitative)
* Within-group analyses (T1, T2, T3, T4) of physical function outcome measures; parkrun participation (attendance); event distances completed; walk or jog speed; pre- and post-event mood, self-confidence and energy levels; disease-specific symptoms; anxiety and depression; QoL; general physical activity levels and sitting time; diet score.

### Participants

* Prospective cohort study of cancer survivors aged 18 years or more. Individuals are eligible for the study if they have been diagnosed with any type of cancer and meet the following Inclusion Criteria.

INCLUSION CRITERIA

* Diagnosed with any type of cancer (e.g. breast, prostate, colorectal, blood, bone)
* Cancer survivor i.e. undergoing medical treatment or in remission
* GP / medical practitioner approval to undertake walking
* Must be registered with parkrun before start of the first walk/run event
* Able to communicate in English or participate with a carer/support person who can communicate in English

EXCLUSION CRITERIA

* Unable to walk
* Undergoing end-of-life care
* Does not have GP / medical practitioner approval to walk
* Current musculoskeletal injury that might cause pain during walking or jogging
* Neurological condition that is a falls risk or exercise risk for participants
* Uncontrolled hypertension and/or serious, uncontrolled cardiac disease symptoms (e.g. angina, arrythmias, heart failure)
* Serious pulmonary disease where forced vital capacity (FVC1) is less than 1 litre
* Uncontrolled metabolic or renal disease
* Unable to communicate in English or follow verbal instructions from parkrun volunteers and/or carer/support person
* Severe visual, and/or auditory impairment, or behavioural, cognitive or psychological disorder, that would affect understanding and complying with clear instructions or communicating with others
* Unable to commit to the 9-month period of the study
* Sample size and statistical or power issues

Sample size was determined via simulation methods using a random intercept model. Exercise adherence (measured as the proportion of cancer patients meeting minimum physical activity guidelines) is one of our primary outcome measures and was the response variable in the sample size model. Data used to create the model were informed by previous studies [13,14]. Time (three levels- baseline, 6months and follow-up), body mass index (BMI) and sex (two levels- male and female) were included as fixed factors within the model. A random intercept was included for individual participants to account for repeated measures (at the three levels of time). BMI and sex were included as fixed factors as these variables can influence exercise adherence in cancer patients [14]. Calculations were made assuming fixed effects of 2.11%, -0.06% and –0.36% for time, BMI, and sex respectively; a standard deviation of the random intercept of 4% and a model error (residual standard deviation) of 9.5%. Based on these assumptions for 80 participants and a type I error rate of 5%, power to detect a fixed effect of time was 80% (95% CI = 77 to 82%). We anticipate being able to recruit 100 participants, which allowing for potential attrition of 20 people, would provide a sample size of 80.

### Recruitment and Consent

See Sections 5 and 9 of the [USC Human Research Ethics Guidelines](https://my.usc.edu.au/_layouts/15/WopiFrame.aspx?sourcedoc=/Documents/HRE%20USC%20Human%20Research%20Ethics%20Guidelines.pdf&action=default) (staff link)/ [Blackboard](https://online.usc.edu.au/webapps/blackboard/content/listContent.jsp?course_id=_11_1&content_id=_26598_1) (students link)

* Participant recruitment strategies and timeframes
  + Social Media including Facebook closed groups (ESSA Cancer group, Cancer Council support group, local cancer support groups)
  + Flyers on campus, by email to cancer support groups and wellness centres, via a third-party (external organizations and clinics putting an item in their newsletter or sending an email to their contacts on our behalf)
  + USC website (USC news) and USC Research online noticeboard
  + Radio and printed media (e.g. Profile magazine)
  + Parkrun research team and website
  + Permissions will be sought as relevant to post to groups/noticeboards and from the appropriate organisations for cancer care nurses and oncologists who would like to advise the project etc. All third-parties will be advised to circulate only ethics-approved materials.
  + We aim to advertise the project initially for 6 weeks but can continue to roll the project through 2023 and into early 2024.
* How will project information be provided to participants? (e.g. with recruiting email, as the landing page on a survey)

The study aims to run over a 9-month period which includes one month of normal activities/usual care, followed by 6 months of parkrun participation, and then a follow up at 3 months post-intervention. Potential participants will be recruited from the Sunshine Coast region. Recruitment will be done with media advertisements (newspapers, radio, Facebook, USC webpage, cancer support groups and state organisations), flyers (in GP clinics, pharmacies, community centres, notice boards, cancer support groups and organisations). Permission to advertise the project in medical clinics and community support groups will be sought from the practice or organization managers to ensure correct governance and procedures are followed. **Potential participants can contact any member of the research team by phone or email** for further project information, and risks and benefits of participating can be explained at this time. Official project information sheets (RPIS) can be emailed or posted to participants. Once participants have read the information sheet, understood their commitment to the project, and decided to volunteer, they must complete and sign an informed consent sheet. The consent form can be (1) scanned and emailed back tothe researchers at the university email addresses; (2) the completed form can be brought to the exercise science laboratory when baseline assessments and screening are done.

The project will be advertised initially for at least 6 weeks, to allow adequate time for recruitment and for potential volunteers to decide to participate**. However, the project can continue on a rolling basis through 2023 and 2024, with Bloomhill and cancer support network ongoing support.**

Participants will attend the University of the Sunshine Coast exercise science laboratory to meet the researchers. The informed consent, pre-screening for exercise contraindications and cardiovascular risks forms, hard-copy questionnaires and medical history will be completed by participants one-month prior to joining in any parkrun event. The hard-copy questionnaires will be also completed immediately post exercise intervention at the 6-month mark. There will be a follow-up survey of open-ended questions 3-months after the end of the parkrun participation intervention. The approximate start date of the project is February 2023 and the approximate end date is July 2024.

The flyers and media advertisements will briefly explain the aims of this study and give detail on the inclusion as well as details about the exercise involved. Potential participants will be encouraged to contact members of the research team by email or phone for further study information, explanation of time frames and commitments for participants. Benefits and risks can be explained at this point, and participants will be reassured that they can withdraw from the study at any time. Interested participants will be emailed or posted paper copies of the official information sheet and consent form. The official project information sheet will include a background and brief description of the study, description of commitment for participants, risks and benefits, and contact details of the researchers.

**Some participants may have NDIS funding for transport. Participants may incur costs associated with travel to and from the University, as well as University parking costs which is $3 per half-day. There is 1-hour free parking in front of the Chancellor Park State School, and there is free parking at the Claymore Road car park. There is also public transport to the main campus.**

* How will you get consent (e.g. written or verbal) for each data collection method/participant group?

Written consent is required from all participants. The consent form can be emailed or posted to participants. Participants can email the completed form back to the researchers or can bring it with them to their baseline screening and assessment visit.

* Will any other parties (e.g. physicians, tutors) be involved in confirming or re-negotiating consent? If so, and as relevant, how will unequal relationships be managed?

Written consent must be provided by each participant. If a participant has poor English verbal and written skills, then a carer, family member or support person can complete the consent document on behalf of the participant but each participant must have the consent content explained to them, and when informed, may agree to participate by signing the document themselves.

* What level of consent are you seeking (specific/extended/unspecified)? Will participants be given an option to select the level of consent they wish to provide?

To participate in this project, we require specific consent for the 6-month study.

* As relevant, how will these processes be managed to acknowledge cultural or other considerations (e.g. language/literacy, disabilities)?

The study is open to any cancer survivor who meets the inclusion criteria, irrespective of ethnic or cultural groups. Participants will need to be able to walk with minimal risk of falling, so those with a disability that prevents them walking would not be eligible for the study. They may like to volunteer with parkrun to be an event volunteer, but that involvement is a personal decision for them and is not part of this project. Any participant who meets inclusion criteria, and has poor English (needing a translator, interpreter or carer) is welcome to join the study provided that their support person can understand the study assessment procedures and parkrun event directions, and can inform the actual cancer survivor participant of all instructions and directions. This is a safety issue for participants and they need to understand any verbal and written directions.

### Research Activities

* What you are going to do?
  + This is a 9-month prospective cohort study with a mixed-methods approach.
  + We will recruit cancer survivors who would like to be involved in parkrun events, either for walking or jogging, as a mode of physical activity whilst they are undergoing treatments or are in remission.
  + We will seek the support of local oncologists and GPs, and cancer care/wellness centres such as Bloomhill, to alert cancer survivors to this study. Potential participants can contact the research team for further information.
  + The study will be advertised through the USC website, parkrun, social media, radio, cancer support services, private and public hospitals and associated oncologists, Sunshine Coast medical practices and the QLD chapter of Exercise and Sports Science Australia (ESSA).
  + Potential participants can contact any of the research team for further information and explanation of the study. Parkrun will also have been provided with study information. People who would like to participate can be sent a copy of the RPIS and informed consent form by email or post. If they wish to volunteer for the study, they can sign the consent form and return by email or bring the form in to the pre-intervention screening and assessment appointment at the USC Exercise Science laboratory.
  + Participants will need to register with the parkrun organization prior to joining in any event and must have their parkrun ID bracelet.
  + We will conduct a participant screening session and baseline data collection 1 month in advance of each participant starting parkrun. There will be a 4-week period of usual care and ADL to establish each participant’s level of physical function, QoL etc. This allows a comparison with participants acting as their own controls.
  + The week before each participant’s first parkrun, we will collect the physical function data and questionnaires to record any changes in physical fitness and activity, QoL, mental health, and diet.
  + The 6-month intervention period will include all parkrun events that participants enrol into and complete. Participants don’t have to do an event each weekend but can select when and where they do a parkrun through the intervention period. An app available for smart watches or phones will be able to record how participants feel before and after each event (mood).
  + At the end of the 6-month period, post-intervention data and a participant survey will be collected at the exercise science laboratory. We will also do a 3-month follow-up contact, which will be online surveys and questionnaires, to establish if participants are continuing with parkrun or other physical activity.
* Participant commitment

We would like participants to try and commit to the full 9 months of the study. There will be an additional commitment time of approximately one hour for baseline screening and assessments, another hour for post-intervention assessments and then approximately 30 minutes to complete a follow-up survey 3-months after the end of the intervention. However, any participant is able to withdraw from the project at any time if they wish; this will be made clear to all participants in the Consent form, RPIS and during initial contact with the researchers. There will be no pressure for participants to attend weekly parkrun events. Participants can attend parkrun events through the 6 months according to their ability to manage the walking or jogging on the day of the event. We appreciate that some participants may be undergoing rounds of therapy and may not be able to participate each weekend, or they may have pressing commitments for other activities on some weekends. Ideally, we would like to know the reasons for participant dropout as this can provide data on possible barriers to parkrun participation, which can inform clinical practice.

* Project duration

The total study period is for 9 months for each participant but we anticipate a rolling data collection period through 2023 and into mid-2024.

* Participant follow-up

There will be a follow-up contact and survey 2 months after the end of the 6-month parkrun intervention. This is to determine whether participants still doing parkrun or some other form of physical activity, and their reflections on their participation, activity levels, wellness and QoL, and diet/nutrition.

* Risks and Benefits

RISKS

* + Some participants may experience treatment side effects at times (e.g. nausea, dizziness) but would be advised not to participate in any parkrun event if walking made them feel worse or if they were at risk of having a fall or injuring themselves.
  + As with any mode of weight-bearing exercise, there is a potential risk of muscle stiffness or soreness, especially if the participant is very unfit to begin with. However, self-paced walking will be advised for people just beginning parkrun walking as a form of exercise, to lower the risk of any musculoskeletal injury.
  + Sunburn and dehydration are potential risks of outdoor exercise.
  + Asthma is a potential risk in an outdoor setting but participants will be reminded to bring all relevant medications with them when they attend parkrun.
  + A cardiovascular event is extremely unlikely and each parkrun event has CPR/1st aid trained volunteers along each route. All participants will have completed the ESSA CVD screening (ESSA APSS, 2019) [31]. Any participant with a current, serious and/or uncontrolled cardiovascular health condition would have been excluded from the study.
* Strategies to mitigate or manage risks
  + Parkrun has volunteer assistants literally every 500 metres along the path or track, who can help any event participant who feels unwell during the event. Medical assistance can be arranged by event organisers if necessary. First-aid trained personnel are also at every parkrun event.
  + All participants must have their GP, medical practitioner and/or oncologist approval to walk as a form of exercise (inclusion criteria).
  + All participants will have completed a CVD risk screening prior to the study and anyone with a serious cardiovascular condition that is a risk for them exercising, will have been excluded from the study.
  + All participants will be advised to exercise at their own pace and for whatever distance they feel comfortable to do. There is no pressure to walk or jog for a full 5 km if the participant is not fit enough or feeling well enough.
  + Participants will be advised to wear appropriate footwear for walking or jogging (non-slip shoes with adequate arch support and shock absorption).
  + All participants will be advised to wear sunscreen, hats and to take water and snacks with them if necessary.
  + Any participant who has asthma will be advised to take their inhaler and any other medication with them.

BENEFITS

* + Potential improvements or maintenance of health status, strength, symptoms
  + Potential improved mental health (anxiety and depression)
  + Potential improved QoL, wellness, mood and enjoyment
  + Increased social activity, connection and interaction; potential to increase one’s social identity through group support with other cancer survivors
  + Summary report of de-identified study findings plus a personal summary report of each individual’s pre- and post-study data
  + Reimbursement of parking paid (if LAUNCH grant funding is successful)

### Data Collection/Gathering

* What information are you going to collect/gather?

This is a mixed-methods study. Collected data will consist of:

* + Signed informed consent form for each participant
  + Participant phone and email contact details for arrangement of USC assessments pre- and post-intervention, and for distribution of de-identified summarized project results
  + Demographics (age, gender, geographical location)
  + Brief medical history (type of cancer, staging, time since diagnosis, current treatments and medications, other medical/health conditions or injuries, cardiovascular disease risk screening [ESSA APSS 2019]) [33]
  + Current symptoms and treatment side effects, if any
  + Physical function (height, weight, resting heart rate and blood pressure, 6MWT [speed and distance], 30 s Sit to Stand [lower leg strength]), Perceived Exertion ([RPE] Borg Rate of Perceived Exertion 6-20 scale) [34]
  + Parkrun data downloaded from parkrun ID bracelet (number of events attended, location of each event, distance completed each event, session step count, average walk speed), and phone or smart watch app (pre- and post-event mood)
  + Wellness and Quality of Life (European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire [QLQ-C30]) [35]. This tool consists of 30 questions in 15 subscales relevant to people with cancer: five distinct aspects of functioning (physical, role, emotional, cognitive, social), eight symptoms (fatigue, nausea/vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhoea), financial difficulties, and global health/quality of life.
  + Hospital Anxiety and Depression Scale (HADS); 14 separate questions on anxiety and depression in the previous 7 days [36]
  + IPAQ-SF Short Form physical activity questionnaire for incidental physical activity and activities of daily living (ADL); 7 domains assessing over the previous 7 days the amounts vigorous, moderate and low intensity activities, walking and sitting (minutes and MET values) [37]
  + Mediterranean Diet Score tool for daily food intake, type of foods consumed and eating behaviour [38,39]; 14-question scored tool identifying types of foods, amounts consumed and daily eating patterns
  + Calculated parkrun adherence and attrition (%)
  + Participant feedback (general comments about parkrun and the study)
* How will you collect/gather the information?
  + Informed consent will be collected using the ethics-approved Consent Form
  + Personal contact details will be gathered via the initial phone or email contact between potential participants and the research team
  + Medical history and baseline physical function will be collected by the research team at the screening visit to the USC Exercise Science laboratory
  + Post-intervention data will be collected by the research team at the final visit to the USC Exercise Science laboratory
  + Parkrun metric data will be downloaded from each participant’s ID bracelet.
  + Participant mood will be recorded using an app on phone or smart watch which can be downloaded
* Impact of and response to participant withdrawal

Participants are free to withdraw from the study at any time, and all participants will be informed of this. Reasons for attrition would be recorded as useful information on barriers to parkrun as a mode of exercise for cancer survivors. (Intention-to-treat would not be an appropriate type of data management for this project, as it is not a controlled trial). We aim to keep the study rolling over 2023 and into 2024 to make sure we have as large a sample size as possible, which would lower the impact of attrition.

### Data Management

* How will you store, provide access to, disclose, use/re-use, transfer, destroy or archive the information that you collect/gather?

Data will be stored on an external hard drive specifically for this project, which can be password-protected. All backed up data can be stored on USC’s R drive. Any hard copy material will be locked in a filing cabinet in the lead researcher’s office. All data will remain confidential and will be not identifiable for purposes of statistical analyses and publication. Data will only be available to the research team members e.g. for statisical analysis, and would be transferred person to person via email attachment (e.g. spreadsheets), USB or external hard drive. All data will be stored for a minimum of 5 years from the completion of the research as per USC guidelines and procedures. After archiving for a minimum of 5 years, any hard copy material may be shredded using USC’s contracted service providers.

* Will data be stored in an identifiable, re-identifiable or non-identifiable format?

Data will be stored:

(1) in an identifiable format for participant contact details, for emailing or phone contact only.

(2) in a re-identifiable format for all consent, demographic, medical, physical, QoL, mental health and dietary information. Participants will have been allocated an ID number, their parkrun ID, which will be used when their data is entered into Excel spreadsheets.

(3) in a non-identifiable format for statistical analyses and dissemination of results (e.g. peer-reviewed journals, conferences, summary reports back to participants).

* Note: Data must be managed according to the [USC Data Management Procedures](https://www.usc.edu.au/about/policies-and-procedures/data-management-procedures)

### Data Analysis

* How will you measure, manipulate and/or analyse the information that you collect/gather?

Quantitative and qualitative data are components of this study. Numerical data from demographic, physical and scored questionnaire outcome measures will be analysed using Excel spreadsheets and IBM©SPSS version 27. Qualitative data (mood, participant feedback survey responses, participants' attitudes towards the intervention, enjoyment, appropriateness, suitability, convenience and perceived effectiveness of the intervention) will be analysed thematically using NVivo and following the process of Braun and Clarke (2006) [40]. Comments will be read, organised and coded using an iterative framework (familiarisation; generation of initial codes; search for themes; review of themes; definition of themes and a final report). The codes will be reviewed, discussed and refined with the coding framework drawn from the data as well as being informed by the survey questions and themes highlighted in wider literature on parkrun outcomes [5,28,29].

Descriptive statistics (mean ± SD) will be reported for each quantitative variable. Mixed models will be used to determine if participating in parkrun improves exercise adherence in cancer patients. Mixed selection will be used to determine predictors included in the model, and the model with the smallest AIC (Akaike Information Criterion) value will be selected as the optimum model. Models where adherence is the outcome variable will include time (baseline, pakrun and follow-up), sex (male or female) and BMI as fixed effects. These models will also include a random intercept for each participant, to account for repeated measures at each level of time. Normal distribution of residual values will be determined using Q-Q plots and histograms. Model fit will be assessed using the adjusted R2 value and the model residual standard error, the most parsimonious model will be selected for inferences. Effect sizes (Cohen’s d) will be calculated where there are significant effects of time using the pooled standard deviation as the denominator.

* Matching and sampling strategies

Given that this study is not a controlled trial, and the expected range of cancer types, stages, treatments, age and genders of participants, it is not feasible to attempt exact matching of participants according to age, cancer type etc. The primary focus of this study is participant acceptability, enjoyment and perceived effectiveness. The qualitative and quantitative data utilises a mixed-methods approach which does not lend itself to exact matching for the outcome measures.

* Accounting for potential bias, confounding factors and missing information

Data will be tested for normal distribution using the Shapiro-Wilk test. If data sets have an unequal or skewed distribution, the pre-post changes can be analysed using a Mann-Whitney U test with calculated effect size.

Because the study runs for a set duration for each participant, there will be no length-bias.

Intention-to-treat would not be a suitable approach for missing data within this mixed-methods study. In the case of participant attrition from the study, or if participants miss various parkrun events in the 6-month intervention period, researchers will follow up with each participant individually, either through the study or at the end of the study. Reasons for reduced attendance or attrition can be gained from the participant and this information is valuable for informing the researchers of potential barriers or issues with parkrun as a mode of cancer rehabilitation exercise.

* Statistical power calculation

Sample size was determined via simulation methods using a random intercept model. Exercise adherence (measured as the proportion of cancer patients meeting minimum physical activity guidelines) is one of our primary outcome measures and was the response variable in the sample size model. Data used to create the model were informed by previous studies [13,14]. Time (three levels- baseline, 6months and follow-up), body mass index (BMI) and sex (two levels- male and female) were included as fixed factors within the model. A random intercept was included for individual participants to account for repeated measures (at the three levels of time). BMI and sex were included as fixed factors as these variables can influence exercise adherence in cancer patients [14]. Calculations were made assuming fixed effects of 2.11%, -0.06% and –0.36% for time, BMI, and sex respectively; a standard deviation of the random intercept of 4% and a model error (residual standard deviation) of 9.5%. Based on these assumptions for 80 participants and a type I error rate of 5%, power to detect a fixed effect of time was 80% (95% CI = 77 to 82%). We anticipate being able to recruit 100 participants, which allowing for potential attrition of 20 people, would provide a sample size of 80.

* Data Linkage: What linkages are planned or anticipated?

None

* Outcome measures

## Demographics and participant information including: age and gender, type and stage of cancer, time since diagnosis, type of treatment(s), symptoms

## Physical function (anthropometry, resting heart rate and blood pressure, 6MWT [speed and distance], parkrun session step count and walk distance], 30 s Sit to Stand [lower leg strength]), Perceived Exertion ([RPE] Borg Rate of Perceived Exertion 6-20 scale)

## Wellness and Quality of Life (European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire [QLQ-C30])

## Mental Health (Hospital Anxiety and Depression Scale)

## IPAQ physical activity questionnaire

## Mediterranean Diet Score Tool

## Adherence (sessions attended, attrition %, participant feedback)

## Results, Outcomes and Future Plans

* Plans for return of results of research to participants
* Plans for dissemination and publication of project outcomes
* Other potential uses of the data at the end of the project
* Project closure processes
* Plans for sharing and/or future use of data and/or follow-up research (Note: where data may be used again consider the level of consent sought for the project)
* Anticipated secondary use of data