



STUDY PROTOCOL

REVISED

The feasibility of implementing an exercise programme for deconditioned cancer survivors in a national cancer centre: FIXCAS Study [version 2; peer review: 2 approved]

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V2 First published: 30 Sep 2019, 2:24
<https://doi.org/10.12688/hrbopenres.12925.1>
 Latest published: 18 Dec 2020, 2:24
<https://doi.org/10.12688/hrbopenres.12925.2>

Abstract

Introduction: As both the number of cancer survivors and the length of survival time are increasing, long-term health issues related to cancer and its treatment are becoming more prevalent. Research suggests that exercise can mitigate several negative health consequences in cancer survivors and improve physical function and quality of life. Multi-modal exercise interventions have been proposed as a cornerstone for survivorship care. However, studies evaluating exercise programmes within the Irish population are lacking.

Purpose: To evaluate the introduction, implementation and acceptability of a multi-modal exercise rehabilitation programme for deconditioned cancer survivors in a real-world, standard practice setting.

Methods and analysis: In this single-arm prospective feasibility study, cancer survivors (n=40) will undergo a 10-week multi-modal exercise programme. The study population will comprise of cancer survivors attending outpatient services in an Irish national cancer centre. Participants will be aged 18 or older and have completed treatment with curative intent. Feasibility will be evaluated in terms of recruitment, adherence and compliance to the programme. Secondary outcomes will examine physical function and quality of life measures. In addition, the acceptability of the programme will be assessed through stakeholder feedback.

Ethics and dissemination: Ethical approval through the St. James's Hospital and Tallaght University Hospital Research and Ethics Committee is currently pending. The study results will be used to optimise the intervention content and may serve as the foundation for a larger definitive trial. Results will be disseminated through peer-

Open Peer Review

Reviewer Status

Invited Reviewers

| | 1 | 2 |
|---|------------|------------|
| version 2 (revision) 18 Dec 2020 | report | report |
| version 1 30 Sep 2019 | report | report |

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Any reports and responses or comments on the article can be found at the end of the article.

review journals, congresses and relevant clinical groups. **Trial registration:** ClinicalTrials.gov [NCT04026659](https://clinicaltrials.gov/ct2/show/study/NCT04026659) (19/07/19)

Keywords

Exercise, Rehabilitation, Cancer

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Author roles: **Devenney K:** Investigation, Methodology, Project Administration, Writing – Original Draft Preparation, Writing – Review & Editing; **Murphy N:** Resources, Writing – Review & Editing; **Ryan R:** Investigation, Project Administration, Writing – Review & Editing; **Grant C:** Investigation, Project Administration, Writing – Review & Editing; **Kennedy J:** Investigation, Project Administration, Writing – Review & Editing; **Manecksha RP:** Investigation, Project Administration, Writing – Review & Editing; **Sheils O:** Supervision; **McNeely ML:** Supervision, Writing – Review & Editing; **Hussey J:** Supervision; **Sheill G:** Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: This work was supported by the Irish Cancer Society [STS19SHE].

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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How to cite this article: Devenney K, Murphy N, Ryan R *et al.* **The feasibility of implementing an exercise programme for deconditioned cancer survivors in a national cancer centre: FIXCAS Study [version 2; peer review: 2 approved]** HRB Open Research 2020, 2:24 <https://doi.org/10.12688/hrbopenres.12925.2>

First published: 30 Sep 2019, 2:24 <https://doi.org/10.12688/hrbopenres.12925.1>

REVISED Amendments from Version 1

Many thanks to the reviewers for their useful feedback and suggestions. We have reflected on the feedback received and have revised the manuscript in line with this. Specifically, this updated version has clarified the primary and secondary outcomes of the study. In addition, further information is now provided on the use of a single-arm study design for this feasibility study. Additional information is now provided on the exercise intervention, including a figure outlining the different components of exercise sessions.

Any further responses from the reviewers can be found at the end of the article

Introduction

There are currently more than 150,000 cancer survivors in Ireland, and this number continues to rise (Department of Health, 2017). Furthermore, with advances in early detection and treatment of cancer in the context of an aging population, by 2020 1 in 2 Irish people will be a cancer survivor (Department of Health, 2017). Subsequently, as both the number of cancer survivors and the length of survival time are increasing, long-term health complications related to cancer treatment are becoming more prevalent (Miller *et al.*, 2016; Rowland & Bellizzi, 2014).

Depending on treatment pathways, cancer survivors can face several negative consequences of cancer treatment that include psychological (depression or anxiety, fear of recurrence, cognitive impairment) and/or physical symptoms (pain, peripheral neuropathy, sexual dysfunction, gait and balance deficits, joint mobility issues and lymphoedema) (Beesley *et al.*, 2007; Caraceni & Portenoy, 1999; Hendren *et al.*, 2005; Massie, 2004; Mehnert *et al.*, 2009; Mock *et al.*, 2001; O'Dell & Stubblefield, 2009; Quasthoff & Hartung, 2002; Vardy *et al.*, 2007). Numerous systematic reviews demonstrate that exercise can mitigate a number of these factors in cancer survivors and improve quality of life, fatigue, physical function and cardiorespiratory fitness and can optimise functional status, preserving the ability to remain in the workforce and fulfil other life roles (Courneya & Friedenreich, 1999; Galvão & Newton, 2005; McNeely *et al.*, 2006).

Despite the robust body of existing literature, the integration and delivery of exercise rehabilitation and survivorship into standard clinical cancer care continues to remain the exception rather than the norm (Mulcahy *et al.*, 2018). Internationally, models of cancer survivorship care have been developing rapidly in recent years, many centring on the provision of exercise rehabilitation programmes across diverse delivery settings (Oeffinger & McCabe, 2006). However, referral to exercise specialists is not a part of the standard care received by oncology patients in Ireland, with a distinct lack of rehabilitation services available for cancer survivors (Mulcahy *et al.*, 2018). There is a need to investigate the feasibility of delivering exercise-based rehabilitation to patients completing cancer treatment.

The aim of the FIXCAS (The Feasibility of Implementing an eExercise programme for deconditioned CAncer Survivors in a national cancer centre) study is to examine the feasibility of

implementing a 10-week multi-modal exercise rehabilitation programme to deconditioned cancer survivors in a National Cancer Centre. The implementation of the programme inform the integration of exercise rehabilitation into survivorship services in Ireland.

Methods**Study aim**

The overall aim of this work is to examine the feasibility of implementing a 10-week multi-modal exercise programme for cancer survivors. Feasibility will be determined by the following outcomes; recruitment, adherence and retention rates, acceptability of the programme and any adverse events.

Secondary aims are:

- To examine the effect of the FIXCAS programme on physical function.
- To examine the effects of the FIXCAS programme on patient reported outcomes including HRQOL and fatigue.
- To examine the costs associated with a ten-week exercise intervention in the cancer setting.

Study design

This is a single-arm prospective feasibility study for deconditioned cancer survivors in a real-world, standard practice setting. A convenience sample of patients (n=40) attending outpatient oncology services in St James's Hospital, a National Cancer Centre, will be recruited. This centre does not currently have an exercise-based rehabilitation service for cancer survivors. This study will primarily assess feasibility of the exercise intervention and the data from the pilot trial will be used to inform a sample size calculation for a definitive randomised controlled trial.

Study population

To be eligible to participate in this study, an individual must provide a signed consent form and meet the following eligibility criteria: 18+ years old, diagnosis of solid tumour, completion of chemotherapy and/or radiotherapy and/or surgery with curative intent within the preceding 12 months. All patients must receive medical clearance from their medical team before participating in the study. Only patients who presented with a self-reported loss of functional capacity, including a loss of physical fitness or muscle tone or a decrease in physical activity levels were considered deconditioned and eligible for participation (Broderick *et al.*, 2013). Individuals with moderate or severe cognitive impairment, currently pregnant or receiving treatment in the palliative setting will be excluded from participation in this study.

Recruitment

Potential participants will be recruited by direct invitation from study personnel in oncology clinics, by recommendation from medical or multidisciplinary colleagues, or by responding to mail-out of a study leaflet (sent out to individuals consenting to mail-out of information). Informed consent will be obtained in writing from participants by designated members of the research team (Extended data (Sheill, 2019)).

Intervention

The FIXCAS multi-modal exercise programme is designed in accordance with international guidelines for best practice exercise prescription for people with cancer (Schmitz *et al.*, 2010). The FIXCAS exercise programme is theoretically underpinned by the Theory of Planned Behaviour, the most widely used theory of exercise motivation for people with cancer (Armitage & Conner, 2001; Rhodes & Courneya, 2003). The intervention consisted of three motivational techniques designed to translate intentions into behavior. Patients set weekly goals for their home-based exercise and also received an exercise information booklet from the research team (instruction on how to perform the behavior). Patients also received feedback on their weekly physical activity from the research team during weekly exercise sessions.

The exercise programme includes 10 weeks of twice weekly group-based exercise sessions administered under the supervision of a physiotherapist with extensive training in the area of oncology. Each exercise session will last approximately 1 hour and consist of a combination of aerobic, resistance and balance and flexibility exercises (Figure 1).

Aerobic exercise will consist of 20 to 30 min of moderate intensity cardiovascular exercise using a variety of modalities such as walking or jogging on a treadmill, cycling or rowing on a stationary ergometer. Patient's baseline activity levels, exercise preferences and physical impairments will inform the choice of exercise modalities. Heart rate will be monitored using Polar FT7 heart rate monitors (Polar Electro, Lake Success, NY) and the BORG Rating of Perceived Exertion (Borg, 1998). Participants will exercise to a target intensity of 40–70% of estimated heart rate reserve (HRR) or 12–15 on the BORG Rating of Perceived Exertion (RPE) scale. Aerobic exercise will commence at a low intensity (40–55% HRR) and progress to moderate intensity (55–70% HRR) over the 10-week programme.

Resistance exercise will target the large muscle groups of the upper and lower extremities be performed at 40% to 70% of the measured one repetition maximum (1-RM) and consist of two sets of 10–15 repetitions. Resistance exercise will commence at a light to moderate intensity and will progress to a moderate intensity over the 10-week programme. Eight major upper limb and lower limb muscle groups will be exercised eg. biceps curl, leg extension.

Flexibility and balance exercise will be incorporated into the two supervised weekly sessions, as per current guidelines.



Figure 1. Outline of Exercise Intervention.

Self-directed care: A home exercise programme is included as a self-managed component of the programme which aligns with national recommendations for survivorship care. This self-management component is included to improve compliance and stimulate physical activity outside the exercise programme. Patients will be encouraged to be moderately physically active for at least 30 minutes, three times per week in addition to the supervised programme in order to meet current physical activity guidelines (Schmitz *et al.*, 2010).

Maintenance of the exercise intervention: All patients completing the FIXCAS programme will receive a written exercise summary upon completion (extended data (Sheill, 2019)) of the programme to facilitate transition to a local community exercise setting.

Outcomes

Outcomes will be assessed at baseline (T1) and at the completion of the 10-week intervention (T2). A follow up Quality of Life (QoL) Questionnaire (EQ-5D-5L) will be posted to participants 3 months postintervention (T3). Table 1 outlines the schedule of study assessments. A member of the research team will collect quantitative measures across all study time points. The qualitative element of the study will be undertaken after completion of the exercise programme.

Primary outcome. The primary outcome of this study will be its feasibility aspects, including recruitment rates (percentage of eligible study population that consented to participation), programme adherence (number of prescribed supervised and unsupervised sessions completed), retention, acceptability of the intervention and adverse events. Reasons for poor enrolment, attrition or non-compliance will be identified through qualitative evaluation with participants and medical professionals upon programme completion.

Secondary outcomes. Several secondary outcomes will investigate the impact of the intervention on physical function and QoL. Physical fitness will be measured by the 6 minute walk test (6MWT), a valid and reliable measure of physical fitness in people with cancer which will be performed according to the American Thoracic Society (ATS) Guidelines (American Thoracic Society, 2002; Schmidt *et al.*, 2013). Self-reported physical activity will be collected using the International Physical Activity Questionnaire (IPAQ) (Hagströmer *et al.*, 2006). Physical Performance will be measured by a Short Physical Performance Battery (SPPB) and a lower limb strength test (Leg extension 1-Repetition Max).

Quality of life is evaluated through the internationally established European Organisation for the Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC-QLQ-C30) (Aaronson *et al.*, 1993). It assesses important functioning domains (e.g. physical, emotional, role) and common cancer symptoms (e.g. fatigue, pain, nausea/vomiting, appetite loss) (Aaronson *et al.*, 1993). Euro-QoL (EQ-5D5L) a generic quality of life measure will also be used (Herdman *et al.*, 2011). This measure will be completed by all participants and

Table 1. Outline of study assessments. EQ-5D-5L: EuroQol-5D-5L; IPAQ: International Physical Activity Questionnaire; SPPB: Short Physical Performance Battery; 1-RM: 1 Repetition Maximum; EORTC-QLQ-C30: European Organisation for Research and Treatment of Cancer-Quality of Life Questionnaire-C30.

| Timepoints | | Pre-Screening Telephone Call | T1 | 10-week intervention | T2 | T3 |
|---|---|------------------------------|------------------|----------------------|-------------------|----------------------------|
| | | | Pre-intervention | | Post Intervention | 3 months post intervention |
| Initial Study Procedures | Explain study | X | X | | | |
| | Screen eligibility criteria | X | X | | | |
| | Sign consent form | | X | | | |
| | Case report form and clinical data | | X | | | |
| Feasibility Outcomes | Enrolment rates | | X | | | |
| | Adherence | | | X | | |
| | Adverse Events | | | X | | |
| | Retention rates | | | X | X | |
| | Stakeholder feedback | | | | | X |
| Secondary Study Outcomes | EQ-5D5L | | X | | X | X |
| | Cost analysis of programme | | | | | X |
| | Six-minute walk test | | X | | X | |
| | IPAQ | | X | | X | |
| | SPPB | | X | | X | |
| | 1-RM | | X | | X | |
| | EORTC-QLQ-C30 | | X | | X | |
| | Brief Fatigue Inventory | | X | | X | |
| | Body composition | | X | | X | |
| | International Consultation on Incontinence Questionnaire (Prostate cancer only) | | X | | X | |
| Brief Male Sexual Function Inventory (Prostate cancer only) | | X | | X | | |

will form part of the cost analysis of the programme. Fatigue will be assessed using the Brief Fatigue Inventory (BFI)

(Mendoza *et al.*, 1999). Prostate cancer survivors will complete questionnaires on incontinence (International Consultation on Incontinence Questionnaire) (Hajebrahimi *et al.*, 2004) and sexual function (Brief Male Sexual Function Inventory) (O'Leary *et al.*, 1995). Both incontinence and sexual function may be affected by the exercise intervention (Baumann *et al.*, 2012).

A needs assessment (impairment screening) of each individual will be collected at T1 and T2 study assessments. Body composition will also be collected at T1 and T2. Weight (kilogrammes (kg)) and height (centimetres (cm)) will be recorded by standard methods and body mass index (BMI) will be calculated as weight (kg)/ height (metres (m²)). Adverse outcomes will be recorded throughout the study period.

Qualitative evaluation. Acceptability of the intervention will be explored through qualitative interviews. Key stakeholders, namely participants in the exercise intervention and health professionals referring to the exercise programme, chosen at random, will be invited to participate in semi-structured feedback interviews. Open-ended questions will be used to encourage open dialogue and elaboration on different aspects of the programme. Health professionals (n=8-10) referring to the programme will be interviewed to examine their experience of referring to the FIXCAS programme to identify barriers and facilitators to referral and to determine areas for review and further development. Patients (n=10-15) will be asked to evaluate satisfaction with the intervention. The interviews will be audio recorded and transcribed, following which data analysis of the interviews will occur through content analysis using simple descriptive thematic analyses.

Safety

All serious adverse events (SAE)/adverse events (AE) will be recorded on study specific adverse event forms. All AEs will be registered with the principal investigator (PI). These will be discussed at regular team meetings and collected and registered at the end of the study. In the case of an SAE, the PI will be informed at time of occurrence (with 24 h). The investigator can decide to withdraw a participant from the study for urgent medical reasons or safety concerns. Participants can leave the study at any time for any reason if they wish to do so without any consequences. Participants who withdraw from the study will be invited to attend assessment.

Data management

Data will be collected and recorded in a paper-based study case report form (extended data (Sheill, 2019)). The case report form will maximise the quality of the data captured and minimise the risk of erroneous data collection. Each case report form will be assigned the participant study identification code to ensure patient anonymity. Qualitative interviews will be recorded using a dictaphone and transcribed. Coded information will be stored on a secure, password protected, encrypted computer. The key to the participants code will be stored separately in a password protected file, on a secure, password protected, encrypted computer at the study site. All hard

copies of study data, electronic interview transcripts and audio recordings will be retained and stored securely for 10 years at Trinity College Dublin.

The data repository will be maintained by designated members of the research team who will input data. Data will be only be accessible to authorised members of the research team. All authorised team members will receive training regarding the data management plan before authorisation is granted for data processing. In line with open access publication requirements, the anonymised final data set will be archived in a secure online data repository.

Sample size and statistical analysis

A sample of 40 participants will be recruited to determine the feasibility of the FIXCAS programme. As this is a feasibility study, a sample size calculation was not performed however similar sample sizes have been utilised in other feasibility trials in cancer survivorship (Quist *et al.*, 2012).

Data analysis will be performed using IBM SPSS Statistics version 24 (SPSS Inc, Chicago, IL). Summary statistics for continuous variables (means and standard deviations or medians and ranges as appropriate) and categorical variables (counts and proportions) will be presented. Graphical summaries will be used to compare the distributions of each response variable and for patient characteristics. A linear mixed model will be used to model the longitudinal change in the primary measures while adjusting for the response variable and for the within subject correlation in the repeated measures across time.

Ethics and dissemination

Ethics approval will be granted by St. James's Hospital and Tallaght University Hospital Research Ethics Committee (approval pending). The study results will be used to optimise the intervention content and may serve as the foundation for a larger definitive trial. We aim to disseminate the results through peer-review journals, presentation at conferences and relevant clinical groups. The International Committee of Medical Journal Editors (ICJME) recommendations will be adhered to in all reporting of trial data.

Study status

The study is currently pending local Research and Ethics Committee approval and is not yet recruiting.

Discussion

The article describes the protocol of a feasibility study evaluating an individualised 10-week FIXCAS multi-modal exercise programme in deconditioned cancer survivors aiming to improve physical function and quality of life.

Research has demonstrated that cancer survivors experience physical deficits including low levels of physical activity, poor cardiorespiratory fitness (Gannon *et al.*, 2017) and sarcopenia (Elliott *et al.*, 2017). As physical fitness has been broadly linked to the quality of life of cancer survivors, fitness can be considered a modifiable factor that can subsequently impact

positively on quality of life (Cheema & Gaul, 2006; Courneya *et al.*, 2003; O'Neill *et al.*, 2018).

Despite robust evidence supporting the role of exercise in cancer recovery, none of the eight cancer centres in Ireland provide exercise based survivorship programmes for cancer survivors and exercise rehabilitation is not an element of standard care for patients with cancer in Ireland (Mulcahy *et al.*, 2018). High feasibility and acceptability of exercise interventions in a research setting has been demonstrated for oesophageal cancer survivors in Ireland. A 12 week supervised and home-based exercise and education sessions resulted in clinically significant improvements in functional performance and QoL (O'Neill *et al.*, 2017). However, the feasibility of offering an exercise rehabilitation programme to a broad range of cancer survivor groups in the clinical setting of a national cancer centre requires further exploration.

The intervention consists of a 10 week (2 sessions weekly) individualised multi-modal exercise programme. The content of the intervention was modelled on national and cancer-specific recommendations of the American College of Sports Medicine and evidence from existing literature and guidelines (Schmitz *et al.*, 2010). The American College of Sports Medicine (ACSM) has concluded that exercise both during and after cancer treatment is safe and should be encouraged, although prescriptions should be individualised according to the patient (Schmitz *et al.*, 2010). Therefore, the FIXCAS programme will be tailored to each individual patient taking into consideration their current health status, physical activity levels, and exercise preferences individual post treatment impairments following the ACSM recommendations.

Important strengths of the intervention include the application of the programme in a real-world clinical practice setting. Secondly, we consider the timing of the intervention to be advantageous. Surveys of cancer survivors clearly show a preference for commencing an exercise program after primary treatments have been completed, with many studies indicating a preference for the 3–6-month period after completion of treatment (Broderick *et al.*, 2013). This time period, termed the 'recovery or rehabilitation period', may be the optimal window for commencing an exercise program to reverse a downward trajectory in activity levels and fitness as well as addressing any lingering treatment-related side effects (Broderick *et al.*, 2013).

Conclusion

In this article, we present the study design to investigate the feasibility of delivering a 10-week multi-modal exercise rehabilitation programme in a national cancer care centre. In addition, we outlined the protocol of an intervention aimed at improving physical fitness, quality of life and other health related outcomes in cancer survivors. The results of the feasibility study may be used for optimisation of the intervention content and may serve as a foundation for evaluating the intervention in a larger randomised controlled trial.

Ethics approval

St. James's Hospital and Tallaght University Hospital Research and Ethics Committee (approval pending). Any protocol

modifications will be communicated in writing to the Research and Ethics Committee and updated on the trial registration.

Data availability

Underlying data

No data are associated with this article

Extended data

Data Archiving and Networked Services (DANS): The Feasibility of Implementing an Exercise Programme for Deconditioned Cancer Survivors in a National Cancer Centre: FIXCAS Study: <https://doi.org/10.17026/dans-26u-qejk> (Sheill, 2019)

This project contains the following extended data:

- FIXCAS Patient Consent_Version2 290819.pdf

- FIXCAS Completion summary v1 2.8.19.pdf (exercise programme completion summary to facilitate transition to community based exercise)
- FIXCAS CASE REPORT FORM Draft Version 2.0 31.7.19.pdf (study case report form including outcome measures)

Reporting guidelines

SPIRIT checklist for ‘The feasibility of implementing an exercise programme for deconditioned cancer survivors in a national cancer centre: FIXCAS Study’, <https://doi.org/10.17026/dans-26u-qejk> (Sheill, 2019)

Data are available under the terms of the [Creative Commons Zero “No rights reserved” data waiver](#) (CC0 1.0 Public domain dedication).

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Open Peer Review

Current Peer Review Status:  

Version 2

Reviewer Report 06 April 2021

<https://doi.org/10.21956/hrbopenres.14333.r28555>

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 **Brian McGuire** 

School of Psychology, Centre for Pain Research, National University of Ireland, Galway, Galway, Ireland

The authors have addressed the main issues and recommendations of the reviewers.

A few minor suggestions (but no need for further review):

1. The title should reflect that this is a protocol paper.
2. The revised sections of text in relation to method/procedure have been written in past tense whereas the rest of the method is in present or future tense (protocols are usually written in future tense). This will need to be revised.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Psychosocial interventions for chronic physical illnesses.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 06 January 2021

<https://doi.org/10.21956/hrbopenres.14333.r28556>

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 **Jessica McNeil**

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Health Services, Calgary, Canada

The revisions made by the authors are acceptable for indexing. I have no further comments.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Physical activity interventions and cancer survivorship.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 17 August 2020

<https://doi.org/10.21956/hrbopenres.14004.r27456>

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Brian McGuire 

School of Psychology, Centre for Pain Research, National University of Ireland, Galway, Galway, Ireland

This protocol outlines a planned evaluation of a supervised exercise programme for deconditioned cancer survivors.

The following comments and queries may help to improve the protocol:

1. Given that “numerous systematic reviews demonstrate that exercise can mitigate” a number of negative outcomes in cancer survivors and improve quality of life, the rationale for evaluating this particular intervention could be more clearly articulated.
2. “Deconditioned” has not been defined or operationalised.
3. While the protocol states that this is primarily a feasibility study, the authors are also looking at evidence of treatment effect and plan to gather information to inform the sample size required for a subsequent definitive trial. Notwithstanding that this is a feasibility study, the proposed sample size of 40 requires some justification.
4. The study design involves a single arm trial with pre-, post- and 3 month follow-up. While single arm evaluations are often proposed for feasibility and pilot studies, they are inevitably weak when compared with a controlled study. Indeed, there are benefits to having a control group in a feasibility or pilot study since this can provide important information about the feasibility of recruiting and retaining a control group and about treatment effectiveness over and above the effect of “attention”.

5. It would be helpful to say a little more about the background to the programme. While it is said to derive from international best practice guidelines, it would be helpful to know whether it is a pre-existing program, or building on something that already exists, or entirely new.
6. The rationale for including a health economics component (EQ-5D-5L) as a primary outcome measure should be justified, especially since there is no comparison group against which to compare costs.
7. The rationale for including prostate-specific measures focused on incontinence and sexual functioning is unclear unless there is evidence that exercise would address these complications (this was not addressed in the introduction).
8. There are some typos: The section headed “maintenance of exercise intervention” has some problems with expression within the sentence. Under “safety”, principle should be principal.

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Psychosocial interventions for chronic physical illnesses.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 10 January 2020

<https://doi.org/10.21956/hrbopenres.14004.r27071>

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Jessica McNeil

Department of Cancer Epidemiology and Prevention Research, CancerControl Alberta, Alberta Health Services, Calgary, Canada

This protocol describes a one-arm intervention aimed at assessing the feasibility of a 10-week multi-modal exercise program offered to cancer survivors within the clinical setting following completion of adjuvant treatments in Ireland. Although this type of feasibility research in the health care setting is needed, some details are missing from the methods section. Furthermore, it is unsure why the authors chose to conduct a one-arm trial, when the evidence provided would be much stronger if a control comparison group (or usual care condition) was used, even if this is a feasibility study. Additional comments are provided for your consideration.

Introduction:

The statements of “implementation of the programme would be a large step towards integration of exercise rehabilitation into survivorship services” is a big leap, considering that this is a one-armed pilot study to assess the feasibility of the proposed intervention. Please amend this statement to better reflect the potential impact of the proposed intervention on survivorship care.

Please define the term “FIXCAS” at first mention.

Methods:

Why did the authors choose to conduct a one-arm study, rather than have usual care as a control comparison?

Having a control comparison group would greatly strengthen the design of the intervention and provide more convincing findings.

Please define what is meant by “deconditioned cancer survivors”. How will this be evaluated?

How will it be determined whether or not the participants are “medically fit” to participate in this trial? Will the study staff or treating physician/oncologist provide medical approval? Please specify.

Is it the norm for patients who have completed adjuvant treatment to continue to visit the National Cancer Center in Ireland? If the patients are “discharged” from seeing their Oncologists after completing adjuvant therapy, it may be difficult to retain participants in the trial and/or convince them to go to the National Cancer Center on a regular basis to exercise.

For the intervention, please update the Schmitz *et al.* (2010) reference to include the new ACSM guidelines publications that came out in 2019.

Why did the authors choose to schedule supervised exercise sessions twice weekly for 60 minutes each, given that exercise recommendations are to participate in 150-300 minutes/week of physical activity? Will there be a ramp-up period to help participants adapt to this intensity and frequency of exercise? Furthermore, which components of the Theory of Planned Behavior are being used to design this intervention, and how are these components being integrated into the intervention? Please provide additional details.

Please specify which resistance training and balance exercises will be performed and how long will

the resistance exercise session last? It seems like a total of 60 minutes may not be enough to complete the proposed 30 minutes of aerobic exercise, resistance and balance exercises. A figure demonstrating a breakdown of each exercise that will be performed during the 60-minute session would be helpful.

Will study outcomes and habitual physical activity participation be assessed after a follow-up time period to determine whether or not the participants were able to maintain the exercise intervention and its benefits on health outcomes?

What instrument(s) will be used to assess body composition? Please specify.

Will the participants and health professionals be randomly selected to participate in the qualitative interviews? If not, how will the study team select the participants to participate in these interviews?

The authors mention that the FIXCAS programme will be tailored to each individual mid-way through the Discussion section, however this is not described in the methods section. Please provide more details on how the exercise programme will be tailored to each individual and which measures will be used to tailor the intervention.

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

No

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Physical activity interventions and cancer survivorship.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
