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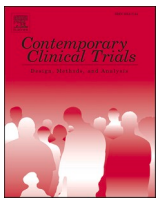

Towards best practice in the delivery of prescribed exercise via telehealth for individuals diagnosed with cancer: A randomised controlled trial protocol.

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ABSTRACT

Introduction: There is a plethora of evidence supporting the therapeutic effects of regular exercise for individuals diagnosed with cancer, particularly during active treatment. The COVID-19 pandemic has complicated delivery of face-to-face exercise programs for individuals with cancer, particularly as this cohort is at much higher risk of morbidity and mortality. The proposed randomised controlled trial explores best practice and assesses the feasibility of exercise programs delivered via Telehealth for individuals diagnosed with cancer.

Methods: Participants (n = 160) must have a current cancer diagnosis, must be undergoing active treatment, receive medical clearance, and have access to a smart device to participate in supervised exercise. Participants will be randomly assigned (two arms; 1:1) to supervised exercise delivered via Telehealth (Coviu) or usual care (receiving physical activity guidelines). Telehealth arm participants will receive an individualised program according to their health status, comorbidities, and exercise history, delivered weekly for eight weeks by an Accredited Exercise Physiologist in a group setting. Outcome measures will assess feasibility, psychological wellbeing, quality of life, symptom management, physical activity and fitness levels. A Telehealth arm participant sub-sample will have the opportunity to share their experience and feedback via an online interview at the intervention completion.

Ethics and dissemination: Outcomes from this study will create evidence to inform best practice for the safe delivery of exercise via Telehealth for individuals diagnosed with cancer. Evidence will be published in peer-reviewed journals and may be presented at national and international conferences. Ethics approval was obtained at the University of Canberra (Project ID: 4604. Version 2: 1st March 2022).

Trial registration number: ANZCTR: ACTRN12620001054909. Universal Trial Number: U1111–1256-4083.

1. Introduction

The prevalence of exercise as an adjunct therapy to cancer treatments including chemotherapy and radiation therapy is growing and has been shown to improve health outcomes, treatment completion rates and quality of life in people affected by cancer [1]. Exercise interventions can improve circulation, reduce cancer-related fatigue, improve body composition and general health and well-being in people diagnosed with cancer [1]. Given the complexity of delivering cancer services during COVID-19, many people who are undergoing cancer treatment are unable to access exercise services. A number of healthcare organizations have adopted online formats as a way to circumvent the disruption to service delivery [2]. Telehealth is one such service and is defined by the Australian Government Department of Health as 'the use of telecommunication techniques for the purpose of providing telemedicine, medical education and health education over a distance' [3]. Prior to the global COVID-19 pandemic, Telehealth was already rapidly growing in cancer, cardiac, neurological and rehabilitation fields [4,5]. The existence of the COVID-19 pandemic has increased the interest and necessity for the utilisation of Telehealth for exercise delivery [6,7].

Individuals affected by cancer are already at higher risk when compared to the general healthy population of developing infections, often leading to potentially life threatening complications [8]. Preliminary evidence suggests people affected by cancer are more likely to

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experience serious illness if they become infected with COVID-19 [9]. COVID-19 poses a significant risk to people affected by cancer, particularly specific cancers including those: undergoing active chemotherapy and radical radiotherapy for lung cancer; blood or bone marrow cancers such as leukaemia or myeloma (at any stage of disease); those receiving immunotherapy; antibody treatments for cancer; targeted cancer treatments which can affect the immune system, such as protein kinase inhibitors; individuals who have received a bone marrow or stem cell transplant in the last 6 months; or those taking immunosuppression drugs. People affected by cancer could be at elevated risk of severe COVID-19 disease and may experience disrupted and delayed delivery of cancer therapies and exercise appointments because of social distancing measures, quarantines, and general disruption in routine cancer service during this pandemic. It remains important for people affected by cancer to continue to engage in and maintain regular exercise under the guidance of qualified health professionals in keeping with evidence-based clinical guidelines [1]. Clinicians working with people affected by cancer are seeking research and guidance for delivering safe and successful Telehealth exercise interventions to individuals diagnosed with cancer.

Early research has provided evidence that exercise programs delivered via Telehealth can result in beneficial physiological health outcomes for cancer survivors [10,11]. However, to the best of our knowledge, there has been no research investigating exercise delivered via Telehealth for those currently receiving treatment for cancer, nor the feasibility of such programs. Therefore, the aim of this study is to investigate the feasibility of exercise delivered via Telehealth for people diagnosed with cancer undergoing active treatment. Secondary aims include investigating the impact of the exercise on physical activity levels, quality of life, mental health and symptom experience for this population, and exploring the participants experience of Telehealth via semi-structured interviews.

2. Methods

2.1. Study design

This is an eight week, two arm randomised controlled trial run by researchers at the University of Canberra. This trial will recruit 160 men or women with a current diagnosis of cancer to compare online supervised exercise programs to usual care in individuals undergoing active treatment. Participants will be randomly assigned (1:1) to either the online supervised exercise (using Telehealth platform Coviu) or usual care following confirmation of eligibility, screening by a qualified health professional and the provision of informed consent (Fig. 1). It is not possible to blind participants to an exercise intervention, however the assessors will be blinded to study arm allocation. Changes in quality of life, psychological wellbeing, physical activity and symptoms in both groups will be monitored.

2.2. Participants

Men or women with a current confirmed cancer diagnosis, irrespective of disease stage or treatment modality, and who meet the study inclusion and exclusion criteria (Box 1) will be recruited to this study.

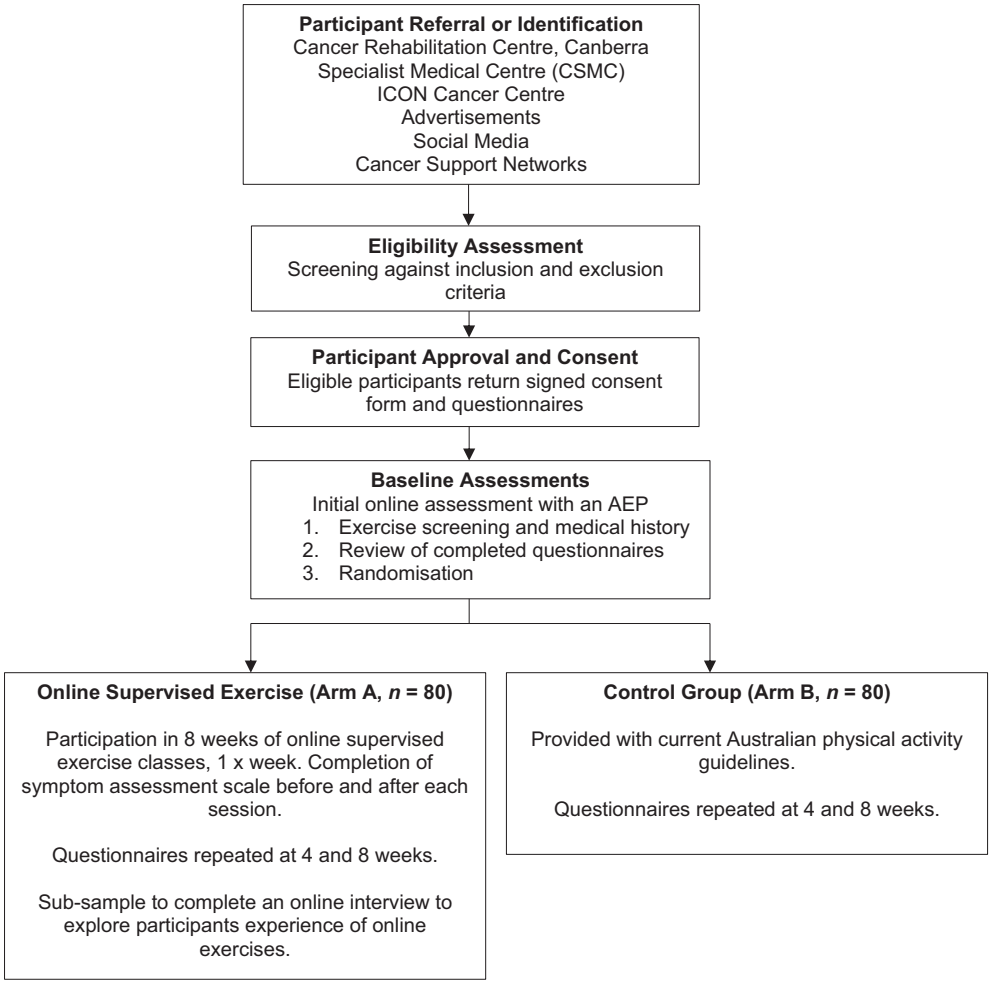

Fig. 1. Flow diagram of recruitment and randomisation process.

Box 1
Participant inclusion and exclusion criteria.

Inclusion

- Aged ≥18 years.
- Current diagnosis of any cancer type (confirmed by pathological or radiological diagnosis).
- Undergoing active cancer treatment for the duration of study.
- Self-assessed written and verbal English proficiency.
- Ability to provide informed consent.
- Written medical clearance from primary care physician or oncologist to participate in online individually prescribed exercise.
- Ownership of a smartphone, computer, laptop or tablet to access Zoom platform.
- Ownership of an automatic blood pressure monitor, digital thermometer and if diabetic, a blood glucose monitor.

Exclusion

- No recent myocardial infarction or other acute cardiac events within the last 2 days.
- No unstable angina.
- No uncontrolled cardiac arrhythmia, causing symptoms or hemodynamic compromise.
- No active endocarditis.
- No acute myocarditis or pericarditis.
- No symptomatic severe aortic stenosis.
- No decompensated heart failure.
- No acute pulmonary embolism, pulmonary infarction or deep venous thrombosis.
- No acute aortic dissection.
- No physical disability which precludes safe and adequate exercise testing or participation.
- No known blood counts below normal levels (white blood cells, platelets and haemoglobin).
- No unusual chest pain, dizziness, blurred vision, loss of consciousness or shortness of breath.

Participants must be undergoing active cancer treatment for any cancer type whilst participating in the study, including surgery, radiation therapy, chemotherapy, hormone deprivation therapy, immunotherapy or other targeted cancer therapies.

2.3. Screening

Once referred to the study, either by self-referral or a member of their clinical care team, potential participants will undergo a screening process to confirm eligibility, where they will be assessed against inclusion and exclusion criteria. If eligible, participants will be asked to sign a consent form and will be asked to complete a series of baseline questionnaires. These baseline questionnaires will include a number of surveys to assess current physical activity levels, current symptoms, psychological status and quality of life (described further in outcomes). Once completed, an initial online assessment will then be scheduled with an Accredited Exercise Physiologist (AEP). This assessment will include a further exercise screening, review of completed questionnaires and notification of which trial arm the participant has been randomised to. Participants must have no known contraindications to exercise to be eligible to participate in this study.

2.4. Randomisation

Participants will be randomised in a ratio of 1:1 to the two study arms. A researcher at the University of Canberra external to the protect with no participant contact will be responsible for randomisation using a concealed, computer generated sequence. This researcher will then provide the supervising AEP with the randomisation schedule, therefore the primary researcher will be blinded to the allocation.

2.5. Outcomes

2.5.1. Primary outcome: Feasibility

The primary outcome of this randomised controlled trial is the feasibility of the study, which will be determined by exercise session attendance, drop-out rates and study completion rates. For the purpose of this trial, the feasibility of the Telehealth exercise program will be defined by recruitment targets being met, attendance of ≥75% Telehealth exercise sessions, and the completion of ≥75% of anticipated data. The percentage of eligible participants who expressed interest but declined to participate (with reasons) will also be recorded. This data will be tracked throughout the intervention and finalised at the completion of the trial. This information will highlight the feasibility of future programmes and potential barriers to participation and adherence.

2.5.2. Secondary outcomes

2.5.2.1. Psychological wellbeing and quality of life. Psychological health will be measured utilising the Depression, Anxiety and Stress Scale – 21 questions (DASS-21) instrument. The DASS-21 instrument has shown internal consistency in both healthy and older adults [12,13]. The Functional Assessment of Cancer Therapy General (FACT-G) survey will also be used to assess health-related quality of life across a number of domains, including social, family, emotional and functional wellbeing. The FACT-G survey is specifically designed for adults diagnosed with cancer and has adequate reliability and validity [14,15]. Both trial arms will complete the DASS-21 and FACT-G at baseline, week four and week eight.

2.5.2.2. Physical activity levels. Current physical activity levels will be measured using the Active Australia Survey (AAS). This survey has shown reliability within the Australian population [16] and has been used in Australian studies investigating physical activity and individuals diagnosed with cancer [17–19]. Physical activity levels will be measured in both trial arms at baseline, week four and week eight.

2.5.2.3. Physical fitness levels. Fitness will be measured through the timed 1 km walk test, where the participant will be asked to time the distance it takes to walk 1 km, or the distance they can comfortably walk [20]. Additionally, strength will be measured using a timed sit to stand test [21]. This will involve the participant getting up and down from a chair as many times as they can manage in 30 s without using their hands for assistance. These physical fitness measures will be completed at home with the results reported to the research team, and assessed in both trial arms at baseline, week 4, and week 8.

2.5.2.4. Symptom management. The Memorial Symptom Assessment Scale (MSAS) is an instrument that has been validated in different patient populations [22] and will be used to determine the presence of adverse symptoms in the exercise group. This assessment is composed of two multipart sections and would take participants approximately five minutes to complete. The MSAS will also be used as a screening tool to identify any new or unusual symptoms requiring further investigation. The MSAS will be made available to participants in the exercise group to fill in before each weekly session via Qualtrics software (version May 2022; Qualtrics; Provo, UT, USA).

2.5.2.5. Qualitative experience. An online interview with a member of the research team that is trained in qualitative research will be conducted with a sub-sample of ten participants from the exercise group within one week of their conclusion from the trial. The first ten participants to complete the exercise program will be invited to participate in the qualitative portion of the study. If participants are not interested, the subsequent participants that complete the exercise program will be invited, until saturation occurs. The interview will follow a semi-structured format lasting a maximum of 45 min and will be audio recorded using a digital recording device. This interview is designed to explore participants experiences of the online exercise sessions and offers an avenue for participants to provide feedback about the program.

2.6. Program safety

Participants who present with any contraindications to exercise will be unable to participate in the study, as per the study exclusion criteria. To ensure the safety of participants, each exercise session will be run by a university qualified AEP. The MSAS tool will be used to monitor adverse signs and symptoms before each exercise session, where the AEP may alter the prescribed exercises or ask the participant to miss the exercise session based on the results. Participants will also be required to measure their individual blood pressure, temperature and if diabetic, blood glucose levels pre and post-exercise (Box 1). A copy of an exercise safety booklet will be provided to all participants in the exercise group with instructions on how to use this equipment. Any adverse events will be recorded by the supervising AEP. If medical clearance from a primary care physician or oncologist is revoked, the participant will be required to withdraw from the study [23–25,26].

2.7. Participant programmes

2.7.1. Exercise prescription

Each participant in the exercise group will receive an individualised exercise program to complete during the supervised online group exercise sessions and also independently on two other days of the week. The completion of the independent exercise sessions will be discussed and recorded by the AEP during the weekly online sessions to monitor compliance. This exercise program will be designed by an AEP to suit the needs of each individual participant, and therefore cannot be predefined. Each program will be designed according to the specific clinical guidelines outlined by Clinical Oncology Society of Australia (COSA) and Exercise and Sports Science Australia (ESSA) for individuals diagnosed with cancer [1,27]. According to the recommendations set by COSA and ESSA, exercise programs should include >150 min of moderate intensity aerobic activity plus two resistance exercise sessions per week [1,27]. However modifications, including the intensity and exercise type, may be made to this based on patient-driven exercise considerations.

2.7.2. Usual care (control) group

Participants randomised to the usual care control group will receive a print or electronic copy of the current Australian physical activity guidelines [28]. Individuals in this group will be asked to continue with their current lifestyle across the eight week period. A control group is necessary to differentiate the effects of the exercise intervention for the study outcomes, however the research team is aware it is unethical to ask participants to abstain from exercise entirely, particularly given the existing known benefits of exercise for cancer patients [1].

2.8. Power and sample size

161 (power set at 90%) patients newly diagnosed with cancer will be recruited (81 in each arm). For the trial designed with 90% power and two-sided 5% significance for standardised small effect size (0.2) a sample of 81 per treatment is recommended.

2.9. Statistical considerations

The questionnaire data will be analysed with a general linear mixed model using the R package lme4 (R Core Team 2018). A random intercept for participants will be included to account for intraindividual dependencies and interindividual heterogeneity. This will also allow for individual baseline adjustment. All models will be estimated using Restricted Maximum Likelihood. P-values will be obtained using Type II Wald F tests with Kenward-Roger degrees of freedom as implemented in the R package car (Fox and Weisberg 2011). Statistical significance will be determined on $p \leq 0.05$, in addition, confidence intervals (CI) will be assessed whether they included zero or not. Results will be reported as mean estimates and 95% confidence intervals.

2.10. Qualitative analysis

Qualitative data from the semi-structured interviews will be analysed utilising a six-staged thematic approach, described by Braun and Clarke [29]. This method is used to identify, analyse and report patterns or themes within the data. An inductive approach will be taken to analyse the data, allowing for themes to be data driven. The data will be accepted at face value and the assumption will be made that participants reports are a true reflection of their experiences. Qualitative data analysis will be completed by two members of the research team, who will analyse the interviews independently with any discrepancies in codes, categories or themes discussed with a third member. Following this, the participants will be asked to confirm that the developed themes are representative of the information they have provided. NVivo software will be employed to organise codes and the COREQ checklist [30] will be used when displaying the analysed data. An audit trail will be utilised and become available with the reporting of the findings.

2.11. Trial management

Operationally the study will be overseen by a team of experienced researchers from the PACES (Prehab Activity Cancer Exercise

Survivorship) Group and the Faculty of Health at the University of Canberra. The research team includes a number of clinical professors, research assistants, AEPs, clinical nurse specialists and administrative support staff. The team will be meeting monthly whilst the study is active to discuss the progress and outcomes of the study.

All participant forms, data and contact details will be kept confidential at all times. This data will be uploaded and stored on the private University of Canberra secure server. Only members of the research team will have access to personal and sensitive participant information. Records will be kept as per University of Canberra policy for five years from the completion of the project.

2.12. Ethics and dissemination

Ethics approval was first obtained at the University of Canberra 4604. Any approved amendments will be submitted to the Human Research Ethics committee for further consideration.

Outcomes of this study will be published in international, peer-reviewed journals and may be presented at national and international conferences. Evidence from this study may also be used to update relevant clinical or medical guidelines and position statements from national and international governing bodies regarding COVID-19 safe alternatives to face-to-face programmes.

3. Discussion

The evidence to support the positive effects of exercise for individuals diagnosed with a range of different cancers is overwhelming [1,31–34]. Participation in regular exercise has been shown to support a healthy immune system, reduce negative treatment side effects, support psychosocial health and improve overall quality of life [1,31–34]. The COVID-19 pandemic has caused a global public health emergency, posing a significant risk to individuals diagnosed with cancer [9] and preventing many face-to-face exercise programmes from continuing. With ongoing COVID-19 outbreaks across the globe likely to occur until a vaccine is developed, programs must adapt to provide ongoing support and optimal care for patients during this challenging time. Despite the return of some face-to-face programmes, many of these exercise centres may still be considered high risk for many individuals, particularly those undergoing active treatment. These individuals are at higher risk of becoming sedentary and isolated, resulting in a decline in health and quality of life [35].

Thus, a randomised controlled trial is warranted to explore best practice in remote exercise interventions to allow cancer patients to continue exercising and socialising with other cancer survivors through the group setting. The addition of semi-structured interviews is a key strength of this project, enabling participants to provide comprehensive feedback which will then be used to inform the development of future Telehealth programs. This study aims to build upon existing preliminary evidence [35–37] that has demonstrated exercise delivered via Telehealth is safe and feasible for individuals diagnosed with cancer.

A strength of the proposed Telehealth study is the potential to reduce time and cost burden for participants. There is evidence from studies in cancer cohorts which highlight Telehealth as a lower cost intervention when compared to face-to-face programs [23–25]. This study aims to remove the cost and time burden for cancer survivors by improving accessibility to exercise programs, particularly as lack of time is a primary barrier to exercise participation for individuals with a cancer diagnosis [26]. A further advantage of Telehealth is the reduced requirement for resources and the ability for staff to deliver the program remotely, which is an important consideration given the likelihood of repeated business lockdowns due to the current global pandemic. Additionally, the inclusion of the qualitative component will strengthen this trial, as the direct feedback from the participants about the program will allow it to be improved in the future. However, a limitation exists within the eligibility criteria of this trial, with the requirement for participants to provide their own communication and health monitoring equipment. This requirement limits the accessibility of the trial and exercise programs, and potentially creates a bias among the participants selected, and should be addressed following this trial of feasibility.

This randomised controlled trial will be the first to assess the feasibility of an exercise program delivered via Telehealth for those currently receiving treatment for cancer. While the utilisation of Telehealth was increasing in previous years, the presence of the COVID-19 pandemic has increased the necessity for such platforms of exercise delivery. Future research should place a focus on increasing the accessibility of exercise programs delivered via Telehealth, to ensure that any individual may have the ability to complete these programs. The feasibility of Telehealth delivery for additional populations should also be investigated, including for further immunocompromised groups, such as a trial being completed for those living with HIV [38]. The findings of this research have the potential to shape the standard of care for those with a preference for remote exercise, particularly those within the oncology population.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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