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Implementing physical activity for individuals with cancer during treatment: protocol for the IMPACT implementation–effectiveness trial

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ABSTRACT

Introduction The prevalence of cancer in Canada is growing, leading to multiple lasting side effects in survivors. The physical and psychosocial benefits of regular physical activity (PA) during and after treatment for individuals with cancer are well established, however, not well implemented in a clinical setting. The overall aim of this project is to build on previous work and conduct a multicentred randomised controlled trial (RCT) and evaluate the effectiveness of a novel implementation strategy using PA and self-management versus usual care during cancer treatment.

Methods and analysis *Study design:* a hybrid implementation–effectiveness RCT will occur at five cancer centres across Ontario, Canada. *Participants:* eligible participants include adults with a cancer diagnosis (any type or stage) who are receiving treatment and cleared for exercise by their oncology care team. *Intervention:* participants (n=129) will be randomised to one of three groups: (1) institution-based exercise and self-management (SM) (eight in-person sessions of aerobic exercise and eight SM modules), (2) SM alone (SM only: eight virtual modules) or (3) usual care (no intervention). *Outcomes:* the Reach, Effectiveness, Adoption, Implementation and Maintenance framework will assess implementation outcomes. The primary effectiveness outcome is self-report PA level postintervention. *Data analysis:* outcomes will be measured at four time points (baseline, postintervention, 6- and 12-month follow-up). Descriptive statistics will be used to present implementation outcomes. An analysis of covariance will assess change between groups over time.

Ethics and dissemination Findings from this trial will build on previous work and inform the way PA services are provided within cancer institutions across Ontario, Canada, and inform decision-making on how to incorporate exercise evidence into real-world clinical practice in cancer care. The Hamilton Integrated Research Ethics Board (ID: 7673 & 17454) has approved this study. Results will be disseminated using a combination of peer-reviewed publications, conference presentations and community organisation presentations. Participants will contribute to dissemination by sharing 'participant perspectives', highlighting their experience in the project and thoughts on the implementation strategies used.

STRENGTHS AND LIMITATIONS OF THE STUDY

⇒ This study will use a multicentre randomised controlled trial methodology and is supported by strong pilot data.
⇒ Implementation characteristics of the intervention aim to maximise accessibility for participants.
⇒ This study examines a variety of outcomes and is guided by the Reach, Effectiveness, Adoption, Implementation and Maintenance framework to evaluate the success of the implementation strategies used, along with the effectiveness of outcomes.
⇒ Patient partners are included in the study team; they have been involved from inception and will continue to be part of the team through implementation and knowledge dissemination.
⇒ Participants in the usual care group will not be restricted from participating in PA or rehabilitation throughout the study, which may lead to co-intervention.

Trial registration number The study is registered on clinicaltrials.gov (ID: NCT06323707).

INTRODUCTION

The burden of cancer in Canada is growing. More individuals are surviving cancer, however, individuals with cancer live with side effects for years after treatments have ended.[1–3] The physical and psychosocial benefits of regular physical activity (PA) during and after treatment for individuals with cancer are well established.[4–7] Regular PA also minimises recurrence and mortality.[8 9] Exercise is a component of PA which includes purposeful movement to improve health outcomes.[10] Less than 30% of survivors meet current exercise guidelines,[10 11] and overall PA levels decline significantly during treatment.[10 12] Institution-based PA services to support well-being during treatment are not available

across Ontario. This leaves individuals with cancer in need of PA services they cannot access.[13 14]

Self-management (SM) is defined as the tasks that individuals must take to live with their condition.[15] SM education includes supportive interventions provided by healthcare staff to increase patients' skills and confidence in managing their condition independently.[15] It includes education on regular assessment of progress, goal setting and problem-solving support.[15] SM education is vital to provide individuals with the knowledge and confidence to independently maintain healthy lifestyle behaviours, such as PA, and is known to result in improvements in quality of life (QOL) for individuals with cancer during and after treatment.[16 17] However, PA-related SM strategies are not implemented across cancer institutions, and patients continue to lack knowledge on how to manage their condition independently after treatments have ended.

Despite abundant evidence on PA effectiveness and SM support in cancer, the breadth of literature on this topic has not addressed 'real-world effectiveness' and novel implementation strategies are needed within the institution to close the gap between the evidence and actual clinical practice. Implementation research allows us to understand how to deliver interventions effectively in diverse settings, within a range of health systems.[18–20] Implementation research shines light on what can be achieved in theory and what happens in clinical practice.[20] This type of research is crucial to improve our understanding of the challenges we face in the real world and deepen our understanding on what factors impact implementation success.[20]

Our team piloted a novel implementation strategy using institution-based exercise and SM (EXSM) at a single cancer institution in Ontario and found it to be feasible and have significant benefits on outcomes for individuals with breast cancer during treatment compared with usual care.[21 22] The overall aim of this project is to build on previous pilot work[21 22] and conduct a multicentred randomised controlled trial (RCT) and evaluate the effectiveness of a novel implementation strategy using PA and SM versus usual care during cancer treatment. To do this, we have two research questions:

1. Is a novel implementation strategy using exercise and SM for individuals with cancer during treatment feasible in cancer institutions across Ontario?
2. Do those who take part in an exercise and/or SM intervention using novel implementation strategies have improved outcomes, compared with usual care?

METHODS AND ANALYSIS

Study design

To build off pilot work and determine the effectiveness of this approach in a clinical setting, a hybrid implementation–effectiveness RCT (type 2)[19] will occur at five cancer centres across Ontario. Hybrid implementation–effectiveness trials offer many benefits, including simultaneously evaluating the *impact of interventions* introduced and the *implementation strategy* used to deliver them and identifying how to actually 'make it work'.[19] This project will be guided by the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework[23] (table 1), and reporting will be in accordance with the Consolidated Standards of Reporting Trials guidelines[24] for pragmatic trials. This protocol is reported in accordance with the Standard Protocol Items for Randomised Trials[25] statement. Figure 1 describes study procedures over time. Recruitment for this study began on 15 March 2024 and is expected to be complete by 31 March 2027.

Participants and randomisation

Eligible participants include: (1) adults with a cancer diagnosis (any type or stage) who are (2) receiving treatment and (3) cleared for exercise by their oncology care team. Potential participants will be excluded if they (1) self-report a chronic condition, cognitive impairment or injury that prevents them from participating in PA. Prior to participant randomisation, eligible participants will complete demographic and baseline information

Table 1 RE-AIM framework[23] and associated measures

Component (definition)	How will this be measured?
Reach (absolute number, proportion and representativeness of participants)	Recruitment, retention and dropout rates. Representativeness of participants to Canadians.
Effectiveness (impact of intervention on important outcomes, including negative effects and economic outcomes)	QOL, PA level, health status, aerobic capacity and treatment completion.
Adoption (absolute number, proportion and representativeness of settings involved)	Number of oncologists approached versus assisting with recruitment, oncologist characteristics.
Implementation (site fidelity to the study protocol, including consistency of delivery as intended, time/cost of the intervention)	Consistency of delivery (measured through observation with criteria to determine fidelity), adaptations needed and costs.
Maintenance (extent to which the programme becomes a part of routine organisational practices and personal behaviours after >6 months from baseline session)	Programme continuation at the institutional level; sustained behaviour change improvement in health outcomes at the participant level.

PA, physical activity; QOL, quality of life; RE-AIM, reach, effectiveness, adoption, implementation and maintenance.

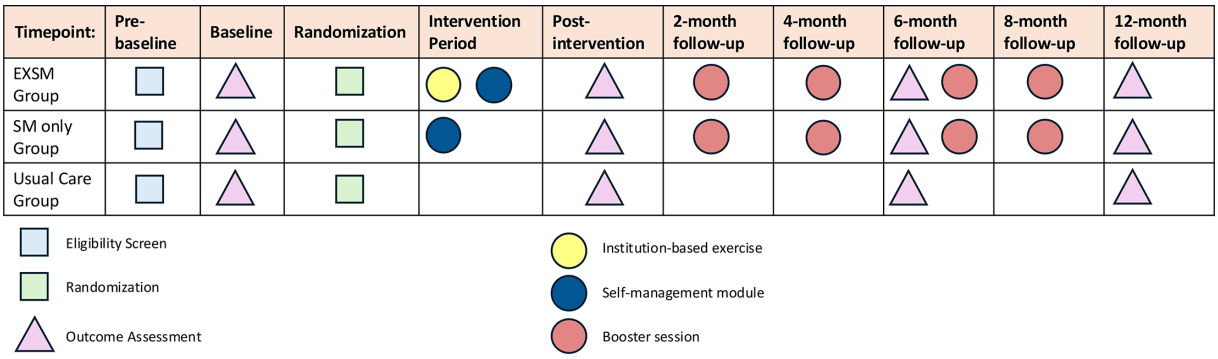

Figure 1 Study timeline.

including: (a) patient information form (assessing personal (age, sex, gender using the Gender Related Attributes Survey,[26] race, ethnicity, geographical location and socioeconomic status) and cancer characteristics (cancer type, stage and treatment type)) and (b) a consent form. A statistician not involved with the study will create a computer-generated randomisation schedule (1:1:1) for each intervention or control group. Allocation of participant randomisation will be concealed, and a research coordinator will hold and release group allocation once the baseline assessment is complete.

Sample size

Power analysis for an analysis of covariance (ANCOVA) test with three groups was conducted in G*Power[27] to determine a sufficient sample size. An alpha of 0.05, power of 0.95 and medium effect size (0.4) for the primary outcome of PA level,[28 29] measured by the Godin Leisure-Time Exercise Questionnaire, was used. Based on these assumptions, the desired sample size is 102 participants. With an expected dropout rate of 25%,[28 29] the total sample size for this study is 128 participants (rounded to *129*; *43 per group*).

Recruitment procedures and settings

Recruitment for this study will occur in two ways: (1) medical oncologists will identify possible participants within their patient caseload. The oncologist will obtain consent from the patient to be contacted by the research team, (2) using printed posters in clinics and social media of various cancer support groups and different community organisations. Potential participants will be contacted by phone to discuss eligibility and potential study enrolment.

Intervention procedure

Participants will be randomised into three groups. This study will be implemented in clinical settings across Ontario. Implementation strategies aiming to increase accessibility include: (1) only eight sessions (one every 2 weeks) with the integration of SM strategies to maintain PA between sessions, (2) sessions scheduled when participants are coming into the cancer centre for another appointment and (3) the inclusion of booster sessions for intervention group participants to maximise the sustainability of outcomes.

Group 1: institution-based EXSM

Exercise component: eight sessions of supervised, in-person moderate-intensity exercise (50–70% of maximum heart rate (HRmax) according to age-standardised norms) using a recumbent bike will occur[30–32] during the participants' cancer treatment. A qualified exercise professional (QEP) with experience in cancer rehabilitation will supervise the exercise component at each location.

SM component: eight SM education modules will be viewed at the same sessions as the exercise, facilitated by the QEP. See table 2 for a description of SM content. Each module includes considerations for different forms of cancer. The goal of the SM modules is to increase exercise knowledge and develop PA goals and action plans for participants to complete between sessions with an overarching goal of helping them reach the exercise guidelines for cancer survivors[30 31] and the Canadian PA guidelines.[33]

Booster sessions: four booster sessions (at 2, 4, 6 and 8 months postintervention) by phone with a research assistant (RA) trained in behavioural counselling. The RA will discuss the current physical and emotional condition of participants, PA level, success with action plans and barriers to action plan completion. The goal of these sessions is to encourage continued PA behaviour. The inclusion of booster sessions in behavioural PA interventions has been shown to maintain treatment effects postactive intervention.[34–36]

Group 2: SM only (SM)

Eight virtual sessions of SM education using video conferencing with a QEP during treatment, as described above. This group will also receive four booster sessions.

Group 3: usual care (UC)

Care is usually provided by the treating oncologist. This can be heterogeneous among different physicians, but usually includes oncologists encouraging their patients to 'stay active'.[37]

Table 2 SM content by session

Session	Content focus
1	► Common side effects of cancer treatment. ► Benefits of exercise during cancer treatment. ► Types of exercise. ► Safety precautions. ► Introduction to SM. ► Goals setting and action planning.
2	► Posture for individuals with cancer. ► Relaxation and breathing techniques to manage anxiety and stress. ► Goal setting and action planning.
3	► Exercise techniques to maintain and increase endurance (description, types and parameters). ► Goal setting and action planning.
4	► Exercise techniques to maintain and increase strength (description, types and parameters). ► Goal setting and action planning.
5	► Exercise techniques to maintain and increase flexibility (description, types and parameters). ► Goal setting and action planning.
6	► How to self-monitor PA levels. ► Goal setting and action planning.
7	► Communicating with others about exercise during and after cancer treatment. ► Available exercise programmes in the community. ► How to evaluate progress. ► Goal setting and action planning.
8	► Review of past sessions. ► Summary of SM components. ► Summary of exercise during cancer treatment. ► Moving forward with exercise after cancer treatment.

PA, physical activity; SM, self-management.

Outcomes

Implementation outcomes

Feasibility (recruitment, retention and adherence), *acceptability*, *fidelity* and *appropriateness*, as outlined in the RE-AIM framework,[23] see table 1, will be tracked through the study period, and be analysed postintervention. An *economic evaluation*, looking at healthcare resource utilisation across groups, will occur at all follow-up times using a piloted self-report questionnaire. All costs will be determined based on current Ontario Healthcare Standards in Canadian dollars.

Effectiveness outcomes

To be collected at baseline, postintervention, at 6- and 12-month follow-up by a trained blinded assessor.

Primary outcome

PA level will be measured using the validated Godin Leisure-Time Exercise Questionnaire.[38] This self-report measure gives weekly frequencies of strenuous, moderate and mild activities and a total weekly leisure activity score and has been found to be reliable, valid and responsive in measuring PA levels in those with cancer.[39–41]

Secondary outcomes

QOL will be measured using the Functional Assessment of Cancer Therapy—General scale,[42] a 27-item self-report questionnaire designed to address four domains (physical, social, emotional and functional well-being) of QOL in those with cancer. Scores range from 0 to 108 with higher scores representing better QOL. [42]This scale has demonstrated reliability, validity and responsiveness in diverse samples of cancer survivors.[43 44]

Exercise knowledge will be assessed using a Theory of Planned Behaviour (TPB) questionnaire.[45] The TPB has been used extensively to determine levels of intention and behaviour for various health behaviours, including exercise.[45–47] Measures using the TPB components are supported in the literature for individuals with cancer.[46 47]

Health status will be measured using the EQ-5D-3L.[48] This scale has two components: a descriptive scale assessing problems with five dimensions of health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), and a visual analogue scale recording respondents' self-rated health on a scale of 0–10 (0 worst health, 10 best health).[48] The EQ-5D is a valid and reliable tool for assessing the health status of individuals with cancer.[48]

Aerobic capacity will be assessed using the six minute walk test (6MWT),[49] a performance-based measure that assesses the total distance walked in 6 minutes. This test has been found to be a valid and reliable tool to assess submaximal aerobic capacity in adults >18 years and with various chronic conditions.[50 51]

Cardiovascular (CV) outcomes (ie, resting blood pressure and heart rate) will be assessed at all time points and will be used to assess changes in basic cardiac function across the study.

Data collection and management

This study will collect data from 129 participants at four time points. All self-report outcome measures will be collected digitally, in person, using a secure Redcap survey and stored in the Redcap secure computing environment. On the survey, participants will be identified by ID number only; no personal information will be recorded on these forms. A blinded assessor will be present to help with completing the outcomes if needed. The assessor will also conduct the objective-assessment components (6MWT and CV outcomes) and upload data into Redcap. Baseline information sheets and consent forms will also be completed digitally and be stored separately from outcome data on a Health Insurance Portability and Accountability Act (HIPAA)-compliant secure

data storage system. All de-identified study data that are not designated as restricted use will be made available as public use data to the research community via a data repository approximately 12 months after study completion.

Data analysis

Implementation outcomes (research question 1) will be analysed using descriptive statistics (mean (SD), frequency (%)). An ANCOVA will test changes in effectiveness outcomes within and between groups over time (research question 2). Covariates will include age, sex, gender, race and socioeconomic status. An intention-to-treat analysis will be used for this analysis using multiple imputation. STATA/MP14 will be used for all statistical analyses with significance set at $p<0.05$. Using the data collected at baseline, we will conduct sex and gender based analyses (SGBA+) for all our objectives by reporting both stratified and adjusted results.

Patient and public involvement

Our research team includes individuals affected by cancer who have been involved in the conception of the project and will be involved in the conduct and completion of the project. These individuals have reviewed the study protocol and provided feedback on the study material. They will also be involved with knowledge translation activities. Further, participants in this trial will be involved in knowledge translation activities by providing short 'participant perspectives'. All patients will be compensated for their participation in the study team.

ETHICS AND DISSEMINATION

Our team pilot tested a novel implementation strategy using institution-based EXSM at a single cancer institution in Ontario and found it to be feasible and have positive trends for effectiveness for individuals with cancer during treatment.[21 22] Preliminary results from participants undergoing treatment found the intervention to be feasible (recruitment rate=96%, retention rate=100% and adherence rate=89%) and showed preliminary effectiveness of the intervention on physical activity levels (p=0.03), perception of health status (p=0.02) and exercise knowledge (p=0.01).[21] Results from these trials demonstrate feasibility, even during the COVID-19 pandemic, and highlight the rationale for moving forward to a multicentre trial to test this implementation strategy in various cancer centres. This study has received approval from the Hamilton Integrated Research Ethics Board (ID: 7673 & 17454) as well as specific institutional research boards at Joseph Brant Hospital and Oakville Trafalgar Memorial Hospital. The study is registered on clinicaltrials.gov (ID: NCT06323707).

Our knowledge translation plan for this project involves several approaches. First, the information assembled and synthesised from the study will be translated to other researchers and clinicians using traditional approaches such as peer-reviewed journal publications and conference presentations at oncology and rehabilitation-related conferences. Furthermore, we will use community media channels to inform community stakeholders of project results (such as the Oncology Division of the Canadian Physiotherapy Association social media platforms). Participants will be involved in this knowledge translation process by sharing 'participant perspectives' which highlight their experience in the project and their thoughts on the implementation strategies used. Further, our knowledge translation strategy includes presentations to relevant policymakers, including hospital administration and government officials. This is necessary to ensure the sustainability of these interventions in the future.

Implementation research is crucial to improve our understanding of real-world factors that impact the successful application of research in healthcare settings.[18–20] Over the last 10 years evidence on the efficacy of PA for individuals with cancer has grown substantially, leading to the development of provincial,[31] national[30] and international guidelines.[32] However, the implementation of these guidelines in Canada has been slow. Findings from this trial will build on previous work and inform the way PA services are provided within cancer institutions across Ontario, Canada and inform decision-making on how to incorporate exercise evidence into real-world clinical practice in cancer care. Further, the evidence from this trial will provide knowledge on how to implement effective, sustainable exercise support for individuals with cancer and has the potential to significantly improve cancer outcomes and survivorship. The goal is to make these services available to all individuals with cancer during treatment. This project is a step towards meeting that goal.

Contributors All authors were involved in the development of the study protocol. JS-T drafted this manuscript, and all other authors reviewed, provided feedback and approved the manuscript for submission. JS-T is the guarantor of this project.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design or conduct or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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