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## Implementing an exercise oncology model to reach rural and remote individuals living with and beyond cancer: A hybrid effectiveness-implementation protocol for Project EXCEL (EXercise for Cancer to Enhance Living Well)

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Complete List of Authors:	<p>Culos-Reed, Nicole; University of Calgary, Faculty of Kinesiology  Wagoner, Chad; University of Calgary,  Dreger, Julianna; University of Calgary, Faculty of Kinesiology  McNeely, Margaret; University of Alberta, Physical Therapy; Cancer Care  Alberta, Supportive Care Services  Keats, Melanie; Dalhousie University, School of Health and Human  Performance; Dalhousie University, Department of Medicine, Division of  Oncology  Santa Mina, Daniel; University of Toronto, Faculty of Kinesiology and  Physical Education; Princess Margaret Hospital Cancer Centre, Cancer  Rehabilitation and Survivorship  Cuthbert, Colleen; University of Calgary, Faculty of Nursing  Capozzi, Lauren; University of Calgary, Department of Clinical  Neurosciences  Francis, George; University of Calgary, Department of Clinical  Neurosciences  Ester, Manuel; University of Calgary, Faculty of Kinesiology  McLaughlin, Emma; University of Calgary, Faculty of Kinesiology  Eisele, Max; University of Calgary, Faculty of Kinesiology  Sibley, Daniel; University of Toronto, Faculty of Kinesiology and Physical  Education  Langley, Jodi; Dalhousie University, School of Health and Human  Performance  Chiekwe, Joy; Dalhousie University, School of Health and Human  Performance  Christensen, Thomas; Dalhousie University, School of Health and Human  Performance</p>
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3 Implementing an exercise oncology model to reach rural and remote individuals living with and beyond cancer: A  
4 hybrid effectiveness-implementation protocol for Project EXCEL (EXercise for Cancer to Enhance Living Well)  
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6 S. Nicole Culos-Reed<sup>1</sup>, Chad W. Wagoner<sup>1</sup>, Julianna Dreger<sup>1</sup>, Margaret L. McNeely<sup>2,3</sup>, Melanie R. Keats<sup>4,5</sup>, Daniel  
7 Santa Mina<sup>6</sup>, Colleen Cuthbert<sup>7</sup>, Lauren C. Capozzi<sup>8</sup>, George J. Francis<sup>8</sup>, Manuel Ester<sup>1</sup>, Emma McLaughlin<sup>1</sup>, Max  
8 Eisele<sup>1</sup>, Daniel Sibley<sup>6</sup>, Jodi Langley<sup>4</sup>, Joy Chiekwe<sup>4</sup>, Thomas Christensen<sup>4</sup>, and the EXCEL Project Team<sup>9</sup>  
9

10 Faculty of Kinesiology, University of Calgary<sup>1</sup>; University of Alberta<sup>2</sup>; Supportive Care Services, Cancer Care  
11 Alberta<sup>3</sup>; Faculty of Health, School of Health and Human Performance, Dalhousie University<sup>4</sup>; Department of  
12 Medicine, Division of Medical Oncology, Nova Scotia Health<sup>5</sup>; Faculty of Kinesiology and Physical Education,  
13 University of Toronto<sup>6</sup>; Faculty of Nursing, University of Calgary<sup>7</sup>; Department of Clinical Neurosciences,  
14 University of Calgary<sup>8</sup>; EXCEL Project Team<sup>9</sup>  
15

16  
17  
18 Corresponding Author:  
19 Chad W. Wagoner  
20 2500 University Dr NW  
21 Faculty of Kinesiology, University of Calgary  
22 Calgary, Alberta, Canada  
23 T2N 1N4

24 Email: [chad.wagoner@ucalgary.ca](mailto:chad.wagoner@ucalgary.ca)  
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## Abstract

**Introduction:** Individuals living with and beyond cancer from rural and remote areas lack accessibility to supportive cancer care resources compared to those in urban areas. Exercise is an evidence-based intervention that is a safe and effective supportive cancer care resource, improving physical fitness and function, well-being, and quality of life. Thus, it is imperative that exercise oncology programs are accessible for all individuals living with cancer, regardless of geographic location. To improve accessibility to exercise oncology programs, we have designed the EXercise for Cancer to Enhance Living Well (EXCEL) study. **Methods and Analysis:** EXCEL is a hybrid effectiveness-implementation study. Exercise-based oncology knowledge from clinical exercise physiologists supports healthcare professionals and community-based qualified exercise professionals, facilitating exercise oncology education, referrals, and programming. Recruitment began in September 2020 and will continue for 5-years with the goal to enroll ~1500 individuals from rural and remote areas. All tumour groups are eligible, and participants must be 18 years or older. Participants take part in a 12-week multi-modal progressive exercise intervention currently being delivered online. The reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework is used to determine the impact of EXCEL at participant and institutional levels. Physical activity, functional fitness, and patient-reported outcomes are assessed at baseline and 12-week timepoints of the EXCEL exercise intervention. **Ethics and Dissemination:** The study was approved by the Health Research Ethics Board of Alberta. This study will disseminate, implement, and assess the impact of the EXCEL exercise intervention, building sustainable delivery to rural and remote individuals with cancer. The clinic-to-community partnership model will “bridge the gap” from clinic to rural and remote communities by building sustainable referral pathways and a community-based fitness partnership network. This work will inform practitioners and researchers how to reduce disparities for exercise oncology programs in rural and remote and communities. **Trial Registration:** <https://clinicaltrials.gov/ct2/show/NCT04478851>

**Keywords:** Exercise; Physical Activity; Implementation; Oncology; Cancer Survivorship; Rural and Remote

### Strengths and limitations of this study

- EXCEL is the first exercise oncology study and program to specifically focus on underserved individuals living with and beyond cancer from rural and remote communities on a national scale.
- This study uses a novel exercise oncology partnership model that provides exercise oncology support and builds partnerships, via clinical exercise physiologists, with healthcare professionals and community-based qualified exercise professionals to deliver effective and sustainable exercise oncology programs for rural and remote individuals living with cancer.
- The primary limitation of the EXCEL study is the inability to compare individuals who exercised to a usual care group as this hybrid effectiveness-implementation study design includes a single exercise group.

## Introduction

While cancer incidence and survival rates are relatively similar across Canada, health disparities in oncologic and survivorship care persist. Many Canadians living with and beyond cancer remain underserved in rural and remote communities with respect to supportive cancer care services and resources, and consequently report greater psychological distress and poorer health compared to urban counterparts<sup>1,2</sup>. Lack of access to supportive cancer care, such as community-based exercise oncology programs, is a significant concern, as exercise is an evidence-based intervention that can improve overall health, well-being, and quality of life (QOL) for those living with and beyond cancer<sup>3</sup>. Barriers to supportive cancer care in rural and remote communities include having populations with lower socioeconomic status as well as geographic isolation resulting in fewer healthcare providers, increased travel distances/times to the nearest supportive resources and facilities, and lack of infrastructure (e.g., unable to access telehealth services)<sup>4-6</sup>. Furthermore, as the COVID-19 pandemic places further strain on healthcare systems, those from underserved communities continue to be disproportionately impacted as supportive cancer care is delayed and inaccessible telehealth services persist<sup>7</sup>. As such, these disparities have increased the burden of cancer on overall health and QOL, and there is a clear need to make exercise as a supportive cancer care resource more easily accessible for those in rural and remote areas.

Exercise improves cancer survivorship outcomes and QOL<sup>7</sup>, and research has resulted in the development of cancer-specific exercise guidelines<sup>9-12</sup>. However, despite this evidence, guidelines, and advocacy, less than a quarter of people with cancer are considered to be physically active<sup>13</sup>, and these participation rates may be even less for rural and remote populations due to a lack of exercise oncology resources within these communities<sup>14</sup>. To ensure equitable access, there must be development, dissemination, and implementation of exercise oncology evidence-based resources to deliver sustainable exercise programs safely and effectively for all individuals with cancer.

Members of our team are conducting a community-based, hybrid effectiveness-implementation exercise oncology study, the Alberta Cancer Exercise (ACE) study<sup>15</sup>. A limitation of the ACE study is that it focuses on delivering services to urban populations and only in one region (Alberta), and as such, the implementation processes may not be generalizable to rural and remote communities. Moreover, an important opportunity exists to examine wide-spread implementation and assess the development and dissemination of exercise intervention effectiveness on a national scale. This type of evaluation is critical for building exercise as a supportive cancer care resource for more individuals living with and beyond cancer in all regions of a geographically and socio-demographically diverse

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3 nation, providing valuable information on feasibility and impact on participant and system-level outcomes in real-  
4 world settings. To specifically address the commonly reported barriers to exercise for rural and remote individuals  
5 with cancer, we aim to improve accessibility of required expertise, make use of digital technology, and develop  
6 community partnerships for sustainable implementation<sup>16,17</sup>. Accordingly, we have designed a 5-year hybrid  
7 effectiveness-implementation study to address these disparities in access to exercise – the EXercise for Cancer to  
8 Enhance Living Well (EXCEL) study.  
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15 Previous work indicates that successful implementation for rural and remote populations requires personnel  
16 training, program support from healthcare professionals (HCPs), and sustainable community-partnerships<sup>14,17</sup>.  
17 Therefore, we will implement our exercise oncology survivorship partnership ‘hub and spoke’ model (Figure 1) that  
18 will provide HCPs with exercise oncology resources, including education and support for participant intake (referral  
19 and screening) in the clinical setting, build clinic-to-community referral pathways that bridge HCPs and rural and  
20 remote communities with qualified exercise professionals (QEPs) that reduces reliance on participant self-referrals,  
21 and provide exercise oncology specific training to QEPs to deliver an evidence-based exercise oncology program  
22 that is safe, effective, and tailored to meet participants’ needs. Our objectives are to disseminate, implement, and  
23 assess the effectiveness of EXCEL to increase the reach and delivery of an exercise intervention to rural and remote  
24 individuals living with cancer. In doing so, the EXCEL study will provide a better understanding of the various  
25 factors associated with making evidence-based exercise oncology interventions accessible and sustainable.  
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## 37 **Methods**

### 38 Design and Setting

39  
40 A hybrid effectiveness-implementation study design<sup>18</sup> that utilizes mixed methods is being used to  
41 determine the effectiveness of the EXCEL exercise intervention as well as its implementation efforts  
42 ([NCT04478851](https://clinicaltrials.gov/ct2/show/study/NCT04478851)). Due to the pandemic, the original clinical trial registration varies in methodology with the current  
43 version of EXCEL. Specifically, EXCEL is now being implemented in an online format, rather than delivering in-  
44 person community-based fitness classes and assessments. As such, fitness assessment methodology differs slightly  
45 from the clinical trial registration to feasibly utilize the online format and maximize participant safety. It is  
46 important to note that EXCEL has always intended to include an online version of delivery via ZOOM™ to increase  
47 reach. Though the online format will remain for EXCEL, as the pandemic allows, the study will begin to implement  
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3 in-person exercise classes and fitness assessments, with slight variations to the current protocol (see Appendix I for  
4 a list of program components for online and in-person delivery).

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7 The effectiveness-implementation research design has been used previously by members of the research  
8 team to implement ACE<sup>15</sup>. EXCEL is implemented by establishing geographic hubs supported by clinical exercise  
9 physiologists (CEPs), responsible for exercise screening of participants, managing the community-based exercise  
10 partnerships within their region, and when required, delivering the supervised exercise intervention for high-risk  
11 participants. Hubs established at the project outset are in Alberta, Nova Scotia, and Ontario, with plans to add  
12 British Columbia and Quebec in years 2-4. See Figure 2 for the current geographical map of EXCEL hub and the  
13 community regions (i.e., spokes) they currently serve. EXCEL employs the Canadian Institutes of Health Research  
14 (CIHR) knowledge to action (KTA) framework<sup>19</sup> to guide the process of translating research evidence into practice,  
15 as well as a participant-oriented research approach to tailor implementation strategies to better address participants'  
16 needs. Specifically, a monthly Participant Advisory Board (PAB) meeting with former exercise oncology program  
17 (including EXCEL) participants discusses recurring implementation issues that need to be addressed, and 6-month  
18 quality improvement (QI) cycles (electronic surveys sent to participations, HCPs, and QEPs), provide feedback to  
19 the study team regarding outreach, intervention delivery, and provision of supportive resources (e.g., educational  
20 webinars), all of which are used to inform the continued implementation and evaluation of EXCEL.  
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### 36 Participants and Screening

37 EXCEL participant enrollment occurs from September 2020 to September 2025. Participants are included  
38 if they are: 18 years or older living with and beyond cancer, able to participate in mild levels of physical activity,  
39 can consent in English\*, and live in underserved rural / remote communities that do not have access to exercise  
40 oncology programs†.

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46 Participants can self-refer or be referred by an HCP to a hub CEP who screens for study eligibility and  
47 provides participants with the electronic study consent form. Consent forms and study data are collected and  
48 managed using REDCap (Research Electronic Data Capture),<sup>20,21</sup>. REDCap is a secure, web-based software platform  
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54 \* French translation work is underway.

55 † The term “underserved” expanded during COVID-19 restrictions to also include those from additional areas (e.g.,  
56 smaller urban areas) who did not have any access to exercise oncology resources  
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3 designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2)  
4 audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data  
5 downloads to common statistical packages; and 4) procedures for data integration and interoperability with external  
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7 sources. After providing informed consent, intake information is gathered about cancer-related medical history,  
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9 treatment-related side-effects, other chronic conditions or injuries, and physical activity readiness via the PARQ+<sup>22</sup>.  
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11 The intake form and PARQ+ are reviewed by the hub CEP to screen for exercise participation.  
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### 16 17 Exercise Intervention

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19 The exercise intervention description is guided by the TIDieR checklist<sup>23</sup> and is based on previous  
20 successful online implementation of ACE<sup>15</sup> and current exercise oncology guidelines<sup>11</sup>. EXCEL's online exercise  
21 intervention is delivered via ZOOM™ with password protected exercise classes, and the exercise class instructor  
22 (QEP or CEP, depending on the participant needs; for example, high risk individuals such as those on-treatment are  
23 always under the exercise supervision of a CEP) is assisted by a trained moderator (QEP). Each class consists of 8-  
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25 15 participants to ensure safety and ability to tailor to meet participant needs within the online delivery format. The  
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27 intervention is a standardized 12-week evidence-based exercise intervention with two sessions per week, with at  
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29 least one day of rest between classes. Classes are 60 minutes in duration and include the following: 1) 5-minute  
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31 warm-up; 2) 45-50 minutes of circuit style training consisting of strength/resistance, balance, and aerobic activities;  
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33 and 3) 5–10-minute cool-down consisting of full-body stretching. Instructors demonstrate each exercise, tailoring to  
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35 address participants' needs including exercise progressions (e.g., push-ups from wall to floor) or regressions (e.g.,  
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37 push-ups from floor to wall). Fidelity checks are carried out by the central (Calgary) hub CEPs to ensure consistency  
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39 and safety in the delivery of the exercise intervention across partner sites. Using a standardized fidelity reporting  
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41 form for each site, a random 10% of exercise classes for each 12-week session are observed and reviewed, and any  
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43 feedback to improve delivery is provided to the exercise leaders (CEP/QEP).  
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### 49 Assessing Implementation – The RE-AIM Framework

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51 The RE-AIM<sup>24</sup> framework is used to evaluate the implementation of EXCEL (refer to Table 1 for a  
52 summary of outcomes), and has been used previously for the ACE exercise oncology program implementation  
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54 evaluation<sup>15</sup>. This framework has also been used to assess health/lifestyle behaviours and their public health  
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3 impact<sup>25-28</sup> as a function of 5 factors: reach, effectiveness, adoption, implementation, and maintenance. Reach and  
4 effectiveness are considered at the individual/participant level, while adoption, implementation and maintenance are  
5 factors typically specific to programs and sites. *Reach* is assessed by tracking referrals and enrollment into the  
6 EXCEL program. Referral types are classified as “direct HCP referral”, “indirect HCP referral”, or “self-referral”.  
7 Direct HCP referral is defined as a hub CEP receiving a referral directly from an HCP, whereas indirect HCP  
8 referrals are defined as a participant contacting the hub CEP after receiving information about EXCEL from an HCP  
9 (e.g., HCP hands participant a study brochure in clinic). Self-referrals are defined as participants contacting the hub  
10 CEP without any interaction with a HCP (e.g., participant heard about EXCEL through word of mouth, saw a poster  
11 or video ad). Enrollment is assessed by tracking the number and characteristics of eligible participants who enroll in  
12 EXCEL compared to those eligible who do not enroll. Reasons for study refusal will be tracked in addition to  
13 context specific needs to rural and remote areas such as distance to the nearest cancer centre and internet  
14 accessibility. *Effectiveness* of EXCEL is assessed through the functional fitness outcomes, patient-reported  
15 outcomes (PRO), and objective and self-reported physical activity measures that are detailed below. To assess  
16 *adoption* of EXCEL, characteristics of adopting and non-adopting spoke sites throughout rural and remote  
17 communities will be tracked. This includes tracking the number of referral sites (clinical sources), resources that are  
18 being used to refer to EXCEL, and the number of clinical personnel involved to implement EXCEL (i.e., who is  
19 involved and how many personnel at the respective clinical site). Additional measures of adoption include fitness  
20 professional partnerships and characteristics, tracking the number of trained QEPs, number of exercise classes  
21 provided at each site, and both the number and type of fitness partnership that is implementing EXCEL (e.g.,  
22 individual QEPs, established fitness centres, fitness partners through health care settings, other sites).  
23 *Implementation* is tracked through fidelity checks, number of adverse events via the Common Terminology Criteria  
24 for Adverse Events (CTCAE V5.0)<sup>29</sup>, exercise class adherence (i.e., attendance at each scheduled exercise session),  
25 and overall program costs per site (training, personnel / administrative support, other costs). *Maintenance* is assessed  
26 through long-term engagement with exercise / physical activity from both program sites (e.g., the number of  
27 established exercise programs in the community) and participants (e.g., long-term physical activity levels and  
28 exercise program participation, assessed at follow-up timepoints up to 1 year after baseline program participation).  
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Table 1. RE-AIM Summary Outcomes

Construct	Reporting Outcomes
<u>Reach</u>	<ul style="list-style-type: none"> <li>▪ Referral               <ul style="list-style-type: none"> <li>○ Indirect-HCP Referral</li> <li>○ Direct-HCP Referral</li> <li>○ Self-Referral</li> </ul> </li> <li>▪ Enrollment               <ul style="list-style-type: none"> <li>○ # of participants enrolled</li> <li>○ # of participants who do not enroll</li> <li>○ Characteristics of enrolled and non-enrolled                   <ul style="list-style-type: none"> <li>▪ Using Canadian Norms as reference</li> </ul> </li> <li>○ Reasons for study refusal</li> </ul> </li> <li>▪ Rural and Remote Specific Barriers               <ul style="list-style-type: none"> <li>○ Internet Accessibility</li> <li>○ Distance to nearest cancer centre</li> </ul> </li> </ul>
<u>Effectiveness</u>	<ul style="list-style-type: none"> <li>▪ Patient-Reported Outcomes               <ul style="list-style-type: none"> <li>○ QOL, Fatigue, Physical Activity, Exercise Barriers, Symptom Burden</li> </ul> </li> <li>▪ Functional Fitness Outcomes               <ul style="list-style-type: none"> <li>○ Aerobic Endurance, Musculoskeletal Fitness, Balance, Flexibility</li> </ul> </li> <li>▪ Self-Report and Objective Physical Activity</li> </ul>
<u>Adoption</u>	<ul style="list-style-type: none"> <li>▪ Characteristics of adopting / non-adopting clinical sites               <ul style="list-style-type: none"> <li>○ # and type of educational and referral resources provided</li> <li>○ Personnel involved – # and type/who</li> </ul> </li> <li>▪ Fitness professional partnerships and characteristics               <ul style="list-style-type: none"> <li>○ # of trained QEPs</li> <li>○ # of exercise classes provided</li> <li>○ # organizations and type (i.e., individuals, fitness centres)</li> </ul> </li> </ul>
<u>Implementation</u>	<ul style="list-style-type: none"> <li>▪ Fidelity Checks               <ul style="list-style-type: none"> <li>○ Consistent delivery of exercise program completed per a review of exercise sessions and standardized checklist by CEPs</li> </ul> </li> <li>▪ Safety of Exercise Program               <ul style="list-style-type: none"> <li>○ Tracking and reporting of adverse events<sup>29</sup></li> </ul> </li> <li>▪ Program Acceptability (i.e., adherence)               <ul style="list-style-type: none"> <li>○ Exercise class attendance tracking</li> </ul> </li> <li>▪ Program Costs               <ul style="list-style-type: none"> <li>○ Training, site delivery, and administrative support costs</li> </ul> </li> </ul>
<u>Maintenance</u>	<ul style="list-style-type: none"> <li>▪ Sustainability of exercise programs within the community               <ul style="list-style-type: none"> <li>○ # of ongoing programs</li> </ul> </li> <li>▪ Participation in home- or centre-based exercise programs               <ul style="list-style-type: none"> <li>○ # of participants continuing to engage in structured exercise post 12-Week EXCEL program</li> </ul> </li> <li>▪ Physical activity levels at 24-week (objective and self-report) and 1-year follow-up (self-report)</li> </ul>

### Outcome Measures

Outcome measures are completed at four timepoints: 1) baseline; 2) 12-weeks (post-intervention); 3) 24-weeks; and 4) one-year (see Table 2 for measurement timepoints). Online functional fitness assessments take place at baseline and 12-week timepoints, PROs are completed at each timepoint via REDCap<sup>20,21</sup>, and wearable physical activity trackers are worn from baseline to the 24-week timepoint, with all wearable data stored in the Wearable

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3 Technology Research and Collaboration (We-TRAC), a Level-4 secure database at the University of Calgary  
4 supported by funding from the Natural Sciences and Engineering Research Council of Canada (NSERC). Qualitative  
5 data collected through semi-structured interviews occur on a rolling basis as part of the 6-month recurring QI cycles.  
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### 10 Functional Fitness Outcomes

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12 Online functional fitness assessments are completed individually for each participant before and after the  
13 12-week exercise intervention, with results recorded in REDCap. Assessments take approximately 30 minutes and  
14 follow the Canadian Society of Exercise Physiology's Physical Activity Training for Health Protocol (CSEP-  
15 PATH)<sup>30</sup>. All assessors at each hub are trained in the assessment protocol and have exercise oncology experience  
16 and specific training. Primary assessors (CEPs) explain and demonstrate each assessment prior to the participants'  
17 attempt. Secondary assessors (QEP or volunteers) help to ensure participant safety through additional monitoring  
18 during fitness assessments and record results, confirming results with the primary assessor after each assessment and  
19 during data entry. The functional fitness assessment includes measures of 1) self-reported height and weight  
20 (calculation of body mass index); 2) upper body flexibility via shoulder flexion range of motion; 3) musculoskeletal  
21 fitness via a 30-second sit to stand assessment; 4) lower body flexibility via a sit and reach assessment; 5) aerobic  
22 endurance with a 2-minute step test; and 6) balance with a single-leg balance assessment. Due to the pandemic,  
23 modifications were required to assess participants to the best of our ability while maintaining scientific rigor (See  
24 Appendix 1 for comparison of in-person vs online assessment tools).  
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### 37 Shoulder Flexion Range of Motion<sup>31</sup>

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39 Participants begin by sitting perpendicular to their computer camera in their chair, with arms by their side  
40 and palms facing inward. Participants are instructed to raise their arm in forward flexion, while remaining in the  
41 sagittal plane, with the goal of bringing their hand above their shoulder. Ensuring that the elbow is visible, this final  
42 position is held briefly while the CEP takes a screen shot on their computer screen. This process is repeated twice  
43 for each arm with the participant changing their chair position for the opposite arm. Range of motion is determined  
44 in degrees by measuring the final angle (screen shot) with a goniometer, using the head of the humerus, midline of  
45 the humerus, and mid-axillary line as anatomical landmarks for consistent measurements.  
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### 53 30-Second Sit to Stand<sup>32,33</sup>

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3 Participants start in a seated upright position (~43cm chair) with arms across the chest and hands placed on  
4 opposite shoulders, with no contact on the back of the chair. Participants are then instructed to complete as many “sit  
5 to stands” as possible within 30 seconds, with one “sit to stand” defined as standing with full hip extension and arms  
6 remaining in the crossed-chest position. On a “ready-set-go” cue, participants begin the assessment and the number  
7 of fully completed sit to stands within the 30-second time frame is recorded.  
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#### 10 11 12 *Chair Sit and Reach*<sup>34</sup>

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14 Participants complete warm-up stretches before the test is conducted. They start in a seated position on the  
15 edge of a chair with one leg fully extended and ankle bent at 90 degrees. Participants are then instructed to place one  
16 hand on top of the other (palms facing down), fully extend their arms, and slowly reach forward while keeping their  
17 back and extended leg straight. They hold this stretch for 20 seconds, on each leg twice. The test is performed by  
18 repeating the same stretching movement in the warm-up, however participants are then asked to measure the  
19 distance from their toes to their fingertips with a tape measure, which is then reported to the nearest  $\pm 0.5\text{cm}$  (+ =  
20 fingers went beyond toes; 0cm = fingers just touched toes; - = fingers did not reach toes). This process is repeated  
21 twice on both legs, with the highest number being reported for each leg.  
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#### 30 *2-Minute Step Test*<sup>35</sup>

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32 Participants begin by standing perpendicular to the camera (i.e., right leg facing the camera) while  
33 marching in place for 2-minutes. The target knee height is determined by having the participant measure the distance  
34 between the patella and iliac crest to find the mid-point of the thigh. Participants are then instructed to measure the  
35 distance from the thigh mid-point to the floor, and this distance is recorded by the assessor. If the participant is  
36 unable to determine the thigh mid-point, target knee height is set so that the thigh is parallel to the floor when  
37 marching. On a “ready-set-go” cue, participants begin marching in place and the number of steps completed within  
38 the 2-minute time frame on the leg facing the camera are recorded. Rate of perceived exertion (RPE; 1-10)<sup>36</sup> is  
39 recorded after the assessment has been completed.  
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#### 47 *Single Leg Balance*<sup>37</sup>

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49 Participants start by standing on a flat surface, with shoes removed and eyes open, near a stable object (i.e.,  
50 chair or wall) for safety purposes, while facing the camera. Participants start with arms placed across their chest (or  
51 hands on hips) with feet shoulder width apart, and the assessment begins when the participant lifts one foot off the  
52 ground to the height of the opposite ankle with eyes remaining open. The assessment ends when either arms move  
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3 away from the body, the raised foot touches the floor, the raised foot touches the standing leg, the raised leg moves  
4 from static position, or the maximum limit of 45 seconds is reached. This process is repeated for the opposite leg  
5 and both balance times are recorded. If the assessments end before three seconds (due to the above listed  
6 conditions), they may repeat the test one more time and the longest duration is recorded.  
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### 10 11 12 Patient-Reported Outcomes

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14 Questionnaires are completed online in REDCap at baseline, 12-weeks, 24-weeks, and 1-year. Self-  
15 reported physical activity is assessed using the modified Godin Leisure Time Exercise Questionnaire (GLTEQ)<sup>38</sup>,  
16 which asks participants to recall average typical weekly exercise. Recall includes the frequency and duration of  
17 mild, moderate, and vigorous aerobic activity, in addition to resistance and flexibility exercise. QOL is measured  
18 with the EQ-5D-5L<sup>39</sup> questionnaire and the Functional Assessment of Cancer Therapy – General (FACT-G)<sup>40</sup>  
19 questionnaire. The EQ-5D 5L measures general health as well as clinical and economic evaluations of healthcare.  
20 The FACT-G assesses QOL through four sub-domains: physical, social/family, emotional, and functional well-  
21 being. A final score is calculated from the sum of each sub-domain score and is representative of overall QOL.  
22 Fatigue is assessed with the Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F)<sup>41</sup> scale. The  
23 Edmonton Symptom Assessment Scale - Revised (ESAS-r)<sup>42</sup> assesses symptom burden from nine cancer related  
24 symptoms. Confidence (i.e., self-efficacy) to participate in exercise is assessed with the Exercise Barriers and  
25 Facilitators questionnaire<sup>43</sup>. Participants are asked to rank their confidence level to participate in exercise in certain  
26 situations (e.g., when they feel nauseated, during bad weather, when there is lack of time, etc.). Barrier and  
27 facilitator self-efficacy scales are rated from 0-100% at 10% intervals. Interpretation of the scales are as follows: 0-  
28 20% = not at all confident; 20-40% = slightly confident; 40-60%= moderately confident; 60-80% = very confident;  
29 and 80-100% = extremely confident.  
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### 47 Objective Physical Activity Levels

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49 An activity tracker (Garmin Vivo Smart4) is used to capture objective data on exercise volume in a subset  
50 of the EXCEL participants. This is a commercially available activity tracker, and similar models have been found to  
51 be highly acceptable in cancer populations<sup>44,45</sup>. Categories of meeting or not-meeting current exercise oncology  
52 guidelines<sup>11</sup> are used as a marker of implementation success (i.e., achieving 90 minutes of moderate to vigorous  
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3 physical activity per week), as well as percent change in physical activity levels over time (baseline to post-  
4 intervention; maintenance to follow-up). Activity trackers are distributed across hubs, based on the number of active  
5 participants at each hub and the number of trackers available. Participants are mailed the tracker after consent into  
6 the study and provided with instructions for use (an additional webinar is available to support use and troubleshoot  
7 common issues). Participants are instructed to wear the activity tracker for at least 10 hours per day, for 24-weeks,  
8 unless the device is charging. To be included for weekly physical activity calculations, at least four valid days are  
9 required. Valid days are defined as wearing the activity tracker for at least 10 hours/day<sup>46,47</sup> with non-wear time  
10 being defined as not wearing the tracker for 60 consecutive minutes<sup>48</sup>. Objective physical activity data is synced  
11 weekly and stored in the NSERC supported We-TRAC secure database at the University of Calgary. Collected data  
12 includes step counts and continuously recorded heart rate.  
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#### 24 Semi-structured Interviews

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26 The RE-AIM QuEST<sup>49</sup> framework guides the semi-structured qualitative interviews conducted as part of  
27 the 6-month recurring QI cycles. RE-AIM QuEST supplements quantitative measures by identifying and providing  
28 additional context to implementation barriers and can subsequently be used to help improve interventions in real-  
29 time. Interviews occur with a purposive sample of participants, QEPs, and HCPs to assess program implementation  
30 as well as outcomes from the exercise program itself. Sampling of participants includes considerations of location,  
31 participation age and cancer diagnosis, gender, and activity levels at baseline. For QEPs and HCPs, sampling  
32 considers location, role, and years of experience. This purposive sampling will ensure diverse views are collected  
33 across program participants and networks of HCPs and QEPs. The interviews are guided by interpretive description  
34 methodology<sup>50</sup>, which has been used as a reliable qualitative guide within multiple health-related disciplines<sup>51-53</sup>.  
35 Interviews are conducted either online (i.e., ZOOM™) or via telephone with trained study personnel. The qualitative  
36 analysis will provide a deeper understanding into program implementation and effectiveness from participant, HCP,  
37 and QEP perspectives, complementary and adding depth of potential understanding to the PROs and exercise data.  
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#### 50 Sample Size and Statistical Analysis

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52 EXCEL will aim to enroll a minimum of 1500 individuals living with and beyond cancer from underserved  
53 rural and remote communities across Canada. In addition, due to physical restrictions imposed during the COVID-  
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3 19 pandemic restrictions, EXCEL will include participants from larger centres (i.e., more urban locations) who do  
4 not have access to exercise oncology resources during this time. This inclusion is practical and ensures reach of the  
5 evidence-based exercise oncology resource during a time of restrictions to an underserved population who may  
6 benefit both physically and mentally during the pandemic by having access to exercise as a supportive cancer care  
7 resource. Analyses will therefore consider geographical location within sub-analyses, and/or as a covariate in the  
8 primary analysis.

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15 Descriptive statistics will evaluate participant demographic, medical and exercise-related variables, as well  
16 as RE-AIM dissemination and implementation components. A single proportion inference test and confidence  
17 interval will be performed to determine the proportion of eligible participants who provide informed consent for  
18 EXCEL and complete the program, in addition to adherence rates to the program. Generalized linear mixed models  
19 will be used to evaluate effectiveness via changes in outcome measures over time. Multi-level modeling will be used  
20 to examine site differences (i.e., geographical location) in relation to reported physical activity levels and adherence  
21 to the exercise intervention. Qualitative analyses will be transcribed in ExpressScribe, coded in NVivo 12, and  
22 thematically analyzed by two independent authors per the interpretive description methodology<sup>50</sup>.

### 31 32 Patient and Public Involvement

33  
34 Rural and remote individuals living with and beyond cancer, in addition to caregivers, have informed the  
35 EXCEL Project conception, delivery, assessments, and implementation of our partnership model. Three individuals  
36 living with cancer from rural and remote communities make up our PAB, which has better informed our team in  
37 conceptualizing and delivery the 12-week exercise intervention. Our team also engages with HCPs and QEPs while  
38 evaluating ongoing implementation components of the entire project (i.e., referral support and exercise program  
39 delivery) to continually improve the exercise program experience for participants.

### 46 47 **Discussion**

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49 Exercise, as an evidence-based supportive cancer care resource, is both safe and effective at alleviating  
50 symptom burden, improving fitness, QOL<sup>3</sup>, and survival<sup>54,55</sup>. Unfortunately, disparities in access to exercise for rural  
51 and remote individuals living with and beyond cancer prevent equitable potential realization of these benefits<sup>5</sup>. The  
52 EXCEL study aims to address this inequity by implementing and evaluating the effectiveness of bringing evidence-  
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based exercise oncology programs to these communities. As the first large scale study to disseminate, implement, and evaluate the effectiveness of exercise for rural and remote individuals living with and beyond cancer, findings will inform how to reduce disparities in access to exercise as a supportive cancer care resource and ensure sustainable implementation of evidence-based exercise oncology interventions. This will enhance the physical and mental well-being, and ultimately the overall QOL, of more individuals living with and beyond cancer.

Table 2. Measure Outcomes and Timepoints

Domain/Outcome	Measure	Baseline	12-Week	24-Week	One Year
<i>Physical Fitness / Function</i>					
Shoulder Range of Motion	Shoulder Flexion	X	X		
Musculoskeletal Fitness	30-Second Sit-to-Stand	X	X		
Lower Body Flexibility	Chair Sit-and-Reach	X	X		
Aerobic Endurance	Two-Minute Step Test	X	X		
Balance	Single-Leg Stance	X	X		
<i>Patient-Reported Outcomes (PROs)</i>					
Physical Activity	Godin Leisure Time Exercise Questionnaire	X	X	X	X
Health Status	EQ-5D 5L	X	X	X	X
Quality of Life	Functional Assessment of Cancer Therapy - General	X	X	X	X
Fatigue	Functional Assessment of Cancer Illness Therapy - Fatigue	X	X	X	X
Symptom Burden	Edmonton Symptom Assessment Scale	X	X	X	X
Barriers and Facilitators	Exercise Barriers and Facilitators	X	X	X	X
<i>Wearable Activity Tracker</i>					
Objective Physical Activity	Garmin Vivo Smart4	X	X	X	
<i>Notes</i>					
All Functional Fitness Assessments are completed online via ZOOM™ with results stored in REDCap, PROs are completed online via REDCap, and Objective Physical Activity is tracked and stored within We-TRAC online secure database.					

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3 The final products for EXCEL dissemination and implementation across Canada will include training,  
4 program protocols (assessment and delivery), and established clinic-to-community partnerships. Resources within  
5 each of these elements will be available to support the continued building of our exercise oncology partnership  
6 model, linking participants in clinical settings to exercise as an evidence-based supportive cancer care resource that  
7 can be accessed within community settings (online and/or in-person). Our exercise partnership model, building  
8 clinic-to-community pathways to support exercise oncology as part of standard supportive cancer care, is a unique  
9 feature and overall strength of the EXCEL study. Implementation will “bridge the gap” from clinic to rural and  
10 remote communities, building referral sources at the clinical level and a network of trained fitness professionals at  
11 the community level. Bridging between these two networks is the critical role of the CEP, which is not yet a  
12 widespread role within cancer care. Building upon our “pathways model”<sup>56,57</sup>, CEP expertise ensures that referral to  
13 exercise resources is appropriately addressed through expert screening, understanding of tailored needs within an  
14 exercise setting, and supports access to safe and effective exercise resources that will meet participant needs.  
15 Ultimately, building exercise via EXCEL into standard supportive cancer care will equip individuals living with and  
16 beyond cancer with the resources to use exercise to manage their wellness, health, and overall QOL.  
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### 31 **Figure Legend**

32 Figure 1. Exercise Oncology Survivorship Hub and Spoke Partnership Model

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36 Figure 2. EXCEL Hub and Spoke Map  
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### **Author Contributions**

S. NC-R, MM, MK, DSM, and CC developed the study concept and protocol. All authors will oversee the implementation of the protocol and contribute to the collection, analysis, and interpretation / application of data. S. NC-R and CW drafted the manuscript in addition to JD, MM, MK, DSM, and CC contributing to manuscript revisions. All authors provided critical feedback and approved of the final manuscript submission.

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### **Competing Interest**

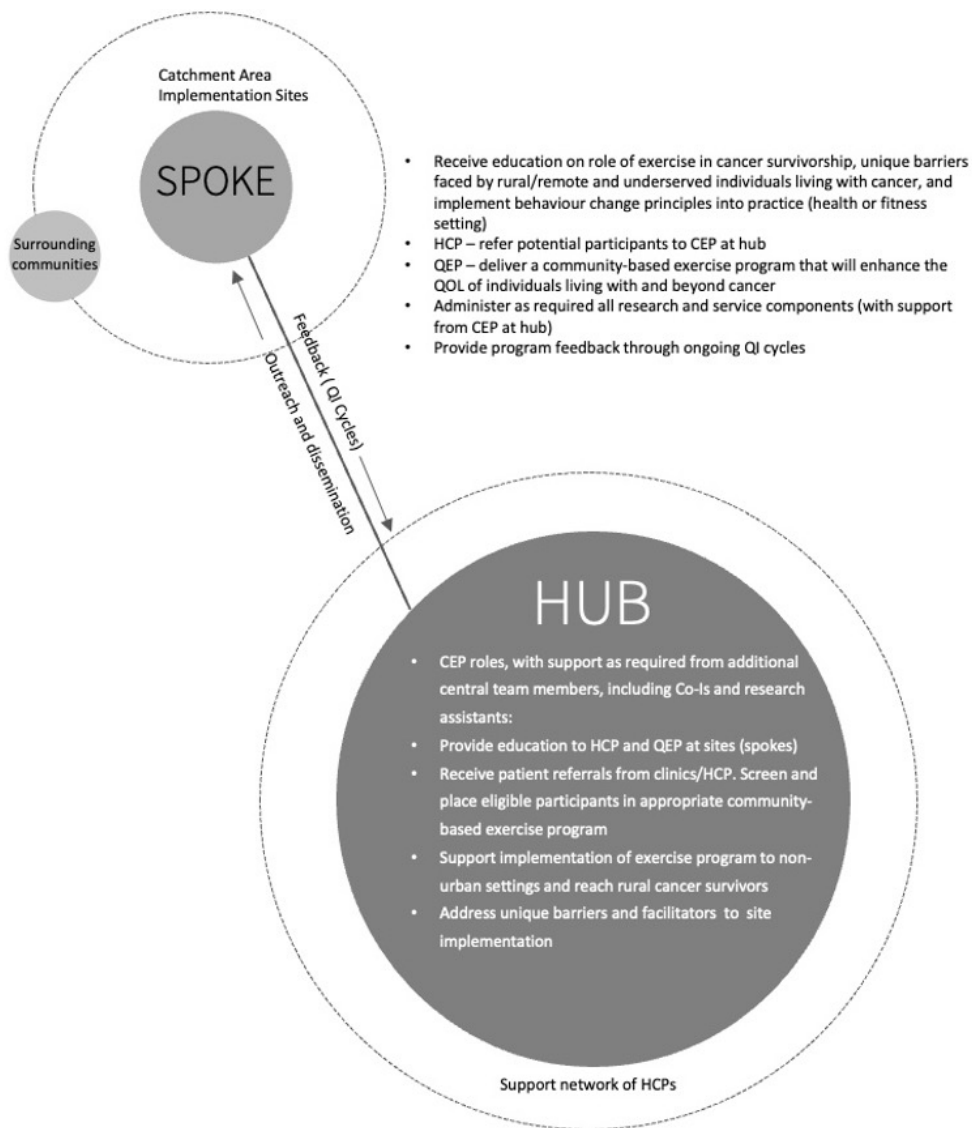
None declared.

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43 Figure 1. Exercise Oncology Survivorship Hub and Spoke Partnership Model

44 135x153mm (144 x 144 DPI)

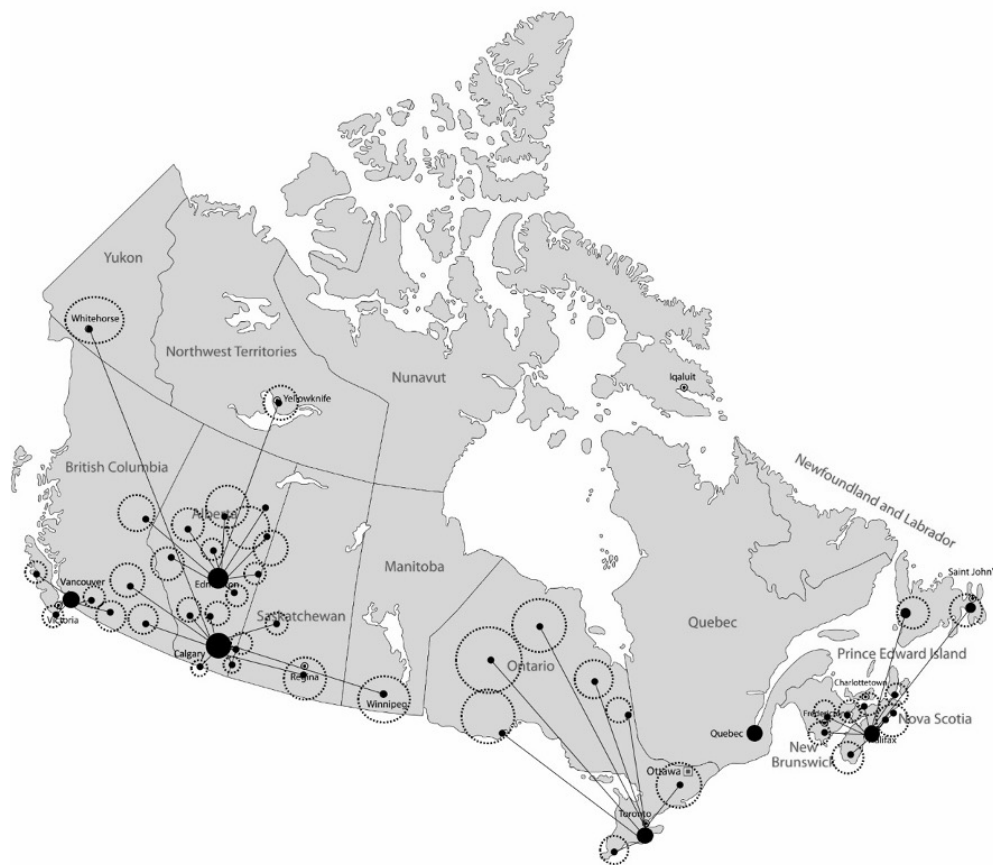


Figure 2. EXCEL Hub and Spoke Map

157x137mm (144 x 144 DPI)



## Appendix I – Comparison of the Online and In-Person Delivery of EXCEL

<b>Domain/Outcome</b>	<b>Online Fitness Assessment</b>	<b>In-Person Fitness Assessment</b>
Balance	Single-Leg Stance	Single-Leg Stance
Musculoskeletal Fitness	<i>30-Second Sit-to-Stand</i>	<i>30-Second Sit-to-Stand &amp; Handgrip Strength</i>
Aerobic Endurance	<i>Two-Minute Step Test</i>	<i>6-Minute Walk Test</i>
Lower Body Flexibility	Chair Sit-and-Reach	Traditional Sit-and-Reach
Shoulder Range of Motion	Shoulder Flexion	Shoulder Flexion

Fitness assessments that occur as part of the online delivery of EXCEL are described within the body of the main text. Here we provide further descriptions of fitness assessments that differ for in-person assessments. Specifically, we provide descriptions for the Handgrip Strength, 6-Minute Walk Test, and the traditional Sit and Reach completed with a flexometer. Furthermore, in-person assessments take place in a group format, completed during the first and final week of the 12-week exercise intervention.

*Handgrip Strength*

A hand-held dynamometer is used to assess muscular strength. Participants are instructed to hold the dynamometer in line with their forearm and level with their thigh. Prior to beginning, participants are instructed to not swing their arm, bend their elbow, or bend their wrist to prevent their arm or dynamometer from coming into contact with their body or any other object during the assessment. The assessment begins by telling participants to take a deep breath squeeze the dynamometer as hard as they can for two to three seconds while exhaling. Hands are alternated after each assessment and a total of two trials are completed for each hand. The highest score, recorded to the nearest 0.5 kilogram, is recorded for each hand.

*6-Minute Walk Test*

The purpose of the 6-minute walk test (6MWT) is to assess aerobic fitness. Participants complete the 6MWT on a flat surface that is a minimum of 20 meters in length. Participants are instructed to walk the course as fast as possible without running in an effort to cover the greatest distance possible within the six-minute timeframe. On a “ready-set-go” cue, participants begin the assessment, and the assessor records the number of laps that are completed. Rate of perceived exertion (RPE; 1-10) is recorded at the two, four, and six-minute marks. During the

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3 assessment, participants are allowed to rest if they need to, though the six-minute timer does not stop. At the  
4 conclusion of the assessment, participants are allowed a cool-down (i.e., light walking) and the final distance is  
5 calculated and recorded in meters.  
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#### 8 *Traditional Sit-and-Reach*

10 The traditional sit-and-reach assessment is used to measure the flexibility in the hamstrings and lower back  
11 with a flexometer. Participants are first instructed to remove footwear and warm-up, which involves completing a  
12 20-second modified hurdler stretch twice on each leg. Participants are then positioned for the sit-and-reach  
13 assessment, which includes placing their feet flat against the flexometer with legs straight. Participants are then  
14 instructed to extend their arms evenly in front of them with one palm of their hand placed on top of the other. The  
15 assessment begins by having participants slowly bending forward (without bouncing) with legs remaining straight to  
16 push the sliding marker on the flexometer forward as far as possible and holding the final position for two seconds.  
17 This process is repeated, twice, and the greatest measurement is recorded to the nearest 0.5 cm. NOTE: If a  
18 flexometer is not available for in-person fitness assessments, the chair sit-and-reach assessment protocol that is used  
19 for online assessments is completed (described within methods).  
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# BMJ Open

## Implementing an exercise oncology model to reach rural and remote individuals living with and beyond cancer: A hybrid effectiveness-implementation protocol for Project EXCEL (EXercise for Cancer to Enhance Living Well)

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3 Implementing an exercise oncology model to reach rural and remote individuals living with and beyond cancer: A  
4 hybrid effectiveness-implementation protocol for Project EXCEL (EXercise for Cancer to Enhance Living Well)  
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6 S. Nicole Culos-Reed<sup>1</sup>, Chad W. Wagoner<sup>1</sup>, Julianna Dreger<sup>1</sup>, Margaret L. McNeely<sup>2,3</sup>, Melanie R. Keats<sup>4,5</sup>, Daniel  
7 Santa Mina<sup>6</sup>, Colleen Cuthbert<sup>7</sup>, Lauren C. Capozzi<sup>8</sup>, George J. Francis<sup>8</sup>, Guanmin Chen<sup>9</sup>, Manuel Ester<sup>1</sup>, Emma  
8 McLaughlin<sup>1</sup>, Max Eisele<sup>1</sup>, Daniel Sibley<sup>6</sup>, Jodi Langley<sup>4</sup>, Joy Chiekwe<sup>4</sup>, Thomas Christensen<sup>4</sup> and the EXCEL  
9 Project Team<sup>10</sup>  
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11 Faculty of Kinesiology, University of Calgary<sup>1</sup>; University of Alberta<sup>2</sup>; Supportive Care Services, Cancer Care  
12 Alberta<sup>3</sup>; Faculty of Health, School of Health and Human Performance, Dalhousie University<sup>4</sup>; Department of  
13 Medicine, Division of Medical Oncology, Nova Scotia Health<sup>5</sup>; Faculty of Kinesiology and Physical Education,  
14 University of Toronto<sup>6</sup>; Faculty of Nursing, University of Calgary<sup>7</sup>; Department of Clinical Neurosciences,  
15 University of Calgary<sup>8</sup>; Data and Analytics, Alberta Health Services<sup>9</sup>; EXCEL Project Team<sup>10</sup>  
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19 Corresponding Author:  
20 Chad W. Wagoner  
21 2500 University Dr NW  
22 Faculty of Kinesiology, University of Calgary  
23 Calgary, Alberta, Canada  
24 T2N 1N4

25 Email: [chad.wagoner@ucalgary.ca](mailto:chad.wagoner@ucalgary.ca)  
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## Abstract

**Introduction:** Individuals living with and beyond cancer from rural and remote areas lack accessibility to supportive cancer care resources compared to those in urban areas. Exercise is an evidence-based intervention that is a safe and effective supportive cancer care resource, improving physical fitness and function, well-being, and quality of life. Thus, it is imperative that exercise oncology programs are accessible for all individuals living with cancer, regardless of geographic location. To improve accessibility to exercise oncology programs, we have designed the EXercise for Cancer to Enhance Living Well (EXCEL) study. **Methods and Analysis:** EXCEL is a hybrid effectiveness-implementation study. Exercise-based oncology knowledge from clinical exercise physiologists supports healthcare professionals and community-based qualified exercise professionals, facilitating exercise oncology education, referrals, and programming. Recruitment began in September 2020 and will continue for 5-years with the goal to enroll ~1500 individuals from rural and remote areas. All tumour groups are eligible, and participants must be 18 years or older. Participants take part in a 12-week multi-modal progressive exercise intervention currently being delivered online. The reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework is used to determine the impact of EXCEL at participant and institutional levels. Physical activity, functional fitness, and patient-reported outcomes are assessed at baseline and 12-week timepoints of the EXCEL exercise intervention. **Ethics and Dissemination:** The study was approved by the Health Research Ethics Board of Alberta. Our team will disseminate EXCEL information through quarterly newsletters to stakeholders, including participants, qualified exercise professionals, healthcare professionals, and community networks. Ongoing outreach includes community presentations (e.g., support groups, fitness companies) that provide study updates and exercise resources. Our team will publish manuscripts and present at conferences on EXCEL's ongoing implementation efforts across the five-year study.

**Trial Registration:** <https://clinicaltrials.gov/ct2/show/NCT04478851>

**Keywords:** Exercise; Physical Activity; Implementation; Oncology; Cancer Survivorship; Rural and Remote

### Strengths and limitations of this study

- A strength of EXCEL is that it incorporates methodology (i.e., outreach, program delivery, continued support) tailored for developing partnerships with healthcare professionals and qualified exercise professionals in rural and remote communities on a national scale for sustainable exercise oncology implementation.
- An additional strength of the EXCEL study is the integration of health behaviour change techniques within the online 12-week exercise intervention, addressing a critical gap in the current exercise oncology literature.
- The primary limitation of the EXCEL study is the inability to compare individuals who exercised to a usual care group as this hybrid effectiveness-implementation study design includes a single exercise group.
- Additional limitations include ensuring consistent delivery of the exercise intervention across different qualified exercise professionals as well as addressing the current culture of 'standard cancer care', which does not include exercise and thus may impact our ability to build clinic-to-community links.

## Introduction

While cancer incidence and survival rates are relatively similar across Canada, health disparities in oncologic and survivorship care persist. Many Canadians living with and beyond cancer remain underserved in rural and remote communities with respect to supportive cancer care services and resources, and consequently report greater psychological distress and poorer health compared to urban counterparts<sup>1,2</sup>. Lack of access to supportive cancer care, such as community-based exercise oncology programs, is a significant concern, as exercise is an evidence-based intervention that can improve overall health, well-being, and quality of life (QOL) for those living with and beyond cancer<sup>3</sup>. Barriers to supportive cancer care in rural and remote communities include having populations with lower socioeconomic status as well as geographic isolation resulting in fewer healthcare providers, increased travel distances/times to the nearest supportive resources and facilities, and lack of infrastructure (e.g., unable to access telehealth services)<sup>4-6</sup>. Furthermore, as the COVID-19 pandemic places further strain on healthcare systems, those from underserved communities continue to be disproportionately impacted as supportive cancer care is delayed and inaccessible telehealth services persist<sup>7</sup>. As such, these disparities have increased the burden of cancer on overall health and QOL, and there is a clear need to make exercise as a supportive cancer care resource more easily accessible for those in rural and remote areas.

Exercise improves cancer survivorship outcomes and QOL<sup>8</sup>, and research has resulted in the development of cancer-specific exercise guidelines<sup>9-12</sup>. However, despite this evidence, guidelines, and advocacy, less than a quarter of people with cancer are considered to be physically active<sup>13</sup>, and these participation rates may be even less for rural and remote populations due to a lack of exercise oncology resources within these communities<sup>14</sup>. To ensure equitable access, there must be development, dissemination, and implementation of exercise oncology evidence-based resources to deliver sustainable exercise programs safely and effectively for all individuals with cancer.

Members of our team are conducting a community-based, hybrid effectiveness-implementation exercise oncology study, the Alberta Cancer Exercise (ACE) study<sup>15</sup>. A limitation of the ACE study is that it focuses on delivering services to urban populations and only in one region (Alberta), and as such, the implementation processes may not be generalizable to rural and remote communities. Moreover, an important opportunity exists to examine wide-spread implementation and assess the development and dissemination of exercise intervention effectiveness on a national scale. This type of evaluation is critical for building exercise as a supportive cancer care resource for more individuals living with and beyond cancer in all regions of a geographically and socio-demographically diverse



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3 nation, providing valuable information on feasibility and impact on participant and system-level outcomes in real-  
4 world settings. To specifically address the commonly reported barriers to exercise for rural and remote individuals  
5 with cancer, we aim to improve accessibility of required expertise, make use of digital technology, and develop a  
6 network of clinic-to-community partnerships for sustainable implementation<sup>16,17</sup>. Accordingly, we have designed a  
7 5-year hybrid effectiveness-implementation study to address these disparities in access to exercise – the EXercise for  
8 Cancer to Enhance Living Well (EXCEL) study.  
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15 Previous work indicates that successful implementation for rural and remote populations requires personnel  
16 training, program support from healthcare professionals (HCPs), and sustainable community-partnerships<sup>14,17</sup>.  
17 Therefore, we will implement our exercise oncology ‘hub and spoke’ model (Figure 1) that connects exercise  
18 oncology expertise and clinical support in primarily hub settings (i.e., urban areas) to intervention implementation  
19 within spokes (i.e., rural and remote communities). Specifically, EXCEL will provide HCPs with exercise oncology  
20 resources, including education and support for participant intake (referral and screening) in the clinical setting, and  
21 build clinic-to-community referral pathways that bridge HCPs and rural and remote communities with qualified  
22 exercise professionals (QEPs). This will reduce the reliance on participant self-referrals. In addition, EXCEL will  
23 provide exercise oncology specific training to QEPs in these ‘spokes’ to deliver an evidence-based exercise  
24 oncology program online that is safe, effective, and tailored to meet participants’ needs. Our objectives are to  
25 disseminate, implement, and assess the effectiveness of EXCEL to increase the reach, delivery, and impact of an  
26 exercise intervention to rural and remote individuals living with cancer. In doing so, the EXCEL study will provide  
27 a better understanding of the various factors associated with making evidence-based exercise oncology interventions  
28 accessible and sustainable.  
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## 43 **Methods and Analysis**

### 44 Design and Setting

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46 A hybrid effectiveness-implementation study design<sup>18</sup> that utilizes mixed methods is being used to  
47 determine the effectiveness and implementation of the EXCEL exercise intervention ([NCT04478851](https://clinicaltrials.gov/ct2/show/study/NCT04478851)). Due to the  
48 pandemic, the original clinical trial registration varies in methodology with the current version of EXCEL.  
49 Specifically, EXCEL is primarily being implemented in an online format, rather than delivering in-person  
50 community-based fitness classes and assessments. As such, fitness assessment methodology differs slightly from the  
51 clinical trial registration to feasibly and safely utilize the online format. It is important to note that EXCEL was  
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intended to include online delivery via ZOOM™ to increase reach to the targeted underserved populations. As the pandemic allows, the study will begin to implement in-person exercise classes and fitness assessments, with slight variations to the current protocol (see Appendix I for a list of program components for online and in-person delivery).

The effectiveness-implementation research design has been used previously by members of the research team to implement ACE<sup>15</sup>. EXCEL is implemented by establishing geographic hubs in urban settings that link to both academic and clinical expertise. Hub expertise includes clinical exercise physiologists (CEPs), responsible for exercise screening of participants, developing and maintaining partnerships with HCPs and QEPs for exercise referral and delivery, and when required, delivering the supervised exercise intervention for high-risk participants. Refer to Table 1 for hub outreach roles. Hubs established at the project outset are in Alberta, Nova Scotia, and Ontario, with plans to add British Columbia and Quebec in years 2-4. See Figure 2 for the current geographical map of EXCEL hub and the community rural and remote regions (i.e., spokes) they currently serve. EXCEL employs the Canadian Institutes of Health Research (CIHR) knowledge to action (KTA) framework<sup>19</sup> to guide the process of translating research evidence into practice, as well as a participant-oriented research approach to tailor implementation strategies to better address participants' needs. Specifically, a monthly Participant Advisory Board (PAB) meeting with former exercise oncology program (including EXCEL) participants discusses recurring implementation issues that need to be addressed, and 6-month quality improvement (QI) cycles (electronic surveys sent to participations, HCPs, and QEPs), provide feedback to the study team regarding outreach, intervention delivery, and provision of supportive resources (e.g., educational webinars), all of which are used to inform the continued implementation and evaluation of EXCEL.

Table 1. Outreach from Central Hubs to Healthcare and Qualified Exercise Professionals

<b>Outreach from Central Hubs</b>	
<i>Healthcare Professionals</i>	<ul style="list-style-type: none"> <li>▪ HCP exercise oncology education sessions are provided to discuss the EXCEL study and provide general exercise oncology information</li> <li>▪ Emailing established cancer centre contacts with EXCEL recruitment materials (i.e., posters, brochures, closed-circuit television slides)</li> <li>▪ Reminder emails for referrals to the EXCEL program ~6-weeks prior to each new program start</li> <li>▪ Direct phone calls to HCPs are made a minimum of twice a year to address referral barriers and provide study updates</li> </ul>

<i>Qualified Exercise Professionals</i>	<ul style="list-style-type: none"> <li>▪ Targeted to QEPs within rural and remote communities interested in delivering cancer-specific exercise</li> <li>▪ QEPs interested in delivering EXCEL exercise classes are provided exercise oncology and behavior training</li> <li>▪ QEPs are provided continuing education</li> <li>▪ QEPs are paid through the EXCEL study to support their delivery of exercise classes, with the goal of establishing a sustainable exercise oncology class at their site and/or online, to facilitate long-term exercise maintenance</li> </ul>
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### Participants and Screening

EXCEL participant enrollment occurs from September 2020 to September 2025. Participants are included if they are: 18 years or older living with and beyond cancer, able to participate in mild levels of physical activity, can consent in English\*, and live in underserved rural / remote communities that do not have access to exercise oncology programs†.

Participants can self-refer or be referred by an HCP to a hub CEP who screens for study eligibility and provides participants with the electronic study consent form (see Supplemental File 1). Consent forms and study data are collected and managed using REDCap (Research Electronic Data Capture)<sup>20,21</sup>. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources. After providing informed consent, intake information is gathered about cancer-related medical history, treatment-related side-effects, other chronic conditions or injuries, and physical activity readiness via the PARQ+<sup>22</sup>. The intake form and PARQ+ are reviewed by the hub CEP to screen for exercise participation.

### Exercise Intervention

Prior to delivering the EXCEL exercise intervention, QEPs are provided with exercise oncology and health behaviour change training to facilitate exercise intervention delivery of our “Exercise and Educate” model (see further description below). Training includes online modules related to exercise screening, cancer exercise

\* French translation work is underway.

† The term “underserved” expanded during COVID-19 restrictions to also include those from additional areas (e.g., smaller urban areas) who did not have any access to exercise oncology resources.

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3 prescription, and psychosocial and health behaviour change principles from Thrive Health Services  
4 ([www.thrivehealthservices.com](http://www.thrivehealthservices.com)). An EXCEL-specific training day also covers study-specific needs, additional  
5 health behaviour change educational topics delivered as part of the intervention, and logistics of the overall exercise  
6 program delivery. Prior to leading an exercise class, QEPs are required to moderate exercise classes to become  
7 familiar with online exercise delivery. Moderating ranges from 6-24 classes and is dependent on the QEPs  
8 background and previous experience working in exercise oncology.

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14 The exercise intervention is guided by the TIDieR checklist<sup>23</sup> and is based on previous successful online  
15 implementation of ACE<sup>15</sup> and current exercise oncology guidelines<sup>11</sup>. EXCEL's online exercise intervention is  
16 delivered via ZOOM™ with password protected exercise classes, and the exercise class instructor (QEP or CEP,  
17 depending on the participant needs; for example, high risk individuals such as those on-treatment are always under  
18 the exercise supervision of a CEP) is assisted by a trained moderator (QEP). Each class consists of 8-15 participants  
19 to ensure safety and ability to tailor to meet participant needs within the online delivery format. The intervention is a  
20 standardized 12-week evidence-based exercise intervention with two sessions per week, with at least one day of rest  
21 between classes. Classes are 60 minutes in duration and include the following: 1) 5-minute warm-up; 2) 45-50  
22 minutes of circuit style training consisting of strength/resistance, balance, and aerobic activities; and 3) 5-10-minute  
23 cool-down consisting of full-body stretching. Instructors demonstrate each exercise, tailoring to address participants'  
24 needs including exercise progressions (e.g., push-ups from wall to floor) or regressions (e.g., push-ups from floor to  
25 wall). Fidelity checks are carried out by the central (Calgary) hub CEPs to ensure consistency and safety in the  
26 delivery of the exercise intervention across partner sites. Using a standardized fidelity reporting form for each site, a  
27 random 10% of exercise classes for each 12-week session are observed and reviewed, and any feedback to improve  
28 delivery is provided to the exercise leaders (CEP/QEP).

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43 To support both adoption and maintenance of physical activity, the EXCEL study implements the "Exercise  
44 and Educate" model within the exercise intervention. The trained QEPs are tasked with implementing "Exercise and  
45 Educate" within each exercise class, via a positive motivational approach to instructing (i.e., teach from the positive,  
46 focusing on what someone can do vs cannot do to build a sense of confidence and control within participants) and  
47 engaging in discussion within classes on the key behaviour change techniques. In addition, throughout the 12-week  
48 exercise intervention participants are provided weekly educational and worksheet handouts and attend webinars to  
49 facilitate further learning and connecting with experts on behaviour change techniques and key exercise principles as  
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3 they relate to their physical activity engagement. Specifically, the education topics include (1) Principles of Exercise  
4 and Cancer, (2) Self-Monitoring for Physical Activity (3) Setting Physical Activity Goals, (4) Behaviour Change  
5 and Relapse Prevention, (5) Fatigue and Stress Management, and (6) Social Support and Long-Term Maintenance.  
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7 These education topics have been built based on participant feedback (i.e., what they want to learn more about), and  
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9 are designed to engage participants in discussion, foster self-efficacy, and equip them with the behaviour change  
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11 techniques to apply in their daily life. Specific skills learned include self-monitoring, barrier management, planning,  
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13 goal setting, how to build social support, and building confidence to see oneself as ‘an exerciser’.  
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### 16 17 18 Assessing Implementation – The RE-AIM Framework 19

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21 The RE-AIM<sup>24</sup> framework is used to evaluate the implementation of EXCEL (refer to Table 2 for a  
22 summary of outcomes), and has been used previously for the ACE exercise oncology program implementation  
23 evaluation<sup>15</sup>. This framework has also been used to assess health/lifestyle behaviours and their public health  
24 impact<sup>25–28</sup> as a function of 5 factors: reach, effectiveness, adoption, implementation, and maintenance. Reach and  
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26 effectiveness are considered at the individual/participant level, while adoption, implementation and maintenance are  
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28 factors typically specific to programs and sites. *Reach* is assessed by tracking referrals and enrollment into the  
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30 EXCEL program. Referral types are classified as “direct HCP referral”, “indirect HCP referral”, or “self-referral”.  
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32 Direct HCP referral is defined as a hub CEP receiving a referral directly from an HCP, whereas indirect HCP  
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34 referrals are defined as a participant contacting the hub CEP after receiving information about EXCEL from an HCP  
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36 (e.g., HCP hands participant a study brochure in clinic). Self-referrals are defined as participants contacting the hub  
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38 CEP without any interaction with a HCP (e.g., participant heard about EXCEL through word of mouth, saw a poster  
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40 or video ad). Enrollment is assessed by tracking the number and characteristics of eligible participants who enroll in  
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42 EXCEL compared to those eligible who do not enroll. Reasons for study refusal will be tracked in addition to  
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44 context specific needs to rural and remote areas such as distance to the nearest cancer centre and internet  
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46 accessibility. *Effectiveness* of EXCEL is assessed through the functional fitness outcomes, patient-reported  
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48 outcomes (PRO), and objective and self-reported physical activity measures that are detailed below. To assess  
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50 *adoption* of EXCEL, characteristics of adopting and non-adopting spoke sites throughout rural and remote  
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52 communities will be tracked. This includes tracking the number of referral sites (clinical sources), resources that are  
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54 being used to refer to EXCEL, and the number of clinical personnel involved to implement EXCEL (i.e., who is  
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involved and how many personnel at the respective clinical site). Additional measures of adoption include fitness professional partnerships and characteristics, tracking the number of trained QEPs, number of exercise classes provided at each site, and both the number and type of fitness partnership that is implementing EXCEL (e.g., individual QEPs, established fitness centres, fitness partners through health care settings, other sites). *Implementation* is tracked through fidelity checks, number of adverse events via the Common Terminology Criteria for Adverse Events (CTCAE V5.0)<sup>29</sup>, exercise class adherence (i.e., attendance at each scheduled exercise session), and overall program costs per site (training, personnel / administrative support, other costs). *Maintenance* is assessed through long-term engagement with exercise / physical activity from both program sites (e.g., the number of established exercise programs in the community) and participants (e.g., long-term physical activity levels and exercise program participation, assessed at follow-up timepoints up to 1 year after baseline program participation).

Table 2. RE-AIM Summary Outcomes

Construct	Reporting Outcomes
<u>Reach</u>	<ul style="list-style-type: none"> <li>▪ Referral               <ul style="list-style-type: none"> <li>○ Indirect-HCP Referral</li> <li>○ Direct-HCP Referral</li> <li>○ Self-Referral</li> </ul> </li> <li>▪ Enrollment               <ul style="list-style-type: none"> <li>○ # of participants enrolled</li> <li>○ # of participants who do not enroll</li> <li>○ Characteristics of enrolled and non-enrolled                   <ul style="list-style-type: none"> <li>▪ Using Canadian Norms as reference</li> </ul> </li> <li>○ Reasons for study refusal</li> </ul> </li> <li>▪ Rural and Remote Specific Barriers               <ul style="list-style-type: none"> <li>○ Internet Accessibility</li> <li>○ Distance to nearest cancer centre</li> </ul> </li> </ul>
<u>Effectiveness</u>	<ul style="list-style-type: none"> <li>▪ Patient-Reported Outcomes               <ul style="list-style-type: none"> <li>○ QOL, Fatigue, Physical Activity, Exercise Barriers, Symptom Burden</li> </ul> </li> <li>▪ Functional Fitness Outcomes               <ul style="list-style-type: none"> <li>○ Aerobic Endurance, Musculoskeletal Fitness, Balance, Flexibility</li> </ul> </li> <li>▪ Self-Report and Objective Physical Activity</li> </ul>
<u>Adoption</u>	<ul style="list-style-type: none"> <li>▪ Characteristics of adopting / non-adopting clinical sites               <ul style="list-style-type: none"> <li>○ # and type of educational and referral resources provided</li> <li>○ Personnel involved – # and type/who</li> </ul> </li> <li>▪ Fitness professional partnerships and characteristics               <ul style="list-style-type: none"> <li>○ # of trained QEPs</li> <li>○ # of exercise classes provided</li> <li>○ # organizations and type (i.e., individuals, fitness centres)</li> </ul> </li> </ul>

<u>Implementation</u>	<ul style="list-style-type: none"> <li>▪ Fidelity Checks             <ul style="list-style-type: none"> <li>○ Consistent delivery of exercise program completed per a review of exercise sessions and standardized checklist by CEPs</li> </ul> </li> <li>▪ Safety of Exercise Program             <ul style="list-style-type: none"> <li>○ Tracking and reporting of adverse events<sup>29</sup></li> </ul> </li> <li>▪ Program Acceptability (i.e., adherence)             <ul style="list-style-type: none"> <li>○ Exercise class attendance tracking</li> </ul> </li> <li>▪ Program Costs             <ul style="list-style-type: none"> <li>○ Training, site delivery, and administrative support costs</li> </ul> </li> </ul>
<u>Maintenance</u>	<ul style="list-style-type: none"> <li>▪ Sustainability of exercise programs within the community             <ul style="list-style-type: none"> <li>○ # of ongoing programs</li> </ul> </li> <li>▪ Participation in home- or centre-based exercise programs             <ul style="list-style-type: none"> <li>○ # of participants continuing to engage in structured exercise post 12-Week EXCEL program</li> </ul> </li> <li>▪ Physical activity levels at 24-week (objective and self-report) and 1-year follow-up (self-report)</li> </ul>

### Outcome Measures

Outcome measures are completed at four timepoints: 1) baseline; 2) 12-weeks (post-intervention); 3) 24-weeks; and 4) one-year (see Table 3 for measurement timepoints). Online functional fitness assessments take place at baseline and 12-week timepoints, PROs are completed at each timepoint via REDCap<sup>20,21</sup>, and wearable physical activity trackers are worn from baseline to the 24-week timepoint, with all wearable data stored in the Wearable Technology Research and Collaboration (We-TRAC), a Level-4 secure database at the University of Calgary supported by funding from the Natural Sciences and Engineering Research Council of Canada (NSERC). Qualitative data collected through semi-structured interviews occur on a rolling basis as part of the 6-month recurring QI cycles.

Table 3. Outcome Measures and Timepoints

<b>Domain/Outcome</b>	<b>Measure</b>	<b>Baseline</b>	<b>12-Week</b>	<b>24-Week</b>	<b>One Year</b>
<i>Physical Fitness / Function</i>					
Shoulder Range of Motion	Shoulder Flexion	<b>X</b>	<b>X</b>		
Musculoskeletal Fitness	30-Second Sit-to-Stand	<b>X</b>	<b>X</b>		
Lower Body Flexibility	Chair Sit-and-Reach	<b>X</b>	<b>X</b>		
Aerobic Endurance	Two-Minute Step Test	<b>X</b>	<b>X</b>		
Balance	Single-Leg Stance	<b>X</b>	<b>X</b>		
<i>Patient-Reported Outcomes (PROs)</i>					

Physical Activity	Godin Leisure Time Exercise Questionnaire	X	X	X	X
Health Status	EQ-5D 5L	X	X	X	X
Quality of Life	Functional Assessment of Cancer Therapy - General	X	X	X	X
Fatigue	Functional Assessment of Cancer Illness Therapy - Fatigue	X	X	X	X
Symptom Burden	Edmonton Symptom Assessment Scale	X	X	X	X
Barriers and Facilitators	Exercise Barriers and Facilitators	X	X	X	X

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#### *Wearable Activity Tracker*

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Objective Physical Activity	Garmin Vivo Smart4	X	X	X
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#### *Notes*

*All Functional Fitness Assessments are completed online via ZOOM™ with results stored in REDCap, PROs are completed online via REDCap, and Objective Physical Activity is tracked and stored within We-TRAC online secure database.*

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#### Functional Fitness Outcomes

Online functional fitness assessments are completed individually for each participant before and after the 12-week exercise intervention, with results recorded in REDCap. Assessments take approximately 30 minutes and follow the Canadian Society of Exercise Physiology's Physical Activity Training for Health Protocol (CSEP-PATH)<sup>30</sup>. All assessors at each hub are trained in the assessment protocol and have exercise oncology experience and specific training. Primary assessors (CEPs) explain and demonstrate each assessment prior to the participants' attempt. Secondary assessors (QEP or volunteers) help to ensure participant safety through additional monitoring during fitness assessments and record results, confirming results with the primary assessor after each assessment and during data entry. The functional fitness assessment includes measures of 1) self-reported height and weight (calculation of body mass index); 2) upper body flexibility via shoulder flexion range of motion<sup>31</sup>; 3) musculoskeletal fitness via a 30-second sit to stand assessment<sup>32,33</sup>; 4) lower body flexibility via a sit and reach assessment<sup>34</sup>; 5) aerobic endurance with a 2-minute step test<sup>35</sup>; and 6) balance with a single-leg balance assessment<sup>36</sup>. Due to the pandemic, modifications were required to assess participants to the best of our ability while maintaining scientific rigor (See Appendix 1 for comparison of in-person vs online assessment tools).



### *Shoulder Flexion Range of Motion*

Participants begin by sitting perpendicular to their computer camera in their chair, with arms by their side and palms facing inward. Participants are instructed to raise their arm in forward flexion, while remaining in the sagittal plane, with the goal of bringing their hand above their shoulder. Ensuring that the elbow is visible, this final position is held briefly while the CEP takes a screen shot on their computer screen. This process is repeated twice for each arm with the participant changing their chair position for the opposite arm. Range of motion is determined in degrees by measuring the final angle (screen shot) with a goniometer, using the head of the humerus, midline of the humerus, and mid-axillary line as anatomical landmarks for consistent measurements.

### *30-Second Sit to Stand*

Participants start in a seated upright position (~43cm chair) with arms across the chest and hands placed on opposite shoulders, with no contact on the back of the chair. Participants are then instructed to complete as many “sit to stands” as possible within 30 seconds, with one “sit to stand” defined as standing with full hip extension and arms remaining in the crossed-chest position. On a “ready-set-go” cue, participants begin the assessment and the number of fully completed sit to stands within the 30-second time frame is recorded.

### *Chair Sit and Reach*

Participants complete warm-up stretches before the test is conducted. They start in a seated position on the edge of a chair with one leg fully extended and ankle bent at 90 degrees. Participants are then instructed to place one hand on top of the other (palms facing down), fully extend their arms, and slowly reach forward while keeping their back and extended leg straight. They hold this stretch for 20 seconds, on each leg twice. The test is performed by repeating the same stretching movement in the warm-up, however participants are then asked to measure the distance from their toes to their fingertips with a tape measure, which is then reported to the nearest  $\pm 0.5\text{cm}$  (+ = fingers went beyond toes; 0cm = fingers just touched toes; - = fingers did not reach toes). This process is repeated twice on both legs, with the highest number being reported for each leg.

### *2-Minute Step Test*

Participants begin by standing perpendicular to the camera (i.e., right leg facing the camera) while marching in place for 2-minutes. The target knee height is determined by having the participant measure the distance between the patella and iliac crest to find the mid-point of the thigh. Participants are then instructed to measure the distance from the thigh mid-point to the floor, and this distance is recorded by the assessor. If the participant is

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3 unable to determine the thigh mid-point, target knee height is set so that the thigh is parallel to the floor when  
4 marching. On a “ready-set-go” cue, participants begin marching in place and the number of steps completed within  
5 the 2-minute time frame on the leg facing the camera are recorded. Rate of perceived exertion (RPE; 1-10)<sup>37</sup> is  
6 recorded after the assessment has been completed.  
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### 10 *Single Leg Balance*

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12 Participants start by standing on a flat surface, with shoes removed and eyes open, near a stable object (i.e.,  
13 chair or wall) for safety purposes, while facing the camera. Participants start with arms placed across their chest (or  
14 hands on hips) with feet shoulder width apart, and the assessment begins when the participant lifts one foot off the  
15 ground to the height of the opposite ankle with eyes remaining open. The assessment ends when either arms move  
16 away from the body, the raised foot touches the floor, the raised foot touches the standing leg, the raised leg moves  
17 from static position, or the maximum limit of 45 seconds is reached. This process is repeated for the opposite leg  
18 and both balance times are recorded. If the assessments end before three seconds (due to the above listed  
19 conditions), they may repeat the test one more time and the longest duration is recorded.  
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### 30 *Patient-Reported Outcomes*

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32 Questionnaires are completed online in REDCap at baseline, 12-weeks, 24-weeks, and 1-year. Self-  
33 reported physical activity is assessed using the modified Godin Leisure Time Exercise Questionnaire (GLTEQ)<sup>38</sup>,  
34 which asks participants to recall average typical weekly exercise. Recall includes the frequency and duration of  
35 mild, moderate, and vigorous aerobic activity, in addition to resistance and flexibility exercise. QOL is measured  
36 with the EQ-5D-5L<sup>39</sup> questionnaire and the Functional Assessment of Cancer Therapy – General (FACT-G)<sup>40</sup>  
37 questionnaire. The EQ-5D 5L measures general health as well as clinical and economic evaluations of healthcare.  
38 The FACT-G assesses QOL through four sub-domains: physical, social/family, emotional, and functional well-  
39 being. A final score is calculated from the sum of each sub-domain score and is representative of overall QOL.  
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41 Fatigue is assessed with the Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F)<sup>41</sup> scale. The  
42 Edmonton Symptom Assessment Scale - Revised (ESAS-r)<sup>42</sup> assesses symptom burden from nine cancer related  
43 symptoms. Confidence (i.e., self-efficacy) to participate in exercise is assessed with the Exercise Barriers and  
44 Facilitators questionnaire<sup>43</sup>. Participants are asked to rank their confidence level to participate in exercise in certain  
45 situations (e.g., when they feel nauseated, during bad weather, when there is lack of time, etc.). Barrier and  
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3 facilitator self-efficacy scales are rated from 0-100% at 10% intervals. Interpretation of the scales are as follows: 0-  
4 20% = not at all confident; 20-40% = slightly confident; 40-60%= moderately confident; 60-80% = very confident;  
5 and 80-100% = extremely confident.  
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### 10 Objective Physical Activity Levels

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12 An activity tracker (Garmin Vivo Smart4) is used to capture objective data on exercise volume in a subset  
13 of the EXCEL participants. This is a commercially available activity tracker, and similar models have been found to  
14 be highly acceptable in cancer populations<sup>44,45</sup>. Categories of meeting or not-meeting current exercise oncology  
15 guidelines<sup>11</sup> are used as a marker of implementation success (i.e., achieving 90 minutes of moderate to vigorous  
16 physical activity per week), as well as percent change in physical activity levels over time (baseline to post-  
17 intervention; maintenance to follow-up). Activity trackers are distributed across hubs, based on the number of active  
18 participants at each hub and the number of trackers available. Participants are mailed the tracker after consent into  
19 the study and provided with instructions for use (an additional webinar is available to support use and troubleshoot  
20 common issues). Participants are instructed to wear the activity tracker for at least 10 hours per day, for 24-weeks,  
21 unless the device is charging. To be included for weekly physical activity calculations, at least four valid days are  
22 required. Valid days are defined as wearing the activity tracker for at least 10 hours/day<sup>46,47</sup> with non-wear time  
23 being defined as not wearing the tracker for 60 consecutive minutes<sup>48</sup>. Objective physical activity data is synced  
24 weekly and stored in the NSERC supported We-TRAC secure database at the University of Calgary. Collected data  
25 includes step counts and continuously recorded heart rate.  
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### 41 Semi-structured Interviews

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43 The RE-AIM QuEST<sup>49</sup> framework guides the semi-structured qualitative interviews conducted as part of  
44 the 6-month recurring QI cycles. RE-AIM QuEST supplements quantitative measures by identifying and providing  
45 additional context to implementation barriers and can subsequently be used to help improve interventions in real-  
46 time. Interviews occur with a purposive sample of participants, QEPs, and HCPs to assess program implementation  
47 as well as outcomes from the exercise program itself. Sampling of participants includes considerations of location,  
48 participation age and cancer diagnosis, gender, and activity levels at baseline. For QEPs and HCPs, sampling  
49 considers location, role, and years of experience. This purposive sampling will ensure diverse views are collected  
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3 across program participants and networks of HCPs and QEPs. The interviews are guided by interpretive description  
4 methodology<sup>50</sup>, which has been used as a reliable qualitative guide within multiple health-related disciplines<sup>51-53</sup>.  
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6 Interviews are conducted either online (i.e., ZOOM™) or via telephone with trained study personnel. The qualitative  
7  
8 analysis will provide a deeper understanding into program implementation and effectiveness from participant, HCP,  
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10 and QEP perspectives, complementary and adding depth of potential understanding to the PROs and exercise data.  
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### 14 Sample Size and Statistical Analysis

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16 Based on previous work with the ACE study<sup>15</sup>, with alpha level set at 0.05, we will need to enroll 1225  
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18 individuals to evaluate the effectiveness of the exercise intervention on our primary outcome of physical activity.  
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20 Assuming a 15% dropout rate, EXCEL will enroll 1500 individuals living with and beyond cancer from underserved  
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22 rural and remote communities across Canada. The sample size estimation and proposed enrollment goal also take  
23  
24 into account testing for differences in secondary outcomes. This helps ensure we will have sufficient power to  
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26 examine the effectiveness of the exercise program on physical activity as well as to examine effects on secondary  
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28 outcomes with consideration for covariates (i.e., age, gender, primary cancer diagnosis, comorbidities, and treatment  
29  
30 received). In addition, due to physical restrictions imposed during the COVID-19 pandemic restrictions, EXCEL  
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32 will include participants from larger centres (i.e., more urban locations) who do not have access to exercise  
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34 oncology resources during this time. This inclusion is practical and ensures reach of the evidence-based exercise  
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36 oncology resource during a time of restrictions to an underserved population who may benefit both physically and  
37  
38 mentally during the pandemic by having access to exercise as a supportive cancer care resource. Analyses will  
39  
40 therefore consider geographical location within sub-analyses, and/or as a covariate in the primary analysis.

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42 Descriptive statistics will summarize participant demographic factors of age, sex, rural/urban, primary  
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44 diagnosis of cancer, comorbidities, treatment received, including the procedure, chemotherapy, radiotherapy, and  
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46 exercise-related variables, as well as RE-AIM dissemination and implementation components. The indicators of  
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48 effectiveness of implementation observed in this study will compare between groups at pre- and post-  
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50 implementation using Chi-square test or student-t test, where appropriate. We will perform generalized linear mixed  
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52 models to evaluate effectiveness changes in outcome measures over time. To deal with the geographical variance in  
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54 effectiveness of implementation, we will employ multi-level modeling to examine site differences (i.e., geographical  
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56 location) in relation to reported physical activity levels and adherence to the exercise intervention. Quantitative data  
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3 will be analyzed using SAS statistical software (version 9.4). Qualitative analyses will be transcribed in  
4 ExpressScribe, coded in NVivo 12, and thematically analyzed by two independent authors per the interpretive  
5 description methodology<sup>50</sup>.  
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### 10 Patient and Public Involvement

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12 Rural and remote individuals living with and beyond cancer, in addition to caregivers, have informed the  
13 EXCEL Project conception, delivery, assessments, and implementation of our hub and spoke model to support the  
14 “Exercise and Educate” training and intervention. Three individuals living with cancer from rural and remote  
15 communities make up our PAB, which has better informed our team in conceptualizing and delivery the 12-week  
16 exercise intervention. Our team also engages with HCPs and QEPs while evaluating ongoing implementation  
17 components of the entire project (i.e., referral support and exercise program delivery) to continually improve the  
18 exercise program experience for participants.  
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### 28 **Ethics and Dissemination**

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30 Ethics approval was received from the Health Research Ethics Board of Alberta (HREBA.CC-20-0098).  
31 Our team will disseminate information regarding the EXCEL study via quarterly newsletters sent to our partnership  
32 networks (i.e., HCPs, QEPs, and participants). Quarterly newsletters will include study updates on overall  
33 recruitment in addition to suggested changes and subsequent actions taken as a result of QI cycle feedback. EXCEL  
34 education sessions will also be provided to both HCPs (i.e., during grand rounds) and QEPs (i.e., wellness  
35 organizations) to continue to build partnership networks. Our team also plans to submit abstracts to research  
36 conferences and publish manuscripts that are guided by the RE-AIM framework. Analyses for conference  
37 presentations and published manuscripts will focus on the ongoing implementation efforts over the course of the  
38 five-year study.  
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### 49 **Discussion**

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51 Exercise is an evidence-based supportive cancer care resource that is both safe and effective at alleviating  
52 symptom burden, improving fitness, QOL<sup>3</sup>, and survival<sup>54,55</sup>. Unfortunately, disparities in access to exercise for rural  
53 and remote individuals living with and beyond cancer prevent equitable potential realization of these benefits<sup>5</sup>. The  
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3 EXCEL study aims to address this inequity by implementing and evaluating the effectiveness of bringing evidence-  
4 based exercise oncology programs to these communities via our hub and spoke model to facilitate online and in-  
5 person delivery when available. As the first large scale study to disseminate, implement, and evaluate the  
6 effectiveness of exercise for rural and remote individuals living with and beyond cancer, findings will inform how to  
7 reduce disparities in access to exercise as a supportive cancer care resource and ensure sustainable implementation  
8 of evidence-based exercise oncology interventions. This will enhance the physical and mental well-being, and  
9 ultimately the overall QOL, of more individuals living with and beyond cancer.  
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16 The final products for EXCEL dissemination and implementation across Canada will include training,  
17 program protocols (assessment and delivery), and established clinic-to-community partnerships that are sustainably  
18 supported within the hub and spoke model. Resources within each of these elements will be available to support the  
19 continued building and implementation of our exercise oncology “Exercise and Educate” intervention, training, and  
20 network development, linking participants in clinical settings to exercise as an evidence-based supportive cancer  
21 care resource that can be accessed within community settings (online and/or in-person). Building clinic-to-  
22 community pathways through the hub and spoke model to support exercise oncology as part of standard supportive  
23 cancer care is a unique feature and overall strength of the EXCEL study. Implementation will “bridge the gap” from  
24 clinic to rural and remote communities, building referral sources at the clinical level and a network of trained fitness  
25 professionals at the community level. Bridging between these two networks is the critical role of the CEP, which is  
26 not yet a widespread role within cancer care. Building upon our “pathways model”<sup>56,57</sup>, CEP expertise ensures that  
27 referral to exercise resources is appropriately addressed through expert screening, understanding of tailored needs  
28 within an exercise setting, and supports access to safe and effective exercise resources that will meet participant  
29 needs. Ultimately, building exercise via EXCEL into standard supportive cancer care will equip individuals living  
30 with and beyond cancer with the resources to use exercise to manage their wellness, health, and overall QOL.  
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## Figure Legend

Figure 1. Exercise Oncology Survivorship Hub and Spoke Model

Figure 2. EXCEL Hub and Spoke Map

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## Author Contributions

S. NC-R, MM, MK, DSM, CC, LC, and GF developed the study concept and protocol. S. NC-R and CW drafted the manuscript in addition to JD, MM, MK, DSM, and CC contributing to major manuscript revisions and providing critical feedback. GC contributed to the sample size determination and development of the statistical analysis plan. MEster, EM, MEisele, DS, JL, JC, and TC all contribute to the acquisition of data for the EXCEL study outcomes, deliver the EXCEL study intervention, and provide critical feedback on the protocol prior to manuscript submission. We want to emphasize that every author listed will oversee the implementation of the protocol and contribute to the analysis and interpretation / application of study data.

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## Competing Interest

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For peer review only



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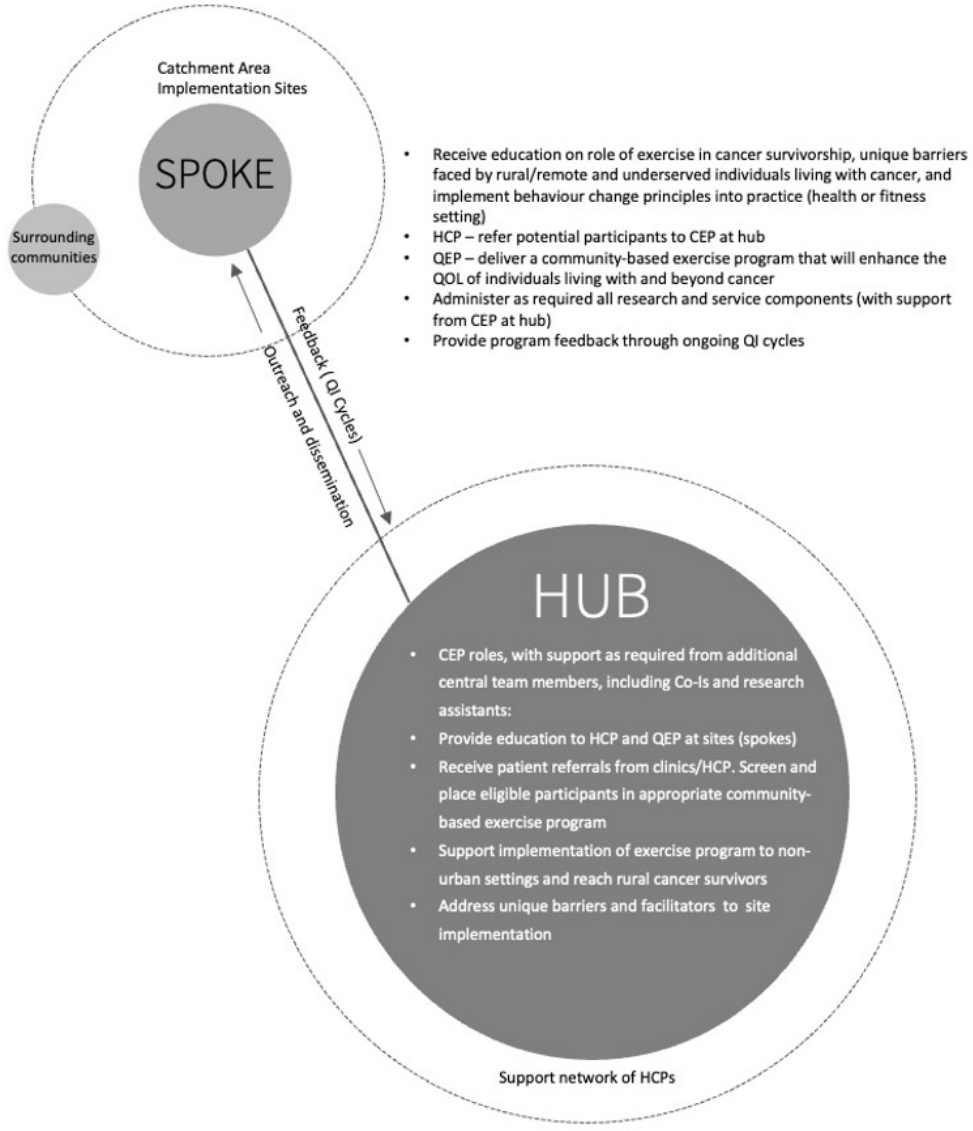


Figure 1. Exercise Oncology Survivorship Hub and Spoke Model

135x153mm (144 x 144 DPI)

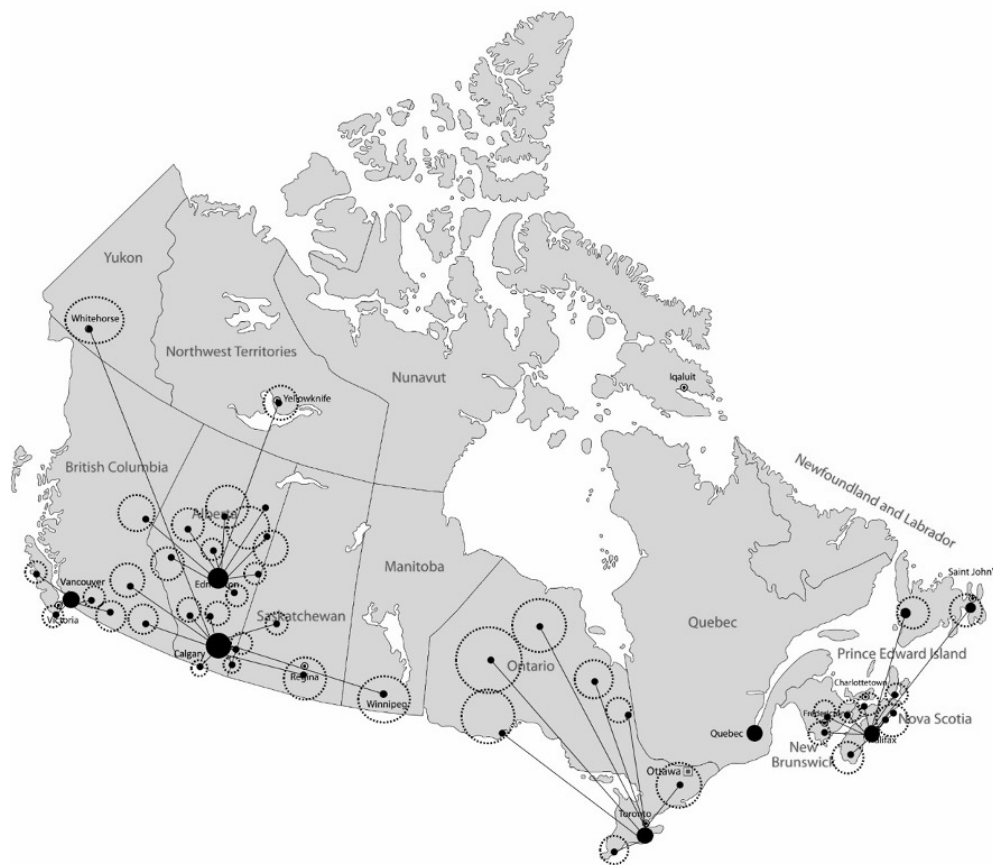


Figure 2. EXCEL Hub and Spoke Map

157x137mm (144 x 144 DPI)

## Appendix I – Comparison of the Online and In-Person Delivery of EXCEL

<b>Domain/Outcome</b>	<b>Online Fitness Assessment</b>	<b>In-Person Fitness Assessment</b>
Balance	Single-Leg Stance	Single-Leg Stance
Musculoskeletal Fitness	<i>30-Second Sit-to-Stand</i>	<i>30-Second Sit-to-Stand &amp; Handgrip Strength</i>
Aerobic Endurance	<i>Two-Minute Step Test</i>	<i>6-Minute Walk Test</i>
Lower Body Flexibility	Chair Sit-and-Reach	Traditional Sit-and-Reach
Shoulder Range of Motion	Shoulder Flexion	Shoulder Flexion

Fitness assessments that occur as part of the online delivery of EXCEL are described within the body of the main text. Here we provide further descriptions of fitness assessments that differ for in-person assessments.

Specifically, we provide descriptions for the Handgrip Strength, 6-Minute Walk Test, and the traditional Sit and Reach completed with a flexometer. Furthermore, in-person assessments take place in a group format, completed during the first and final week of the 12-week exercise intervention.

#### *Handgrip Strength*

A hand-held dynamometer is used to assess muscular strength. Participants are instructed to hold the dynamometer in line with their forearm and level with their thigh. Prior to beginning, participants are instructed to not swing their arm, bend their elbow, or bend their wrist to prevent their arm or dynamometer from coming into contact with their body or any other object during the assessment. The assessment begins by telling participants to take a deep breath squeeze the dynamometer as hard as they can for two to three seconds while exhaling. Hands are alternated after each assessment and a total of two trials are completed for each hand. The highest score, recorded to the nearest 0.5 kilogram, is recorded for each hand.

#### *6-Minute Walk Test*

The purpose of the 6-minute walk test (6MWT) is to assess aerobic fitness. Participants complete the 6MWT on a flat surface that is a minimum of 20 meters in length. Participants are instructed to walk the course as fast as possible without running in an effort to cover the greatest distance possible within the six-minute timeframe. On a “ready-set-go” cue, participants begin the assessment, and the assessor records the number of laps that are completed. Rate of perceived exertion (RPE; 1-10) is recorded at the two, four, and six-minute marks. During the

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3 assessment, participants are allowed to rest if they need to, though the six-minute timer does not stop. At the  
4 conclusion of the assessment, participants are allowed a cool-down (i.e., light walking) and the final distance is  
5 calculated and recorded in meters.  
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#### 8 *Traditional Sit-and-Reach*

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10 The traditional sit-and-reach assessment is used to measure the flexibility in the hamstrings and lower back  
11 with a flexometer. Participants are first instructed to remove footwear and warm-up, which involves completing a  
12 20-second modified hurdler stretch twice on each leg. Participants are then positioned for the sit-and-reach  
13 assessment, which includes placing their feet flat against the flexometer with legs straight. Participants are then  
14 instructed to extend their arms evenly in front of them with one palm of their hand placed on top of the other. The  
15 assessment begins by having participants slowly bending forward (without bouncing) with legs remaining straight to  
16 push the sliding marker on the flexometer forward as far as possible and holding the final position for two seconds.  
17 This process is repeated, twice, and the greatest measurement is recorded to the nearest 0.5 cm. NOTE: If a  
18 flexometer is not available for in-person fitness assessments, the chair sit-and-reach assessment protocol that is used  
19 for online assessments is completed (described within methods).  
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## **Informed Consent Form for Participation in a Research Study**

### **EXCEL: EXercise for Cancer to Enhance Living well Study**

#### **(A study to evaluate the benefit of a community-based exercise program for cancer survivors in rural and remote Canada)**

Protocol ID: *HREBA.CC-20-0098*

Principal Investigator: Dr. Nicole Culos-Reed, PhD  
Health & Wellness Lab, Faculty of Kinesiology  
University of Calgary  
Phone: 403-220-7540

Sponsor/Funder(s): The Canadian Institutes of Health Research/ Canadian Cancer Society  
and the Alberta Cancer Foundation

You are being invited to participate in a research study because you have indicated that you are interested in participating in a community-based or online exercise program for cancer survivors. This consent form provides detailed information about the study to assist you with making an informed decision. Please read this document carefully and ask any questions you may have. All questions should be answered to your satisfaction before you decide whether to participate.

The study staff will tell you about timelines for making your decision. You may find it helpful to discuss the study with family and friends so that you can make the best possible decision within the given timelines.

Taking part in this study is voluntary. You may choose not to take part or, if you choose to participate, you may leave the study at any time without giving a reason. Deciding not to take part or deciding to leave the study will not result in any penalty or any loss of medical or health-related benefits to which you are entitled.

The principal investigator, who is one of the researchers, or the site research coordinator, will discuss this study with you and will answer any questions you may have. If you do consent to participate in this study, you will need to sign and date this consent form. You will receive a copy of the signed form.

#### **WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?**

The growing population of cancer survivors in Canada has brought attention to the long term toll of cancer and its treatment on the body, mind, and overall health of survivors. Exercise is an effective intervention that can optimize the health and well-being of cancer survivors and possibly reduce rates of cancer recurrence and secondary cancers.



The Health Research Ethics Board of Alberta – Cancer Committee (HREBA-CC), which oversees the ethical acceptability of research involving humans, has reviewed and granted ethics approval for this study.

### WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate the benefit of a community-based or online exercise program for cancer survivors who live in rural and remote locations. The study is called EXCEL and includes an evidence-based exercise program (Alberta Cancer Exercise, ACE; Ethics ID: HREBA-CC-16-0905). ACE has been successfully implemented in urban centres throughout Alberta. Our aim is to provide an exercise program to cancer survivors living in rural and remote locations to promote adoption of an active lifestyle in order and improve health outcomes. EXCEL will increase accessibility to exercise as a supportive cancer care resources for all cancer survivors.

### WHAT ARE OTHER OPTIONS IF I DECIDE NOT TO PARTICIPATE IN THIS STUDY?

You do not have to take part in this study in order to receive continued medical care. You may choose not to participate in this study. Your healthcare provider will discuss lifestyle recommendations with you. Right now, usual treatment is to receive counseling on the value of physical activity and healthy living after the completion of cancer treatments.

### HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 1500 people across Canada will take part in this study.

### WHAT WILL HAPPEN DURING THIS STUDY?

#### STUDY INTERVENTION

If you agree to take part in this study, you will undergo screening and fitness testing and will be referred to a suitable exercise program. The exercise program will take place either online or at selected community-based fitness facilities. You will take part in a twice weekly exercise program for an 8 to 12-week period, and will be followed for study outcomes for up to a year. The duration of the program will depend on the session you register for – we will offer 8 to 12 week programs, throughout the year. The exercise program will be tailored to your fitness level and designed to address your personal fitness or lifestyle goals.

All participants will have measurements taken at the start of the study, at the end of the exercise program, 24-weeks and one year, to see the effect of exercise on their physical activity levels and quality of life. Participants taking part in the study will have the option to receive a follow-up questionnaire after completing the exercise program each year for up to 5 years (remaining length of the study).

### STUDY PROCEDURES

#### Established Procedures

The following established procedures may be done as part of this study, and are dependent on availability of a qualified exercise professional and the necessary testing equipment at your site.

For online-only participants, these assessments may be adapted, as indicated below. If the results show that you are not able to continue participating in the study, the research coordinator will let you know.

- **Body composition measurement:** We will measure your height and body weight. These measurements take between 2 and 3 minutes to complete. For online participants, you will report both to us.
- **Aerobic endurance measurement:** We will have you perform a 6-minute walk test in a hallway on a flat surface to determine your fitness level. This is a submaximal test, meaning that you will walk at a moderate pace for the 6-minute time period. The walk test takes around 10 minutes to complete. For online participants, we will use a modified 2-minute step test. This is also a submaximal test, where you will step in place with high knees for 2 minutes.
- **Musculoskeletal fitness measurement:** we will measure your grip strength, measure your lower body endurance (30s Sit to Stand), and assess your flexibility using a sit-and-reach test and shoulder elevation measure. We will also assess your balance using a one-legged stance balance test. These tests take around 20 minutes to complete. For online participants, you will complete the same musculoskeletal tests except for the grip strength. Tests will be modified based on your equipment at home.

### Questionnaires

You will be sent an email to complete a questionnaire package at the start of the study, at the end of the exercise intervention, 24 weeks, and one year. You will have the option to complete the follow-up questionnaire package each year for the duration of the study (up to 5 years). The purpose of the questionnaire is to understand how the program affects different aspects of your life.

- **The revised Edmonton Symptom Assessment Scale:** This questionnaire asks you to rate symptoms related to your cancer and cancer treatment. This questionnaire is usually administered as part of your standard care. This questionnaire takes about 3 minutes to complete.
- **Physical activity level:** We will ask you about your physical activity level using the Godin Leisure-time Exercise Questionnaire. This 6-item questionnaire asks specific questions about the type, intensity, frequency and duration of your average weekly physical activity. This questionnaire takes around 2-3 minutes to complete.
- **Cancer-related Fatigue:** We will assess your rating of fatigue using the Functional Assessment of Chronic Illness Therapy-Fatigue. This 13-item questionnaire asks specific questions about the impact of your cancer related fatigue on your daily life. This questionnaire takes around 5 minutes to complete.
- **Cancer-related Quality of Life:** We will assess your general well-being and quality of life using the Functional Assessment of Cancer Therapy-General Scale. This 27-item questionnaire will ask you about your physical, social/family, emotional and functional wellbeing. It will take around 8-10 minutes to complete.
- **Cancer-related Cognition:** We will assess how your cognitive function using the Functional Assessment of Cancer Therapy-Cognitive Scale. This 37-item questionnaire will ask you

about your ability to think, reason and remember and how that may impact your quality of life. It will take around 10 minutes to complete.

- Exercise Barriers and Facilitators: We will assess what makes it difficult to exercise and what assists you in exercising, with an Exercise Barriers and Facilitators questionnaire.
- Cost effectiveness: We will assess the cost effectiveness of the program using the EQ5D. This 5-item questionnaire asks questions about your mobility, self care, usual activities, pain/discomfort and anxiety/depression. This questionnaire should take 2-3 minutes to complete.
- At the end of the exercise intervention, you will be provided an additional questionnaire asking about your intentions to stay physically active. At the 24-week time point, you will be provided an additional questionnaire asking about what actions you actually took to stay active over the past 12-weeks.

The information you provide is for research purposes only and will remain strictly confidential. Some of the questions are personal; you may choose not to answer them.

Even though you may have provided information on a questionnaire, these responses will not be reviewed by individuals not involved in this study, e.g., your health care practitioner/team. If you would like them to know this information, please bring this to their attention.

#### Health Tracking App

You may be provided a year subscription to an app called Zamplo, which assists in tracking your symptoms and physical activity levels. It can also be used to set reminders for appointments and exercise class times. All of your data is encrypted and stored in an encrypted database. Only you and any of your appointed caregivers will have access to your personal information.

#### Activity Tracking Watch

Some participants will be asked if they would like to use an Garmin Vivo Fit4 watch throughout the intervention. The watch will keep track of the amount of activity you participate in each day. If you are asked to participate in using the activity tracking watch, the study team will provide you with instructions to use/wear, and request it be sent back at the end of the intervention. The data that is collected will be transferred to the University of Calgary's We-TRAC Server (Level 4 Security; REB20-0572) and only authorized individuals will have access to the data for analysis through software programs. You will be assigned a participant ID for use with the activity tracker, and no identifying information will be linked to your data.

#### Additional Study Needs

You give permission to the study research coordinator or member of the study team to attempt to contact you in relation to additional study needs.

Yes       No      Participant's Initials: \_\_\_\_\_

## WHAT ARE THE POTENTIAL SIDE EFFECTS FROM PARTICIPATING IN THIS STUDY?

You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be side effects that are not expected. You should discuss these with the principal investigator or research coordinator. The risks and side effects of the standard or usual treatment will be explained to you as part of your standard care. These risks are not included in this consent form.

The main side effect from exercise testing and training is secondary muscle soreness. You may notice that your muscles are sore for a couple of days after the testing session and during the first week or so of the exercise program. We expect that these symptoms will get better as you get used to the exercise. As well, the exercise program will be personalized to you to minimize excessive soreness and modified as needed if you experience any excessive muscle soreness or fatigue from your exercise sessions.

It is important that you know and understand the possible risks of the treatments (exercise) given in this study. The main risk associated with exercise is musculoskeletal injury (injury to the muscles, tendons, joints or bones). Your exercise sessions will be supervised and your program designed to minimize this risk by slowly increasing the amount and intensity of your exercise over time.

There is also a very small risk of heart issues (such as chest pain, irregular heart rate, heart attack) should you exercise too intensively. To avoid any risks associated with exercise, you will be screened to ensure it is safe and appropriate for you to take part in the exercise program. All exercise will be of a low to moderate intensity level to minimize the stress on the heart and body. If any issues develop during the study period, your exercise sessions may be postponed or discontinued.

If you have any negative side effects, you should call the principal investigator or research coordinator in charge of the study. The telephone numbers are on the last page of this form.

## WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Participation in this study may or may not be of personal benefit to you. Possible benefits include improved physical fitness and better energy. Based on the results of this study, it is hoped that in the long-term, patient care can be improved.

## WHAT ARE MY RESPONSIBILITIES AS A STUDY PARTICIPANT?

If you choose to participate in this study, you will be expected to:

- Tell the study research coordinator about your current medical conditions;
- Tell the study research coordinator about all prescription and non-prescription medications and supplements, including vitamins and herbals, that you may be taking and check with the research coordinator before starting, stopping or changing any of these. This is for your safety as these may interact with the intervention you receive on this study;
- Tell the study research coordinator if you are thinking about participating in another research study;

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Version date of this form: June 21, 2021, V6

- Attend all scheduled study visits, undergo all of the procedures described above and complete the questionnaires.
- Inform the study research coordinator of any injuries, side effects or health problems that you may be experiencing or that develop at any point during the intervention.

### HOW LONG WILL I BE PARTICIPATING IN THIS STUDY?

The study exercise program will last for 8 to 12-weeks, depending on what session you have signed up for. You will be asked to come back to the fitness centre, or be assessed online, for a follow-up at the end of the exercise program, which will take 30 minutes. You will be asked to complete the questionnaires at baseline, at the end of the exercise program, 24-weeks, and 1 year. You will have the option to complete the questionnaires once a year for up to 5 years. If provided with a subscription to Zamplo for one year, you will be encouraged to use the app throughout the year to track your symptoms and physical activity levels.

### WILL THERE BE ANY LONG-TERM FOLLOW-UP INVOLVED WITH THIS STUDY?

If you stop receiving the study intervention early, we would like to keep track of your health for up to the one year study period to look at the long term effects of the exercise intervention on your health. You will complete the fitness assessments and/ or the questionnaires at your community-site or online, as able.

In the event it is necessary to further evaluate the safety or efficacy of the community-based or online EXCEL program, access to additional information about your health status may be required. The study team may attempt to obtain study-related information about your health from you or from your care physician. This may include contacting you again by phone or email, but only if you have not withdrawn your consent for future contact. However, contacting you, your care physician or using other private sources of information, is optional, please indicate your decision using the check boxes below.

You give permission to the study research coordinator or member of the study team to attempt to obtain study-related information about your health status to further evaluate the safety or efficacy of the EXCEL program. This may include contacting your care physician, or by contacting you by phone or email (i.e., future contact).

Yes       No      Participant's Initials: \_\_\_\_\_

Name/phone number of care physician: \_\_\_\_\_

### CAN I CHOOSE TO LEAVE THIS STUDY EARLY?

You can choose to end your participation in this research (called early withdrawal) at any time without having to provide a reason. If you choose to withdraw early from the study without finishing the intervention, procedure or follow-up, you are encouraged to contact the principal investigator or research coordinator. If you decide to stop participating in the study, we encourage you to talk to your doctor first. You may be asked questions about your experience with the study intervention.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research coordinator know. However, this would also mean that you withdraw from the study. Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no additional information will be collected or sent to the sponsor after you withdraw your permission.

### CAN MY PARTICIPATION IN THIS STUDY END EARLY?

In discussion with you, your doctor at the cancer care clinic or primary care network, either at his/her own initiative or at the request of the sponsor of this study, may withdraw you from the study at any time if it is in your best interests. The principal investigator may stop your participation in the study early, and without your consent, for reasons such as:

- You are unable to tolerate the exercise.
- You sustain an injury as a result of participation.
- You experience an adverse event during or after exercising.
- Your doctor no longer feels this is the best treatment for you.
- The sponsor decides to stop the study;

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form. If you are removed from the study, the principal investigator will discuss the reasons with you and plans will be made for your continued care outside of the study.

### HOW WILL MY PERSONAL INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the principal investigator and study staff will only collect the information they need for this study.

Records identifying you, including information collect from your medical files/records, such as your Electronic Medical Records (EMR), Netcare, charts, etc., will be kept confidential to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organization may look at your identifiable medical/clinical study records at the site where these records are held for quality assurance purposes and/or to verify that the information collected for the study is correct and follows proper laws and guidelines:

- The Health Research Ethics Board of Alberta – Cancer Committee, which oversees the ethical conduct of this study

Authorized representatives of the above organization may **receive** information related to the study from your medical/clinical study records that will be kept confidential in a secure online server, under Dr. Culos-Reed in the Faculty of Kinesiology at the University of Calgary, and may be used in current or future relevant health research. Your name or other information that may identify you will not be provided (i.e., the information will be de-identified). The records received by these organizations will be coded with a number. The key that indicates what number you

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5 have been assigned will be kept secure by the researchers directly involved with your study and  
6 will not be released. To protect your identity, the information that will be on your assessment  
7 forms and questionnaires will be limited to your study ID and initials.

8  
9 Any disclosure of your identifiable health information will be done in accordance with federal and  
10 provincial laws including the Alberta Health Information Act (HIA). The organization listed above  
11 are required to have organizational policies and procedures to protect the information they see  
12 or receive about you, except where disclosure may be required by law. The principal  
13 investigator will ensure that any personal health information collected for this study is kept in a  
14 secure and confidential location (at the University of Calgary) as also required by law.

15  
16 If the results of this study are published, your identity will remain confidential. It is expected that  
17 the information collected during the study will be used in analyses and will be published and/or  
18 presented to the scientific community at meetings and in journals, but your identity will remain  
19 confidential. It is expected that the study results will be published as soon as possible after  
20 completion. This information may also be used as part of a submission to regulatory authorities  
21 around the world to support the approval of this intervention.

22  
23 Even though the likelihood that someone may identify you from the study data is very small, it  
24 can never be completely eliminated. Every effort will be made to keep your identifiable  
25 information confidential, and to follow the ethical and legal rules about collecting, using and  
26 disclosing this information. Studies involving humans sometimes collect information on race and  
27 ethnicity as well as other characteristics of individuals because these characteristics may  
28 influence how people respond to different interventions. Providing information on your race or  
29 ethnic origin is voluntary.

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33 Data collected will be entered into the secure RedCap server held at the University of Calgary  
34 and data will only be used for research purposes. If you are given the opportunity to use m-  
35 health app, Zamplo, data will also be entered into the app. The developers, Hanalytics  
36 Solutions, are not data custodians. All of your data is encrypted and stored in an encrypted  
37 database. Only you and any of your appointed caregivers will have access to your personal  
38 information. No data is shared with any third party users without your consent. If at any point  
39 you wish to revoke your caregiver's access or remove your account (with all data destroyed)  
40 you may do so by contacting the research coordinator or principal investigator.

#### 41 42 43 44 WILL MY HEALTHCARE PROVIDER(S) BE INFORMED OF MY PARTICIPATION IN THIS 45 STUDY?

46  
47 Your family doctor/health care provider will be informed that you are taking part in a study so  
48 that you can be provided with appropriate medical care. If you do not want your family  
49 doctor/health care provider to be informed, please discuss with your study team to find out your  
50 options.

### WILL THERE BE ANY COSTS INVOLVED WITH PARTICIPATING IN THIS STUDY?

You will not have to pay for the exercise program you receive in this study. Costs associated with attending the exercise program in the community or online will be covered. You will have to pay if you wish to continue to take part in any maintenance exercise classes offered after the baseline program. The cost to continue in a maintenance exercise program may vary among facilities (fee for service). There may be additional costs to you for taking part in this study such as:

- transportation
- parking costs at fitness centres
- meals
- babysitting, etc.

### Possible Costs After the Study is Complete

You may not be able to participate in a maintenance exercise program, after your participation in the study is completed. There are several possible reasons for this, some of which are:

- Your caregivers may not feel it is the best option for you;
- You may decide it is too expensive and insurance coverage may not be available;
- The intervention may not be available free of charge.

The principal investigator will discuss these options with you.

### WILL I BE COMPENSATED FOR PARTICIPATING IN THIS STUDY?

You will not be paid for taking part in this study. However in the case of research-related side effects or injury, as a direct result of participating in this research, you will receive all medical treatments or services recommended by your doctors.

Although no funds have been set aside to compensate you in the event of injury or illness related to the study treatment or procedures, you do not give up any of your legal rights for compensation by signing this form.

### WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study. You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of these results, please contact the principal investigator.

The results of this study will be available on a clinical registry; refer to the section titled "Where can I find online information about this study?". Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the hospital, investigators, sponsor, involved institutions for compensation or their agents, nor does this form relieve these parties from their legal and professional responsibilities.

Version date of this form: *June 21, 2021, V6*



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6 IS THERE CONFLICT OF INTEREST RELATED TO THIS STUDY?  
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8 There are no conflicts of interest declared between the principal investigator and sponsor of this  
9 study.  
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11 WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME AS A RESEARCH  
12 PARTICIPANT?  
13

14 During the study, the researchers may learn something about you that they didn't expect. For  
15 example, the researchers may find out that you have another medical condition.  
16

17 If any clinically important information about your health is obtained as a result of your  
18 participation in this study, you will be given the opportunity at that time to decide whether you  
19 wish to be made aware of that information.  
20

21 WHERE CAN I FIND ONLINE INFORMATION ABOUT THIS STUDY?  
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23 A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by  
24 U.S. Law. This Web site will not include information that can identify you. At most, the Web site  
25 will include a summary of the results. You can search this Web site at any time.  
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28 The study registration number to use this website is: NCT04478851  
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## WHO DO I CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you should talk to the research coordinator or principal investigator. These person(s) are :

Ms. Julianna Dreger CSEP-CEP (Research Coordinator)      Ph: 403-210-8482  
Email: [jdreger@ucalgary.ca](mailto:jdreger@ucalgary.ca)

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Dr. Nicole Culos-Reed, PhD (Principal Investigator)      Ph: 403-220-7540  
Email: [nculosre@ucalgary.ca](mailto:nculosre@ucalgary.ca)

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If you have questions about your rights as a participant or about ethical issues related to this study and you would like to talk to someone who is not involved in the conduct of the study, please contact the Office of the Health Research Ethics Board of Alberta – Cancer Committee at:

Telephone: 780-423-5727

Toll Free: 1-877-423-5727



**SIGNATURES**

**Part 1** - to be completed by the potential participant.

	<b><u>Yes</u></b>	<b><u>No</u></b>
Do you understand that you have been asked to take part in a research study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand why this study is being done?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand the potential benefits of taking part in this study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand the risks of taking part in this study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand what you will be asked to do should you decide to take part in this study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand the alternatives to participating in this study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that you are free to leave the study at any time, without out having to give reason and without affecting your future health care?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand who will see your records, including health information that identifies you?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that by signing this consent form you are giving us permission to access your health information if applicable?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that by signing this consent form that you do not give up any of your legal rights?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that your family doctor/health care provider will/may be informed of your participation in this study?	<input type="checkbox"/>	<input type="checkbox"/>
Have you had enough opportunity to ask questions and discuss this study?	<input type="checkbox"/>	<input type="checkbox"/>



By signing this form I agree to participate in this study.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
PRINTED NAME

\_\_\_\_\_  
Date

**Part 2** - to be completed by the principal investigator or designee who conducted the informed consent discussion. Only complete this section if the potential participant has **agreed** to participate.

I believe that the person signing this form understands what is involved in the study and has freely decided to participate.

\_\_\_\_\_  
Signature of Person

\_\_\_\_\_  
PRINTED NAME

\_\_\_\_\_  
Date

Conducting the Consent Discussion

**\*\*You will be given a copy of this signed and dated consent form prior to participating in this study.\*\***

For peer review only

SPIRIT Checklist Link: <https://www.spirit-statement.org/title/>

- 1
- 2
- 3 - **Descriptive title acronym (1)**
- 4     o Page 1
- 5 - **Trial Identifier and Registry Name (2)**
- 6     o Page 2 (last line of abstract)
- 7 - **Date and Version Identifier (3)**
- 8     o N/A
- 9 - **Funding (4)**
- 10    o Page 18 under the section Funding Statement
- 11 - **Contribution (5)**
- 12    o Page 18 under Author Contributions
- 13    o Page 1 under Corresponding Author
- 14    o Page 18 under the section Funding Statement
- 15    o Page 18 under Author Contributions
- 16 - **Background and Rationale (6)**
- 17    o Page 4
- 18 - **Objectives (7)**
- 19    o Page 5
- 20 - **Trial Design (8)**
- 21    o Page 5
- 22 - **Study Setting (9)**
- 23    o Pages 5 & 6
- 24 - **Eligibility Criteria (10)**
- 25    o Page 7
- 26 - **Interventions (11)**
- 27    o Pages 7 & 8
- 28 - **Outcomes (12)**
- 29    o Pages 9-14
- 30 - **Participant Timeline (13)**
- 31    o Table 3: Outcome Measures and Timepoints
- 32 - **Sample Size (14)**
- 33    o Page 15
- 34 - **Recruitment (15)**
- 35    o Page 7
- 36 - **Allocation (16)**
- 37    o N/A – is a hybrid effectiveness-implementation study design
- 38 - **Blinding (17)**
- 39    o N/A
- 40 - **Data Collection Methods (18)**
- 41    o Table 2: RE-AIM Summary Outcomes; Table 3: Outcome Measures and Timepoints
- 42 - **Data Management (19)**
- 43    o Page 7 under Participants and Screening
- 44 - **Statistical Methods (20)**
- 45    o Page 15
- 46 - **Data Monitoring (21)**
- 47    o N/A – no data monitoring committee was established
- 48    o Page 16 under Ethics and Dissemination section – outlines plan for potential publications (i.e., interim analyses)
- 49 - **Harms (22)**
- 50    o Pages 9 & 10 under *Implementation* – we will track safety of the exercise program
- 51 - **Auditing (23)**
- 52    o N/A – no independent reviews are planned
- 53 - **Ethics and Dissemination (24-31)**
- 54    o Information related to ethics and dissemination can be found on Page 16
- 55 - **Appendices (32-33)**
- 56    o Informed Consent was uploaded as supplemental material during submission.
- 57
- 58
- 59
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