

Innovative approach for increasing physical activity among breast cancer survivors: protocol for Project MOVE, a quasi-experimental study

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ABSTRACT

Introduction: Physical activity is a cost-effective and non-pharmaceutical strategy that can help mitigate the physical and psychological health challenges associated with breast cancer survivorship. However, up to 70% of women breast cancer survivors are not meeting minimum recommended physical activity guidelines. Project MOVE is an innovative approach to increase physical activity among breast cancer survivors through the use of Action Grants, a combination of microgrants (small amounts of money awarded to groups of individuals to support a physical activity initiative) and financial incentives. The purpose of this paper is to describe the rationale and protocol of Project MOVE.

Method and analysis: A quasi-experimental pre-post design will be used. Twelve groups of 8–12 adult women who are breast cancer survivors (N=132) were recruited for the study via face-to-face meetings with breast cancer-related stakeholders, local print and radio media, social media, and pamphlets and posters at community organisations and medical clinics. Each group submitted a microgrant application outlining their proposed physical activity initiative. Successful applicants were determined by a grant review panel and informed of a financial incentive on meeting their physical activity goals. An evaluation of feasibility will be guided by the reach, effectiveness, adoption, implementation, maintenance (RE-AIM) framework and assessed through focus groups, interviews and project-related reports. Physical activity will be assessed through accelerometry and by self-report. Quality of life, motivation to exercise and social connection will also be assessed through self-report. Assessments will occur at baseline, 6 months and 1 year.

Ethics and dissemination: Ethical approval was obtained from the University of British Columbia's Behavioural Research Ethics Board (#H14-02502) and has been funded by the Canadian Cancer Society Research Institute (project number #702913). Study findings will be disseminated widely through peer-reviewed publications, academic conferences, local community-based presentations, as well as partner organisations, including the Canadian Cancer Society.

Strengths and limitations of this study

- Project MOVE presents a unique opportunity to study the effectiveness of a 'bottom-up', community-based approach in a real world setting.
- The microgrant model can be recreated and transferred to other cancer site populations, helping to reduce health issues and enhance overall well-being for those with cancer.
- This study uses objective and subjective measures of physical activity.
- Given the exploratory nature of this new and innovative approach, this study is limited in examining cause in behaviour change.

INTRODUCTION

Breast cancer (BC) is the most common cancer among women worldwide.¹ For example, in North America, Australia and Europe, approximately one in every eight women will be diagnosed with BC in their lifetime.^{2–4} With survival rates approaching 88%, there are increasing numbers of women who require long-term surveillance and support to manage the detrimental effects of treatment for BC. Specifically, morbidity, decline in functional status and disability that result from the disease itself, BC-related treatments (ie, surgery, chemotherapy and/or radiation) and/or subsequent health sequelae (ie, anxiety related to prognosis and physical changes) are significant concerns.⁵ Physical activity is a cost-effective and non-pharmaceutical strategy that can help mitigate the physical and psychological health challenges associated with BC survivorship.^{6,7} Physical activity is safe, effective and feasible for most women diagnosed with BC,^{8–11} and is associated with numerous health benefits among cancer

survivors, including weight loss or maintenance, reduction in pain and fatigue, reduced depression and anxiety, management of post-treatment symptoms, improved social support and reduced mortality.^{7 12 13} However, up to 70% of BC survivors are not meeting the minimum recommended physical activity guidelines (150 min of moderate to vigorous) for optimal health benefits.^{14–16} As such, BC survivors are an important target for intervention research focused on ways to increase physical activity.

Community-based intervention programmes targeting women diagnosed with and treated for BC (eg, dragon boating, yoga and hiking) offer women a chance to be active among ‘similar others’, to experience physical activity in natural environments, to challenge themselves physically and mentally and to build autonomy and confidence for physical activity.^{17–19} However, these are exclusive activities that are not easily practiced by, or of interest to, all women treated for BC. As such, the development and implementation of new community-based programmes that are targeted, inclusive and of interest to a wider range of women are needed. One particular strategy which aims to do this is the use of Action Grants, an innovative approach which combines the use of microgrants and financial incentives to prompt and sustain physical activity and stimulate community action.²⁰

Microgrants, a strategy which originated from a loans programme referred to as microfinancing,^{21 22} is a scheme in which a small amount of funds are awarded to successful community-based applicants to develop and/or implement a community programme. This model has long been used to stimulate personal growth and improve access to basic social, health and family services for people in developing countries who are from low-income communities.^{23 24} Although relatively unique to the health promotion field, a small number of evaluation studies have shown that similar schemes can stimulate community health-related activities.^{20 25–27} For example, The Australian-based Women’s Active Living Kits (WALK) project²⁵ awarded 48 community microgrants (up to \$A1500) to establish women’s walking groups throughout Australia. The microgrants were successful in enabling women’s engagement in physical activity and created a group-oriented environment that women enjoyed because it provided support for those who found it difficult to ‘get moving’, helped build confidence and provided an outlet for social interaction.²⁵ Nonetheless, these earlier studies did not examine behaviour change nor did they examine a supplementary strategy (such as financial incentives) as an additional tool for increasing physical activity motivation. Economic theorists, in collaboration with health promotion professionals, have indicated that financial incentives have had a positive effect on various health behaviours and health outcomes including smoking cessation,²⁸ weight reduction^{29 30} and most recently physical activity behaviours.^{31–33} A recent meta-analysis of randomised controlled trials (RCTs) that provide financial incentives for the promotion of physical activity in

adults, reported a significant positive effect concerning physical activity session attendance, adherence and maintenance over a 6-month period.³³ In addition, physical activity participation rates progressively increased in many of the RCTs after incentives were withdrawn.³³

Within this context, Project MOVE uses the Action Grant model as a strategy to make physical activity more accessible (and enjoyable) for women who are BC survivors. Specifically, BC survivors are encouraged to come together as a group (pre-existing or newly formed), develop a physical activity initiative and apply for a small microgrant to support this initiative. In addition to the microgrant, successful applicants are also informed of an additional financial incentive contingent on increasing their groups’ physical activity. Thus, the overarching aim of this study is to evaluate the feasibility of the Project MOVE Action Grant model (microgrants+financial incentive), and estimate changes in physical activity motivation, physical activity behaviour and social relatedness in these groups. The specific objective of this paper is to describe the intervention design and methodological protocols of the Project MOVE Action Grant Model.

METHODS AND ANALYSIS

Study design

This study is based on a quasi-experimental pre-post design to determine the feasibility of Project MOVE, an Action Grant programme aimed at increasing physical activity and subsequently reducing health complications faced by BC survivors. The study period extends from May 2015 to January 2017. Recruitment occurred in two phases: phase 1 recruitment period began May 2015 through to July 2015, and phase 2 recruitment period began September 2015 through to November 2015. Baseline assessments for participants recruited during the first phase occurred in September 2015. Baseline assessments for participants recruited in the second phase will occur in January 2016. Six-month and one-year follow-up measures will be collected accordingly in 2016. A process evaluation, guided by the RE-AIM framework and used to determine feasibility, will also be undertaken at the 6-month and 1-year follow-up. Participants recruited in phase 1 provided written informed consent prior to baseline assessments. Informed consent will also be obtained prior to baseline assessments from all participants recruited in phase 2.

Participants, recruitment and eligibility

Groups of 8–12 adult (18 years+) women BC survivors living in the Okanagan region in British Columbia, Canada, were recruited for the study. For the purpose of this study, a survivor is defined based on the National Coalition for Cancer Survivorship as someone who has lived with, through and beyond a cancer diagnosis.³⁴ Women who self-defined themselves as a BC survivor were eligible to participate. Based on challenges faced with recruiting groups consisting of all survivors, Project

MOVE team members adjusted the recruitment eligibility during the initial recruitment phase so that groups comprised of at least 50% BC survivors were eligible. Women living in the Okanagan who wished to participate but were not BC survivors were eligible providing there was space in the groups after all interested BC survivors were accommodated.

Participants were recruited from communities spanning ~200 km across the Okanagan Region and included rural and urban centres. A variety of recruitment techniques were employed, including face-to-face meetings between researchers and community stakeholders with existing connections to BC survivors (eg, local health and fitness centres, community activity centres, established community groups), news items in local print and radio media, paid advertisements in local news media and online media, social media announcements (Facebook and Twitter), and pamphlets and posters distributed to local businesses, community centres and medical clinics. Also, a paid advertisement appeared on Facebook, targeting users with various tags such as Okanagan, cancer survivors, BC, health and wellness, and physical activity. Advertising tactics were designed to emphasise the benefits of physical activity for cancer survivors, creating social relationships and support networks, and promoting autonomy and empowerment by allowing women to create their own physical activity initiative. Two public 'drop-in' information sessions (one during each recruitment phase) were also held at a local community centre to allow prospective participants to meet the researchers, connect with potential group members and ask questions about the study. Based on the outcomes of phase 1 recruitment, the research team focused on a more targeted approach in phase 2 placing greater emphasis on face-to-face meetings with community stakeholders who had connections to local BC survivors or community partners and who expressed interest in extending their current health and fitness mandate to include tailored programmes for BC survivors.

All recruitment approaches were aimed at building community awareness about Project MOVE and provided detailed information about the Action Grants, including a brief introduction outlining the purpose of the grants, sample ideas about eligible initiatives and important dates concerning grant applications. All communication directed interested participants to the project website (<http://www.projectmove.ca>) for more detailed information about the grants and the submission process.

Application process

A project-specific website was created in Spring of 2015 and contained information about the programme, BC and the importance of physical activity, contact information for the research team, application guidelines and step-by-step instructions for filling out the online application forms. Hard copy application forms were made

available on request. Applications for phase 1 recruitment were open for 6 weeks beginning 1 June through to 15 July 2015. Applications for phase 2 recruitment were open for 4 weeks beginning 1 October and closing 1 November 2015. In order to apply, each group designated a leader who acted as the primary contact and was responsible for submitting the application and liaising with research staff and their respective group members. The application form required each group leader to describe the physical activity their group planned to do each week, explain how this activity would contribute to increasing the group's overall physical activity levels and social connectedness, and to outline a proposed budget and timeline. All submitted applications were initially screened for eligibility by three research team members and those deemed eligible were then processed and distributed to a Grant Review Panel for further evaluation.

The Grant Review Panel consisted of three research team members, a representative from the Canadian Cancer Society and a local BC survivor. Review panel members were allocated up to 4 applications each and required to review each grant and assess them based on the following criteria: ability to engage target population (BC survivors) and facilitate social support, the potential of project sustainability, the presence of clearly stated goals and objectives, feasibility of implementation and the project's potential to engage the community. The evaluation was based on a 7-point scale, where 1 indicated no potential or ability and 7 indicated high potential or ability. Reviewers were also asked to provide comments and notes to accompany their evaluation.

Successful applicant groups were notified in August and November 2015 (phase 1 and phase 2) and were informed of programme obligations. These include the requirement of each group member to participate in data collection and of the group leader to keep track of expenditures, liaise with the research team and provide a group photo and summary to appear on the Project MOVE website. The group leader was asked to sign and return a letter of acceptance indicating agreement to these terms. Unsuccessful applicants were also notified and provided feedback outlining why they were not funded.

Project MOVE intervention

The microgrants served as a stimulus for women who are BC survivors to come together as a group and propose an ongoing physical activity initiative (aka 'intervention') they believe to be enjoyable and meaningful to them and that they could perform on a regular basis. The microgrants provided groups with up to \$2000 to enable access to equipment, resources, facilities, instruction or transportation that groups needed to implement their initiative. It is important to note that there was no predetermined intervention promoted or developed by the researchers, instead each group was invited to design their own intervention. This allowed groups to develop their own intervention based on their own

needs and preferences, and more importantly, to address any unique circumstances and specific barriers that may have limited them from being active. Groups were encouraged via the website to contact members of the research team for support with conceptualising their project and with the application process. Advice and/or information given by research team members, if contacted, was focused on helping groups determine if their ideas were eligible for submission and assist them with transferring their ideas onto 'paper' (ie, the application form). The research team did not provide initiative/programme ideas to the participant groups, but rather guidance with further developing their already determined initiative/programme idea. Additionally, given the high number of emails received from individual women who were not able to form a group independently, a section on the website for 'Individual Expressions of Interest' was created. Through this forum, individual women were invited to indicate their preferred activities, best time of day to engage in activity and their contact information. The research team then facilitated connections between these individual women and community centres and partners with the capacity to provide facilities and expertise to lead a group. In this way, steps were taken to accommodate all interested women.

In addition, each group was also informed that if they meet their group goals (developed in collaboration with the project team) for increasing physical activity, they will have an opportunity to receive an additional \$500 financial incentive at 6 months post baseline. This will be determined by a group mean increase in physical activity assessed by accelerometry at 6 months (phase 1 groups: March 2016 and phase 2 groups: June 2016) follow-up. Dependent on the agreed on group goals, this may include an increase in group mean minutes of physical activity, an increase in physical activity sessions or a group mean increase in steps. Approximately 1 month post baseline, a brief email will be sent to all group leaders asking about group progress and encouraging them to contact the Project MOVE team with any questions or concerns. The email will also include a reminder about the financial incentive available and that this will be determined once 6 months data collection was complete. **Figure 1** provides a flow summary of the progression of Project MOVE.

Outcome measures

Assessments will be conducted at baseline (these have already been collected for phase 1 groups; phase 2 groups will undergo baseline assessments in January 2016), 6 months and 1 year post baseline. Once successful groups return their signed acceptance form, a research team member will contact the primary contact person to organise a baseline data collection day, time and place convenient for all group members. Dependent on the group, baseline data collection may take place at a local community centre, a cancer treatment centre and at the homes of the group leaders. If a group member cannot

attend the group session, a research team member will organise a separate time with the individual to collect their baseline data. This will occur within 1 week of the group baseline data assessment time. Baseline assessments will include the collection of demographic, anthropometric and BC-specific information, as well as objective and subjective measures of physical activity, quality of life (QoL), motivation to exercise, levels of social support and connectedness to others. All measures are described in further detail below. In addition, **table 1** provides a summary of measures and data collection time points.

Demographics, anthropometrics and BC information

Demographic variables include date of birth, ethnicity, education, marital status and employment. Self-report height and weight will be collected to calculate body mass index (BMI). Questions related to BC will include date of most recent diagnosis, stage of BC at diagnosis, type of treatment, date of last treatment received and menopausal status.

Physical activity

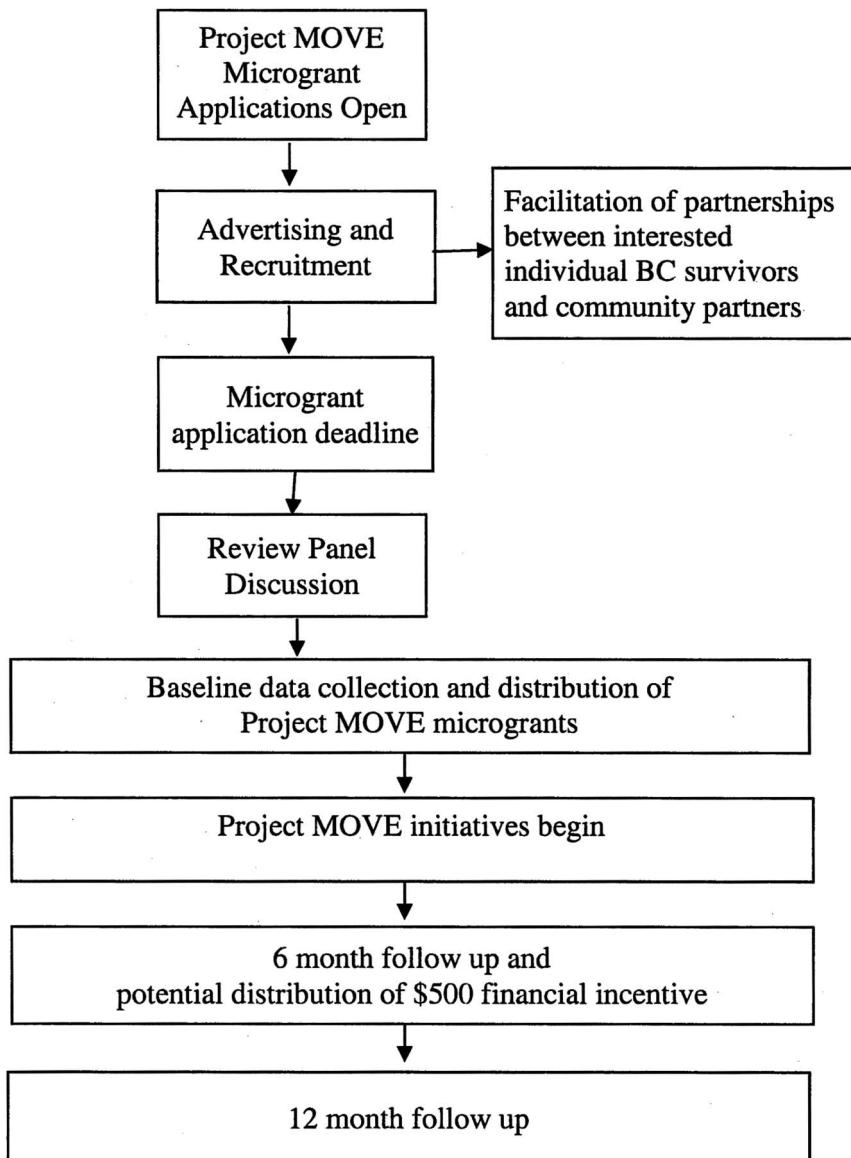
Physical activity will be assessed objectively using an ActiGraph GT3X accelerometer (ActiGraph, Pensacola, Florida, USA) and by self-report using a modified version of the Godin Leisure-Time Exercise Questionnaire (GLTEQ).³⁵ All participants will be fitted with an ActiGraph GT3X accelerometer at baseline assessment. Participants will be instructed to wear the accelerometer, mounted on an elastic belt around the waist with the unit positioned over the right hip, all day during all waking and non-water-based activities over a 7-day period. The accelerometers will be programmed to record steps, inclination and acceleration counts in tri-axial mode, using a 60 s epoch.^{36 37} Participants will be asked to fill out a daily log and record what time the device was put on and taken off each day, as well as any circumstances which they felt relevant to explain (eg, illness or forgot to put it on). Participants will be asked to return their accelerometers to their group leader after the 7-day period. A research team member will pick up the accelerometers from group leaders.

The GLTEQ will be used to collect self-reported physical activity data from all participants. It is a reliable and valid self-report tool^{35 38} which asks participants to indicate the frequency and type of intensity (light, moderate, vigorous) of their physical activity sessions and the duration (minutes) of these sessions.^{38 39} All responses will be converted to minutes. Physical activity levels will be calculated in accordance with the metabolic equivalent (MET) minutes⁴⁰ method. A cut-off point of ≥600 MET minutes will then be used to dichotomise participants as 'adequately active for health benefit' or 'inadequately active'.^{40 41}

Sedentary behaviour

Accelerometers will also be used to objectively assess sedentary behaviour using a 30 s epoch. In addition,

Figure 1 Flow summary of protocol progression of Project MOVE. BC, breast cancer.



sedentary behaviours will be assessed by self-report using The Marshall Sitting Questionnaire (MSQ).⁴² This measure has demonstrated reliability and validity in the adult population⁴² and assesses time spent sitting on weekdays and weekend days at work, traveling and at home. Data from the sitting time questionnaire will be used to create an estimate of total weekday and weekend-day sitting times (min/day) by summing the time reported in each domain.⁴²

Quality of life

Quality of life (QoL) will be assessed through the 36-item short-form Medical Outcomes Study Survey (SF-36/RAND 36), a 36-item valid and reliable tool used to measure overall QoL across eight domains, including physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being,

Table 1 Summary of measures and data collection time points

Outcome measures	Collection points
Demographics (self-report)	0 (baseline only)
BC information (self-report)	0, 6 and 12 months
Anthropometrics (self-report)	0, 6 and 12 months
Physical activity (accelerometry and self-report)	0, 6 and 12 months
Sedentary behaviour (accelerometry and self-report)	0, 6 and 12 months
Quality of life (self-report)	0, 6 and 12 months
Motivation to exercise (self-report)	0, 6 and 12 months
Social support (self-report)	0, 6 and 12 months
<i>Process evaluation measures</i>	
Focus groups and interviews	6 months
Project reports and website usage (Google Analytics)	12 months
BC, breast cancer.	

social functioning, energy/fatigue and general health perceptions.^{43 44} RAND 36 was developed from the original commercial SF-36⁴⁴ and has since been released license free from the RAND Corporation. In terms of scoring protocol for the RAND 36, pre-coded numeric values are assigned to each scale, and all items are then scored on a 0 to 100 range, with a high score representing a more favourable health state. Additionally, items in each of the eight domains are averaged together to create eight separate domain scores. Any items left blank are treated as missing data and are used when calculating the scale scores.⁴⁵

Reasons for engaging in exercise

Motivation to engage in exercise will be captured via the Behavioural Regulation in Exercise Questionnaire V.3 (BREQ-3),^{46 47} a 24-item self-report measure adapted from the original BREQ.⁴⁸ The BREQ-3 has been reported as valid and reliable^{49 50} and measures external regulation (eg, 'I exercise because other people say I should'), introjected regulation (eg, 'I feel guilty when I don't exercise'), identified regulation (eg, 'I value the benefits of exercise') and intrinsic regulation (eg, 'I exercise because it's fun') of exercise behaviour based on Deci and Ryan's^{51 52} continuum conception of extrinsic and intrinsic motivation. Participant responses are scored using an item aggregation approach.⁵³ This involves summarising participant responses by averaging the items of each individual subscale into six unique scores.

Social support

Social support will be assessed by the 6-item 'Positive Relationship with Others' subscale of the Ryff Scales of Psychological Well-being (RSPW).^{54 55} The RSPW is a theoretically grounded instrument that measures multiple facets of psychological well-being and has been used in a variety of settings and samples.^{56–58} The subscale presents statements regarding one's personal relationships with others. Participants will be asked to rate statements on a scale of 1–6, with 1 indicating strong disagreement and 6 indicating strong agreement.

Statistical analysis

Descriptive analyses will be completed and presented as means and SDs for continuous variables and as frequencies and proportions for categorical data. Data analysis of outcome variables including estimates of change in physical activity, motivation, QoL and social support will be examined using paired t-tests with Bonferroni correction to adjust for the multiple tests. Residual change scores will be calculated in linear regression models and Pearson correlation coefficients will be used to estimate covariance among change scores. The level of significance (α) will be set at 0.05. As the primary outcome is feasibility, a power calculation was not performed.

Evaluation and analysis of feasibility is detailed in the following section.

Process evaluation and analysis

The feasibility of the Action Grant programme will be evaluated using RE-AIM, a comprehensive evaluation framework that captures process and outcome data. RE-AIM is widely used to evaluate health-related, and specifically physical activity, interventions^{59–61} and is often proposed as a framework for feasibility studies.^{62 63} RE-AIM includes five dimensions: (1) *Reach*—proportion of the target population aware of and will potentially participate in the intervention; (2) *Effectiveness*—an estimate of the extent to which the intervention achieves its anticipated outcomes; (3) *Adoption*—proportion of settings, practices and plans that adopt this intervention; (4) *Implementation*—extent to which the intervention is implemented as intended; and (5) *Maintenance*—extent to which a programme is sustained over time. Focus groups, with all groups (N=12), and semistructured interviews with a subsample of individuals (N=15) across all groups will be undertaken at 6-month follow-up to gain understanding of participants' perceptions concerning satisfaction and practicality of the Action Grant programme, and to understand the challenges/enablers associated with design, implementation and adoption of the programme, including feasibility parameters such as recruitment, accrual, adherence and acceptability of the programme. Project-related statistics, including website usage patterns (Google Analytics—frequencies, means, etc), as well as project reports concerning phone calls and emails to the project office, number of grant applications received, enquiries concerning the project, etc will also be collected. Finally, outcome assessments outlined above will be used to provide an estimate of effectiveness. For example a change in physical activity behaviour assessed via accelerometry and the GLTEQ will be used to provide an estimate of programme effectiveness. Table 2 provides a summary of RE-AIM measures.

Data from the focus groups and interviews will be audio recorded to ensure accurate transcription. The audio recording will be transcribed verbatim with all identifiable information removed, and the recording will be deleted after transcription to ensure anonymity and confidentiality. All data will be analysed using thematic content analysis⁶⁴ to explore participant satisfaction and enjoyment and to identify any challenges experienced during programme implementation as well as factors that may have facilitated implementation. To enhance rigor, two members of the research team will independently identify and code participant responses into relevant subthemes. Once all coding has been completed, subthemes will be discussed among the two research team members to ensure bias is minimised. Any disagreements or concerns that may arise during the analysis will be presented at this time and further discussion will be carried out with the research team until consensus is reached.

Table 2 RE-AIM process/outcome measures

Dimension	Methods	Process/outcome measures
Reach	Focus groups, interviews, project-related statistics	<ul style="list-style-type: none"> ▶ Number and diversity of women's groups who apply for the microgrants ▶ Characteristics of applicants compared with non-applicants or target population ▶ Issues concerning recruitment and application process
Effectiveness	Accelerometry, GLTEQ, MSQ, BREQ-3, SF-36, RSPW focus groups, interviews	<ul style="list-style-type: none"> ▶ Changes in physical activity behaviour, sedentary behaviour, quality of life, motivations and social support
Adoption	Focus groups, interviews, project-related statistics	<ul style="list-style-type: none"> ▶ Assessment of barriers and enablers to adoption of the programme ▶ Website usage statistics (eg, application views, registrations, logins, frequency of visits) ▶ Review of initiatives/programmes developed by participants to examine if they were implemented as they were intended ▶ Assessment of barriers, challenges, enablers to implementing initiatives/programmes ▶ Suggestions for future implementation
Implementation	Focus groups, interviews	<ul style="list-style-type: none"> ▶ Is the initiative/programme still occurring at 6 and 12 months? ▶ Are participants still participating at 6 and 12 months (via the initiative/programme, another programme, or on their own)? ▶ Have changes occurred and/or been maintained over 6 and 12 months in terms of physical activity, sedentary behaviour, motivations, quality of life, social support?
Maintenance	Accelerometry, GLTEQ, MSQ, BREQ-3, SF-36, RSPW, focus groups, interviews, project-related statistics	

BREQ-3, Behavioural Regulation in Exercise Questionnaire V.3; GLTEQ, Godin Leisure-Time Exercise Questionnaire; MSQ, Marshall Sitting Questionnaire; RE-AIM, reach, effectiveness, adoption, implementation, maintenance; RSPW, Ryff Scales of Psychological Well-being; SF-36, 36-item short-form health survey.

RESULTS

Follow-up results concerning feasibility (process evaluation) and outcome measures will be available in Fall 2016 (6-month follow-up) and Winter 2016 (1-year follow-up).

DISCUSSION

The current intervention model presents a unique opportunity to study the effectiveness of an innovative 'real-world', community-based approach for increasing physical activity among women BC survivors. Engaging women in preventive health measures, such as physical activity, can be challenging. Research indicates that this is in part due to circumstances following BC treatment, in which survivors are often faced with pain, fatigue and weight gain, as well as low self-esteem and social isolation.^{10 12 13} As such, BC survivors are an important target for intervention research focused on ways to increase physical activity. However, in order to engage this particular segment of the population, these types of initiatives must be developed in a way that enhances and fosters autonomy and confidence and meets the specific needs and interests of these women. Project MOVE is conceptualised to accommodate and address these considerations. Specifically, it supports groups of women to

design and implement community-based physical activity initiatives from the 'bottom-up'—meaning designed and implemented by BC survivors for BC survivors. Most importantly, the process of design and implementation has the potential to promote a sense of empowerment and ownership for women, providing them with the opportunity to optimise their own strengths and knowledge aimed at reducing health concerns that often emerge post BC treatment.

A further unique aspect of this feasibility trial is that it will be conducted in a real-world setting, influenced by naturally occurring external variables that are not always apparent in laboratory or tightly controlled RCT settings. Although RCTs are often considered the gold standard of trial design due to their ability to provide valuable information concerning efficacy and internal validity and their ability to minimise the impact of selection and information biases and control for confounding variables,^{65 66} they can be challenged on the grounds of external validity.^{67 68} This is not to say that RCTs are not important or necessary, indeed they are an essential part of the research process as a sufficiently powered, methodologically sound design is vital to maximising internal validity and providing an indication of efficacy. However, prior to undertaking an RCT in a community or population level setting, it is necessary to investigate the



feasibility and acceptability of an intervention under normal, everyday conditions in order to identify and address potential variables or circumstances that may impact the future transferability of the intervention to public health/health promotion practice.^{63–69–71} The unique design of this trial allows for the examination of intervention components in a real-world setting providing us with the opportunity to examine a number of feasibility parameters, such as various methods of identifying/recruiting participants, practicality of delivery, SD of the outcome measures to estimate sample size, participant acceptability and satisfaction with the intervention model,⁷² all of which are important considerations prior to carrying out a sufficiently powered RCT.

In conclusion, the knowledge gained from the current study protocol will provide important insights into the successes and challenges associated with an Action Grants approach to physical activity interventions targeting BC survivors. Lessons learnt from this study will facilitate further study refinement and inform protocol approaches that encompass a ‘bottom-up’ philosophy. Importantly, this approach could ultimately extend the delivery of physical activity interventions for diverse populations of cancer survivors because it has the potential to capture a wide range of interests and needs. Researchers interested in developing and testing new and innovative intervention approaches will be able to use this detailed protocol as a resource for study replication concerning other cancer-specific sites or cancer prevention initiatives.

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Contributors CMC, CMS, JLB, KLC, NDE, SLE and CG conceived the project and procured project funding. CMC and MIC are leading the coordination of the study. CMC, CMS, JLB, KLC, NDE, SLE and CG assisted with protocol design. MIC is managing the project including data collection with assistance from RT. CMC, MIC and RT drafted the manuscript and all authors read, edited and approved the final manuscript.

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