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Renewing caregiver health and wellbeing through exercise (RECHARGE): A randomized controlled trial

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ABSTRACT

Background: Family caregivers (FCs) to cancer patients are at increased risk for physical and emotional health problems as a result of being in the caregiver role. Current research on interventions for FCs has focused on psychological support or educational interventions, with very little investigation of exercise in maintaining or improving health. Based on our preliminary survey, participation in regular exercise to improve health was noted as a priority for FCs.

The purpose of the study described in this protocol is to examine the impact of a 12-week structured exercise program on physical functioning (primary outcome), physical activity levels and psychological well-being (secondary outcomes), in FCs caring for adult cancer patients. In addition, the trial described here will examine the outcomes from a 12-week maintenance program, immediately following the initial program.

Methods/design: A mixed methods design using a randomized control trial (RCT) with a 50/50 allocation ratio for the quantitative portion, followed by face to face interviews and qualitative data analysis. Approximately 86 participants will be enrolled over a 10 month period. The intervention will consist of a structured exercise program of aerobic and resistance training. An intention to treat principle using mixed effects modeling will guide data analysis.

Discussion: FCs will continue to play a pivotal role in the care of cancer patients as the incidence and chronicity of cancer increases. The research described in this protocol will provide information about the impact of an exercise program in supporting FC health.

Trial registration: ClinicalTrials.gov Identifier: NCT02580461

1. Background and rationale

Approximately 900,000 Canadians [1] and 2.4 million Americans [2] are family caregivers (FCs) to cancer patients. Family caregivers are an important health care resource as estimates suggest they provide a cost savings to the health care system of approximately $25 billion dollars per year in Canada [3] and $470 billion per year in the US [4]. In cancer care, FCs have become paramount to the delivery of care. There has been a shift toward more complex treatments, the disease trajectory has changed to that of a chronic condition, and cancer treatments are largely delivered in the outpatient setting [5]. As such, FCs are increasingly relied upon to provide care for longer periods and to perform more complicated caregiving tasks [6–8].

Abbreviations: FCs, Family caregivers; RCT, randomized controlled trial; PCS, physical component score; IEG, immediate exercise intervention group; DEG, delayed exercise intervention group; M, maintenance intervention; CEP, certified exercise physiologist; FITT, frequency, intensity, timing and type; CPT, certified personal trainer; PSQI, Pittsburgh sleep quality index; CES-D, Centers for epidemiological studies-depression; SF-36, Short Form 36 v2; STAI, State trait anxiety index; MSPSS, Multidimensional scale of perceived social support; GLTEQ, Godin leisure time equivalent questionnaire; CSEP, Canadian society of exercise physiology; CSEP-PATH, Canadian society of exercise physiology physical activity training for health; 6MWT, 6 min walk test; RPE, rating of perceived exertion.

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Being in the caregiver role may have negative effects on physical and emotional health [9]. Compared to non-caregivers, FCs have increased rates of hypertension, heart disease, and stroke [10–12]. There may also be a mortality effect from being a caregiver [13], where an increased risk for mortality (RR 1.63) was found in FCs experiencing emotional strain (CI 1.00, 2.65, *p* value not reported). Emotional health disturbance is often cited, with depression and anxiety as the most common psychological problems experienced by FCs [5,7,8,14]. Finally, caregiving also impacts the ability to carry out leisure and daily activities, including health maintenance activities such as exercise [15,16–18].

Given the number of FCs, the increased risk for health problems, and difficulty participating in health maintaining activities, interventions targeting FC health are needed. In cancer care, interventions to date have largely focused on psychological support or education, [5,6] with a paucity of research testing exercise interventions. The call for more research focused on promotion of healthy behaviors, including exercise, has been consistently cited as an important future direction in FC research [5,15,16,19–22]. This call stems from the recognition of the accumulated evidence since the 1950s that exercise has health benefits for everyone including healthy people, non-healthy people, and older persons [23–25]. In addition, there is evidence that the negative psychological impacts of caregiving, including depression, anxiety, and decreased quality of life, could be alleviated with exercise [26–28]. Finally, caregivers themselves have reported interest in physical activity programs as documented in a recent survey of cancer FCs (unpublished thesis).

Of the 14 exercise interventions in FCs published to date [20,29–41], only three have included cancer FCs [30,31,40], and the other 11 studies have been with Alzheimer's/dementia patients. In most of the published studies, not enough information has been provided to determine if the studies were designed with enough power to detect an effect on their outcome. Outcomes measured have been heterogeneous, however, caregiver depression, anxiety, sleep quality, and quality of life have been reported to significantly improve [20,29–36]. There has been lack of reporting of effect sizes and lack of data reported to calculate effect sizes in most of the published studies, making it difficult to understand the effect of exercise as an intervention.

Of the fourteen studies published to date, two of the three cancer caregiver interventions [31,40] were not randomized controlled trials and tested the effects of a yoga program. In addition, only one of the cancer caregiver studies included caregivers only [31], while the other two cancer caregiver intervention included patients and caregivers together. Thus, randomized control trial evidence on the effects of aerobic and resistance training (i.e. general exercise recommendations) is lacking with respect to cancer caregivers. The cancer caregiving experience is different from Alzheimer's/Dementia in that caregiving is not a common barrier to leaving the home and participating in a structured exercise program (unpublished thesis). The benefits of a center based exercise program, which is superior to home based for exercise adherence [42], should be explored in cancer caregivers. Finally, maintenance of exercise behaviors has not been adequately evaluated to date, with only 3 of the 14 published studies reporting maintenance. Maintenance is something lacking in most exercise trials [43], however, in a population such as caregivers where additional barriers to maintaining exercise are present, it would be important to understand if exercise behaviors could be maintained with a structured exercise program.

The research to date provides some evidence that exercise may be feasible and acceptable to cancer FCs [30,31,40], however, further research is needed to understand if exercise is effective for improving the physical and psychological health of those caring for cancer patients. Thus, the aim of this research is to examine the impact of a 12-week structured exercise program on physical functioning (primary outcome), physical activity levels and psychological well-being (secondary outcomes), in FCs caring for adult cancer patients. In addition, the trial described here will examine the outcomes from a 12-week maintenance program.

2. Objectives

1. To examine whether a 12-week exercise program increase the physical component score (PCS) on the SF-36 measure of quality of life in those FCs randomized to intervention compared to those randomized to control condition.
2. To examine whether a 12-week exercise program increases physical activity levels, fitness levels, overall quality of life, sleep quality and perceived social support, and decreases depression and anxiety in those FCs randomized to intervention compared to those randomized to control condition.
3. To determine adherence rates to the exercise intervention.
4. To examine FCs perceptions about the effects of the intervention including the benefits of exercise and the feasibility of participating in exercise while in the caregiver role.
5. To examine whether physical activity levels obtained during a 12 week exercise program are maintained during a 12-week maintenance exercise program for FCs.

3. Study design

A concurrent mixed method design, as outlined by Greene [44], will be used. As the focus of this work is to investigate a novel way of supporting cancer FCs, both quantitative and qualitative data can provide an expanded understanding of the benefits and perceived value of an exercise intervention [44]. Further, mixed methods are increasingly utilized to examine outcomes for behavioral interventions and help to highlight some of the contextual factors needed for knowledge translation [45].

The quantitative portion of the study will be a randomized controlled trial with an immediate exercise intervention group (IEG) and a delayed exercise intervention group (DEG) with a 50/50 allocation ratio. The DEG will serve as a control group during the 12 weeks of the intervention and will not have any active treatment. The DEG will then be enrolled into the exercise intervention. Wait list control groups are common in exercise interventions and are more acceptable to research ethics boards and patients versus no treatment control groups. Both groups will eventually be enrolled in the maintenance exercise intervention (M) after completing 12 weeks of the exercise program. Flow through the study is depicted in Fig. 1.

4. Methods: participants, intervention, and outcomes

4.1. Study setting

The trial will be conducted at a research lab (Health and Wellness lab) housed within a University in a large city in Canada. The research lab has a dedicated exercise space that is separate from the general university population and contains aerobic and resistance training equipment. As it is within a larger university, there is access to other exercise space (large gym facility and running track), regulated response to emergency protocols, and standard fitness testing protocols and equipment. There is also a research coordinator, research assistants, and exercise physiologists trained in physical fitness testing and program design for cancer and adult populations with co-morbid illness, employed by the lab. The research lab also educates and trains those who are already certified personal trainers to work with cancer patients and others persons with co-morbid illness.

4.2. Eligibility criteria and screening

Based on previous research with this population (unpublished thesis) and difficulty in recruiting FCs to patients with specific types of cancer (e.g. breast), it was decided to include all types of cancer patient FCs. For this study, FCs are defined as "a family member or friend who provides unpaid physical, psychological/emotional, or instrumental