

A Social Ecological Approach to Understanding Physical Activity

A mixed methods exploration of the individual, family and neighbourhood characteristics that influence physical activity among Family Heart Health: Randomized, Controlled Trial participants

Dana L. Riley

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Faculty of Graduate and Postdoctoral Studies
Institute of Population Health
University of Ottawa

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ABSTRACT

The purpose of this thesis was to better understand physical activity (PA) behaviour change among family members of people with coronary heart disease (CHD) who participated in a randomized controlled trial of a behavioural risk reduction intervention.

Study 1 - Individual

The purpose was to determine whether a 12-week behavioural risk reduction intervention caused self-reported MVPA to increase and to identify associated Theory of Planned Behaviour (TPB) constructs. Three hundred twenty-four physically inactive (<150 minutes/week moderate-vigorous PA) participants were included. Intervention participants were significantly more likely to meet PA guidelines at 12-weeks (OR=3.54, 95% CI 2.22-5.63, $p<.001$), which was significantly correlated with increases in TPB constructs.

Study 2 - Family

Semi-structured interviews were conducted with 36 participants to elicit perceptions of factors that influence PA. Interviews were audiotaped, transcribed, coded and analyzed. Spouses were more likely to engage in PA with their spouse after the CHD event; however this may be limited by their partners' capabilities. The data suggests awareness of an increased susceptibility to CHD is not stimulating participants to increase their own

PA to prevent future risk, particularly among offspring, but they may take other actions. The shared family environment can promote PA, although intensity may be limited.

Study 3 - Neighbourhood

Self-reported PA from a prospective behavioural risk reduction intervention was explored in the context of objectively measured Walk Scores and neighbourhood walkability in Ottawa, Canada. Participants in the intervention arm had significantly higher odds of meeting PA guidelines at 12-weeks compared to the standard care control group. This was not influenced by Walk Scores or walkability. This individual-level intervention was effective in assisting participants to overcome potential structural barriers presented by their neighbourhood to meet PA guidelines at 12-weeks.

Conclusion

This thesis provides novel insights into the relationships between PA and factors at the individual, family and neighbourhood levels. Specifically, the FHH-RCT intervention was effective for increasing self-reported moderate-vigorous PA, regardless of Walk Score or neighbourhood walkability. To gain even greater health benefits, family members may need additional information or intervention in order to translate their perceived future risk of CHD into current PA behaviour change.

CO-AUTHORSHIP

The manuscripts presented in this thesis are the works of Dana Riley in collaboration with her co-authors. Dana Riley was responsible for developing the research question, identifying methods to be used, completing the data analysis and writing the initial drafts of all three manuscripts.

Manuscript 1: *Effects of a 12-week behavioural risk reduction program on physical activity levels in family members of patients with coronary heart disease: Secondary outcomes from a randomized controlled trial.* This manuscript is presented for submission to Annals of Behavioral Medicine. The co-author for this manuscript is Dr. Robert D. Reid. Dr. Reid provided valuable input with regards to the design, statistical analyses, interpretation of results and provided editorial feedback on successive drafts of the manuscript. This research was funded by grants secured by Dr. Reid.

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CHAPTER 1: INTRODUCTION

1.1 Overview and Purpose of the Thesis

Using a social ecological perspective, the purpose of this thesis is to examine intra-individual factors and factors in the social and physical environments that influenced physical activity (PA) patterns among participants in a randomized, controlled trial that compared a 12-week behavioural risk reduction intervention to standard care for cardiovascular risk factor reduction among family members of people with coronary heart disease (CHD).

Manuscript 1 (Individual) focuses on the effect of the intervention for increasing PA by comparing PA outcomes between the intervention and standard care control groups among participants who were not sufficiently physically active at study entry. Once the relationship between the intervention and PA was established, constructs from the *Theory of Planned Behavior* were examined as potential correlates of PA behaviour change.

Manuscript 2 (Family) focuses on the role of recent hospitalization of a spouse or parent for CHD in activating family members to engage in PA; a *Family Systems Perspective* and a qualitative research design were used.

Manuscript 3 (Neighbourhood) examines the impact of the neighbourhood on PA outcomes among participants. Individual-level data from the randomized, controlled trial were linked to data from the Ottawa Neighbourhood Study to explore the relationship between achieving PA targets (i.e. ≥ 150 minutes of moderate-vigorous PA per week) and neighbourhood environment.

1.2 Rationale

Physical inactivity presents a major challenge for public health. Almost half (48%) of Canadians were considered inactive (equivalent to less than 30 minutes of walking per day) in their leisure time based on self-report data from the Canadian Community Health Survey (1). Furthermore, objective data from the Canadian Health Measures Survey indicate that approximately 15% of Canadian adults are accumulating 150 minutes or more of moderate-vigorous PA per week (2). Physical inactivity is a risk factor for obesity and several chronic diseases, including CHD (3), the leading cause of death in Canada (4). CHD in Canada and in most parts of the world is related to the presence of known coronary risk factors, particularly physical inactivity, smoking, abnormal blood lipids, and hypertension (5). Engaging in regular PA has cardioprotective benefits, and can reduce the incidence of cardiovascular events (6, 7). In men and women without pre-existing CHD, engaging in moderate-vigorous PA can reduce the risk of developing CHD by up to 50% (8).

Family members (including siblings, offspring and spouses) of patients with CHD may themselves be at increased risk for developing CHD for genetic, biochemical and/or behavioural reasons (9-13). Family history of CHD has been identified as an independent risk factor for CHD (11, 13) and familial aggregation of CHD has been described. Much of this disease aggregation can be explained by familial aggregation of established coronary risk factors (14-17). Targeted screening and interventions directed towards family members of those with established CHD may be an effective way to identify persons at high risk and link them to effective risk factor modification.

The Family Heart Health Program is a 12-week behavioural risk reduction intervention, developed by behavioural and clinical scientists at the University of Ottawa Heart Institute (UOHI), aimed specifically at family members of patients with CHD who have one or more modifiable risk factors. The intervention was tested in a randomized controlled trial, which compared the Family Risk Reduction (FRR) intervention group (consisting of weekly telephone lifestyle coaching sessions with a health educator for 12 weeks) versus standard care (SC). While individual behaviour change was the goal of the intervention, the focus of the current research is to gain greater understanding of the intra-personal factors and factors in the social and physical environment that influence PA so that future prevention programs may incorporate the broader, structural dimensions that influence health, and more specifically, PA (18).

Evidence supports the relationship between intra-individual factors and factors in the social and physical environments that influence health behaviours (19-23). Consistent with a social ecological approach, broadening the focus to incorporate an understanding of the impact of the social and physical environment on health behaviours, such as PA, allows greater insight regarding avenues for maximizing the “fit” between the person and their environment (24). To gain greater breadth and depth of knowledge regarding the multiple factors that influence PA participation and subsequent health outcomes, a more in-depth evaluation is warranted.

1.3 Background

1.3.1 Theoretical Background

The current research is informed by the theoretical assumptions of population health, which look to the broader social and physical environment in which people live. Dunn and Hayes state that “a population health perspective is fundamentally concerned with the social structural nature of health influences, and, although it is embodied in the health outcomes experienced by specific individuals, the domains of influence that shape health experiences transcend the characteristics or circumstances of any one individual” (25). The population health approach is not focused on the individual’s “choice” to engage in a healthy or health damaging behaviour, but rather seeks to understand the characteristics of the social and physical environments that create variations both between and within populations. This approach is concerned with the distribution of determinants of health throughout the population and the interactions that exist between these determinants (26).

Within the population health framework, a social ecological theoretical perspective permits the exploration of the connections between individuals and their surrounding environment, to understand health behaviour by attending to the nature of people’s interactions with their social, physical and cultural settings (27). Social ecological theory considers the various levels of influence on health behaviours, including individual, interpersonal, organizational, community and public policy factors that facilitate or impede behaviour change (28). The interactions between these multiple levels of influence create a synergistic effect above and beyond individual

characteristics (29). The physical, social, economic and political aspects of the surrounding environment over the life course contribute to variations in the adoption of both enhancing and damaging health-related behaviours. Interventions to promote PA need to consider both the individual and the social and physical environment in which they live (30). If the environment supports unhealthy behaviours or discourages healthy behaviours, it is unrealistic to expect positive health behaviour changes among large segments of the population (31-33). People living in “less supportive” environments may respond less favourably to intervention, after controlling for other factors. Thus, if the desired outcome is a specific behaviour change, such as increasing PA levels, this must be conceptualized as a function of multiple individual, interpersonal, organizational, community and public policy factors.

There is ongoing debate about the relationship between place and health, and how this should be conceptualized in health research (34, 35). Neighbourhood factors are important for understanding the relationship between place and health, providing a potential avenue for implementing and managing policy interventions. Ross provides two overarching perspectives through which neighbourhood may influence health behaviours and outcomes; the “contagion perspective” posits that people are influenced by others in their neighbourhood, thus creating social norms and traditions, and the “structural perspective” refers to the resources and opportunities that either constrain or facilitate health behaviours (36). MacIntyre and colleagues argue for the inclusion of the collective dimension in explorations of the relationship between place and health, which goes beyond the compositional and contextual explanations to

incorporate socio-cultural and historical dimensions of communities or neighbourhoods (37). Physical (in)activity may be a normative behaviour that is largely influenced by the collective social structure, which is not entirely separate from the context in which individuals live.

Frohlich and colleagues have expanded this notion of collective to explain how “collective lifestyles” of various subgroups within populations may influence health behaviours (38, 39). In arguing for a better understanding of the influence of context on disease, the researchers propose a reframing of lifestyle as an attribute of the collective rather than the individual. A key concept from *Collective Lifestyle Theory* is recursivity, which refers to the bidirectional relationship between the individual and their surrounding environment that creates and recreates values and behaviours (39). Applying this theory may help in generating an understanding of how the various determinants of health influence and reinforce PA behaviours, particularly in the context of understanding the role of the family in shaping PA behaviour and its impact on PA behaviour change.

The aforementioned authors provide conceptual models for understanding how the social and physical environment may influence health behaviours, which can be applied to the familial level. The family is part of the social and physical environment closest to the individual; members of the family form close intrapersonal ties. Although the specifics and idiosyncrasies of these relationships are highly variable, the family provides a unique setting for understanding coping and adaptation mechanisms when faced with chronic illness, such as CHD. Since the participants in the FHH-RCT have

experienced CHD in a member of their family (spouse, sibling or parent) within the past five years, explorations into the role of the family are warranted.

Family Systems Theory can be used to gain greater understanding at this level of influence. The family operates in a state of equilibrium which is disturbed in response to the illness or death of one of its members. Since the interactions and relationships between family members are reciprocal, changes in the health status of one family member influence the family as a whole (40). In the aftermath of illness, families go through the process of role reorganization to re-establish equilibrium. During this process, family members incorporate their values, attitudes and beliefs to re-establish behaviour patterns to continue operating in a stable manner, restoring the family's balance. As adaptation proceeds, the individual recommendations (i.e. increased PA) for the ill patient may be assimilated into the daily functioning of the family at large (41). Throughout this process, the family's resiliency is challenged; if the stressor (i.e. illness) encourages new capabilities without overwhelming the family with demands, improved functioning within the family structure can be achieved (42).

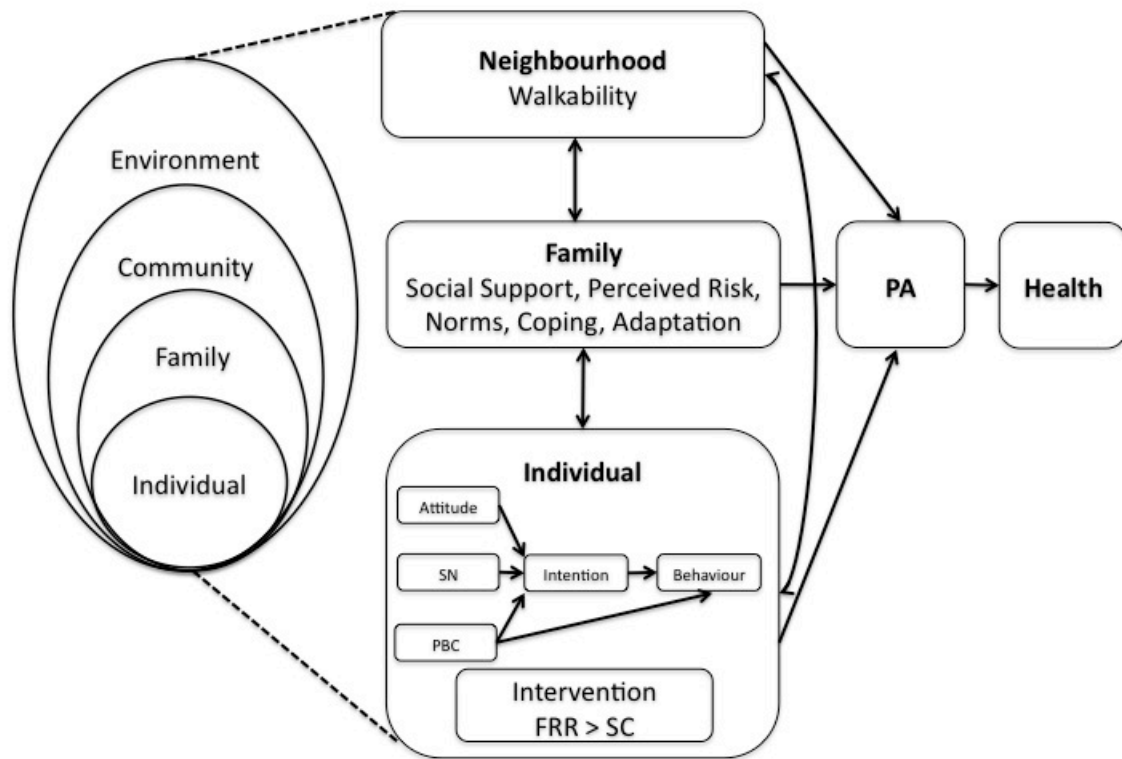
Finally, within the context of the family, Ajzen's *Theory of Planned Behaviour* (TPB) provides insight into how these assimilations translate into individual behaviour change (43). According to the TPB, behavioural beliefs determine the individual's attitude towards the behaviour, normative beliefs (i.e. perceived behavioural expectations of important others) formulate the subjective norm, and control beliefs relate to the individual's resources or capabilities to perform a behaviour, resulting in their perceived behavioural control (44). These beliefs reflect the underlying cognitive

structure that influence the performance of the behaviour (45). These three main constructs exert their influence on the desired outcome (i.e. the target behaviour) via intention, which is a direct antecedent of the behaviour. Perceived behavioural control exerts its effect on the target behaviour both directly and indirectly (via intentions). Perceived behavioural control represents the individual's appraisal regarding the effort required to adopt the behaviour, including personal resources and skills (46). Perceived behavioural control encompasses both internal (i.e. self-efficacy) and external (i.e. personal/environmental barriers) aspects of control (47). In situations where volitional control may be diminished (i.e. when faced with significant personal and/or environmental barriers), perceived behavioural control may act directly on the target behaviour, reflecting the individual's self-efficacy, or willingness to exert additional effort to overcome these barriers and achieve the desired outcome (45). Several reviews and meta-analyses provide empirical support for intentions' predictive ability with regards to PA (47, 48).

Positive changes in PA as a result of participation in the FHH-RCT need to be examined within the broader social and physical environment to gain a greater understanding of the factors that facilitate behaviour change within the context of this intervention. The aforementioned theories provide the overarching framework and guiding principles for the subsequent analyses at the individual, family and neighbourhood levels, which is depicted in Figure 1.

1.3.2 Conceptual Model

Figure 1. Conceptual Model



SN: Subjective Norm

PBC: Perceived Behavioural Control

FRR: Family Risk Reduction Intervention Group

SC: Standard Care Control Group

PA: Physical Activity

In the conceptual model, the social ecological perspective is depicted on the left, highlighting the individual embedded within multiple levels of influence. Factors at the individual, family and neighbourhood level influence PA both directly and through interactions. PA, in turn, influences health.

1.4 Literature Review

1.4.1 Physical Activity and Coronary Heart Disease

There is a well-established body of literature that provides evidence for the cardioprotective benefit of PA. Numerous cohort studies have repeatedly demonstrated the inverse relationship between PA and cardiovascular disease (49-53). Physical inactivity is a significant independent risk factor for myocardial infarction, a common manifestation of CHD, in both men and women worldwide (5). While the inverse relationship between PA and CHD is well-established, the biological mechanisms and the role of various pathways underlying this association remain unclear. Some of the proposed mechanisms by which PA may reduce CHD risk include through improvements in cardiac endothelial cell function, collateral circulatory changes, or through improved oxygen uptake (54). In the Women's Health Study, potential mediating factors that may contribute to the activity-related risk reduction in CHD were examined in 27,055 women who were followed up over a mean period of 10.9 ± 1.6 years (55). Inflammatory/hemostatic biomarkers made the largest contribution to the lowered risk of CHD observed among physically active women, followed by blood pressure, lipids, and body mass index (55). Despite the lack of definitive knowledge regarding the exact mechanisms by which PA affects CHD, the relationship between increased PA and CHD is evident. Since PA is a well-documented modifiable risk factor for CHD, continued research into interventions to increase PA for the purpose of preventing CHD is warranted.

1.4.2 Family History and Coronary Heart Disease

A positive family history for CHD is generally associated with about a 1.5- to two-fold increase in CHD risk among first-degree relatives (56-60). In an analysis from the multinational INTERHEART study, which included 12,149 cases of first myocardial infarction (MI) and 14,467 matched controls, self-reported parental history of MI in either parent was associated with a near doubling of risk of MI, regardless of background risk factors, country or age (61). Clustering of CHD in families has also been demonstrated in several longitudinal studies. In the Framingham cohort study of 2,336 men and 2,873 women, 3,933 participants were evaluated for parental history of coronary artery disease (CAD) and CAD outcomes during the study period. Parental history of CAD was found to be an independent risk factor for the development of CAD in both men and women (62).

In the prospective Nurses' Health Study, follow-up data was collected on 117,156 women who were free from known cardiac disease at enrolment to investigate the role of positive parental history of CHD on subsequent development of CHD (63). Among women with a positive parental history of CHD (at age ≤ 60 years), the relative risk for nonfatal myocardial infarction was 2.4 (95% CI: 2.0 to 3.0), for fatal coronary heart disease was 4.9 (95% CI: 3.3 to 7.1) and for angina pectoris was 3.2 (95% CI: 2.5 to 4.0), controlling for important covariates, including age, hypertension, smoking, diabetes, high cholesterol, obesity, use of oral contraceptives, menopause and postmenopausal hormone use (63).

In the European Prospective Investigation of Cancer (EPIC)-Norfolk cohort, which followed 10,288 men and 12,553 women aged 40-79 years for a mean of 10.9+/-2.1 years, a family history of CHD was associated with an increased risk of future CHD (Hazard Ratio = 1.74, 95% CI: 1.56 to 1.95), controlling for established risk factors (56).

In the PRIME study, which examined the 5-year incidence of CHD in a sample of 9,758 asymptomatic males, those with a strong family history of CHD showed a relative odds of developing CHD of 1.93 (95% CI: 1.25 to 3.00) controlling for age and other risk factors (57). Similarly, in the Reykjavik prospective cohort study of 9,328 males and 10,062 females (mean follow-up of 18 and 19 years, respectively), the hazard ratio for the development of CHD among men and women with a positive family history of CHD was 1.66 (95% CI: 1.51 to 1.82) and 1.64 (95% CI: 1.43 to 1.89), respectively, controlling for other risk factors (59).

These longitudinal cohort studies provide strong evidence to conclude that a family history of CHD is an independent risk factor for the development of CHD. In order to examine how family history might interact with other CHD risk factors, the Multi-Ethnic Study of Atherosclerosis (n=5,347 asymptomatic individuals) found that the odds ratio of coronary artery calcification, a precursor to CHD, was significantly higher for participants with a family history of premature CHD (Odds Ratio = 1.94, 95% CI: 1.64 to 2.29) (58). Given the well-documented risk of CHD among individuals with a positive family history, the family unit provides a unique opportunity for the investigation of CHD prevention via health behaviours, such as PA.

1.4.3 Benefits and Individual Correlates of Physical Activity

The individual benefits of PA are extensive and well documented (64), including decreased risk of mortality associated with cardiovascular disease (65), some forms of cancer (66), type 2 diabetes (67) and obesity (68), greater longevity (69, 70) and improved functioning in old age (71-73). Even in the presence of a family history of CHD, participation in at least moderate-level PA can decrease the odds of developing CHD compared to sedentary individuals (7). The evidence also suggests that the relationship between PA and health is linear, such that incremental increases in PA can lead to additional health benefits (74), and that these benefits outweigh the increase in risk (i.e. such as the increased risk of injury) (75).

Given the numerous benefits associated with PA, many researchers have sought to determine which factors predict physical (in)activity. For example, in a cross-sectional study to examine the relationship between dog ownership and walking, Brown et al. (2006) found that intention, perceived behavioural control and dog obligation influenced walking behaviour (76). In a qualitative study of older women, Conn et al. (2003) found that control beliefs and behavioural beliefs were significant predictors of exercise behaviour (77). In a systematic review of potential environmental correlates of PA among adults, Wendel-Vos et al. (2007) found that, at the individual level, social support and companionship for PA were associated with a variety of PA behaviours (78).

Among a diverse population of employed adults, analysis of focus group transcripts revealed that time was a common barrier and self-reported good health was an enabling factor for participation in worksite PA, and there were socioeconomic

differences in the motivators for exercise (79). Similarly, Chiang et al. (2008) found that environmental factors, exercise program characteristics, social support and individual factors influenced adherence to a PA program (80). Further evidence at the individual level suggests that older women may have uncertainties regarding the risks and benefits associated with engaging in PA (81); minority women report consistent barriers to PA including time, availability, safety and motivation, and women may perceive their activities of daily living as sufficient for meeting PA recommendations (82). Since PA is equally beneficial to men and women, an understanding of gender differences in the factors associated with PA is warranted.

1.4.4 Individual-Level Interventions to Reduce CHD Risk

The high prevalence of CHD and the potentially modifiable risk factors associated with its development have led numerous researchers to explore interventions to modify CHD risk factors and subsequent health outcomes, including morbidity and mortality. The majority of individual-level interventions designed to reduce CHD risk usually employ educational or counselling methods or some combination of both.

A Cochrane systematic review of randomized controlled trials of interventions to encourage PA among sedentary individuals with a minimum of six months of follow-up found a positive, moderate sized effect of PA interventions on increasing self-reported PA (19 studies; 7,598 participants, pooled standardized mean difference random effects model 0.28, 95% confidence interval 0.15 to 0.41) (83-89).

A recent Cochrane systematic review of multiple risk factor interventions for primary prevention of coronary heart disease provided somewhat disappointing results

(90). In the review of 55 trials (163,471 participants) with a median duration of 12 months follow-up, the authors concluded that these multiple risk factor interventions aimed at behaviour change do not reduce total or CHD mortality or clinical events in general populations (90). However, these interventions may be effective in reducing mortality in high-risk hypertensive and diabetic populations (90), who may be more comparable to the FHH-RCT population in the current analysis since they are also considered high risk due to their positive family history of CHD.

There is evidence that interventions can increase PA but this is not clearly linked with changes in hard endpoints, such as decreased morbidity or mortality. Long-term studies that link health outcomes to behavioural interventions are lacking. The FHH-RCT is a behavioural intervention that may be effective for increasing PA and improving health outcomes.

1.4.5 The Impact of Family on Physical Activity Behaviour

While an understanding of the individual determinants of PA is valuable, this approach has received considerable criticism because it places emphasis on the individual while failing to consider the context in which health behaviours occur (24, 91, 92). Beyond the individual, PA is largely influenced by the social and physical environment (64, 93, 94). Yen and Syme (1999) state that “the social environment includes the groups to which we belong, the neighborhoods in which we live, the organization of our workplaces, and the policies we create to order our lives” ((18), p. 288).

There is a variety of literature that highlights the impact of the family on PA. Over a five year follow-up period, results from the San Antonio Family Heart Study (n=

1,364) show that PA behaviours accumulate within families (95). In a study of sons ($n = 571$) of parents with premature CHD, only 25% of sons were engaging in regular exercise, despite elevated concerns about future risk (15). Similarly, in the Quebec Family Study, familial aggregation of physical activity was investigated among 696 subjects from 200 families (312 parents; 384 offspring; mean family size 3.6 ± 2.0 individuals) (96). The authors found that there was 1.40 to 1.52 times more variation in PA characteristics between families than within families, which suggests that genes and factors in the shared familial environment (social and physical) contribute to the heritability of PA patterns (96).

The spousal relationship also provides an important context for understanding the impact of the family on CHD risk factors. To explore the presence of CHD risk among partners of men with acute myocardial infarction (AMI), Wood and colleagues surveyed a sample of 89 female partners and compared them to 133 matched controls (97). The researchers found that elevated body mass index ($OR = 2.17$, 95% CI 1.11 – 4.23) and cholesterol levels ($OR = 2.21$, 95% CI 1.08-4.49) were significantly more common in partners of those with AMI; however, PA levels were not reported (97). To examine the role of social support for promoting adherence to an exercise program, Wallace et al. (1995) compared married pairs who spontaneously joined an exercise program to married singles in the same program (i.e. individuals who were married but did not have their spouse accompanying them) (98). Married couples who attended the exercise program together had significantly higher attendance ($54.2\% \pm 10.3$ vs $40.3\% \pm 14.3$) and lower drop-out rates (6.3% vs 43.0%) than married singles, suggesting that

partnership is an important factor in initiating and maintaining PA changes (98). Similarly, research on the impact of CHD on couples found that three distinct coping patterns emerged: (1) the illness is transformative, bringing the couple closer together, (2) the illness evokes fear, so the couple approaches new routines and tasks together, or (3) the illness presents a missed opportunity for change, and the couple maintains their relationship and behaviour patterns as usual (99). Both the existence of a spousal relationship and its quality can be important factors in how a couple deals with CHD. Looking at other psychosocial correlates of PA, research with both women and men has indicated that higher work-family conflict decreases the odds of achieving PA targets (100). These studies illustrate the importance of the familial environment in shaping PA behaviour patterns.

When a person experiences chronic illness, the repercussions of the illness often extend beyond the individual and influence the family (101). Families are required to adapt to the changes that the illness has presented, going through the processes of coping and reorganization to continue functioning (42, 102, 103). Further investigations into how the family adapts to chronic illness and subsequent PA behaviour changes are warranted.

1.4.6 Family-Based Interventions to Reduce CHD Risk

Family-based interventions may be an effective strategy for identifying persons at risk and linking them to behaviour change interventions to reduce their risk of CHD. The importance of screening family members of patients with established CHD is documented as an important preventive strategy (10, 17, 104). However, few studies

have examined behavioural risk reduction interventions implemented at the unit of the family.

The Tromso Survey: The Family Intervention Study identified 1,373 men who were at high risk of CHD based on cholesterol levels (low high density lipoproteins and/or high total cholesterol) (105). These men and their families (including 1,143 wives and 2,838 children) were randomly allocated to the intervention (n=673 men) or control (n=700 men) groups. Six hundred eight (90.3%) men and their families completed the intervention, which included a letter outlining their increased CHD risk, risk factor measurements among family members, two home visits, physician counselling, quarterly newsletters and two personal telephone calls during follow-up (105). At the 6-year follow-up, intervention group participants showed several significant improvements in CHD risk compared to control group participants, including decreased coronary risk scores, total cholesterol and serum triglyceride levels in men; there was no significant change in the PA behaviours of family members (105). However, the intervention offered to participants in the Tromso Survey was far less intensive in terms of the frequency of contact than the FHH-RCT intervention described here.

The British Family Heart Study identified men through primary care practices and invited them and their families (n=12,472) to participate in a randomized controlled trial of a nurse-led behavioural intervention (106). The intervention included a screening interview, where demographic, lifestyle and medical data were collected, a booklet for recording personally negotiated behaviour changes, and follow-up visits every two, three, four, six or 12 months based on CHD risk at study entry, with higher risk indicating

a greater frequency of visits (106). The authors found a 16% reduction in overall CHD risk scores after one year in men and women in the intervention group, with PA outcomes not reported (106). A secondary analysis of data from this same study found that risk factor levels and changes were correlated between partners, which led the authors to conclude that targeting couples may be more effective for reducing CHD risk, possibly due to mutual reinforcement of lifestyle changes (107). As suggested by these authors, alternative, more efficient strategies for the reduction of CHD risk need to be developed and evaluated, such as targeting individuals at high risk.

The Family Atherosclerosis Risk Intervention Study (FARIS) identified patients who had recently experienced a cardiac event or procedure (acute myocardial infarction, coronary artery bypass graft or percutaneous transluminal coronary angioplasty) and offered screening to them and their families. Six hundred twenty-eight patients (516 male, 112 female) and their family members (n=1723) were enrolled and screened (14). Family members had significantly worse risk factor profiles (based on lipid profiles, body mass index (BMI), waist circumference, blood pressure, and smoking status) at baseline than a comparable randomly selected age- and sex-matched sample; however, PA outcomes were not reported (14).

In the ProACTIVE UK study of sedentary adults (n=365) who had a parental history of Type 2 diabetes, participants were randomly assigned to one of three groups: a telephone-based intervention, a face-to-face, home-based intervention or a comparison group, which included an advice leaflet (108). Both interventions commenced with a face-to-face introduction in the participant's home. The telephone-

based intervention included four 45-minute calls and two 15-minute calls during the first five months followed by seven monthly contacts by mail. The face-to-face home-based intervention included four 1-hour home visits and two 15-minute telephone calls during the first five months and monthly 30-minute telephone calls for the remainder of the year (108). At the 1-year follow-up, there was no significant difference in PA outcomes between participants who received an advice leaflet and those who received a more intensive telephone or in-person TPB-based intervention (108). This study had a less intensive contact frequency than the FHH-RCT and the parental history of disease was Type 2 diabetes, not CHD, which may influence the participants perceived susceptibility or severity and subsequent behaviour change.

EUROACTION was a paired, cluster randomized controlled trial that investigated the impact of a nurse-coordinated multidisciplinary, family-based intervention for preventive cardiac care delivered in two settings, hospitals and primary care practices, compared to usual care in both locations (109). Both interventions commenced with a nurse assessment of risk factor profiles for cardiac (hospital) or high-risk (primary care) patients and their families; family support packs and personal record cards for lifestyle and risk factor targets, including physical activity goals, were provided. In the hospital-based intervention, participants attended eight weekly sessions with a multidisciplinary team, attended a group workshop and a supervised exercise class; participants were reassessed after 16 weeks and a report was sent to their primary care physician. In the primary care-based intervention, couples were assessed by the nurse and physician and attended weekly group workshops. At the 1-year follow-up assessment, participants in

both the hospital and primary care intervention groups were significantly more likely to achieve physical activity targets (30-45 minutes of moderate intensity physical activity 4-5 times per week) than usual care participants (109).

In the FIT Heart randomized controlled trial, which is most similar to the FHH-RCT intervention, 501 healthy adult family members of patients hospitalized with cardiovascular disease were randomly allocated to receive the intervention (personalized risk factor screening, behaviour change counselling, and progress reports to physicians) versus control. At the 1-year follow-up, both intervention and control groups significantly reduced their low-density lipoprotein (LDL) cholesterol levels (-4.4 mg/dL and -4.5 mg/dL, respectively), intervention participants had significantly better diet scores ($P<0.04$), and high-density lipoprotein (HDL) cholesterol declined significantly in the control group but not in the intervention group (-3.2% [95% CI: -5.1 to -1.3] versus +0.3% [95% CI: -1.7 to +2.4]; $P<0.01$) (110). Intervention participants were significantly more likely than controls to exercise >3 days per week ($P=0.04$) (110).

Based on these previous studies, it remains unclear how effective a theory-based, behavioural intervention is at improving CHD risk factors, especially PA. There is a need to confirm the effectiveness of theory-based, behavioural interventions for CHD risk reduction. Continued investigations into the impact of such interventions on CHD risk reduction, particularly PA, are needed.

1.4.7 Physical Activity and Neighbourhood

There are a wide range of social and physical attributes of neighbourhoods that have been assessed in relation to PA. The numerous environmental features that may

influence PA include physical features of the area common to all residents, the availability of healthy home, work and play environments, the provision of services to support daily living, sociocultural features of neighbourhoods, and the reputation of an area (111). A brief overview of these findings will highlight the importance of continued research and analysis in this domain.

Several reviews have demonstrated evidence that supports the relationship between the environment and PA. A review of research examining the relationship between the built environment and obesity supports a link between BMI and the social and physical characteristics of neighbourhoods (112). In a systematic review of 47 observational studies, Wendel-Vos et al. found that social support, connectivity of trails, and availability of recreation facilities have demonstrated associations with PA (78). A review of PA and environment research in the health field from an urban planning and transport perspective supports the association between the neighbourhood environment and PA, with accessibility of recreational facilities and local destinations, safety, visual quality, and neighbourhood walkability/bikability showing consistent relationships with PA (113). In a review of the built environment correlates of walking, density, distance to non-residential destinations and land use mix were positively associated with walking for transport; however, findings for route/network connectivity, parks and open space, and personal safety were less consistent (114). As studies are systematically reviewed and meta-analyzed, the link between the physical environment and PA will continue to become more clearly articulated.

Looking more specifically at the existing research, Kazynski et al. (2008) analyzed characteristics of parks in relation to PA behaviours and found that certain features of parks, notably the presence of paved trails, unpaved trails and wooded areas, were predictive of the occurrence of PA (115). In a study of middle aged women, King et al (2000) found that lack of hills in one's neighborhood, the absence of enjoyable scenery, and infrequent observation of others exercising in one's neighborhood were related to physical inactivity (116).

Neighbourhoods with greater residential street density, greater street connectivity and greater land use mix are also predictive of walking among residents (113, 117-119). In a cross-sectional analysis that included 16,543 adults (5,017 women, 11,526 men) aged 18-90 years in Texas, an association between neighborhood walkability and cardio-respiratory fitness and BMI was found (120). Consistent with these findings, a study that used objective measures of PA (accelerometers) and objective measures of the physical environment (a walkability index developed using a Geographic Information System) found that residents in the highest walkability neighbourhoods were 2.4 times more likely (95% CI: 1.18 to 4.88) than individuals in the lowest walkability neighbourhood to meet the recommended levels of moderate PA (30 minutes or more) per day (121). In a sample of 1,200 adults aged 20-65 years in Ghent, Belgium, accelerometer-assessed moderate-vigorous PA (MVPA) mediated the relationship between neighbourhood walkability and BMI and waist-to-hip ratio, which suggests that PA may be an important factor in the pathway between PA, neighbourhood walkability and health status (122). In a 6-year follow-up on 500 adults

living in Edmonton, Alberta, Canada, younger adults, those in lower socioeconomic status (SES) neighborhoods and those who perceived that traffic made it unpleasant to walk were at greater risk of increased BMI, however neighbourhood walkability was not significantly associated with changes in BMI (123). These studies highlight some of the physical attributes of the environment that have been explored in relation to PA behaviours and demonstrate the need for continued research into the role of neighbourhood characteristics and PA outcomes.

Several researchers have found that merely residing in a more affluent neighbourhood may increase PA, over and above individual demographic characteristics (e.g. age, gender, social class, income) (111, 124, 125). In a comparative case study that examined the inter-relationship of neighbourhood SES and walkability characteristics in Ottawa, Ontario, Canada, higher SES neighbourhoods provided more favourable environments for walking than their lower SES counterparts and inequities contribute to these differences (126).

The understanding of the attributes of environments that promote PA behaviour highlights the need to link the individual to the broader context of peoples' lives. In a social ecological project that examined the relative influence of individual, social environmental and physical environmental determinants of recreational PA, Giles-Corti et al. (2002) found that recreational facilities located near home were used by more respondents than facilities located elsewhere (127). Accessible facilities determined whether or not they were used for PA; however, the influence of the physical environment was secondary to individual and social characteristics. This suggests that

access to a supportive physical environment is necessary, but may be insufficient to increase recommended levels of PA in the community.

As suggested by Giles-Corti et al (2003), more research on the association between PA in the general population and the environment is needed including a wider range of objectively measured environmental factors (128). In a study exploring the associations between PA and measures of the built environment, McGinn et al. (2007) found that the combined effect of both objective and perceived environmental measures of the built environment exerted independent associations with PA (129). However, several studies have shown no relationship between perceived environment and PA (23, 116, 130). Given these inconsistencies, there is a need to incorporate both perceived and objective measures of the physical environment into the same study to gain greater insight regarding their influence on PA behaviours (131).

1.4.8 Summary of Literature Review

Based on the review of the literature, it is clear that a variety of factors at multiple levels influence whether or not people engage in PA. The effectiveness of targeted interventions, such as the FHH-RCT, for increasing PA levels is unclear. Furthermore, it remains unknown how variations at the level of the individual, the family, and the neighbourhood will influence participants' ability to achieve recommended PA targets in the context of such an intervention. This provides support for the current analysis, which aims to investigate the impact of the FHH-RCT intervention on PA, taking into

account the social ecological theoretical perspective and incorporating analyses at the individual, family and neighbourhood levels.

1.5 Research Questions

1. i) At the individual level, does the FHH-RCT intervention cause self-reported PA to increase over the 12-week intervention period?

ii) What factors at the individual level are associated with achieving PA targets during the 12-week intervention period?
2. What is the role of the family in activating participants to engage in PA behaviour change?
3. i) How does neighbourhood walkability influence self-reported PA outcomes among FHH-RCT participants at baseline?

ii) Is there an interaction between neighbourhood walkability and the effectiveness of the intervention on self-reported PA outcomes at 12-weeks?

1.6 Hypotheses

1.6.1 Study 1 (Individual)

It was hypothesized that (i) participants in the family risk reduction (FRR) intervention group would significantly increase their MVPA during the 12-week intervention period compared to the standard care (SC) control group and (ii) constructs from the Theory of Planned Behavior would partially mediate this relationship.

1.6.2 Study 3 (Neighbourhood)

It was hypothesized that (i) participants living in high walkability neighbourhoods would be more likely to meet the PA guidelines at baseline compared to participants living in low walkability neighbourhoods and (ii) walkability would interact with the intervention arm (FRR vs. SC), with participants allocated to the intervention and living in the highest walkability neighbourhoods having the highest odds of achieving the PA target (≥ 150 minutes MVPA/week) at 12-weeks.

1.7 Research Participants

The participants for the current research were those individuals in the FHH-RCT at the University of Ottawa Heart Institute (UOHI) who met the following inclusion criteria: 1) spouse, offspring or sibling of patient hospitalized at UOHI within the past 5 years for: acute coronary syndrome, elective percutaneous coronary intervention or coronary artery bypass surgery; 2) 20 to 80 years of age; 3) willing to provide informed consent; 4) at least one of the following modifiable risk factors: i) current smoker, ii) systolic blood pressure (BP) ≥ 140 mmHg and or diastolic BP ≥ 90 mmHg and/or currently on medication to treat high blood pressure, iii) total cholesterol/HDL-cholesterol ratio ≥ 5.0 and/or on antilipemic medication, iv) abdominal obesity (for men, waist circumference > 102 cm; for women, waist circumference > 88 cm) or v) physical inactivity (less than 150 minutes per week of MVPA); and 5) geographically available for assessment, intervention and follow-up. Exclusion criteria were as follows: 1) unable to understand

English or French; 2) history of diabetes mellitus or any atherosclerotic disease; 3) fasting glucose ≥ 7.0 mmol/L at screening; 4) presence of life threatening illness; 5) chronic kidney disease and/or undergoing dialysis; 6) active liver disease; 7) pregnant or planning to become pregnant within the next year; 8) cognitive impairment; or 9) other family member already participating in study.

All participants from the FHH-RCT who did not meet MVPA guidelines (≥ 150 minutes MVPA per week) at baseline were included in Study 1 (Individual). For Study 2 (Family), a randomly selected subsample of 36 spouses and offspring who completed the 12-week FHH intervention were invited to participate in the qualitative interviews. For Study 3 (Neighbourhood), individual-level data from the FHH-RCT was linked to data from the Ottawa Neighbourhood Study (ONS); all participants in the FHH-RCT who lived in an Ottawa neighbourhood were invited to participate.

1.8 FHH-RCT Procedures

Baseline Assessment. For the FHH-RCT, family members who contacted the research coordinator were pre-screened to ensure they met basic eligibility criteria and were scheduled for a baseline assessment at UOHI. Participants provided signed, informed consent and completed a medical history questionnaire (including current medication use) and questionnaires concerning dietary patterns (132), physical activity (133), smoking status (134), and recent (past 3 months) use of health care resources. Measures of height, weight, waist circumference and blood pressure were collected using standardized procedures (135). Fasting blood samples were collected and

analyzed using standardized laboratory procedures (136). After the baseline assessment, once eligibility for the study was established, participants were randomly assigned to a Family Risk Reduction (FRR) intervention group or a Standard Care (SC) control group by the research coordinator using a single-blind, computer-generated, stratified (spouse, sibling, offspring), permuted block randomization sequence (block size = 6; allocation ratio 3:3); the treatment allocation was concealed in an envelope until the time of random assignment.

Intervention. The SC control group received a printed package containing general information about nutrition, physical activity, smoking, medications and CHD risk reduction and did not receive any further intervention. The FRR group received one in-person counselling session with a health educator to identify their risk reduction goals and create a personalized behaviour change plan followed by 12 weekly telephone counselling sessions. During the initial counselling session, the educator and participant negotiated a personal plan for achieving behaviour change goals, including physical activity, through lifestyle change. Educational modules were developed to address specific lifestyle issues and were provided to participants as required. The weekly sessions began with a discussion of progress toward stated goals and were structured using principles from the TPB (44) and ecological models (27). Each coaching session for those needing to increase their PA was designed to accomplish five goals: (1) to strengthen intentions to engage in physical activity; 2) to maintain and develop positive attitudes towards lifestyle change to support increased physical activity; 3) to provide social support and reinforcement; 4) to increase perceived control over physical activity

(by identifying facilitators to change and assisting participants to overcome barriers), and 5) to help participants identify resources in the home, neighbourhood and community that could support long-term physical activity behaviour change and facilitate links to these resources.

To standardize the intervention between participants, the health educators followed a designated script for each counselling session. Each session had accompanying educational modules that the health educator could prescribe for review, as appropriate, based on the participants' needs. The health educators received group training on motivational interviewing techniques, identified strategies to address individual issues that arose throughout the counselling sessions, and participated in regular case reviews where randomly selected counselling sessions were recorded and analysed for consistency, training purposes and providing feedback.

Post-assessment and follow-up data collection. All participants returned to UOHI for in-person assessments at 12 weeks. Questionnaires assessing MVPA and smoking status were repeated at this time. Measures of height, weight, waist circumference and blood pressure were collected. Fasting blood samples were collected and analyzed. Outcome assessments were blinded.

1.9 Summary and Statement of Purpose

In summary, the overall purpose of this thesis was to better understand PA behaviour change among family members of people with CHD who participated in the FHH-RCT. To accomplish this purpose, a three-part research program was developed to examine the

relationship between PA outcomes and factors at the individual, family and neighbourhood levels, respectively.

Study 1 - Individual. This study shows that the FRR intervention caused self-reported MVPA to increase over the 12-week intervention period; this was significantly correlated with an increase in control belief, behavioural belief, subjective norm, attitude, perceived behavioural control and intention (all $p < .01$) among intervention participants, and attitude ($p < .05$) and intention ($p < .01$) among controls.

Study 2 - Family. The qualitative interviews revealed that there were fundamental differences in how spouses and offspring engage in PA and how they adapt to a CHD event in a family member. The data suggests that awareness of an increased susceptibility to CHD did not stimulate participants to increase their own PA to prevent future risk, particularly among offspring. Spouses were more likely to engage in PA with the former CHD patient than offspring, indicating that this shared environment can promote PA, although intensity may be limited. Family members may need additional information and support to translate their perceived future risk of CHD into current PA behaviour change.

Study 3 - Neighbourhood. Self-reported PA from a prospective behavioural risk reduction intervention was explored in the context of objectively measured Walk Scores and neighbourhood walkability in Ottawa, Canada. Participants in the intervention arm with high or low Walk Scores or walkability had significantly higher odds of meeting PA guidelines at 12-weeks compared to the standard care control group. This individual-

level intervention was effective in assisting participants to overcome potential structural barriers presented by their neighbourhood environment to meet PA guidelines at 12-weeks.

1.10 Organization of the Remainder of the Thesis

This thesis is divided into four additional chapters. Chapter 2 is represented by the article from Study 1 (Individual) entitled “Effects of a 12-week behavioural risk reduction program on physical activity levels in family members of patients with coronary heart disease: Secondary outcomes from a randomized, controlled trial”. This article is formatted for submission to *Annals of Behavioral Medicine*. Chapter 3 includes the article from Study 2 (Family) entitled “A qualitative exploration of physical activity patterns among family members of people with heart disease”. This article is formatted for submission to *Social Science and Medicine*. Next, Chapter 4 includes the article from Study 3 (Neighbourhood) entitled “Neighbourhood walkability and physical activity patterns among family members of people with heart disease who participated in a randomized controlled trial of a 12-week behavioural risk reduction intervention”. This article is formatted for submission to *Health and Place*. To synthesize results from across these three studies, Chapter 5 discusses the overall findings and presents conclusions. Finally, the appendices include the relevant questionnaires, ethics documentation, including information and consent forms, and the semi-structured interview guide.

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CHAPTER 2: MANUSCRIPT 1 (Individual)

Effects of a 12-week behavioural risk reduction program on physical activity levels in family members of patients with coronary heart disease: Secondary outcomes from a randomized controlled trial

Abstract

Background

Interventions to increase moderate-vigorous physical activity (MVPA) among family members of patients with coronary heart disease are needed.

Purpose

To determine whether a 12-week behavioural risk reduction intervention caused self-reported MVPA to increase and to identify the associated Theory of Planned Behaviour (TPB) constructs.

Methods

Three hundred twenty-four physically inactive (<150 minutes/week MVPA) participants were enrolled in a randomized controlled trial. The main outcome was achievement of guideline recommended levels of MVPA (≥ 150 minutes/week) at 12-weeks. Groups were compared using logistic regression. TPB constructs were examined using t-tests and Spearman rank correlations.

Results

Intervention participants were significantly more likely to meet MVPA guidelines at 12-weeks (OR=3.54, 95% CI 2.22-5.63, $p < .001$). The outcome was significantly correlated with increases in control belief, behavioural belief, subjective norm, attitude, perceived

behavioural control and intention (all $p < .01$) among intervention participants and attitude ($p < .01$) and intention ($p < .01$) among controls.

Conclusion

The intervention caused self-reported MVPA to increase; this was significantly correlated with greater increases in TPB constructs among intervention participants.

Abstract word count: 165

Keywords: Physical Activity, Randomized Controlled Trial, Behavioural Intervention, Theory of Planned Behaviour, Coronary Heart Disease, Family History

Introduction

Coronary heart disease (CHD) is the leading cause of death in Canada (1) and worldwide (2). CHD is related to the presence of known coronary risk factors, particularly physical inactivity, smoking, abnormal blood lipids, and hypertension (3). Family history of CHD is also important. Family members of patients with CHD (including siblings, offspring and spouses) may themselves be at increased risk for developing CHD for genetic, biochemical and/or behavioural reasons (4-8). Family history of CHD is an independent risk factor for CHD (6, 8) and familial aggregation of CHD has been described (9).

Physical inactivity is a modifiable risk factor for CHD (10). The individual benefits of physical activity are extensive and well documented (11-14), including decreased risk of cardiovascular events (15, 16) and cardiovascular-related mortality (17, 18). In men and women without pre-existing CHD, engaging in moderate-vigorous physical activity (MVPA) can reduce the risk of developing CHD by up to 50% (19). The evidence also suggests that the relationship between physical activity and health is linear, such that incremental increases in physical activity can lead to additional health benefits (13), and that these benefits outweigh the potential increase in risk (e.g. injury) (20).

Interventions among sedentary individuals can effectively increase physical activity (21), leading to improvements in cardiovascular disease risk profiles (22-25). Several interventions targeting family members of patients with CHD have been evaluated (26-

28), yet few report significant changes in physical activity outcomes. The Tromso Family Intervention Study (n=1,373 men and their families) included a letter outlining their increased CHD risk, risk factor measurements among family members, two home visits, physician counselling, quarterly newsletters and two personal telephone calls during follow-up (26). At the 6-year follow-up, intervention group participants showed several significant improvements in CHD risk compared to control group participants, including decreased coronary risk scores, total cholesterol and serum triglyceride levels in men; but there was no significant change in the physical activity behaviours of family members (26). The British Family Heart Study identified men through primary care practices and invited them and their families (n=12,472) with no known CHD to participate in a randomized controlled trial of a nurse-led behavioural intervention (28). A 16% reduction in overall CHD risk scores was observed after one year in men and women in the intervention group, with physical activity outcomes not reported (28). In the FIT Heart randomized, controlled trial, 501 healthy adult family members of patients hospitalized with cardiovascular disease were randomly allocated to receive the intervention (personalized risk factor screening, behaviour change counselling, and progress reports to physicians) versus control (27). At the 1-year follow-up, intervention participants were significantly more likely than controls to exercise >3 days per week ($p=0.04$) (27). There is a need to confirm the effectiveness of theory-based interventions for reducing CHD risk factors, especially physical inactivity.

The Theory of Planned Behaviour (TPB) is one potential theoretical approach that can be used in the design of physical activity interventions (29). The TPB states that behavioural beliefs (i.e. beliefs about what the behaviour will lead to) determine the individual's attitude towards a behaviour, normative beliefs (i.e. beliefs about what important others think about the behaviour) formulate the subjective norm, and control beliefs relate to the individual's resources or capabilities to perform a behaviour, resulting in their perceived behavioural control (29, 30). These three main constructs exert their influence on the desired outcome (i.e. the target behaviour, such as physical activity) via intention, which is a direct antecedent of the behaviour. Several reviews and meta-analyses provide empirical support for intentions' predictive ability with regards to physical activity behaviour (31, 32). However, interventions to increase PA based on the TPB have shown inconsistent results regarding the theoretical constructs associated with physical activity behaviour change (33-35). A better understanding of the theoretical predictors of physical activity behaviour change and the impact of interventions on these predictors is needed (36), especially in individuals at risk for CHD.

Targeted, theory-based interventions aimed at family members of those with established CHD may be a cost-effective way to identify persons at high risk and link them to effective risk factor modification. Clinicians and behavioural scientists at the University of Ottawa Heart Institute (UOHI) have developed a 12-week TPB-based behavioural risk reduction intervention for family members of patients with CHD who themselves have one or more modifiable CHD risk factors. The intervention has been

evaluated in the Family Heart Health: Randomized Controlled Trial (FHH-RCT); the methods and primary results of this trial are reported elsewhere (37).

The purpose of the current analysis of secondary outcomes from the FHH-RCT was (i) to determine whether the FHH-RCT intervention caused self-reported MVPA to increase over the 12-week intervention period and (ii) to identify the key individual-level TPB constructs correlated with the relationship between the intervention and MVPA. It was hypothesized that (i) participants in the family risk reduction (FRR) intervention group would significantly increase their MVPA during the 12-week intervention period compared to the standard care (SC) control group and (ii) constructs from the TPB would be significantly correlated with this relationship.

Methods

Study design and participants

This study was approved by the Human Research Ethics Board at UOHI. In the current analysis, only participants who reported engaging in less than 150 minutes/week MVPA at baseline (n=324) were included. Participants in the FHH-RCT who reported engaging in ≥ 150 minutes/week MVPA (n=99) were excluded since they did not receive any intervention to increase physical activity level.

Recruitment/Baseline Assessment

Participants in the FHH-RCT were recruited through media advertising and through patients attending a cardiac rehabilitation program at UOHI. Family members who

contacted the research coordinator were pre-screened to ensure they met basic eligibility criteria and were scheduled for a baseline assessment at UOHI. Inclusion criteria were as follows: 1) spouse, offspring or sibling of patient hospitalized at UOHI within the past 5 years for CHD; 2) 20 to 80 years of age; 3) willing to provide informed consent; 4) at least one of the following modifiable risk factors: i) current smoker, ii) systolic blood pressure ≥ 140 mmHg and or diastolic BP ≥ 90 mmHg and/or currently on medication to treat high blood pressure, iii) total cholesterol/HDL-cholesterol ratio ≥ 5.0 and/or on antilipemic medication, iv) abdominal obesity (for men, waist circumference > 102 cm; for women, waist circumference > 88 cm) or v) physical inactivity (less than 150 minutes per week of MVPA); and 5) geographically available for assessment, intervention and follow-up. Exclusion criteria were as follows: 1) unable to understand English or French; 2) history of diabetes mellitus or any atherosclerotic disease; 3) fasting glucose ≥ 7.0 mmol/L at screening; 4) presence of life threatening illness; 5) chronic kidney disease and/or undergoing dialysis; 6) active liver disease; 7) pregnant or planning to become pregnant within the next year; 8) cognitive impairment; or 9) other family member already participating in study.

At the baseline assessment participants provided written, informed consent and completed a medical history questionnaire (including current medication use) and questionnaires concerning dietary patterns (38), physical activity (39), smoking status (40), and recent (past 3 months) use of health care resources. Measures of height, weight, waist circumference and blood pressure were collected using standardized

procedures. Fasting blood samples were collected and analyzed using standardized laboratory procedures (41). Confirmation of eligibility was established after the baseline assessment. Eligible participants were randomly assigned to a FRR intervention group or a SC control group by the research coordinator using a single-blind, computer-generated, stratified (spouse, sibling, offspring), permuted block randomization sequence. The treatment allocation was concealed in an envelope until the time of random assignment.

Intervention

The FRR group received one in-person counselling session with a health educator to identify their risk reduction goals and create a personalized behaviour change plan. During the initial counselling session, the educator and participant negotiated a personal plan for achieving MVPA goals consistent with Canadian guidelines (42). The initial session was followed by 12 weekly telephone counselling sessions. The weekly sessions began with a discussion of progress toward stated goals and were structured using principles from TPB (30) and ecological models (43). Personalized risk factor profiles were sent to the participant's primary care provider to promote continuity of care.

To standardize the intervention between participants, health educators followed a flow sheet and designated script for each counselling session. Each session had accompanying educational modules to address specific physical activity issues that the health educator could prescribe for review, as appropriate, based on participants' needs. The health educators received training on motivational interviewing techniques,

identified strategies to address individual issues that might arise during counselling sessions and participated in regular case reviews that were recorded, analysed and discussed.

The SC control group received a printed package containing general information about nutrition, physical activity, smoking, medications and CHD risk reduction and did not receive any further intervention.

Post-assessment and follow-up data collection

All participants returned to UOHI for in-person assessments at 12 weeks. All measures and questionnaires collected at baseline were repeated.

Measures

Primary Outcome: Physical Activity

Physical activity was measured using a modified version of the Godin Leisure-Time Exercise Questionnaire (44). Participants were asked 'How many days in a typical week out of the past 6 months did you do moderate (e.g. fast walking, easy bicycling, easy swimming, dancing) exercise for at least 10 minutes at a time?' and 'On the days when you did moderate exercise(s) (for at least 10 minutes at a time), how much total time on average did you spend per day doing these moderate exercise(s)?' The same two questions assessed the frequency and duration of vigorous activities (e.g. running, jogging, squash, cross country skiing, vigorous swimming, vigorous bicycling, vigorous

aerobic classes). For the 12-week assessment, the timeframe for the questionnaire was modified from 6 months to 3 months to reflect the duration of the intervention period. The modified version of the questionnaire has been validated (45). The total minutes of moderate and vigorous exercise per week were calculated and summed. The accumulation of ≥ 150 minutes of MVPA per week was used as the indicator of achievement of recommended MVPA targets based on current Canadian guidelines (42).

Theory of Planned Behaviour Constructs

As per the recommended methodology of Ajzen, a questionnaire based on the TPB for physical activity was constructed for use in this population (29). In brief, the TPB physical activity questionnaire included 12 items related to behavioural beliefs, 6 items related to attitudes, 5 items related to normative beliefs, 5 items related to subjective norms, 7 items related to control beliefs, 2 items related to perceived behavioural control and 8 items related to intentions. Pilot testing of the questionnaire with a sample of FHH-RCT participants (n=11) indicated that the internal consistency was good with Cronbach's coefficient alphas ranging from 0.90 - 0.95 for each subscale (46). The reliability of the TPB physical activity questionnaire subscales were: behavioural beliefs (.803), attitudes (.787), normative beliefs (.846), subjective norms (.803), control beliefs (.914), perceived behavioural control (.781) and intentions (.949). The questionnaire is included in Appendix C.

Covariates

Demographic data, including ethnicity, marital status, income and education, was collected at baseline by self-report questionnaire. Participant relationship to the index patient (i.e. spouse, sibling or offspring) was determined based on self-report.

Current smokers were defined as individuals who smoked any cigarettes (even a puff) in the past seven days (40). Claims of non-smoking were verified on all participants using a carbon monoxide analyzer (Bedfont Smokerlyser) with carbon monoxide levels ≤ 10 ppm confirmatory for non-smoking (47).

Height and weight were measured at baseline and at the 12-week follow-up for the determination of body mass index (BMI) using a standardized protocol. Waist circumference was measured using a non-stretchable standard tape measure. All anthropometric measures were collected based on the standardized methods from the Canadian Physical Activity, Fitness & Lifestyle Approach (CPAFLA) (48) .

Statistical Analyses

Participants missing 12-week MVPA (n=78, 24.1%) were compared to those who were not missing 12-week MVPA to test for patterns of missingness; data were found to be missing at random. For participants missing 12-week MVPA, multiple imputations were used to impute the value for 12-week MVPA with set parameters (i.e. minimum=0 and

maximum=525), controlling for intervention arm and self-reported baseline MVPA. 12-week MVPA values were examined for outliers using z-scores and these values were adjusted accordingly, using the value for MVPA at z-score=3.29 plus one. At 12-weeks, there was one participant with a z-score for MVPA greater than 3.29 which was adjusted to 526 minutes/week.

The distribution of MVPA at baseline and 12-weeks was examined. Since data were not normally distributed, possible transformations to normalize the data were explored. None of these transformations fit the data well since there was a large proportion of participants with zero MVPA at baseline and at 12-weeks. Therefore, the 12-week MVPA outcome was dichotomized for those who met the Canadian MVPA guidelines (MVPA $\geq$ 150 minutes/week coded 1) versus those who did not (MVPA < 150 minutes/week coded 0) (42).

Sample Size. Sample size calculations indicated a final sample of 116 participants would give 80% power ($\alpha=0.05$; 2-tailed) to detect a two-fold greater proportion (50%) of participants achieving the MVPA target ($\geq$ 150 minutes/week) in the intervention group compared to the standard care control group (25%).

Baseline characteristics were compared between intervention groups to test for chance significant differences using chi-square and t-tests as appropriate. At 12-weeks, participants who met the MVPA guidelines were compared to those who did not based

on intervention allocation, demographic characteristics, and covariates. Logistic regression was used to compare the proportion of participants who met the MVPA guidelines at the end of the 12-week intervention between the FRR and SC groups, controlling for significant differences in baseline characteristics and covariates, where applicable. Self-reported MVPA at 12-weeks was compared to changes in BMI as an anthropometric indicator of MVPA. Independent t-tests were performed to examine differences in TPB constructs between groups. Spearman rank correlations were performed to examine the relationship between intervention group, MVPA, and TPB constructs. All analyses were performed using SPSS 18.0.

Results

Characteristics of the study sample

Study recruitment and participant flow are depicted in Figure 1. Four hundred twenty-three participants were enrolled in the FHH-RCT. At baseline, all participants (n=423) self-reported physical activity; 99 participants (24.3% of FHH-RCT) met the MVPA guidelines (MVPA $\geq$ 150 minutes/week). Significantly more males than females ($p=.002$) met the MVPA guidelines at baseline. There were no significant differences by age, education, BMI, waist circumference, intervention arm, marital status, employment, or smoking. After excluding participants who met the MVPA guidelines at baseline (n=99), there were three hundred twenty-four eligible participants for the current analysis.

Baseline characteristics of participants are presented in Table 1. The mean age of participants was 51.4 ± 11.5 years, 65.4% were female, and 156 (48.1%) were allocated to the FRR intervention group. There were no significant differences between the FRR and SC groups on demographic variables examined at baseline.

The univariate relationships between demographic variables and covariates (i.e. age, sex, marital status, ethnicity, education, employment status, BMI, waist circumference, systolic and diastolic blood pressure and smoking) and the primary outcome, achieving ≥ 150 minutes of MVPA per week, were examined. Allocation to the intervention group was the only significant variable associated with achieving the target (≥ 150 minutes MVPA/week) at the 12-week follow-up ($p < .001$).

Trajectory of physical activity patterns during study period

At 12-weeks, participants in the FRR intervention group reported significantly more minutes of MVPA/week (mean = 167.1 ± 106.9) than SC participants (mean = 93.9 ± 99.0 ; $p < .001$). This corresponded to a mean decrease in BMI among FRR participants of 0.1 ± 5.0 , compared with a mean increase in BMI among SC participants of 0.2 ± 4.0 ($p = \text{NS}$). There were no significant differences between those who met the PA guidelines at 12-weeks versus those who did not based on age, waist circumference, height, weight, education, sex, marital status, employment status, or stratum.

Effect of intervention allocation on MVPA

At 12-weeks, 56.1% (n=88) of FRR participants met the MVPA guidelines compared to 26.8% (n=45) of SC participants (chi-square, $p < 0.001$). There were no significant differences in demographic variables or covariates between intervention groups, therefore the logistic regression model was unadjusted. FRR intervention participants were significantly more likely to meet the MVPA guidelines at 12-weeks (OR=3.54, 95% CI 2.22-5.63) compared to SC participants. Participants who met the MVPA guidelines showed a significantly greater reduction in waist circumference than participants who did not meet MVPA guidelines (-2.9 ± 7.2 cm versus -0.9 ± 3.9 cm; $p < .01$). Results are presented in Table 2.

Associations between intervention group, TPB constructs and MVPA

TPB constructs were examined to understand potential mechanisms by which the FRR intervention caused the increase in MVPA. There were significant differences in the 12-week scores for perceived behavioural control (PBC), attitude, subjective norm, control beliefs, behavioural beliefs, and intentions, with the FRR intervention participants reporting significantly higher scores on all of these scales. These results are presented in Table 3. Spearman rank correlations between the TPB constructs and the MVPA outcome by experimental group are presented in Table 4. Among FRR intervention participants, control belief, behavioural belief, subjective norm, attitude, PBC and intention were significantly correlated (all $p < .01$) with the MVPA outcome (≥ 150 minutes/week). Among SC participants, attitude ($p < .05$) and intention ($p < .01$) were significantly correlated with the MVPA outcome.

Discussion

This study has demonstrated that the FRR intervention caused self-reported MVPA to increase over the 12-week intervention period. Participants in the FRR group were significantly more likely to meet the MVPA guidelines at the 12-week follow-up (OR=3.54, 95% CI: 2.22-5.63, $p<.001$). Control belief, behavioural belief, subjective norm, attitude, PBC and intention were significantly correlated with the MVPA outcome (≥ 150 minutes/week) among FRR intervention participants (all $p<.01$). These results provide insight regarding a behavioural risk reduction intervention that is effective for increasing PA levels among a relatively healthy group of adults.

In a similar RCT among family members of patients with cardiovascular disease, participants received a less intensive intervention with five contacts from a health educator over a 1-year period (27). The study results indicated that allocation to the intervention group, among other factors, was a significant predictor of physical activity outcomes at 1-year follow-up (49). These findings are in agreement with the results found here. Combined, these results suggests that a structured intervention delivered by a health professional (e.g., a health educator) may be an effective means for addressing physical inactivity among adults, particularly those who are family members of people with cardiovascular disease.

Another RCT, which compared an intervention (medical screening, website and coaching) to usual care (medical screening only), also found that intentions predicted changes in physical in a comparable population (50). The significant correlations observed in the current study provide greater clarification regarding several of the potential theory-based mechanisms by which the intervention translates into an increase in physical activity.

In contrast to the current findings, an RCT among people at risk for developing Type II diabetes failed to show the predictive power of intentions and perceived behavioural control on physical activity outcomes (33). This study compared three intervention arms: the 'face-to-face' arm (introductory meeting followed by four visits and two brief support telephone calls over five months, then monthly follow-up telephone calls up to one year), the 'distance' arm (introductory meeting followed by six telephone calls over five months, and then monthly by mail up to one year) and the control arm (brief advice) (51). This intervention was less intensive than that FHH-RCT described here. Also, data were collected at baseline, 6- and 12-months; the measurement interval of six months in that study may have missed important, short term changes in cognitive TPB constructs that were captured in the 12-week questionnaires administered in the current study.

The findings from the current study provide support for the efficacy of a tailored, TPB based intervention to increase MVPA among family members of people with CHD. This

is important because this population is at increased risk of developing CHD themselves; therefore linking family members to interventions at a time of heightened awareness regarding the risks of CHD may prove to be an effective prevention strategy.

This study has several strengths. It used a rigorous, randomized controlled trial design, thus allowing the identification of cause and effect relationships. The intervention was developed and delivered based on the TPB theoretical background. Once the link between the intervention and increased MVPA was established, mechanisms by which this change occurred were also examined. This provides further insight into some of the potential avenues for physical activity behaviour change so that future interventions can be based on similar, theory-based constructs. The limitations of this study must be considered throughout interpretation. First, the sample may not generalize to other regions of Canada or internationally due to differences in population characteristics. Second, the MVPA outcome was dichotomized since the results did not normalize with transformation. Although continuous outcomes tend to be more desirable, it was impossible to overcome the large proportion of participants who reported zero MVPA at the 12-week time point. This is an important consideration for the interpretation and application of these results, since people who are inactive both pre- and post-intervention may require different strategies to engage them in physical activity behaviour change. Finally, the MVPA measure was self-report which can introduce measurement error (52). Future replication research using objective measures of physical activity, such as pedometers or accelerometers, would be beneficial.

Conclusion

In summary, this study has demonstrated that the FRR intervention caused self-reported MVPA to increase over the 12-week intervention period; this relationship correlated with increases in several TPB constructs. Overall, family members of people with CHD are an at-risk population who may benefit from health interventions to decrease their future risk.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) Diagram

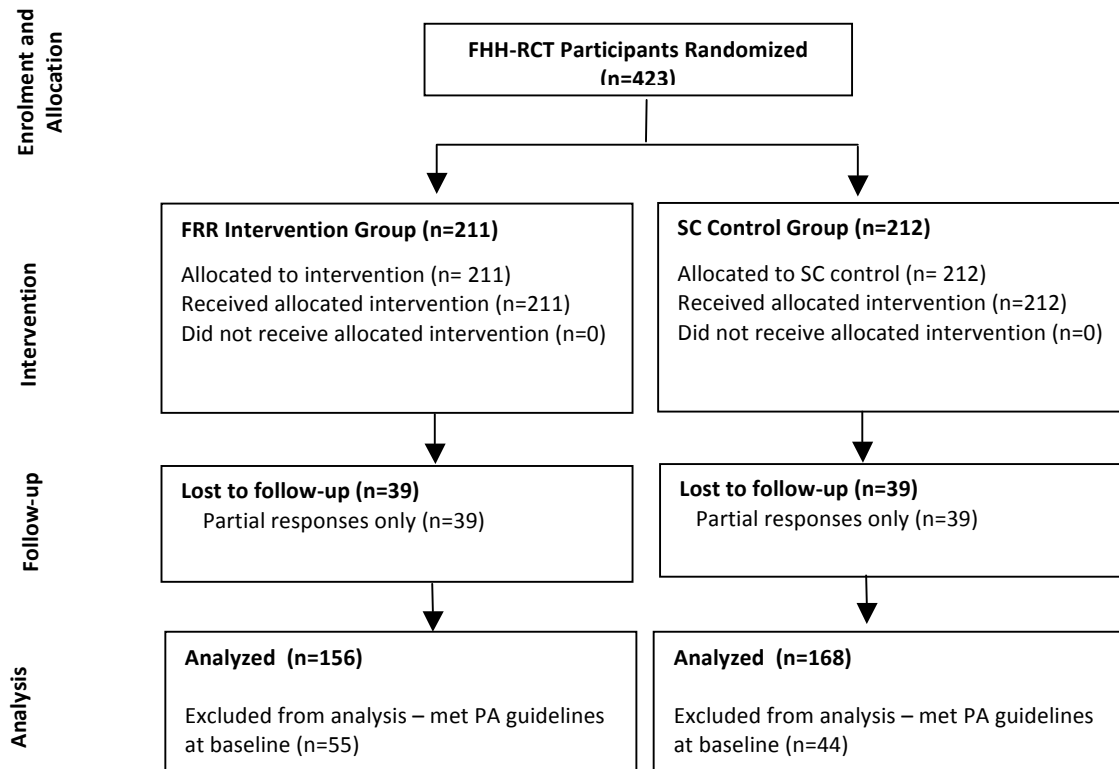


Table 1. Baseline characteristics of participants in the Family Heart Health: Randomized, Controlled Trial who did not meet physical activity guidelines at baseline

Characteristic	TOTAL N=324	FRR n=156	SC n=168	p- value
Age (years $\pm$ SD)	51.4 $\pm$ 11.5	51.5 $\pm$ 11.6	51.3 $\pm$ 11.5	NS
Female (%)	212 (65.4)	96 (61.5)	116 (69.0)	NS
Education (years $\pm$ SD)	14.6 $\pm$ 2.7	14.5 $\pm$ 2.7	14.7 $\pm$ 2.7	NS
Income (\$)				NS
<25,000	15 (4.6)	8 (5.1)	7 (4.2)	
25,000 – 49,999	39 (12.0)	16 (10.3)	23 (13.7)	
50,000 – 74,999	63 (19.4)	35 (22.4)	28 (16.7)	
75,000 – 99,999	43 (13.3)	22 (14.1)	21 (12.5)	
$\geq$ 100,000	99 (30.6)	43 (27.6)	56 (33.3)	
Missing	65 (20.1)	32 (20.5)	33 (19.6)	
Employed Full-Time (%)	176 (54.3)	92 (59.0)	84 (50.0)	NS
Ethnicity (White, %)	308 (95.1)	149 (95.5)	159 (94.6)	NS
Married (%)	244 (75.3)	113 (72.4)	131 (78.0)	NS
Height (cm)	167.4 $\pm$ 9.2	167.7 $\pm$ 9.6	167.2 $\pm$ 8.8	NS
Weight (kg)	82.4 $\pm$ 18.0	82.1 $\pm$ 16.4	82.6 $\pm$ 19.4	NS
BMI (kg/m ²)	29.4 $\pm$ 5.8	29.2 $\pm$ 5.2	29.5 $\pm$ 6.3	NS
Waist circumference (cm)	96.6 $\pm$ 14.5	96.7 $\pm$ 13.0	96.5 $\pm$ 15.7	NS
Smoker (%)	38 (11.7)	17 (10.9)	21 (12.5)	NS
Stratum:				NS
Spouse (%)	102 (31.5)	49 (31.4)	53 (31.5)	
Sibling (%)	154 (47.5)	75 (48.1)	79 (47.0)	
Offspring (%)	68 (21.0)	32 (20.5)	36 (21.4)	

Table 2: Logistic regression comparing 12-week PA outcomes between FRR and SC intervention groups

Condition	Met PA Guidelines at 12-weeks OR (95% CI)	p-value
Intervention Arm		
SC	1.00	
FRR	3.54 (2.22 - 5.63)	<.001

Table 3: Between-Groups Comparisons of Theory of Planned Behaviour Constructs at Baseline and 12-week Follow-up

Characteristic		Intervention (FRR) (n=64)	Standard Care (SC) (n=67)	p-value
Behavioural Beliefs	Baseline	5.77 ± 0.65	5.76 ± 0.61	NS
	12-week	5.90 ± 0.70	5.81 ± 0.62	NS
	Δ	0.13 ± 0.77	0.05 ± 0.59	NS
Attitude	Baseline	5.92 ± 0.55	5.91 ± 0.72	NS
	12-week	6.09 ± 0.50	5.84 ± 0.76	.032
	Δ	0.16 ± 0.58	-0.07 ± 0.58	.025
Normative Beliefs	Baseline	5.97 ± 0.83	5.64 ± 1.09	NS
	12-week	5.77 ± 1.06	5.54 ± 0.99	NS
	Δ	-0.20 ± 1.10	-0.10 ± 1.17	NS
Subjective Norm	Baseline	5.94 ± 0.69	5.76 ± 1.02	NS
	12-week	5.93 ± 0.69	5.64 ± 0.90	.045
	Δ	-0.01 ± 0.62	-0.12 ± 0.90	NS
Control Beliefs	Baseline	4.27 ± 1.14	3.91 ± 1.24	NS
	12-week	4.57 ± 1.25	3.74 ± 1.15	<.001
	Δ	0.30 ± 1.21	-0.17 ± 0.94	.013
Perceived Behavioural Control	Baseline	5.84 ± 0.88	5.63 ± 0.90	NS
	12-week	5.89 ± 0.88	5.56 ± 1.06	.055
	Δ	0.05 ± 1.11	-0.07 ± 1.19	NS
Intentions	Baseline	5.14 ± 0.98	4.79 ± 1.34	NS
	12-week	5.74 ± 1.07	4.86 ± 1.47	<.001
	Δ	0.60 ± 1.16	0.06 ± 1.42	.021

*The scale for each construct is out of seven, with 7 being more favourable.

Table 4: Spearman Rank Correlations Among Physical Activity and the Theory of Planned Behaviour constructs by Experimental Group

Variable	1	2	3	4	5	6	7	8
<i>Standard care control group</i>								
1. Met MVPA guidelines (≥ 150 minutes/week)	--	.271**	.087	.244**	.062	.096	.037	.045
2. Intention		--	.482**	0.410**	.229*	.261**	.197	.569**
3. Perceived behavioural control			--	.407**	.348**	.396**	.278**	.408**
4. Attitude				--	.331**	.454**	.252*	.304**
5. Subjective norm					--	.379**	.478**	.264**
6. Behavioural belief						--	.421**	.277**
7. Normative belief							--	.320**
8. Control belief								--
<i>Family risk reduction intervention group</i>								
1. Met MVPA guidelines (≥ 150 minutes/week)	--	.463**	.360**	.409**	.271**	.260**	.130	.461**
2. Intention		--	.656**	.589**	.359**	.424**	.226*	.527**
3. Perceived behavioural control			--	.543**	.426**	.328**	.333**	.534**
4. Attitude				--	.422**	.503**	.248*	.512**
5. Subjective norm					--	.310**	.460**	.389**
6. Behavioural belief						--	.422**	.378**
7. Normative belief							--	.342**
8. Control belief								--

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

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CHAPTER 3: MANUSCRIPT 2 (Family)

**A qualitative exploration of physical activity patterns among family members of
people with coronary heart disease**

Abstract

Introduction

Physical inactivity is a well-known risk factor for coronary heart disease (CHD). Targeted interventions aimed at family members of those with established CHD may be an effective way to identify individuals at high risk and link them to effective risk factor modification. The objective of the current study was to investigate, using a family systems perspective, the role of recent hospitalization of a spouse or parent for CHD in activating family members to engage in physical activity (PA).

Methodology

A qualitative research design was employed involving semi-structured interviews to elicit perceptions of the factors in the social and physical environment that influence PA. Interviews were audiotaped, transcribed, coded and analyzed, which involved inductively documenting emerging themes.

Findings

Interviews were conducted with 36 participants; 17 spouses and 19 offspring. Spouses were more likely to provide care and support and to engage in PA with their spouse after the CHD event. Many spouses expressed that their own PA was limited by the capabilities of their partner. Offspring expressed an increased perception of their own

future risk of CHD, citing genetics as a prominent concern; however, this did not necessarily translate into PA behaviour change.

Conclusion

There are fundamental differences in how spouses and offspring engage in PA and how they adapt their PA following a CHD event in a family member. The data suggests awareness of an increased susceptibility to CHD is not stimulating participants to increase their own PA to prevent future risk, particularly among offspring, but they may take other actions. Spouses are more likely to engage in PA with the CHD patient than offspring, suggesting this shared environment can promote PA, although intensity may be limited. Family members may need additional interventions to translate their perceived future risk of CHD into current PA behaviour change.

Abstract word count: 297

Research Highlights

- Qualitative exploration of physical activity behaviour in spouses and offspring of recent coronary heart disease patients (123)
- Offspring concerned about increased risk of CHD, but this is not consistently reflected in physical activity patterns (120)
- Shared environment is important for promoting physical activity among spouses, but intensity may be limited (108)

Keywords

Qualitative, physical activity, coronary heart disease, family systems theory, intervention, behaviour change

Introduction

Physical inactivity is a risk factor for obesity and several chronic diseases, including coronary heart disease (CHD) (1). Numerous cohort studies have repeatedly demonstrated the inverse relationship between physical activity (PA) and CHD (2-6). Engaging in PA has cardioprotective benefits, and can reduce the incidence of cardiovascular events (7, 8). In men and women without pre-existing CHD, engaging in moderate-vigorous PA can reduce the risk of developing CHD by up to 50% (9).

A family history of CHD is also an independent risk factor for the development of this disease; the risk of CHD among first-degree relatives is generally associated with a 1.5- to two-fold increase in risk (10-14). Clustering of CHD in families has been demonstrated in several longitudinal studies (10, 11, 13, 15, 16). Family members of patients with CHD (including siblings, offspring and spouses) may themselves be at increased risk for developing CHD for genetic, biochemical and/or behavioural reasons (17-21). Even in the presence of a positive family history, participation in at least moderate-level PA can decrease the odds of developing CHD compared to sedentary individuals (8, 22).

When a person experiences chronic illness, such as CHD, the repercussions of the illness extend beyond the individual and influence the family (23). Families are required to adapt to the changes that the illness has presented, going through the processes of coping and reorganization to continue functioning (24). Furthermore, different families have various levels of influence on PA (25). Investigations into how the family adapts to chronic illness and subsequent PA behaviour changes are required.

There is a variety of literature that highlights the impact of the family on PA. In a study of sons ($n = 571$) of parents with premature CHD, only 25% of sons were engaging in regular exercise, despite elevated concerns about future risk (22). Over a five-year follow-up period, results from the San Antonio Family Heart Study show that PA behaviours accumulate within families (26). Similarly, in the Quebec Family Study, familial aggregation of physical activity was investigated among 696 participants from 200 families (312 parents; 384 offspring; mean family size 3.6 ± 2.0 individuals) (27). The authors found that there was 1.40 to 1.52 times more variation in physical activity characteristics between families than within families, which suggests that factors in the shared familial environment (social and physical) contribute to the heritability of PA patterns (27). The Family Atherosclerosis Risk Intervention Study (FARIS) found that family members ($n=1,723$) enrolled in a CHD risk reduction intervention had significantly worse risk factor profiles (based on lipid profiles, BMI, waist circumference, blood pressure, and smoking status) at baseline than a comparable randomly selected age- and sex-matched sample; PA outcomes were not reported (28). Looking at other psychosocial correlates of PA that may be influenced by family, research with both women and men has indicated that higher work-family conflict decreases the odds of achieving PA targets (29). These studies illustrate the importance of the familial environment in shaping PA behaviour patterns.

The spousal relationship also appears to be important. To explore the presence of CHD risk among partners of men with acute myocardial infarction, Wood and colleagues surveyed a sample of 89 female partners and compared them to 133 matched controls

(30). The researchers found that elevated body mass index (OR = 2.17, 95% CI 1.11 – 4.23) and cholesterol levels (OR = 2.21, 95% CI 1.08-4.49) were significantly more common in partners; however, PA levels were not reported (30). Similarly, Wallace et al. (1995) compared married pairs who spontaneously joined an exercise program to married singles (i.e. individuals who were married but did not have their spouse accompanying them) (31). Couples who attended the exercise program together had higher attendance and lower drop-out rates, suggesting that partnership is an important factor in initiating and maintaining PA changes (31).

The importance of screening family members of patients with established CHD has been documented as an important preventive strategy (18, 32, 33), but few studies have examined lifestyle interventions implemented to family members of CHD patients. The Tromso Family Intervention Study of over 1,000 men with CHD and their families is one exception. At the 6-year follow-up, they found there was no significant change in the PA behaviours of family members (34). The British Family Heart Study enrolled families with no known CHD to a randomized controlled trial of a nurse-led behavioural intervention and found only a 12% reduction in risk after one year; PA outcomes were not reported (35). The San Diego Family Health Study enrolled 206 families with no known CHD to a randomized controlled trial and found that the intervention group showed increased knowledge of skills required to increase PA, but no change in PA at one year follow-up (36). In the FIT Heart randomized controlled trial, which is most similar to the intervention at the focus of the current investigation, 501 healthy adult family members of patients hospitalized with cardiovascular disease were randomly allocated to receive

the intervention (personalized risk factor screening, behaviour change counseling, and progress reports to physicians) versus control. At the 1-year follow-up, intervention participants were significantly more likely than controls to exercise more than 3 days per week ($P=0.04$) (37). Based on these previous studies, it remains unclear how effective this type of intervention is at reducing CHD risk factors, especially physical inactivity. Targeted approaches aimed at family members of those with established CHD may be an effective way to identify high-risk persons and help modify their risk factors.

Family Systems Theory. Family systems theory can be used to gain greater understanding of this level of influence. According to this theory, the family operates in a state of equilibrium which is disturbed in response to the illness or death of one of its members. Since the interactions and relationships between family members are reciprocal, changes in the health status of one family member influence the family as a whole (38). In the aftermath of illness, families go through the process of role reorganization to re-establish equilibrium. During this process, family members incorporate their values, attitudes and beliefs to re-establish behaviour patterns to continue operating in a stable manner, restoring the family's balance. As adaptation proceeds, the individual recommendations (i.e. increased PA) for the ill patient may be assimilated into the daily functioning of the family at large (39). Throughout this process, the family's resiliency is challenged; if the stressor (i.e. illness) encourages new capabilities without overwhelming the family with demands, improved functioning within the family structure can be achieved (24). From this perspective, it is likely that family members with different relationships to the index patient (i.e. spouse versus

offspring) will experience different role reorganization and subsequent PA behaviour change.

The Family Heart Health: Randomized Controlled Trial Intervention. The Family Heart Health: Randomized Controlled Trial (FHH-RCT), a prospective randomized, controlled trial, investigated the effectiveness of a 12-week behavioural risk reduction intervention aimed specifically at family members of patients with CHD. Participants in the FHH-RCT were randomized to one of 2 arms: family risk reduction (FRR) intervention or standard care (SC) control. FRR participants received one in-person counseling session with a heart health educator to identify their risk reduction goals and create a personalized behaviour change plan followed by 12 weekly telephone counseling sessions. Educational modules were developed to address specific lifestyle issues and were provided to participants as required. The weekly sessions began with a discussion of progress toward stated goals and were structured using principles from the theory of planned behaviour (40) and ecological models (41). SC participants received a printed package containing general information about PA, nutrition, smoking and medications and CHD risk reduction and did not receive any further intervention.

It was unclear how different family members (i.e. spouses versus offspring) would respond to the intervention and modify their PA behavior. The objective of the current study was to investigate the role of the family in activating spouses and offspring of CHD patients to engage in PA behaviour change among a subsample of participants from the FHH-RCT.

Methodology

A qualitative research design was employed involving semi-structured interviews to collect in-depth data on the factors in the social and physical environment that influence PA. Purposive sampling techniques were used to recruit an equal number of participants from two family categories (spouse and offspring, since family members of varying relationships to the index patient may exhibit different perspectives regarding family adaptation) to complete interviews. A family systems perspective was incorporated to understand the role of the family member's illness in activating the participant to change their PA behaviour.

Participants

Spouses and offspring of patients recently hospitalized at the University of Ottawa Heart Institute (UOHI) with CHD who completed the FHH-RCT were eligible to participate in the interview.

FHH-RCT Inclusion and Exclusion Criteria. Inclusion criteria for the FHH-RCT were as follows: 1) spouse, offspring or sibling of patient hospitalized at UOHI within the past 5 years for CHD; 2) 20 to 80 years of age; 3) willing to provide informed consent; 4) at least one of the following modifiable risk factors: i) current smoker, ii) systolic blood pressure ≥ 140 mmHg and or diastolic BP ≥ 90 mmHg and/or currently on medication to treat high blood pressure, iii) total cholesterol/HDL-cholesterol ratio ≥ 5.0 and/or on antilipemic medication, iv) abdominal obesity (for men, waist circumference > 102 cm;

for women, waist circumference > 88cm) or v) physical inactivity (less than 150 minutes per week of MVPA); and 5) geographically available for assessment, intervention and follow-up. Exclusion criteria were as follows: 1) unable to understand English or French; 2) history of diabetes mellitus or any atherosclerotic disease; 3) fasting glucose ≥ 7.0 mmol/L at screening; 4) presence of life threatening illness; 5) chronic kidney disease and/or undergoing dialysis; 6) active liver disease; 7) pregnant or planning to become pregnant within the next year; 8) cognitive impairment; or 9) other family member already participating in study.

Recruitment. Upon completion of the FHH-RCT intervention, eligible participants were mailed an invitation letter that described the research study and invited them to contact the first author to participate in the interview. In order to maximize the response rate, a modified Dillman's method was used (42). All eligible participants were assigned a random number using the random number generator in SPSS 18.0 and potential participants were contacted sequentially. If participants did not respond to the letter, approximately two weeks later the researcher called them by phone to ascertain that it was received, provide them with the opportunity to ask questions, and invite them to participate. If the participant did not respond to the telephone call, a second letter was sent to the potential participant two weeks later. If the potential participant did not respond to the second letter, no additional contact attempts were made.

Eligible participants provided signed informed consent prior to the interview. Sociodemographic characteristics and health outcomes were collected during the FHH-

RCT. The UOHI Human Research Ethics Board approved both the FHH-RCT and this qualitative study.

Four hundred twenty-three participants were enrolled in the FHH-RCT at the time of the current study. Siblings, study dropouts or participants who had not yet completed their twelve month follow-up for the FHH-RCT at the time of data collection were not invited to participate in the interview. Three hundred thirteen participants from the FHH-RCT were eligible for the current study. Of the 313 potential recruits, 45 offspring and 41 spouses were sent invitations by mail. Of the 45 offspring who were invited, 19 participated, three refused, 21 did not respond to any contact attempts, one was unreachable by mail and phone, and one agreed to participate but did not need to complete the interview because it was felt that saturation was reached. Of the 41 spouses who were invited, 17 participated, nine refused, 11 did not respond to any contact attempts, and three were unreachable.

Interview Guide and Process

Thirty-six interviews were completed between May 2010 and September 2010. One interviewer (DLR) performed all of the interviews using a semi-structured interview guide developed by the research team based on existing PA literature using a social ecological and family systems approach. Participants were allowed to complete the interview in person or by telephone. Participants were asked questions about general PA habits, the role of the family in shaping PA and how the spouse's or parent's CHD event influenced their own PA. The interview guide can be found in Appendix I.

Analysis

Interviews were audiotaped and transcribed verbatim (except to preserve anonymity). The interview text was imported into NVivo 8 (43), a software program that facilitates coding and analysis of the interviews, searching and retrieving of related segments and sub-themes, and theorizing. Data transcription and analysis were concurrent with data collection, and involved inductively documenting emerging themes. Themes were coded and analyzed based on the constant comparative method (112). The codes that emerged from the data were quite descriptive at first, reflecting the content of the interview guide. As coding progressed, more analytic themes emerged, with codes clustering together more conceptually, reflecting similarities and differences in the factors associated with PA among the study sample. The coding frame was developed and revised through ongoing communication between members of the research team. Emerging themes and corresponding codes were discussed at regular intervals throughout the data collection process. The number of participants interviewed was dependent upon the attainment of saturation of themes, which was ascertained by two independent researchers (DLR and ILB) simultaneously. A random sample of five interviews was independently coded by a second researcher (CN) to establish inter-rater reliability and validate the coding. When all interviews were complete, two investigators (DLR and CN) independently re-indexed the data by code. To ensure the transparency and validity of the results, an audit trail was developed, incorporating the technique of overall checks of the representativeness of the coding and categories. Key components of the audit trail include the instrument development procedure, sampling frame

selection, process notes, field notes, raw data and data reduction, analysis and synthesis techniques.

Findings

The characteristics of the qualitative study participants are shown in Table 1. Fifteen out of 36 (41.7%) interview participants received the FHH-RCT intervention and 17 (58.3%) received standard care. The mean age of participants was 54.7 ± 13.5 years; as expected, offspring were generally younger than spouses. Overall, just over half of the sample was female, with a slightly higher proportion of female spouses ($n=11$) than female offspring ($n=10$). The average education of participants was 14.6 ± 2.9 years. The majority of participants were married. Offspring were more likely to be employed full time ($n=14$), whereas spouses were more likely to be retired ($n=8$) or employed part-time ($n=4$).

The subsequent findings are presented in chronological order as discussed during the interview. To start, participants were asked about their general PA patterns. Then participants discussed the cardiac event in their family member, their resulting role reorganization and family adaptation, including changes to their own PA and the impact of the event on engaging in PA together. Factors that influence PA, including support for PA from family members and important others, were discussed to gain insight regarding the motivators, facilitators and barriers to PA that participants experience.

Participants accounts of their physical activity patterns

To initiate the discussion about PA, participants were asked a general question about their PA patterns. In general, many participated in PA on a regular basis, including activities such as walking outdoors, cycling, organized sports and going to the gym. Active participants also described trying to incorporate PA into their daily routine to ensure that it is accomplished:

DOUG (Spouse): I ride a bike a lot....in the last five years of my working career ... I was able to ... ride to work ... I can do it if I bike for about seven months of the year...

BRENDA (Offspring): Well first thing in the morning I walk to the bus and there's, you know, a bit of walking when I get to my destination downtown and I work downtown so there is a lot of opportunity for just walking...It may not be every day but I would say every second day. And I also belong to a health club...And I go there 2 to 3 times a week. I try to go every second day... but then some days if I have done particularly strenuous things like I've gone to an aqua-fit class or something like that, I might skip. So I also do that aqua-fit once a week. It is a boot-camp so it is not just floating around with a belt.

Participants had different conceptualizations of what constitutes PA. Some participants discussed their PA in terms of exercise (e.g. running, walking purposefully, lifting weights), whereas others believed that their activities of daily living represented PA. Several women reported activities such as housework, cleaning and going up and down the stairs at home as their PA:

BETH (Offspring): ...I do all the housework, any carrying groceries and things that, I try to carry heavy things to keep my strength up; I have, in the past gone to the gym. I have in the past lifted weights but I don't do anything like that now.

EVELYN (Spouse): ... I like to exercise while I'm doing my cleaning.

This is an important distinction because family members may need to increase their knowledge about what constitutes PA in order to achieve cardiovascular benefits. Specifically, to achieve health benefits, adults should accumulate at least 150 minutes of moderate- to vigorous-intensity aerobic physical activity per week, in bouts of 10 minutes or more (48). Quotes that exemplify the PA of active versus inactive participants are presented in Table 2. The main difference between those who were active versus those who were not sufficiently active is that active participants were more likely to engage in PA for the purpose of getting exercise.

Coping with their family member's cardiac event

After discussing their general PA patterns, participants were asked about how they coped with their family member's cardiac event. The majority of participants provided support during their family member's cardiac event. Spouses seemed to take on a more active role during the acute phase of the illness and throughout the subsequent recovery, acting as the caregiver for their spouse. Offspring offered their support in a less direct manner; they were more removed from the event and the recovery process. Offspring also mentioned providing support to both parents, that is, the one who had the cardiac event and their partner or "caregiver".

LEANNE (offspring): Well we all rallied around and were there for him [my father]. We went to the hospital and that kind of thing and helped mother, like when dad came home, we helped her as much as we could.

Participants described a wide range of emotions they felt during the acute phase of their family member's event and thereafter. Intense emotions, such as guilt and fear were

mentioned by spouses. Some of both the spouses and offspring were surprised by the cardiac event in their family member, yet overall spouses had a tendency to be more shocked by the event, whereas offspring were more likely to have anticipated the event.

TREVOR (offspring): How did we cope? Well we were all concerned of course. There's a fairly strong history of heart disease in our family and so, we, it was not unexpected, I guess, but it was new to my immediate family...

In this particular example, the participant was making reference to the fact before his father's cardiac event there was no prior history of heart disease in his immediate family (i.e. parents or siblings), although older generations had experienced cardiac events in the past. Among participants, there was a general awareness of the role of family history in the development of heart disease; however, the impact was greater once a member of the immediate family actually experienced a cardiac event. This awareness of the importance of family history translated into the majority of participants taking on an active role in trying to understand the cardiac event in their family member and searching for solutions to improve their family member's health as well as their own.

Impact of event on individual physical activity

The next portion of the interview sought to evoke participants' perceptions about how the cardiac event in their family member stimulated their own PA behaviour change. This question was illuminating because, although individual PA patterns and the family member's cardiac event were discussed separately earlier, this portion of the interview assisted the participants in considering the link between these two risk factors (physical inactivity and a positive family history for CHD). The family member's CHD event

influenced the participants own PA in a variety of different ways. Offspring were more likely to be fearful about their own future, citing genetics as a possible mechanism that may influence them later in life.

ANNE (Offspring): I mean [the event] brought to the fore the possibility that we could also suffer that same kind of thing, being hereditary in some ways. I also suffer from high blood pressure. So you think, well, you know, it's a possibility [that I may have a heart attack] so you better get with it. But I have always exercised.

Increased awareness about their future risk of CHD was a common theme, but this did not necessarily translate into a reported change in PA. Some participants' reported PA levels were not influenced at all by their family member's cardiac event, particularly offspring.

BETH (Offspring): No [I did not change my PA], not at all, never occurred to me.

PAUL (Offspring): No we're all the same [as before the cardiac event] probably... but as far as joining gyms or anything, I didn't go sign any memberships or change my diet or anything like that.

ZACHARY (Offspring): No...all my family members kind of lead their own lives basically so...whether they go to the gym or not...has no bearing on me and perhaps likewise, whether I go to the gym has no impact on them...

This suggests that awareness of an increased susceptibility to CHD did not stimulate participants to increase their PA to prevent future risk. Family members may need additional information or intervention in order to translate their perceived future risk of CHD into current PA behaviour change.

Impact of event on engaging in physical activity together

When discussing how the event in their family member influenced engaging in PA together, spouses were more likely to try to engage in PA with their partner who had experienced the cardiac event.

NORAH (Spouse): Yes. I try to go walking with my husband. It just keeps him company and keeps me company too except when I'm doing my fast walking.

Spouses were also more likely to cite differences in their physical capabilities and interests as barriers to engaging in PA with their spouse.

PENELOPE (Spouse): We walk together a great deal. It's very frustrating because just when we get to the point where he can walk at least half of the distance I can...My husband can't just get up and walk down. He has to time it. He can't walk right after a meal for example so all of these things require just a little bit more organizing for him. I guess we're hoping that at some point his health will be well enough that we can do all of it ourselves... Because I've really outgrown those little walks down the road and back.

So, the spousal relationship provided an opportunity for engaging in PA that is mutually beneficial. After their partner's cardiac event, spouses seemed to be protective of their partners and unsure of their physical limitations, which oftentimes resulted in them limiting the intensity and/or frequency of their own PA. Spouses needed to acknowledge their different physical capabilities and interests to find a common ground for engaging

in PA together, particularly in the context of one spouse rehabilitating from a cardiac event while the other spouse is healthy.

Social support for physical activity from spouse

Many participants noted the benefit of having their spouse encourage them to engage in PA. Spousal support for PA was an important factor influencing PA, regardless of whether the person who experienced the cardiac event was a parent or spouse.

HARRIET (Spouse): Oh, [my husband's] always checking up on me. I think ... it's one of those things when you commit into something and ... your partner you want your partner to come along with you ... the camaraderie ... and partnership of doing ... having a healthy lifestyle, which includes your physical exercise, you're gonna encourage the other person.

NEIL (Spouse): Oh yes. [My wife] understands my need for [PA]. And she understands when I go and do it even though not with her together. She still understands that and she supports it. And also, she makes an effort to try to have some periods where we both can either go for a walk or for a cycle.

Spouses provided each other with support and encouragement for PA, regardless of whether they were engaging in PA together. Often spouses reciprocated between the role of motivating their spouse versus needing encouragement to engage in PA. They described a mutual understanding of each other's need for PA and the varying capabilities of each partner. This exemplifies the importance of spousal support for PA.

In some cases, the spousal relationship may have also been neutral or negative in providing social support for PA. Active participants tended to be self-motivated for PA, and their spouse's support seemed somewhat irrelevant.

SAMUEL (Offspring): But as far as what I'm doing [for PA], [my wife] doesn't care 'cause literally she's ambivalent towards it... Not that that is a bad thing or a good thing. It's just like she's completely neutral on it ... [PA is] kind of always been something that I've done so like she said, it's part of the package.

VALERIE (Offspring): I have a partner who doesn't exercise...[My husband]'s not a hindrance but no, he definitely doesn't help.

Participants who did not get social support from their spouse may need assistance in formulating strategies to overcome this lack of support, which may include identifying mechanisms to increase their spouses PA concurrently or finding other sources of support for PA in their social environment.

Seeing others engage in physical activity

Seeing others, such as neighbours, friends and other family members, engage in PA was also a key motivator. The majority of participants noted that seeing other people engaging in PA was encouraging.

ALLAN (Offspring): Well, it's encouraging to me [to see others engaging in PA]. It's ... it gives me ideas of what I can do with myself also. And if I'm not participating then I feel almost like I'm missing out. You know, it's not like I feel bad ... it's more like: 'Oh, I should be out doing stuff too. I should be participating'.

VALERIE (Offspring): Oh encouraged. It's a big support for me. To surround yourself by people who are physically active makes a big difference.

Several participants noted that seeing others engaging in PA made them feel like they should do more. Feelings of guilt were common among those who were not sufficiently physically active. Participants felt guilty because they know that PA is good for them, yet they are not engaged. Inactive participants were more likely to mention needing to increase their PA as a result of seeing others engage in PA.

BETH (Offspring): Guilty, guilty. I do feel badly when I see my neighbours out riding a bike or walking or something, I think I should be out walking or doing something...I haven't got my bike out yet...that kind of thing. Look at him-he is so much fitter than I am. I do feel guilty about it.

However, several participants, primarily males, did not feel that seeing others, such as family members or neighbours, had any influence on their own PA.

TREVOR (Offspring): [Seeing others engage in PA] has very little influence on my goals. Everyone has their goals so I'm not going to change my goals because I see other people out jogging on the street or I see my wife doing the Wii Fitness ...and things like that... So it's not going to change my goals at all...I mean, it doesn't encourage me more.

Active participants who were self-motivated were less likely to be influenced by the PA of others, which suggests that intrinsic factors are important determinants of PA levels. Overall, seeing others engage in PA was a motivating factor for increasing PA.

Factors that positively influence physical activity

Participants also mentioned a variety of factors that positively influence their ability to engage in PA. The intrinsic enjoyment of the PA undertaken, the positive effects it has on weight loss/control and other tangible health benefits were key themes that emerged from the data.

Participants were motivated by the positive feelings they associate with engaging in PA, such as satisfaction and enjoyment.

CHARLES (Spouse): Well, number one [PA is] enjoyable. I do enjoy being active. Whether it's gardening or chopping down trees at our cottage in the summer time...or painting, hammering, sawing. Doing a lot of physical things on the property.

Very different levels of motivation to engage in PA were reported, and a lack of motivation was often presented as an obstacle to PA among inactive participants.

BETH (Offspring): I don't, I just don't [engage in PA]. I have other things to do. I don't know what to say. Sometimes things seem more important, more urgent. Sometimes [PA] just does not seem appealing.

Overall, motivation was a key positive factor associated with PA. Enjoyment was closely linked to motivation. Participants who reported enjoying PA tended to be fairly physically active; they were not likely to state that they enjoy PA and not carry out their PA goals. Interestingly, very few participants explicitly reported the event in their family member as a motivating factor encouraging them to engage in PA, which suggests that greater emphasis may be needed to assist participants in addressing the link between their family member's event and their own PA behavior.

Weight loss and/or control was another important motivator for PA. Participants, particularly male participants, independently discussed weight loss and weight control as reasons for engaging in regular PA.

SHANE (Spouse): One, I think you control how fat you can get. You know if you do something every day you can burn off calories, right?... So it's important that way ...

Participants seemed knowledgeable about the numerous health benefits associated with engaging in regular PA; there were no large differences between men and women or spouses and offspring. All participants were able to identify the health benefits associated with regular PA regardless of whether or not they were themselves

sufficiently active. Both mental and physical benefits of PA were mentioned. The mental benefits of PA generally reflected positive feelings about one's self.

GEORGE (Offspring): Benefits. Well mentally, I mean there's a good feeling whenever you do exercise you generally feel good about yourself.

The physical benefits of PA mentioned by participants included comments about energy levels, physical capabilities and physical attributes.

RITA (Offspring): Oh benefits-I think you have more energy is one, a sense of well-being and your physical attributes improve, I think.

In most cases, participants noted the link between physical and mental fitness.

ALLAN (Offspring): [PA] cuts down on my stress level...For sure. The more physically fit you are the easier everything is in life.

ZACHARY (Offspring): Well, the benefits [of PA] - again it makes you feel good mentally. It makes you feel good, I guess, physically and...if you get to a level where...you're happy with how you look physically, then it also makes you feel good confidence wise.

Understanding these positive associations with PA is instrumental in formulating interventions to encourage PA among family members of people with CHD. Spouses and offspring of patients with CHD tended to be fairly knowledgeable about the factors that influence PA and the benefits associated with a physically active lifestyle; interventions to increase PA among family members should incorporate mechanisms to translate this knowledge into effective PA behaviour change strategies.

Barriers to physical activity

Despite their knowledge of the well-documented benefits of engaging in regular PA, participants noted several personal barriers to PA. The key themes that emerged from the data included lack of time, competing responsibilities, lack of motivation, health issues, money and weather; these barriers are summarized in Table 3. The time required to engage in regular PA was mentioned often, particularly among offspring. Offspring were more likely to mention that their work and family obligations interfered with the time they had available for PA, whereas spouses were more likely to cite interferences due to social responsibilities. Competing responsibilities also presented a barrier to engaging in regular PA; this is of particular importance among employed participants. A lack of motivation and a variety of health issues were mentioned, with pain and injuries being the most commonly mentioned physical impediment to engaging in PA. Several participants mentioned financial barriers to engaging in PA. Finally, given the northern climate in Ottawa, Ontario, Canada, it is not surprising that several participants mentioned inclement weather as a barrier to PA. Overall, these barriers interfered with participants' abilities to engage in PA on a regular basis.

Discussion

This is the first study of its kind to explore how a cardiac event in a family member translates (or not) into individual PA behaviour change. The qualitative methodology employed captured each participant's individual experience with a family member who

suffered a CHD event. Taken together, themes and patterns emerged from the data, allowing for meaningful interpretation.

The data collected during the qualitative interviews emphasizes some key similarities and differences in how participants coped with a family member's CHD event and incorporated PA into their daily lives, and the potential links between these two. Overall, participants were knowledgeable about the benefits of PA, and the importance of family history of CHD, but they surprisingly did not necessarily draw the link between their family member's cardiac event and their own PA behavior. The findings reported here add significantly to the current literature as there is very little published information on PA among family members of people recently hospitalized for CHD.

This study also adds to the body of knowledge in this area as it shows that the reaction to their family member's cardiac event differs between spouses and offspring; spouses pursued a more active role in the recovery process, which often included PA, whereas offspring were more removed from the event and its aftermath. Given that the offspring are adults leading independent lives, these varied reactions to the cardiac event may not be surprising. That is, the cardiac event seemed to have less of a direct effect on the PA behaviours of offspring. Although offspring seemed aware of the familial risks associated with PA, this did not consistently translate into PA behaviour change, perhaps due to greater time barriers associated with work and family commitments which present a more immediate demand on their time. Despite this main difference,

there were several consistent themes that emerged from the data for both spouses and offspring.

The cardiac event in a family member made participants more aware of their own mortality but this did not translate into changed behavior for all. Many participants engaged in PA primarily for the overall health benefit but also to potentially mitigate their own risk of future CHD. Perceived future risk of CHD did not consistently translate into PA behaviour change; some participants used this opportunity to become more active, yet others did not. This lack of behaviour change is consistent with similar research (22).

The cardiac event seemed to affect the PA levels of spouses more directly, which is promising, given that other research has found that women married to men who experienced a myocardial infarction had elevated CHD risk factors (30). Spouses tended to increase their PA more than offspring, both with and without their partner, as a result of the cardiac event. It was also found that the spousal relationship provided a significant source of social support for PA, which often entailed participating in PA together. Given that the spousal relationship can have such a strong influence on PA behaviour, additional research to explore the factors associated with PA for dyads, such as spouses, is warranted.

Participants cited enjoyment, weight loss/control and health benefits as factors that influence PA, which is consistent with other research (44, 45). Despite the positive factors associated with PA, such as enjoyment and health benefits, participants

experienced numerous barriers to PA. A lack of motivation and/or time, competing responsibilities, health issues, money and weather were all documented throughout the interviews. These results are consistent with other research on PA in similar, healthy adult populations (46, 47).

It is important to note that the findings are limited in several ways. First, since all of the participants were previously enrolled in the FHH-RCT, the results may not be transferable to the general population. These participants have self-selected to participate in a health behaviour change study, and therefore may be more highly motivated. Secondly, participants were well-educated, employed and lived in Ottawa, Ontario, Canada; therefore, the emergent findings may not be transferable to populations with different demographic profiles. Despite these limitations, the current findings provide unique insights into the PA patterns at the level of the family.

This research highlights important areas for future research and/or interventions to increase PA among family members of people with CHD. There are some fundamental differences in how participants conceptualize PA. Consistent with other research, women may perceive their activities of daily living as sufficient for meeting PA guidelines which they often are not (48). For the purpose of maintaining or improving cardiovascular health, people need to be engaging in activities at a moderate-vigorous level of sufficient duration (49). Individuals may need further education about activities that are of sufficient intensity for obtaining cardiovascular benefit. Individuals who are inactive could be encouraged to restructure their activities of daily living to support an increase in their PA level, which may make it easier for people to gradually increase their

activity level by taking small opportunities throughout the day, with the goal that they would gradually become sufficiently active to gain cardiovascular benefits. Future research should explore different interventions to increase PA that are implemented at the unit of the family, incorporating CHD rehabilitation and prevention as the impetus for change.

Table 1: Characteristics of the study sample

Characteristic	Spouse n=17	Offspring n=19	Total N=36
Age (mean $\pm$ SD)	58.8 $\pm$ 16.6	51.1 $\pm$ 8.9	54.7 $\pm$ 13.5
Female (%)	11 (64.7%)	10 (52.6%)	21 (58.3%)
Education, years (mean $\pm$ SD)	14.4 $\pm$ 3.5	14.7 $\pm$ 2.6	14.6 $\pm$ 2.9
Marital Status			
Never married	0	1	1
Married	16	16	32
Common Law	1	0	1
Separated/Divorced	0	1	1
Widowed	0	1	1
Employment			
Full-time	2	14	16
Part-time	4	4	8
Homemaker	1	1	2
Retired	8	0	8
On disability	2	0	2
Urban	13	13	26
Rural	4	6	10

Table 2: Exemplary quotes from active versus inactive participants by family category and gender

Family Category	Gender	Active vs. Inactive (n)	Examples	Quote
Spouse	Female	Active (n=3)	Walking the dog, home exercise equipment, yoga classes, aquafit.	Norah: I do my water aqua-fit and that is a standard thing Mondays and Wednesdays and I try to let nothing interfere with that. And then usually I will go for a walk with [husband] in the morning. That may be...maybe about 4 times a week. My aqua-fit is twice a week-that is a definite....Walking is about 4, I'd say 4 to 5 times a week and the last couple of weeks I've started, because [husband] can't walk as fast as I want to walk for aerobic walking, I'm starting to walk in the evenings now 25 minutes and I do real aerobic walking there.
		Inactive (n=8)	Housework, laundry, chores, walking to and from the car.	Trudy: Well, to be honest, I don't think PA, running is against my religion and so if anything I would do is walking and I haven't been walking too much so...Maybe an hour a week if I go out for a walk in the last 6 months or so. So I haven't done too much exercise except for...The normal walk to, you know you get up go downstairs, make your coffee, go to work in the car out of the car so really it's been terrible.
	Male	Active (n=5)	Biking, walking, weight-lifting, stretching, curling.	Neil: I cycle about five days a week and I walk three or four days a week.... So, I do between two fifty and three fifty minutes of activities a week.
		Inactive (n=1)	Mowing the grass, gardening, snow shoveling, janitorial job.	Shane: Well today I just came in from cutting the lawn so I have quite a bit of gardening and grass cutting and stuff in the summertime and I have a lawnmower which isn't motorized so it's a lot of extra work so...So instead of walking or jogging, I do that in the summertime...and in the winter I basically just have the snow-shovel so I do that too

Offspring	Female	Active (n=4)	Gym, walking, aquafit, workplace lunch hour activities.	Winona: I try to walk every day ... 20 to 25 minutes and on top of that I try to go at lunch hour to a sport activity that's organized in our building.
		Inactive (n=6)	Walking (low intensity, infrequent), parking at the back of the lot, nothing.	Ursula: Yeah, but I am active...I'm very active with my dogs and the poodle club.
	Male	Active (n=3)	Yoga, triathlon training, gym, walking, power swimming, running, elliptical machine.	Zachary: Well, I guess try and make a point of going to the gym every day. I'm usually pretty good at it at keeping ...a consistent, I guess schedule. Sometimes I fall off but I usually try and get back on when I do fall off so I don't know. There's nothing that, there's nothing that actually advises me to go other than my willingness to go. Just try and stay in shape and be active.
		Inactive (n=6)	Nothing, very little, not enough, caring for property, working, boating.	Paul: I guess try and, if I can, walk or exercise instead of taking the lazy way if possible but I do still take elevators and stuff like that instead of the stairs... I should be doing more but it's one of those things-time too with doing the actual activity I guess.

Table 3. Barriers to physical activity experienced by participants and exemplary quotes

Family Category	Gender	Barriers to PA	Quote
Spouse	Female	Injuries Scheduling/planning Weather Family/home responsibilities Time Pain Lack of self-motivation Lack of transportation Cost	Harriet: Does laziness count?...Everybody I'm sure goes through stages of being unmotivated ... you know...you sort of think oh I just ... I don't feel like doing this today, and you don't. And I think the hard thing is that you ... if you have a day like that you can't have another day and another day ... you know ... like I sort of find ... catch myself if I think oh man I haven't done anything for a couple of days ... there's just sort of that inner thing that says ... you know ... like don't let it go too long, because if you do then you never get back to it.
	Male	Lack of self-motivation Time Health issues Injuries Travelling Laziness Scheduling Competing priorities	Charles: One is the laziness factor, and the second is ... I guess probably the bigger would be the gout. And the third [barrier], if you wanted a third one, is the pollen in the air.

Offspring	Female	Time Laziness/lack of self-motivation Health issues Fatigue/tiredness Attitude Injuries Lack of knowledge	Beth: Laziness. I choose to do something else. It's always not convenient right now.
	Male	Time Lack of self-motivation Injuries Work and family commitments Health issues Inconvenience No friends living close by	George: Myself [is the biggest barrier to PA]. You know, that motivating yourself. Giving yourself that kick in the butt to get out the door and do something. You know, like yes it's been a long day but get off the couch or get off the computer. It's a bad habit-we all get home check your emails and do this and do that and fire up the computer. Before you know it an hour has been wasted. You know, we blame time but that's part of the equation. I mean the other part is self-motivation.

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CHAPTER 4: Manuscript 3 (Neighbourhood)

Neighbourhood walkability and physical activity among family members of people with heart disease who participated in a randomized controlled trial of a behavioural risk reduction intervention

Abstract

This study adds to the current literature investigating the relationship between individuals' physical activity (PA) and the built environment. Self-reported PA from a prospective behavioural risk reduction intervention was explored in the context of objectively measured Walk Scores and neighbourhood walkability in Ottawa, Canada. Participants in the intervention arm had significantly higher odds of meeting PA guidelines at 12-weeks compared to the standard care control group. This was not influenced by Walk Scores or walkability. This individual-level intervention was effective in assisting participants to overcome potential structural barriers presented by their neighbourhood to meet PA guidelines at 12-weeks.

Keywords: Physical Activity, Intervention, Neighbourhood, Walk Score, Walkability, Social Ecological

Introduction

The benefits of physical activity (PA) are extensive and well documented (1), including decreased morbidity and mortality associated with numerous chronic diseases (2-5), greater longevity (6, 7) and improved functioning in old age (8-10). Despite these benefits, physical inactivity continues to present a serious challenge for public health. In 2005, almost half (48%) of Canadians were considered inactive (equivalent to less than 30 minutes of walking per day) in their leisure time (11).

Physical inactivity is an independent risk factor for the development of coronary heart disease (CHD) (12-16). Family history is another risk factor: first-degree relatives of those with CHD have a 1.5- to two-fold increase in risk (17-21). Family members of people with CHD may be a key group to target with interventions to increase PA since they carry an excessive burden of CHD risk associated with both a positive family history and physical inactivity. Even in the presence of a family history of CHD, participation in at least moderate-level PA can significantly decrease the odds of developing CHD compared to remaining sedentary (22).

Interventions to increase PA are an essential component of health promotion strategies. A Cochrane systematic review of randomized controlled trials of interventions to encourage PA among sedentary individuals with a minimum of six months of follow-up found that the evidence supports a positive, moderate sized effect on increasing self-reported PA (23). This suggests that PA is amenable to improvements with appropriate intervention.

It is important to understand PA behaviour change in terms of a social ecological perspective, which permits the exploration of PA in the context of personal, behavior-specific, socio-environmental and physical environmental factors (24). Social ecological theory considers the various levels of influence on health behaviours, including individual, interpersonal, organizational, community and public policy factors that facilitate or impede behaviour change (25). PA interventions need to be examined from a social ecological perspective to gain a better understanding of the broader context in which PA behaviour change is achieved.

A substantial body of research has examined the attributes of the built environment that are conducive to PA; several reviews have demonstrated the relationship between neighbourhood characteristics and PA outcomes (26-29). Higher density, greater connectivity, greater land use mix, accessibility of recreational facilities and local destinations, safety and visual quality are associated with greater self-reported walking and cycling (27). Similarly, land use mix, connectivity, population density and overall neighbourhood design are significant determinants of PA (26). Social support, connectivity of trails, and availability of recreation facilities have also demonstrated associations with PA (28). Density, distance to non-residential destinations and land use mix were positively associated with walking for transport, but findings for route/network connectivity, parks and open space, and personal safety were less consistent (29). These reviews highlight some of the important characteristics of neighbourhoods that are associated with PA; however, the majority of the existing research is largely based on cross-sectional or longitudinal research. An examination of

how neighbourhood characteristics influence PA outcomes in the context of an individual-level behavioural risk reduction intervention is warranted.

Walkability is a commonly measured characteristic in studies examining neighbourhood influences on health outcomes (30-39). In general, walkability indices incorporate measures of several neighbourhood characteristics (e.g. land use mix, residential density, etc.) into one scale and use geospatial mapping techniques to link walkability to individual areas (e.g. the area surrounding an individual's home address). One of the most commonly used walkability indices is that proposed by Frank and colleagues (2010), which incorporates measures of intersection density, residential density, retail floor area ratio and land use mix (33). A simpler, readily available, cost-free approach for measuring neighbourhood walkability is Walk Score (available at [walkscore.com](https://www.walkscore.com)), which uses data from multiple sources to estimate the walkability of the local area based on distance to amenities (e.g. grocery stores, restaurants, parks, libraries, fitness centres, retail establishments) and two pedestrian-friendly metrics, intersection density and average block length (40). Walk Score has recently been validated as a neighbourhood measurement tool (41-43); however, it has not been applied in the context of a PA behaviour change intervention.

Few studies have examined whether or not the neighbourhood environment influences the effectiveness of interventions to increase PA. The purpose of the current study was to (1) create a walkability index using an existing built environment dataset from the Ottawa Neighbourhood Study (ONS), (2) compare walkability to Walk Scores, and (3) to

link both walkability and Walk Scores to PA outcomes from the Family Heart Health: Randomized Controlled Trial (FHH-RCT). The analyses examined (1) whether or not FHH-RCT participants met the PA guidelines (≥ 150 minutes moderate-vigorous PA per week); (2) the effect of the intervention arm (family risk reduction (FRR) vs. standard care (SC)), (3) individual level Walk Scores (high vs. low) and aggregate walkability of participants' home residential neighbourhood (high vs. low) on the dichotomous PA outcome (met PA guidelines vs. not) at baseline and at the end of the intervention period (12-weeks); (4) and the interaction between these conditions. It was hypothesized that (1) participants living in high walkability neighbourhoods would be more likely to meet PA guidelines at baseline compared to participants living in low walkability neighbourhoods and (2) that participants in the FRR intervention arm living in high walkability neighbourhoods would be most likely to meet PA guidelines at 12-weeks.

Methodology

Participants

To be included in the current analysis, participants were required to (i) be enrolled in the FHH-RCT, which has been described in detail elsewhere (44), (ii) live in an Ottawa neighbourhood and (iii) provide verbal informed consent for the data linkage. The University of Ottawa Heart Institute (UOHI) Human Research Ethics Board approved the FHH-RCT and this data linkage study.

Between January 2008 and October 2010, 423 participants were recruited for the FHH-RCT through a hospital-based prevention and wellness centre. In addition to being the spouse, offspring or sibling of a patient hospitalized at UOHI within the past 5 years for CHD, eligible participants were required to have at least one modifiable CHD risk factor (i.e. physical inactivity, smoking, poor nutrition, abdominal obesity or medication nonadherence), to speak English or French, be 20 to 80 years of age, be willing to provide informed consent, and be geographically available for assessment, intervention and follow-up. Exclusion criteria for the FHH-RCT were as follows: (1) unable to understand English or French; (2) history of diabetes mellitus or any atherosclerotic disease; (3) fasting glucose ≥ 7.0 mmol/L at screening; (4) presence of life threatening illness; (5) chronic kidney disease and/or undergoing dialysis; (6) active liver disease; (7) pregnant or planning to become pregnant within the next year; (8) cognitive impairment; or (9) other family member already participating in the study.

Intervention

Briefly, the FHH-RCT was a prospective, 1-year, randomized, controlled trial to evaluate the effects of a 12-week telephone-based risk reduction intervention provided to individuals at risk for CHD. Participants in the FHH-RCT were randomized to one of 2 arms: FRR intervention or SC control. FRR participants received one in-person counseling session with a heart health educator to identify their risk reduction goals and create a personalized behaviour change plan followed by 12 weekly telephone counseling sessions. SC participants received a printed package containing general information

about PA, nutrition, smoking and medications and CHD risk reduction and did not receive any further intervention.

Measures

Physical Activity

Physical activity was measured using a modified version of the Godin Leisure-Time Exercise Questionnaire (45). Participants were asked 'How many days in a typical week out of the past 6 months did you do moderate (e.g. fast walking, easy bicycling, easy swimming, dancing) exercise for at least 10 minutes at a time?' and 'On the days when you did moderate exercise(s) (for at least 10 minutes at a time), how much total time on average did you spend per day doing these moderate exercise(s)?' The same two questions assessed the frequency and duration of vigorous activities (e.g. running, jogging, squash, cross country skiing, vigorous swimming, vigorous bicycling, vigorous aerobic classes). For the 12-week assessment, the timeframe for the questionnaire was modified from 6 months to 3 months to reflect the duration of the intervention period. The modified version of the questionnaire has been previously validated (46). The total minutes each of moderate and vigorous exercise per week were calculated and summed as a measure of moderate-vigorous PA. The accumulation of ≥ 150 minutes of moderate-vigorous PA per week was used as the indicator of achievement of recommended PA targets based on current Canadian guidelines (47).

Neighbourhood walkability

Individual Walk Scores were extracted from walkscore.com using the postal code of each participant. Walk Scores have been validated as a neighbourhood environment measurement tool (42, 43). Walk Scores were dichotomized at the mean into high versus low for comparison.

Objective neighbourhood walkability was measured via the ONS. The ONS provides data on the social and physical environment using a multitude of data collection techniques (e.g., census data, geographic information system (GIS) data, telephone contact with businesses, web-based research and field techniques). Neighbourhoods were spatially defined using a geomatics approach; the data sources integrated in a GIS included spatial data from DMTI Spatial, Quickbird imagery, spatial data from the City of Ottawa and the National Capital Commission and tabular data from the 2001 Canadian Census at the geographic level of the dissemination area (48). Variables included in the walkability index were selected based on a review of the literature examining the relationships between PA and neighbourhood, consultation with experts in the field of population health and availability in the ONS dataset. Based on these criteria, using the approach proposed by Frank and colleagues (2010), the equation used to calculate walkability was:

$$\text{Walkability} = 2(\text{z-Intersection Density}) + \text{z-Residential Density} + \text{z-Retail Floor Area Ratio} + \text{z-Land Use Mix}$$

where

Intersection Density = Number of true intersections (3 or more legs) by neighbourhood area

Residential Density = Total number of block dwellings per square kilometer

Retail Floor Area Ratio = the retail building floor area footprint divided by land area devoted to retail

Land Use Mix = the degree to which a diversity of land use types were present in a neighbourhood

The walkability index was dichotomized at the mean to create comparable categories of high and low neighbourhood walkability to facilitate interpretation of the findings. The correlation between this measure of neighbourhood walkability and neighbourhood-level Walk Scores in the City of Ottawa was strong (Pearson's $r=0.79$), therefore walkability was the only aggregate-level measure used. Participants' home address postal code was geocoded to ONS neighbourhoods to link individual-level outcome data to the walkability index.

Since this was a post-hoc analysis, participants in the FHH-RCT were not recruited based on neighbourhood walkability. Similarly, the ONS data was not initially collected for the purpose of calculating walkability.

Individual-level variables

Demographic data, including ethnicity, marital status, income and education, were collected at baseline via a self-report questionnaire. Participants were asked about their

past medical history. Participant relationship to the index patient (e.g. spouse, sibling or offspring) was determined based on self-report.

Current smokers were defined as individuals who smoked any cigarettes (even a puff) in the past seven days (49). Claims of non-smoking were verified on all participants using a carbon monoxide analyzer (Bedfont Smokerlyser) with carbon monoxide levels ≤ 0 ppm confirmatory for non-smoking (50).

Height and weight were measured at baseline and at the 12-week follow-up to determine body mass index (BMI) using a standardized protocol. Waist circumference was measured using a non-stretchable standard tape measure. All anthropometric measures were collected based on the standardized methods from the Canadian Physical Activity, Fitness & Lifestyle Approach (CPAFLA) (51).

Data Analysis

The flow diagram of study participants is presented in Figure 1. Chance differences in key variables at baseline were tested using chi square or t-tests as appropriate. Participants were compared at baseline based on intervention arm (FRR vs. SC), Walk Score (high vs. low), walkability (high vs. low), and the PA guidelines (met guidelines vs. not).

Two hundred ninety-two (93.0%) participants were eligible for the baseline analysis. In cross-sectional analyses at baseline, controlling for significant differences as appropriate, logistic regression analyses for the dichotomous PA outcome were

performed to test separately for the effect of the intervention arm (FRR vs. SC), Walk Score (high vs. low) and neighbourhood walkability (high vs. low).

Power Calculation. At a significance level $\alpha=0.05$, using the probability of living in a high walkability ($Pr_{\text{walkability}}=.42$) and the probability of achieving the PA guidelines at baseline ($Pr_{\text{PA}}=.21$), with a detectable/alternative odds ratio=2, the sample size=292 had 73.6% power to detect significant differences.

For the 12-week analyses, participants who met the PA guidelines at baseline ($n=62$, 21.2%) were excluded because they did not receive a PA intervention. A series of logistic regression models were used to test for the effect on the dichotomous PA outcome (met guidelines vs. not). The first model examined the effect of the intervention arm (FRR vs. SC); the second model examined the effect of Walk Score (high vs. low); the third model examined the effect of neighbourhood walkability (high vs. low); the fourth model examined the interaction effect of intervention arm x Walk Score; and the final model examined the interaction effect of intervention arm x neighbourhood walkability. Data analyses were performed using SPSS version 19.0.

Results

Baseline characteristics of participants ($n=292$) are presented in Table 1. There were no significant differences in demographic characteristics at baseline between the FRR and SC intervention arms.

Variables from the ONS used to derive the neighbourhood walkability scores are presented in Table 2. At baseline, participants (n=292) lived in 84 unique neighbourhoods; 16 out of the 84 neighbourhoods had only one participant living there. The mean walkability was 0.54 ± 3.09 (range = -5.85 – 11.63). One hundred seventy (58.2%) participants lived in low walkability neighbourhoods.

Walk Scores in this sample ranged from zero to 98 (mean = 50.0 ± 22.7 ; possible range: 0-100). One hundred thirty-five participants (46.2%) had a low Walk Score. A comparison of the dichotomous classification (e.g., high versus low) by Walk Score and walkability at baseline was not uniform: 38 participants were classified as low Walk Score and high walkability and 78 participants were classified as high Walk Score and low walkability (39.4% discordance).

At baseline, participants with low Walk Scores or low neighbourhood walkability were significantly more likely to be married ($p < .05$). There were no other significant differences in baseline demographic characteristics between participants with high versus low Walk Scores or high versus low neighbourhood walkability (results not shown).

At baseline, there was no significant difference between FRR and SC arms for meeting the PA guidelines (>150 minutes moderate-vigorous PA/week) (Odds Ratio (OR) = 1.44, 95% Confidence Interval (CI): 0.82 – 2.53). At baseline, controlling for marital status, there was no significant difference between participants with high versus low Walk Scores for meeting the PA guidelines (OR = 0.78, 95% CI: .44 – 1.35). Similarly,

controlling for marital status, there was no significant difference between participants living in high versus low walkability neighbourhoods for meeting the PA guidelines at baseline (OR = 0.57, 95% CI: 0.31 – 1.04, $p=.067$).

Descriptive characteristics comparing those who met the PA guidelines at baseline to those who did not are presented in Table 1b. Participants who met the PA guidelines at baseline were significantly more educated ($p=.032$), taller ($p=.038$), and less likely to be female ($p=.018$). There were no other significant differences between those who met the PA guidelines at baseline and those who did not based on demographic characteristics, intervention arm, Walk Score or neighbourhood walkability.

Among participants who did not meet the PA guidelines at baseline ($n=230$), there were no significant differences between the FRR and SC intervention arms, between those with high versus low Walk Scores or between those living in high versus low walkability neighbourhoods (results not shown).

The results from the series of logistic regressions are presented in Table 3. At 12-weeks, participants in the FRR intervention arm had significantly higher odds of meeting PA guidelines compared to SC participants (OR = 4.42, 95% CI: 2.50 – 7.83, $p<.001$). There was no significant difference in meeting PA guidelines at 12-weeks between participants with high versus low Walk Scores (OR = 0.71, 95% CI: 0.42 – 1.21, $p = .21$) or high versus low walkability neighbourhoods (OR = 0.62, 95% CI: 0.36 – 1.06, $p = .081$).

There was no interaction between the intervention and Walk Scores. Participants in the FRR intervention arm with both low Walk Scores (OR = 4.32, 95% CI: 1.88 – 9.95, $p=.001$) and high Walk Scores (OR = 5.03, 95% CI: 2.23 – 11.36, $p<.001$) had significantly higher odds of meeting the PA guidelines at 12-weeks compared to SC.

Similarly, walkability did not interact with the intervention; participants in the FRR intervention arm living in both low walkability neighbourhoods (OR = 6.48, 95% CI: 2.97 – 14.15, $p<.001$) and high walkability neighbourhoods (OR = 2.79, 95% CI: 1.18 – 6.57, $p<.05$) had significantly higher odds of meeting the PA guidelines at 12-weeks compared to SC. An overall summary of the results is presented in Figure 2.

Discussion

These analyses demonstrate that the FHH-RCT intervention is effective for increasing self-reported PA. The individual-level intervention appears to have a stronger effect on PA outcomes than either measure of neighbourhood walkability; participants with both high and low walk scores or living in high versus low walkability neighbourhoods were more likely to achieve the PA targets if allocated to the FRR intervention.

There was no significant difference based on Walk Score or walkability for meeting the PA guidelines in the cross-sectional analyses at baseline. These results were somewhat surprising, considering that several other cross-sectional studies have found a consistent, positive relationship between neighbourhood walkability and PA (37, 52). These results may reflect the nature of the study sample; the current participants were

motivated to enrol in a behavioural risk reduction intervention for which physical inactivity was an inclusion criteria. Another issue is that only 62 out of 292 (21.2%) of the study participants met PA guidelines at baseline, which may not be sufficient for detecting meaningful significant differences.

The correlation between Walk Scores and walkability showed a moderate positive correlation. These results suggest that Walk Scores are an acceptable and easily accessible measure of neighbourhood walkability in the absence of more rigorous, detailed data. This finding is consistent with another validation study of Walk Score (41). However, the high discordance rate (39.4%) in dichotomous classification by Walk Score and walkability warrants caution. This discordance reflects the difference in scale of the two measures – Walk Scores are measured at the individual level, whereas walkability is an aggregate measure at the neighbourhood level. Additional research that compares Walk Score to other objective measures of walkability is warranted.

This study has several strengths. It examines the context in which the intervention is delivered, linking an effective individual-level intervention to the broader built environment context in which PA occurs using two objective measures of the neighbourhood environment.

Limitations of this study must be considered. The sample size was fairly small, which may have limited the ability to detect meaningful effects of Walk Scores and walkability on PA outcomes. PA was measured by self-report, which may have an impact on the observed PA outcomes, since objective PA may be over- or under-estimated (53). Only

moderate-vigorous PA was assessed in the current study, but light PA, such as walking for transport, may be more directly associated with neighbourhood characteristics (54). Perceptions of neighbourhood were not assessed in the current study; perceived walkability is an important consideration when examining the link between PA and neighbourhood (52, 55). Finally, among participants who achieved the PA target, there was no assessment of where the PA episode actually occurred. Other research has found that only one third of PA episodes occurred in participants' own neighbourhood (56). The use of Global Positioning Systems (GPS) may shed some light on where PA is taking place (57).

Conclusion

This study found that the intervention was effective for increasing PA among participants with both high and low Walk Scores and neighbourhood walkability. These results are promising, given that neighbourhood redevelopments to create more walkable environments are both time-consuming and expensive (36). Future interventions and policies to promote PA should consider the social ecological context in which PA takes place. Additional research using objective measures of PA, such as accelerometers and GPS, and perceptions of neighbourhood walkability in the context of similar interventions is needed.

Figure 1. Family Heart Health Randomized Controlled Trial – Ottawa Neighbourhood

Study Data Linkage Participant Flow Diagram

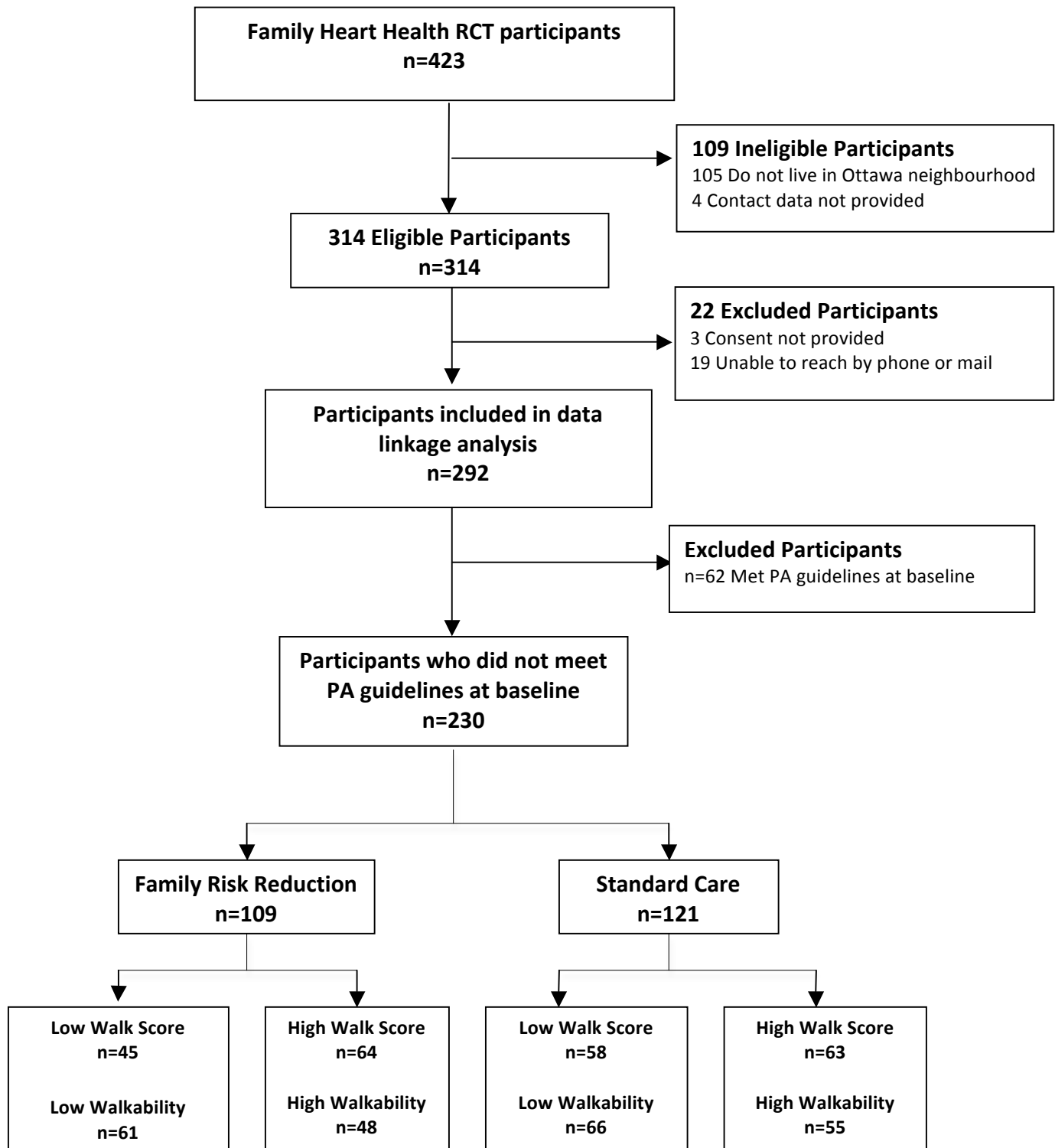


Table 1. Baseline Characteristics of Participants in the Family Heart Health Randomized Controlled Trial – Ottawa Neighbourhood Study Data Linkage

Characteristic	Total N=292	FRR n=144	SC n=148	p- value
Age, years $\pm$ SD	52.7 $\pm$ 11.2	52.8 $\pm$ 11.2	52.6 $\pm$ 11.2	.910
Female (%)	184 (63.0)	92 (62.2)	92 (63.9)	.809
Education (years $\pm$ SD)	14.7 $\pm$ 2.6	14.7 $\pm$ 2.5	14.7 $\pm$ 2.7	.967
Income (\$)				
<25,000	16 (5.5)	10 (6.9)	6 (4.1)	
25,000 – 49,999	35 (12.0)	15 (10.4)	20 (13.5)	
50,000 – 74,999	51 (17.5)	25 (17.4)	26 (17.6)	
75,000 – 99,999	38 (13.0)	22 (15.3)	16 (10.8)	
$\geq$ 100,000	94 (32.2)	42 (29.2)	52 (35.1)	
Missing	58 (19.9)	30 (20.8)	28 (18.9)	.584
Employed Full-Time (%)	154 (53.1)	81 (56.6)	73 (49.7)	.242
Ethnicity (White, %)	275 (94.8)	135 (94.1)	140 (94.6)	1.000
Married (%)	272 (93.2)	133 (92.4)	139 (93.9)	.649
Height (cm)	167.7 $\pm$ 9.6	167.1 $\pm$ 9.9	168.4 $\pm$ 9.3	.255
Weight (kg)	82.5 $\pm$ 18.3	81.3 $\pm$ 17.0	83.7 $\pm$ 19.4	.272
BMI (kg/m ²)	29.4 $\pm$ 5.8	29.3 $\pm$ 5.4	29.5 $\pm$ 6.1	.863
Waist circumference (cm)	96.5 $\pm$ 14.4	95.8 $\pm$ 13.2	97.3 $\pm$ 15.4	.381
Smoker (%)	32 (11.0)	14 (9.7)	18 (12.2)	.576
Stratum:				
Spouse (%)	97 (33.2)	51 (35.4)	46 (31.1)	
Sibling (%)	124 (42.5)	61 (42.4)	63 (42.6)	
Offspring (%)	71 (24.3)	32 (22.2)	39 (26.4)	.630
FHHP Intervention Arm (%)	144 (49.3)	---	---	---
Baseline Physical Activity (minutes/week $\pm$ SD)	84.1 $\pm$ 105.6	86.2 $\pm$ 107.9	82.0 $\pm$ 103.6	.736
Baseline Met PA Guidelines (>150 minutes mod-vig/week)	62 (21.2)	35 (24.3)	27 (18.2)	.252
Low Walk Scores*	135 (46.2)	74 (54.8)	61 (45.2)	.199
Low Walkability**	170 (58.2)	85 (59.0)	85 (57.4)	.813

*low Walk Score defined as < mean Walk Score

**low walkability defined as < mean walkability

Table 1b. Baseline Characteristics of Participants in the Family Heart Health Randomized Controlled Trial – Ottawa Neighbourhood Study Data Linkage Who Met the PA Guidelines versus Those Who Did Not Meet the PA Guidelines

Characteristic	Total N=292	Met PA Guidelines at Baseline n=62	Did Not Meet PA Guidelines at Baseline n=230	p- value
Age, years $\pm$ SD	52.7 $\pm$ 11.2	52.4 $\pm$ 12.4	52.8 $\pm$ 10.8	.809
Female (%)	184 (63.0)	31 (50.0)	153 (66.5)	.018
Education (years $\pm$ SD)	14.7 $\pm$ 2.6	15.3 $\pm$ 2.3	14.5 $\pm$ 2.7	.032
Income (\$)				
<25,000	16 (5.5)	3 (4.8)	13 (5.7)	
25,000 – 49,999	35 (12.0)	7 (11.3)	28 (12.2)	
50,000 – 74,999	51 (17.5)	10 (16.1)	41 (17.8)	
75,000 – 99,999	38 (13.0)	7 (11.3)	31 (13.5)	
$\geq$ 100,000	94 (32.2)	26 (41.9)	68 (29.6)	
Missing	58 (19.9)	9 (14.5)	49 (21.3)	.578
Employed Full-Time (%)	154 (53.1)	36 (58.1)	118 (51.8)	.393
Ethnicity (White, %)	275 (94.8)	59 (95.2)	216 (94.7)	1.00
Married (%)	272 (93.2)	59 (95.2)	213 (92.6)	.584
Height (cm)	167.7 $\pm$ 9.6	170.0 $\pm$ 10.6	167.1 $\pm$ 9.3	.038
Weight (kg)	82.5 $\pm$ 18.3	85.8 $\pm$ 19.2	81.6 $\pm$ 17.9	.109
BMI (kg/m ²)	29.4 $\pm$ 5.8	29.9 $\pm$ 5.7	29.2 $\pm$ 5.8	.406
Waist circumference (cm)	96.5 $\pm$ 14.4	97.6 $\pm$ 14.9	96.2 $\pm$ 14.2	.513
Smoker (%)	32 (11.0)	7 (11.3)	25 (10.9)	1.00
Stratum:				
Spouse (%)	97 (33.2)	21 (33.9)	76 (33.0)	
Sibling (%)	124 (42.5)	25 (40.3)	55 (23.9)	
Offspring (%)	71 (24.3)	16 (25.8)	99 (43.0)	.920
FHHP Intervention Arm (%)	144 (49.3)	35 (56.5)	109 (47.4)	.252
Baseline Physical Activity (minutes/week $\pm$ SD)	84.1 $\pm$ 105.6	248.3 $\pm$ 102.1	39.6 $\pm$ 45.6	<.001
Low Walk Score*	135 (46.2)	32 (51.6)	103 (44.8)	.390
Low Walkability**	170 (58.2)	43 (69.4)	127 (55.2)	.059

*low Walk Score defined as < mean Walk Score

**low walkability defined as < mean walkability

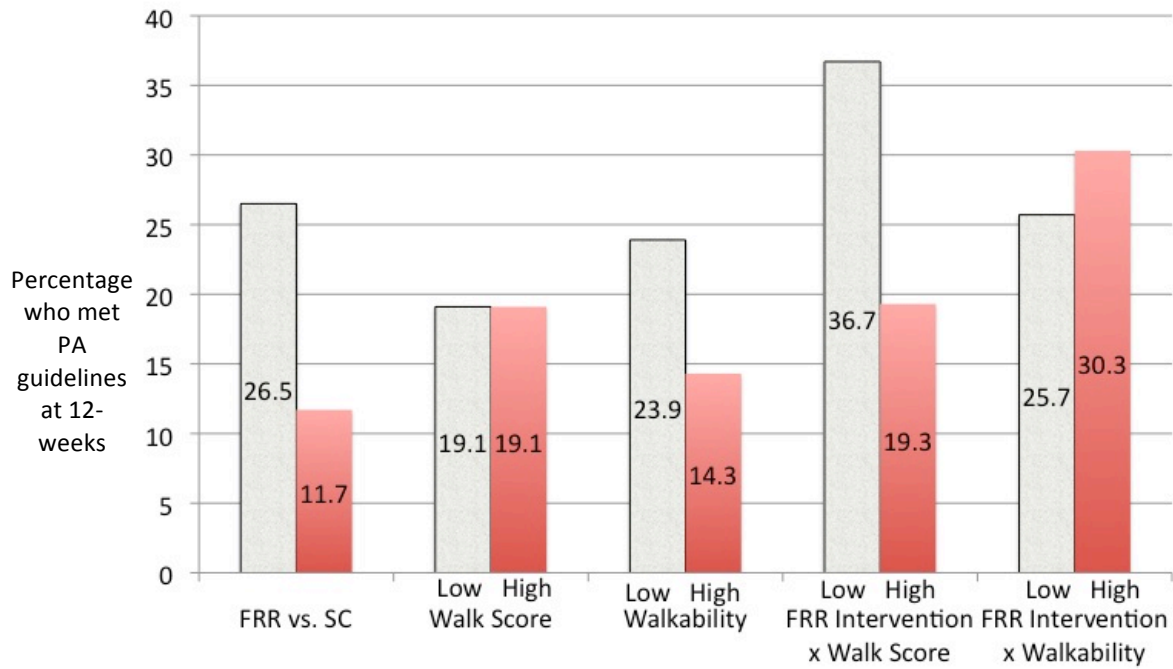
Table 2. Neighbourhood dimensions associated with PA and corresponding Ottawa Neighbourhood Study data used to calculate walkability

Walkability Dimension	Description	Data Source
Net Residential Density	The ratio of residential units to the land area devoted to residential use per block group.	City of Ottawa Zoning Data Statistics Canada 2006 Block-Face Dwelling points
Retail floor area ratio	The retail building floor area footprint divided by retail assessment parcel area property boundary.	DMTI Inc. Enhanced Points of Interest (EPOI) City of Ottawa Building Footprints City of Ottawa Zoning Terranet Inc. Property Assessment Parcels for Ontario
Intersection density	The ratio between the number of true intersections (three or more legs) to the land area of the neighbourhood,	City of Ottawa Roads
Land use mix, or entropy score	The land use mix indicates the degree to which a diversity of land use types were present in a neighbourhood. For this research, the mix measure considered seven land use types: retail trade (NAICS 44-45), finance (NAICS 52), Libraries, Rental Stores (NAICS 53), Educational Services (NAICS 61), Health Care and Social Assistance (NAICS 62), Food Services (NAICS 72), Other Services (Religious organizations, Laundromats, dry cleaners etc.) (NAICS 81).	DMTI Inc. Enhanced Points of Interest (EPOI)

Table 3. Odds ratios for meeting the PA guidelines at 12-weeks according to different scenarios in the FHH-RCT – ONS data linkage study

Condition	Met PA Guidelines at 12-weeks OR (95% CI)	p-value
Intervention Arm		
SC	1.00	
FRR	4.42 (2.50 - 7.83)	<.001
Walk Score		
Low	1.00	
High	0.71 (.42 – 1.21)	.211
Neighbourhood Walkability		
Low	1.00	
High	0.62 (0.36 – 1.06)	.081
Walk Score x Intervention Arm		
Low x SC	1.00	
Low x FRR	4.32 (1.88 – 9.95)	.001
High x SC	1.00	
High x FRR	5.03 (2.23 – 11.36)	<.001
Neighbourhood Walkability x Intervention Arm		
Low x SC	1.00	
Low x FRR	6.48 (2.97 – 14.15)	<.001
High x SC	1.00	
High x FRR	2.79 (1.18 – 6.57)	<.05

Figure 2. Summary of analysis examining the effect of intervention arm, Walk Scores, neighbourhood walkability, and interactions on meeting PA guidelines at 12-weeks



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CHAPTER 5: DISCUSSION AND CONCLUSION

5.1 Summary of Key Findings

Findings from each of the three manuscripts provide detailed information regarding PA outcomes of participants in the Family Heart Health: Randomized Controlled Trial (FHH-RCT), a behavioural risk reduction intervention for family members of patients with CHD. Using a social ecological approach, PA behaviour change in the context of this intervention was examined at the individual, family and neighbourhood level.

Although each study was conceptualized individually, the findings from the first study (Individual) were used to inform subsequent studies. The first study (Individual) was carried out to establish the effect of the FHH-RCT intervention on PA outcomes, which was necessary prior to conducting the second (Family) and third (Neighbourhood) studies. Participation in the second study (Family) occurred once the FHH-RCT intervention period was complete for two primary reasons: 1) to ensure the FHH-RCT results were not confounded by an additional intervention (i.e. the interview), and 2) to permit the exploration of the impact of the FHH-RCT intervention on PA outcomes and family dynamics. Finally, the results from the first study (Individual) were used to inform the analyses investigating the effect of the interaction between neighbourhood and PA outcomes (Study 3). The data linkage for the third study also occurred after the FHH-RCT intervention period was complete.

The first manuscript (Individual) explored the efficacy of the intervention for increasing self-reported moderate-vigorous PA over the 12-week intervention period. This study demonstrated that the family risk reduction (FRR) intervention caused self-

reported moderate-vigorous PA to increase over the 12-week intervention period; this relationship was significantly correlated with increases in TPB constructs, including control belief, subjective norm, attitude, perceived behavioural control and intention among intervention participants and attitude and intention among controls. The results demonstrate the intervention not only worked, but also that the effect of the intervention was related to significant changes in theoretically derived variables the intervention sought to influence. It will be important to assess the impact of the intervention on long-term maintenance of PA behaviour change in the future. It will also be important to consider other populations for whom a similar intervention might be appropriate. Overall, family members of patients with CHD are an at-risk population who may benefit from health interventions such as the FHH-RCT to increase their PA and potentially decrease their future risk.

The second manuscript (Family) employed a qualitative research design involving semi-structured interviews to elicit perceptions of the factors in the social and physical environment that influenced PA. The findings suggest that there are fundamental differences in how spouses and offspring engage in PA and how they adapt to a CHD event in a family member. Awareness of an increased susceptibility to CHD does not appear to activate participants to increase their own PA to prevent future risk, particularly among offspring. Spouses are more likely to engage in PA with the former CHD patient than offspring, suggesting that a shared environment can promote PA, although the intensity of the activity may be limited for the non-CHD spouse. Family members may need additional information or intervention in order to translate their

perceived future risk of CHD into current PA behaviour change. This study was unique in that it explored PA behaviour change in an at-risk population who were at least somewhat motivated for behaviour change, given that they responded to the recruitment messages for the FHH-RCT. For many participants, the intervention alone was not sufficient to translate into meeting the PA guidelines after 12-weeks. It is possible that the participants did not receive a PA-based intervention; that is, the intervention focused on nutrition and/or smoking and/or medication adherence, but these outcomes are beyond the scope of this thesis. Additional research in similarly at-risk populations should consider techniques for increasing family-based PA, particularly among spouses, that can be modified to individual capabilities as appropriate.

The third manuscript (Neighbourhood) used two objective measures of the neighbourhood, Walk Scores and walkability, to examine the influence of the built environment on PA outcomes among FHH-RCT participants living in Ottawa, Ontario, Canada. Walk scores and walkability were examined for their independent effects on PA and for their interaction with the intervention arm. Similar to Study 1, the analyses from Study 3 revealed that allocation to the FRR intervention was the most significant factor associated with achieving the PA guidelines at 12-weeks. Walk Scores and walkability had less impact than the intervention allocation for achieving the PA guidelines at 12-weeks. Participants with both high and low walk scores, and those living in high versus low walkability neighbourhoods, had significantly greater odds of achieving the PA guidelines if they were allocated to the FRR intervention group. These results are promising since the intervention is likely more cost-effective than retro-fitting

neighbourhoods to encourage people to engage in PA. These analyses also provide a unique example of how the broader social and physical environment can be considered when examining the impact of an individual-level behavioural risk reduction intervention, such as the FHH-RCT.

Collectively, the three manuscripts integrated both quantitative and qualitative techniques to describe in rich detail a complex phenomenon, PA behaviour change. These manuscripts present an in-depth exploration of the interactions between intrapersonal, interpersonal and neighbourhood characteristics that influence PA behaviour change in the context of the FHH-RCT intervention. This provides greater depth of insight regarding how these multiple levels influence PA. The interactions between these various levels cannot be ignored, and these analyses shed some light on the contextual and setting factors related to PA behaviours among family members of people with CHD. PA behaviour change is a dynamic process, and the combination of both quantitative and qualitative research techniques allowed new data to emerge from the findings to afford a more detailed account of the process of PA behaviour change.

The social ecological theoretical perspective applied throughout the current research is an effective approach for exploring the connections between individuals and their surrounding social and physical environment to understand the impact on health outcomes. This perspective has facilitated greater understanding of the multiple levels of influence on PA behaviour change by attending to the nature of participants' interactions with their social and physical settings (1). Each level of influence impacts PA

differently, and their effects interact synergistically. Taken together, these studies provide new insights regarding potential avenues to promote PA participation.

5.2 Strengths of the Thesis

This thesis has several strengths. The participants were enrolled in a randomized controlled trial of a behavioural risk reduction intervention for family members of patients with CHD. This is a rigorous study design to test the efficacy of the intervention for increasing PA. Cause and effect relationships between the intervention and PA were investigated and established.

This thesis is unique in its design and approach. A social ecological theoretical perspective was incorporated to explore PA outcomes at the individual, family and neighbourhood level. Each study provides insight into the processes of PA behaviour change and PA outcomes of study participants. Taken together, these three studies provide an in-depth analysis of the multiple levels of influence on PA in this population.

As previously stated, both quantitative and qualitative methodologies were used to gain greater breadth and depth of knowledge regarding factors at the individual, family and neighbourhood level that influenced PA outcomes among study participants. This mixed methodologies approach drew on the strengths of both quantitative and qualitative research paradigms to incorporate techniques that were most appropriate for answering the research questions (2). In the first study (Individual), a quantitative approach was employed to make predictions about the impact of the FHH-RCT intervention on PA and permitted testing hypotheses and theories. Once the effect of the intervention on PA was established, the second study (Family) employed a

qualitative approach to elaborate on how and why the FHH-RCT intervention changed PA for different family members. Finally, the third study (Neighbourhood) incorporated quantitative techniques to link individual-level PA data to neighbourhood characteristics to understand the interaction between neighbourhood contextual factors and participants' ability to achieve PA targets as recommended by Canadian PA guidelines (3). Each study provided unique insights regarding the multilevel factors associated with PA behaviour change.

5.3 Limitations of the Thesis

As aforementioned in the discussion sections of Study 1 (Individual) and Study 3 (Neighbourhood), the results from these analyses are based on self-reported PA. A recent systematic review comparing self-reported and objective measures of PA found that self-reported PA may over- or under-estimate objective PA (4). This is a methodological limitation that must be considered when interpreting these results. Additional research using objective measures of PA, such as accelerometry, is warranted.

A second limitation is the use of a dichotomous PA outcome (met PA guidelines of 150 minutes moderate-vigorous PA versus not). The original PA data was collected as a continuous measure of minutes of moderate-vigorous PA per week. Most analytical techniques are based on the assumption that the outcome is normally distributed. In this sample, the PA outcome was not normally distributed, with a high proportion of participants reporting zero PA at baseline and 12-weeks. Several manipulations of the outcome were considered, including the logarithmic, power and square root

transformations. None of these transformations fit the data well. Several statisticians were consulted for additional guidance on this matter. The consensus was that using a dichotomous PA outcome would be the most appropriate approach to overcome the non-normal distribution of PA. In post-hoc sensitivity analyses for Study 1 (Individual), the dichotomous PA outcome (≥ 150 minutes moderate-vigorous PA versus not) was modified to 100 or 200 minutes of moderate-vigorous PA per week to determine how these changes in the outcome might influence the results of the analyses. In both of these scenarios, the effect of the intervention on PA outcomes persisted; participants in the FRR intervention arm had significantly higher odds of achieving the PA targets at the 12-week follow-up. This supports the robustness of the use of the dichotomous PA outcome and the results of the analyses.

This thesis is also limited by the small sample size, which is most apparent in Study 3 (Neighbourhood). In addition, the sample is not ethnically diverse (95.1% Caucasian), which may limit the generalizability or transferability of these results to populations with different ethnic backgrounds. The participants were also highly educated with fairly high self-reported incomes, further limiting the generalizability of these findings to populations with more varied socioeconomic backgrounds. Additional research on the effectiveness of interventions to increase PA among more diverse populations is needed.

5.4 Knowledge Dissemination

Several knowledge dissemination strategies have been actively pursued while completing this thesis. The results from Study 1 (Individual), *Effects of a 12-week risk*

reduction program on physical activity levels in family members of patients with coronary heart disease: Secondary outcomes from a randomized clinical trial, have been accepted for oral presentation at the CDPAC Fourth Pan-Canadian Conference: Integrated Chronic Disease Prevention: It Works! in Ottawa, Ontario, Canada on February 8-10, 2012. Preliminary analyses from Study 2 (Family), *A qualitative exploration of physical activity patterns among family members of people with heart disease: Preliminary results*, were presented orally at The Second Biennial Bilingual Conference of the Canadian Society for the Sociology of Health on October 29, 2010 in Ottawa, Ontario, Canada. The preliminary results from Study 3 (Neighbourhood), *Neighbourhood Characteristics Associated with Physical Activity Behaviour Change Among Family Members of People with Heart Disease*, were presented in poster format at the Canadian Public Health Association Conference in Montreal, Quebec, Canada on June 19-21, 2011. A synthesis of all three studies, *A social ecological approach to understanding physical activity: A mixed methods study of the individual, family and neighbourhood characteristics that influence physical activity among Family Heart Health program participants*, was presented in poster format at the PHIRN Building a Healthier Ontario Forum in Toronto, Ontario, Canada on September 30, 2011. All three studies were presented in poster format at the University of Ottawa Heart Institute Research Day on May 7, 2012 in Ottawa, Ontario, Canada; a synthesis of all three studies was presented orally at the same venue. Finally, a synthesis of all three studies is scheduled to be presented as a free webinar via CHNET-Works! Fireside Chat on June

14, 2012. These presentations provide opportunities to disseminate the results and gain feedback from other researchers and individuals interested in population health.

In addition, each study is formatted for submission to a peer-reviewed journal to broaden the dissemination of these research findings. Other knowledge translation strategies that may be pursued in the near future include sharing the study results with participants (one page summary and/or community forum) and policy personnel at the City of Ottawa (briefing note). Overall, multiple knowledge translation strategies are being implemented.

5.5 Contribution to Population Health

As aforementioned, the population health approach is concerned with the distribution of the determinants of health throughout the population and the interactions that exist between these determinants (5). The Public Health Agency of Canada recognizes twelve determinants of health, including: income and social status, social support networks, education and literacy, employment/working conditions, social environments, physical environments, personal health practices and coping skills, healthy child development, biology and genetic endowment, health services, gender and culture (6). The FHH-RCT focused primarily on targeting personal health practices (e.g. PA) and gave consideration to biology and genetic endowment (e.g. family history of CHD). The FHH-RCT was not a population health intervention, but rather a clinical intervention for individuals at increased risk of developing CHD. While individual behaviour change was the goal of the intervention (e.g. increased PA), changes in this personal health behaviour were explored at the individual, family and neighbourhood levels. This was

consistent with a social-ecological approach, which considers the multiple layers of influence on health behaviours, including factors in the social and physical environment (1, 7). By attending to the nature of the individual's interactions with the broader social and physical environment, greater detail is garnered regarding the broader contextual factors influencing PA outcomes and the determinants of health associated with PA behaviour change.

5.6 Policy Implications

This research has provided a broader understanding of the contextual factors that influence PA interventions. Physical and social aspects of the surrounding environment over the life course contribute to the variations in the adoption of both enhancing and damaging health-related behaviours. Implementing interventions to increasing levels of PA is a public health priority that must be conceptualized as a function of multiple individual, interpersonal, organizational, community and public policy factors. Positive changes in the population health status as a result of health behaviour changes (including increased PA) may be achieved through the implementation of interventions, community actions, and policies that are directed at the family, community, or societal level.

This research has provided new insights regarding some of the factors in the social and physical environment that facilitate engaging in PA among family members of patients with CHD living in Ottawa, Ontario who participated in a behavioural risk reduction intervention. This research provides preliminary evidence supporting the efficacy of the intervention for increasing PA.

5.7 Future Research Directions

Future interventions and policies should consider the context in which PA behaviours are occurring to maximize the likelihood of achieving PA targets. Further research is needed to explore the effect of the FHH-RCT intervention on PA outcomes among more diverse populations using objective measures of PA. Future research on individual-level interventions to increase PA should incorporate a measure of the neighbourhood environment to explore its influence on PA behaviour change. Data concerning neighbourhood contextual awareness may shed additional light on the relationship between PA and walkability. Walk Scores are an easily accessible measure of the neighbourhood environment that are moderately correlated with walkability, as measured using the method proposed by Frank and colleagues (8). Additional validation studies comparing Walk Scores to other objective measures of the neighbourhood and PA outcomes are warranted. Finally, future interventions among family members of patients with CHD should explore mechanisms to translate increase perceived risk of CHD into PA behaviour change.

5.8 Conclusion

In conclusion, the findings of this thesis provide novel insights into the relationships between PA, an individual-level intervention, family interactions and neighbourhoods among family members of patients with CHD. Specifically, the FHH-RCT intervention was effective for increasing self-reported moderate-vigorous PA to the level recommended by current Canadian PA guidelines (3). The intervention was effective regardless of whether the participant had a high versus low Walk Score or lived in a high versus low

walkability neighbourhood. To gain even greater health benefits, family members may need additional information or intervention in order to translate their perceived future risk of CHD into current PA behaviour change.

5.9 References

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APPENDIX A: Family Heart Health Program: Randomized, Controlled Trial Ethics Approval



August 1, 2007

RE: HI Protocol # 2007438-01H Family Heart Health Program: Randomized, Control Trial (FHHP RCT)

Protocol approval valid until - October 1, 2008

The above listed protocol was reviewed by the full Board of the Human Research Ethics Board (HREB). You have met the requirements of the HREB and your protocol is approved for two months to start recruiting English-speaking patients. Approval has been granted for the revised Research Summary, dated June, 2007, the revised Protocol, Version 2, dated June, 2007, the English Radio and Print Advertisement, the English Background Questionnaire, the English Risk Factor Profile, the English Food Frequency Questionnaire and the English Patient Information Sheet and Consent Form, Version 2, dated June, 2007. Upon receipt and review of the French documents, approval may be extended to June 14, 2008 (one year from the initial meeting date) and the recruitment of French-speaking patients may commence. No changes, amendments or addenda may be made to the protocol without the HREB review and approval.

The Tri-Council Policy Statement requires a greater involvement of the HREB in studies over the course of their execution. The HREB will review the new information to determine if the protocol should be modified, discontinued, or should continue as originally approved.

APPENDIX B: Godin Leisure Time Exercise Questionnaire

ID: _____

Date: _____

Please recall your average/typical weekly physical activity during the past 6 months and write your responses to the questions (i.e. 1 to 6) in the spaces provided. If you did not participate in any activity(s), please put a zero (0) in the “days” AND the “minutes per day” spaces.

(1) How many days in a typical week out of the past 6 months did you do MILD (e.g., easy walking, yoga, archery, fishing, bowling, horseshoes, golf) exercise for at least 10 minutes at a time? _____ days

(2) On the days when you did MILD exercise(s) (for at least 10 minutes at a time), how much total time on average did you spend per day doing these mild exercise(s)? _____ minutes per day

(3) How many days in a typical week out of the past 6 months did you do MODERATE (e.g., fast walking, tennis, easy bicycling, easy swimming, dancing) exercises for at least 10 minutes at a time? _____ days

(4) On the days when you did MODERATE exercise(s) (for at least 10 minutes at a time), how much total time on average did you spend per day doing these moderate exercise(s)? _____ minutes per day

(5) How many days in a typical week out of the past 6 months did you do VIGOROUS (e.g., running, jogging, squash, cross country skiing, vigorous swimming, vigorous bicycling, vigorous aerobic classes) exercise(s) for at least 10 minutes at a time? _____ days

(6) On the days when you did VIGOROUS exercise(s) (for at least 10 minutes at a time), how much total time on average did you spend per day doing these vigorous exercise(s)? _____ minutes per day

Family Heart Health Program

BASELINE PHYSICAL ACTIVITY QUESTIONNAIRE

Theory of Planned Behavior
Ecological Framework

The information you are providing on this questionnaire is personal, and we assure you that it will remain confidential. You may notice that you are identified only by a study and identification number (i.e. FHHP 001) on the questionnaire. The questions deal with several aspects of your health and well-being. There are no right or wrong answers; we ask only that you answer each question as honestly and accurately as you can.

We appreciate you taking the time to complete this questionnaire.

SHOULD YOU HAVE ANY QUESTIONS OR NEED CLARIFICATION ABOUT HOW TO ANSWER ANY QUESTION, PLEASE DO NOT HESITATE TO CONTACT THE STUDY COORDINATOR.

Study #:
Participant ID#:.....
Date (d/m/yyyy):.....

Physical Activity

IMPORTANT: For this survey, we are focusing on leisure-time physical activity. Leisure time means activity done during your free time and does not include your work/job or household chores. Physical activity means any exercise or sport that results in a substantial increase in energy expenditure (resulting in a noticeable increase in heart rate and breathing rate). Examples of exercises include brisk walking, jogging, cycling, swimming, and dancing. By sport, we mean any physical activity where physical skill influences the outcome of a competition. Examples include golf, soccer, bowling, curling, tennis, and skiing. Please do not include sports that don't require much energy expenditure (e.g., shooting pool, darts, etc.).

Regular physical activity (PA) is defined as participating in at least 150 minutes/week of physical activity, at a moderate intensity (e.g. fast walking, tennis, easy bicycling), 5-7 days of the week or 100 minutes/week of physical activity, at a vigorous intensity (e.g. jogging, squash, cross-country skiing), 4-7 days of the week.

The following questions ask you to rate how you feel about regular PA over the next 3 months. Please pay careful attention to the words at each end of the scale and circle the number that best represents how you feel. Please answer all items from (a) to (f).

I think that for me to participate in regular PA over the next 3 months would be:

(a) 1 2 3 4 5 6 7
 extremely quite slightly slightly quite extremely
 useless useless useless useful useful useful

(b) 1 2 3 4 5 6 7
 extremely quite slightly slightly quite extremely
 unenjoyable unenjoyable unenjoyable enjoyable enjoyable enjoyable

(c) 1 2 3 4 5 6 7
 extremely quite slightly slightly quite extremely
 harmful harmful harmful beneficial beneficial beneficial

(d) 1 2 3 4 5 6 7
 extremely quite slightly slightly quite extreme
 painful painful painful pleasureable pleasureable pleasureable

(e) 1 2 3 4 5 6 7
 extremely quite slightly slightly quite extremely
 unimportant unimportant unimportant important important important

(f) 1 2 3 4 5 6 7
 extremely quite slightly slightly quite extremely
 boring boring boring fun fun fun

This next set of questions asks you to rate how other people in your life may feel about you participating in regular PA over the next 3 months. Please pay careful attention to the words at the end of each scale and circle the number that best represents how you might feel. Please answer all items from (a) to (c).

I think that if I participate in regular PA over the next 3 months, most people who are important to me would be:

(a)	1	2	3	4	5	6	7
	extremely	quite	slightly		slightly	quite	extremely
	disapproving	disapproving	disapproving		approving	approving	approving

(b)	1	2	3	4	5	6	7
	extremely	quite	slightly		slightly	quite	extremely
	discouraging	discouraging	discouraging		encouraging	encouraging	encouraging

(c)	1	2	3	4	5	6	7
	extremely	quite	slightly		slightly	quite	extremely
	unsupportive	unsupportive	unsupportive		supportive	supportive	supportive

This next question asks you to rate how active (how much PA participation) you think other people in your life are likely to be over the next 3 months.

I think that over the next 3 months, most people who are important to me will be:

(a)	1	2	3	4	5	6	7
	extremely	quite	slightly		slightly	quite	extremely
	inactive	inactive	inactive		active	active	active

I think that over the next 3 months, most people who are important to me will participate regularly in PA.

(a)	1	2	3	4	5	6	7
	strongly	moderately	slightly		slightly	moderately	strongly
	disagree	disagree	disagree		agree	agree	agree

These next questions ask you to rate how likely you feel it is that you would be able to participate in regular PA over the next 3 months if you were really motivated. Pay careful attention to the words in each scale. Circle the number that best represents how you feel.

If you were really motivated...

a) How much control would you have over doing regular PA over the next 3 months?

1	2	3	4	5	6	7
very little control			some control		complete control	

b) How confident are you that you could do regular PA over the next 3 months?

1	2	3	4	5	6	7
not at all confident		somewhat confident		quite confident	completely confident	

This next set of questions ask you about your motivation and plans to do regular PA over the next 3 months. Pay careful attention to the words at the end of each scale.

I definitely intend to participate in regular physical activity over the next 3 months:

1	2	3	4	5	6	7
no, not really			somewhat intend		strongly intend	

How motivated are you to do regular PA over the next month?

1	2	3	4	5	6	7
not at all motivated		somewhat motivated		quite motivated	extremely motivated	

I have made plans concerning 'when' I am going to participate in regular physical activity over the next 3 months:

1	2	3	4	5	6	7
no specific plans			some general ideas		very detailed plans	

I have made plans concerning 'where' I am going to participate in regular physical activity over the next 3 months:

1	2	3	4	5	6	7
no specific plans			some general ideas		very detailed plans	

I have made plans concerning the 'type' of PA I am going to participate over the next 3 months:

1	2	3	4	5	6	7
no specific plans			some general ideas		very detailed plans	

I have made plans concerning '*how I am going to get to a place*' to participate in physical activity over the next 3 months:

1	2	3	4	5	6	7
no specific plans			some general ideas		very detailed plans	

How much vigorous intensity PA do you intend to do over the next month?

____ days per week for ____ minutes each day (write in numbers including 0)

How much moderate intensity PA do you intend to do over the next month?

____ days per week for ____ minutes each day (write in numbers including 0)

If you were to do regular PA over the next 3 months, do you think it would...

	Extremely unlikely	Quite Unlikely	Slightly Unlikely	Neutral	Slightly Likely	Quite Likely	Extremely likely
(1) improve your energy level	1	2	3	4	5	6	7
(2) help you lose/control your weight	1	2	3	4	5	6	7
(3) improve your heart health	1	2	3	4	5	6	7
(4) make you live longer	1	2	3	4	5	6	7
(5) help you feel better and improve your well-being	1	2	3	4	5	6	7
(6) improve your overall health	1	2	3	4	5	6	7
(7) improve fitness	1	2	3	4	5	6	7
(8) reduce your risk of ill health	1	2	3	4	5	6	7
(9) improve your physical appearance	1	2	3	4	5	6	7
(10) provide more social interaction	1	2	3	4	5	6	7
(11) increase your risk of injury	1	2	3	4	5	6	7
(12) be too time consuming/difficult to schedule	1	2	3	4	5	6	7

How supportive do you think each of the following people would be if you tried to do regular PA over the next 3 months?

	Extremely unsupportive	Quite unsupportive	Slightly unsupportive		Slightly supportive	Quite supportive	Extremely supportive
spouse/ partner	1	2	3	4	5	6	7
other family members	1	2	3	4	5	6	7
friends	1	2	3	4	5	6	7
family physician/ health care provider	1	2	3	4	5	6	7
co-workers	1	2	3	4	5	6	7

How confident are you that you could do regular PA over the next 3 months if...

	Not at all confident		Somewhat confident		Quite Confident		Completely confident
you feel tired/fatigued	1	2	3	4	5	6	7
you are lacking motivation	1	2	3	4	5	6	7
you get very busy and have limited time	1	2	3	4	5	6	7
you have additional family responsibilities	1	2	3	4	5	6	7
you have medical/health problems	1	2	3	4	5	6	7
it costs too much	1	2	3	4	5	6	7
the weather is bad (i.e., too hot, too cold, rain)	1	2	3	4	5	6	7

Physical Activity Resources

Below is a list of things you may have in your neighbourhood or at work. Please '√' one box to indicate which ones are already available to you.

	Yes	No
(a) Walking paths	√	√
(b) Neighbourhood or mall walking program	√	√
(c) Public park with playing fields	√	√
(d) Public recreation centre	√	√
(e) Swimming pool, beach or lake	√	√
(f) Basketball or tennis courts	√	√
(g) Health club or gym near home	√	√
(h) Hiking trails	√	√
(i) Organized sports (like adult leagues)	√	√

APPENDIX D: Qualitative Study Ethics Approval



Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches

751 Parkdale Avenue Suite 106, Ottawa, Ontario K1Y 1J7 613-798-5555 ext. 14902 Fax: 613-761-4311
<http://www.ohri.ca/ohreb>

Wednesday, March 31, 2010

Re: Protocol # 2010093-01H Qualitative Exploration of Physical Activity Patterns and Family Relationships Among Participants in the Family Heart Health Program: Randomized Controlled Trial

Protocol approval valid until - Monday, May 31, 2010

Thank you for the letter dated March 19, 2010. I am pleased to inform you that this protocol underwent expedited review by the Human Research Ethics Board (HREB) and is approved for two months to begin recruiting English-speaking participants. No changes, amendments or addenda may be made to the protocol or the consent form without the HREB's review and approval.

Approval is for the following:

- Research Protocol received March 19, 2010
- English Consent to Participate in a Research Study (version 2) dated March 19, 2010
- English Letter of Invitation to Participate received March 19, 2010
- English Repeat Letter of Invitation to Participate received March 19, 2010
- English Reminder Telephone Script received March 19, 2010
- English Semi-Structured Interview Guide received March 19, 2010
- French Letter of Invitation to Participate received March 19, 2010
- French Repeat Letter of Invitation to Participate received March 19, 2010
- French Reminder Telephone Script received March 19, 2010
- French Semi-Structured Interview Guide received March 19, 2010

Upon receipt and review of the French Consent to Participate in a Research Study, the study approval may be extended for up to a year and the recruitment of French-speaking participants may begin.

The validation date should be indicated on the bottom of all consent forms and information sheets (see copy attached).

... 2

APPENDIX E: Invitation Letter to Participate in Qualitative Study



{insert date}

{insert participant's address}

Dear {insert name}:

Re: Qualitative Exploration of Physical Activity Patterns and Family Relationships
Among Participants in the Family Heart Health Program: Randomized Controlled Trial

You have recently completed your 52 week follow-up for the Family Heart Health Program: Randomized, Controlled Trial. Thank you for your participation.
The purpose of this letter is to invite you to participate in an interview study.

Briefly, we are looking for spouses or siblings of heart disease patients who have completed the Family Heart Health Program. We would like to interview you to obtain more information on your physical activity patterns throughout the program and how the changes in your physical activity influenced your family.

Please find enclosed a copy of the Participant Information Sheet and Consent Form. Please read this information carefully. If you would like to participate, please contact the study coordinator to make an appointment to further discuss your participation. Your decision to participate is entirely up to you. If you do agree to participate, your information may help us to better understand how physical activity patterns influence your family relationships. This may help to create programs and interventions in the future that target the family unit and its interactions.

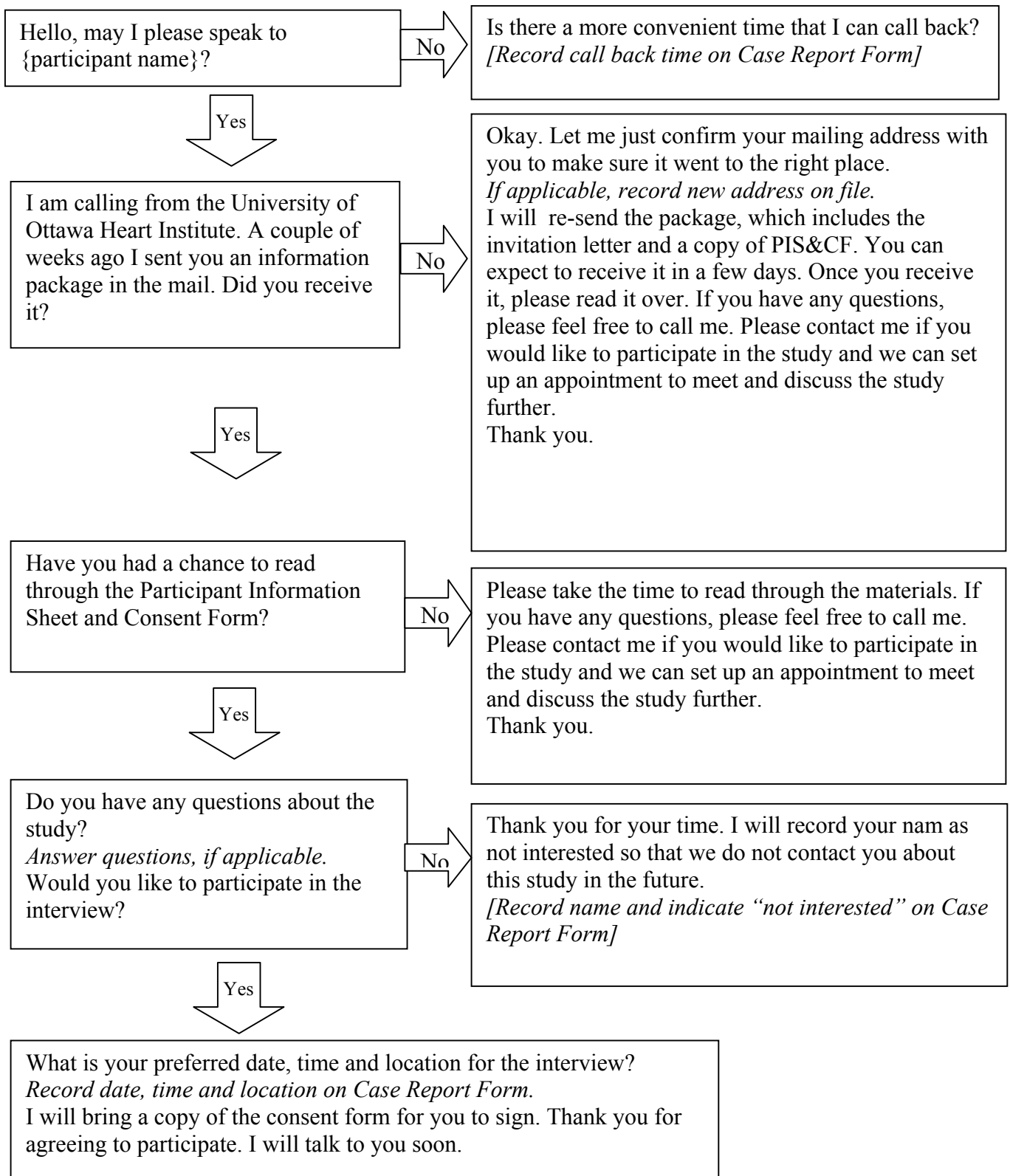
If you have any questions about this study, please call the study coordinator.

Thank you for your consideration.

Sincerely,

{insert signature}

APPENDIX F: Reminder Telephone Script



APPENDIX G: Repeat Invitation Letter to Participate in Qualitative Study



{insert date}

{insert participant's address}

Dear {insert name}:

Re: Qualitative Exploration of Physical Activity Patterns and Family Relationships
Among Participants in the Family Heart Health Program: Randomized Controlled Trial

A few weeks ago I sent you a letter regarding this study, but I have not heard back from you. I am writing to you again today to ensure that you are aware of this interview study with participants from the Family Heart Health Program: Randomized Controlled Trial.

Briefly, we are looking for spouses or offspring of heart disease patients who have completed the Family Heart Health Program. We would like to interview you to obtain more information on your physical activity patterns throughout the program and how the changes in your physical activity influenced your family.

Please find enclosed 1 copy of the Participant Information Sheet and Consent Form. Please read this information carefully. If you would like to participate, please contact the study coordinator in order to make an appointment to meet and further discuss your participation. Your decision to participate is entirely up to you. If you do agree to participate, your information may help us to better understand how physical activity patterns influence your family relationships. This may help to create programs and interventions in the future that target the family unit and its interactions.

If you have any questions about this study, please call the study coordinator.

Thank you for your consideration.

Sincerely,

{insert signature}

APPENDIX H: Qualitative Study Information Sheet and Consent Form



CONSENT TO PARTICIPATE IN A RESEARCH STUDY

A Qualitative Exploration of Physical Activity Patterns and Family Relationships Among Participants in the Family Heart Health Program: Randomized Controlled Trial
HI Protocol Number: 2010093-01H

Please read this Information Sheet and Consent Form carefully and ask as many questions as you like before deciding whether to participate.

Introduction:

You are being asked to take part in this new research study because you have completed the Family Heart Health Program: Randomized Controlled Trial. This consent form explains the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background:

Physical inactivity is a risk factor for obesity and several chronic diseases, including heart disease. Engaging in regular physical activity is good for your health. Programs to promote healthy lifestyles directed at the family unit may be an effective way to help people increase their physical activity levels and improve their health.

Purpose:

The purpose of this research study is to investigate the role of the family in helping participants to engage in physical activity behaviour change.

Procedure:

If you agree to participate in the study you will be asked to complete an interview either in person or over the phone. The interview will take approximately 30-45 minutes to complete and will be scheduled on a date and time that is convenient for you. The interview will be recorded using a digital recorder. You will be asked about your physical activity patterns and experiences with physical activity over the past year.

About 40 people from the University of Ottawa Heart Institute will be in the study.

Risks and Discomforts of Participation:

There are no risks associated with your participation in this study. The time required to complete the 30-45 minute interview may be an inconvenience to you.

Benefits of Participation:

You will not receive any direct benefit from your participating in this study. Your participation in this research may allow the researchers to have a better understanding of how families make changes to their physical activity which may be of benefit to future patients.

Compensation/Remuneration:

There will be no financial remuneration for participation in this study. If you choose to complete the interview at the University of Ottawa Heart Institute, a parking voucher will be provided to cover the cost of this expense. By participating in the study and signing this Consent, you are not waiving your legal rights that may be available to you.

Confidentiality:

All personal health information will be kept confidential, unless release is required by law. Representatives of the University of Ottawa Heart Institute Research Ethics Board, as well as the University of Ottawa Heart Institute, may review your interview responses under the supervision of the principal investigator's staff for audit purposes.

You will not be identifiable in any publications or presentations resulting from this study. No identifying information will leave the Heart Institute. All information which leaves the hospital will be coded with an independent study number. The link between your name and the independent study number will only be accessible by the principle investigator and/or his staff. The link and study files will be stored separately and securely. Both files will be kept for a period of 15 years after the study has been completed. All paper records, including the interview transcripts, will be stored in a locked file and/or office. All electronic records, including the audio recording of the interview, will be stored on a secure computer network and protected by a user password, again only accessible by Dr. Reid and/or his staff. At the end of the retention period, all paper records will be disposed of in confidential waste or shredded, and all electronic records will be deleted.

Ethics:

This study has been reviewed and received ethics approval through the Human Research Ethics Board (HREB) of the University of Ottawa Heart Institute. This body considers the ethical aspects of research projects involving human subjects. If you have any questions about your right as a research subject you may contact the Chair of the Human Research Ethics Board at the University of Ottawa Heart Institute.

Participation:

Participation in research is completely voluntary. You are free to choose to participate or not to participate in this research study. If you agree to participate in this study, you may choose to withdraw your participation at any time by contacting the investigator at the telephone number provided. This will not affect your present or future care. You may also choose not to answer any specific questions.



UNIVERSITY OF OTTAWA
HEART INSTITUTE
INSTITUT DE CARDIOLOGIE
DE L'UNIVERSITÉ D'OTTAWA

Consent Form

A Qualitative Exploration of Physical Activity Patterns and Family Relationships Among Participants in the Family Heart Health Program: Randomized Controlled Trial

Consent to Participate in Research

I understand that I am being asked to participate in a research study about physical activity patterns among participants in the Family Heart Health Program: Randomized Controlled Trial. This study has been explained to me by _____.

I have read and understood this two page Patient Information Sheet and Consent Form (or have had this document read to me). All my questions have been answered to my satisfaction. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

I voluntarily agree to participate in this study.

A copy of the signed Information Sheet and/or Consent Form will be provided to me.

Signatures

Participant's Name (Please Print)

Participant's Signature

Date

Investigator Statement (or Person Explaining the Consent)

I have carefully explained to the research participant the nature of the above research study. To the best of my knowledge, the research participant signing this consent form understands the nature, demands, risks and benefits involved in participating in this study. I acknowledge my responsibility for the care and well being of the above research participant, to respect the rights and wishes of the research participant, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

Name of Investigator/Delegate (Please Print)

Signature of Investigator/Delegate

Appendix I: Semi-Structured Interview Guide

Section 1: General Physical Activity (PA) Information

How do you incorporate PA into your daily life?
What factors influence your ability to engage in PA?

Section 2: Perceptions of Neighbourhood

How do you feel that your neighbourhood influences your PA behaviours?
What are there factors in the physical environment that make it easier to achieve your PA goals?
What are the factors in the physical environment that make it more difficult to achieve your PA goals?
In your community, will you describe any safe places for people to exercise, such as sidewalks and parks?
In your neighbourhood, are there recreational facilities with programs for adults?
If you could change something in your environment to make PA more appealing, what would that be?
Are you in favour or not in favour of public money going toward making neighbourhoods more PA friendly? Why or why not?

Section 3: The Role of the Family

How did your family cope with the illness in one of your family members?
How has the illness in your family member influenced your own PA behaviour, if at all?
Has the index event had any impact on how you engage in PA together?
If you see your neighbours or family engaging in PA, how does that make you feel about your own PA goals?
What are some of the reasons you would want to include daily PA into your life?
Can you list 3 benefits and 3 negative points of adhering to daily?
Would you say your husband/wife helped you try to achieve your PA goals? Skip if not married.
Who would you say was the most supportive of your PA efforts? In what ways were they supportive (prompt: emotional, physical etc.)?
Does your job/position in community/family role influence your efforts to engage in PA?
What about the job/position in community/family role of your husband/wife/family?
What do you feel would help you initiate and maintain daily PA?
What were some of the barriers preventing you from reaching your PA goals? Among these, which was the biggest barrier?

APPENDIX J: Family Heart Health Program: Randomized, Controlled Trial – Ottawa Neighbourhood Study Data Linkage Ethics Approval



Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches

761 Parkdale Avenue Suite 108, Ottawa, Ontario K1Y 1J7 613-798-5555 ext. 14902 Fax: 613-761-4311
<http://www.ohri.ca/ohreb>

April 13, 2010

Re: Protocol # 2010059-01H Data Linkage Between the Family Heart Health Program: Randomized Controlled Trial and the Ottawa Neighborhood Study

Protocol approval valid until - June 13, 2010

I am pleased to inform you that this protocol underwent expedited review by the Human Research Ethics Board (HREB) and is approved for two months to start recruiting English-speaking patients. Approval has been granted for the following:

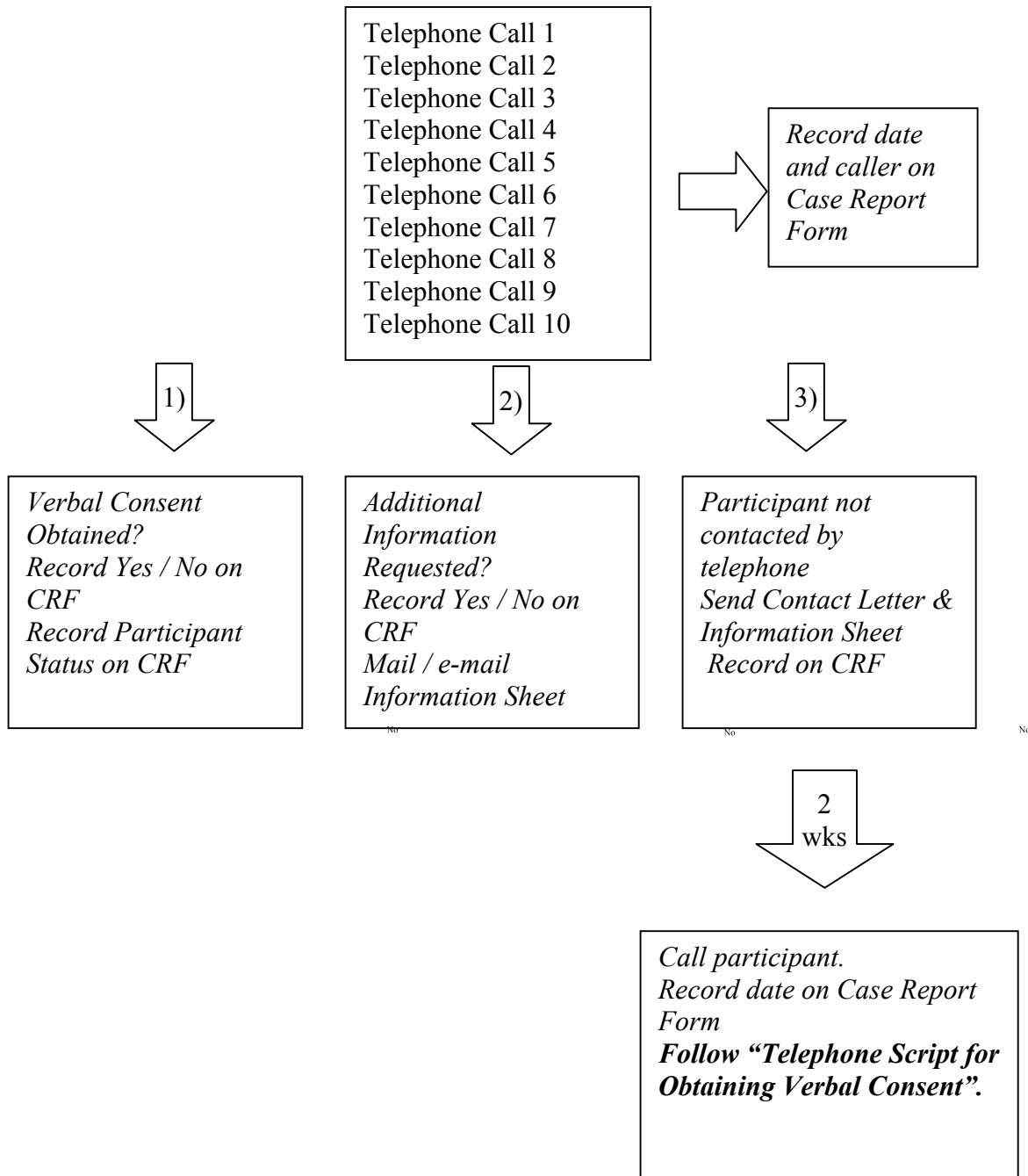
- Research Protocol, received on April 12, 2010
- Case Report Form, received on April 6, 2010
- 'Contact Protocol', received on April 12, 2010
- English 'Letter of Invitation', received on April 12, 2010
- English 'Telephone Script for Obtaining Verbal Consent', received on April 6, 2010
- English 'Research Study Information Sheet', Version 2, dated April 6, 2010

Upon receipt and review of the French 'Letter of Invitation', the French 'Telephone Script for Obtaining Verbal Consent', and the French 'Research Study Information Sheet', approval may be extended to April 12, 2011, and the recruitment of French-speaking patients may commence.

No changes, amendments or addenda may be made to the study without the HREB's review and approval.

The Human Research Ethics Board is constituted in accordance with, and operates in compliance with the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; Health Canada Good Clinical Practice: Consolidated Guideline; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Health Information Protection Act 2004 and its applicable Regulations.

APPENDIX K: Contact Protocol for the Data Linkage Between the Family Heart Health Program: Randomized Controlled Trial and the Ottawa Neighborhood Study



APPENDIX L: Telephone Script for Obtaining Verbal Consent

Data Linkage Between the Family Heart Health Program: Randomized Controlled Trial
and the Ottawa Neighborhood Study
HI Protocol Number: #2010059-01H

Good morning/afternoon. May I please speak to {participant name}?

This is Dana Riley/Amy Mark calling from the University of Ottawa Heart Institute. I would like to discuss a secondary study we would like to complete. Is this a convenient time for us to talk?

If no, record call back date on CRF. Okay, I will call you back at that time. Thank you.

You are being asked to take part in a research study because you are a participant in the Family Heart Health Program: Randomized Controlled Trial.

To give you some background information, we know that physical inactivity and poor nutrition are risk factors for obesity and several chronic diseases, including heart disease. Engaging in regular physical activity and eating well is good for your health. Your neighbourhood influences your food and activity choices. It is important to understand the impact of your neighbourhood on health outcomes so that we can design programs and interventions according to what people need. Therefore, the purpose of this research study is to investigate the impact of the physical and social environment on physical activity and nutrition behaviour change.

If you agree to participate in the study, you will not be required to complete any additional questionnaires, surveys or appointments. We will use your existing data from the Family Heart Health Program and link it to the data from another study, the Ottawa Neighbourhood Study. The Ottawa Neighbourhood Study contains information about the social and physical characteristics of the different neighbourhoods throughout the City of Ottawa. For example, details such as residential density, presence of sidewalks, green space, and land use mix are included. We will look at how different neighbourhood characteristics influence physical activity and nutrition behaviours.

Do you have any questions so far? *Answer questions (if applicable).*

Everyone who is participating in the Family Heart Health Program: Randomized, Controlled Trial will be invited to participate. There are no risks associated with your participation in this study.

You will not receive any direct benefit from your participating in this study; however your participation in this research may allow us to have a better understanding of how the social and physical environment influences physical activity and nutrition, which may be of benefit to future patients.

There will be no financial remuneration for participation in this study. By participating in the study, you are not waiving your legal rights that may be available to you.

All personal health information will be kept confidential. Representatives of the University of Ottawa Heart Institute Research Ethics Board, as well as the University of Ottawa Heart Institute, may review your information under the supervision of the principal investigator's staff for audit purposes. You will not be identifiable in any publications or presentations resulting from this study. No identifying information will leave the Heart Institute.

Participation in research is completely voluntary. You are free to choose to participate or not to participate in this research study. If you agree to participate in this study, you may choose to withdraw your participation at any time by contacting the investigator at the telephone number provided. This will not affect your present or future care.

This study has been reviewed and received ethics approval through the Human Research Ethics Board (HREB) of the University of Ottawa Heart Institute.

Do you have any questions about the study? *Answer questions as applicable.*

If participant requests additional information:

I can send you some more information by mail or e-mail. What is your preference? I will send that information to you today. Please call me back once you have reviewed it to indicate whether or not you would like to participate.

Do you consent to participating in this study? *Record "Yes" or "No" on CRF, date and initial.*

Thank you for your time.

APPENDIX M: Invitation Letter to Participate in a “Data Linkage Between the Family Heart Health Program: Randomized Controlled Trial and the Ottawa Neighbourhood Study”



{insert date}
{insert participant's address}

Dear {insert name}:

Re: Data Linkage Between the Family Heart Health Program: Randomized Controlled Trial and the Ottawa Neighbourhood Study

Thank you for your ongoing participation the Family Heart Health Program: Randomized, Controlled Trial.

The purpose of this letter is to inform you about a secondary study we would like to complete. We have tried to contact you over the past month but we have been unable to reach you. Briefly, we would like to link some of your existing data from the Family Heart Health program to the Ottawa Neighbourhood Study. This would give us more information about how physical activity and nutrition is influenced by the resources in your neighbourhood. No additional information is required from you.

Please find enclosed a copy of the Participant Information Sheet. Please read this information carefully. Your decision to participate is entirely up to you. If you do agree to participate, your information will help us to better understand how different neighbourhoods influence physical activity and nutrition. This may help to create programs and interventions in the future.

If you would like to participate in this study, or if you have any questions, please call the study coordinator.

Thank you for your consideration.

Sincerely,

{insert signature}

APPENDIX N: Repeat Invitation Letter to Participate in a “Data Linkage Between the Family Heart Health Program: Randomized Controlled Trial and the Ottawa Neighbourhood Study”



{insert date}
{insert participant's address}

Dear {insert name}:

Re: Data Linkage Between the Family Heart Health Program: Randomized Controlled Trial and the Ottawa Neighbourhood Study

A few weeks ago I sent you a letter regarding this study, but I have not heard back from you. I am writing to you again today to ensure that you are aware of a secondary study we would like to complete. Briefly, we would like to link some of your existing data from the Family Heart Health program to the Ottawa Neighbourhood Study. This would give us more information about how physical activity and nutrition is influenced by the resources in your neighbourhood. No additional information is required from you.

Please find enclosed 2 copies of the Participant Information Sheet and Consent Form. Please read this information carefully. Please indicate whether or not you would like to participate, sign the consent form, and return it in the envelope provided. Your decision to participate is entirely up to you. If you do agree to participate, your information will help us to better understand how different neighbourhoods influence physical activity and nutrition. This may help to create programs and interventions in the future.

If you have any questions about this study, please call the study coordinator.

Thank you for your consideration.

Sincerely,

{insert signature}

APPENDIX O: Information Sheet



RESEARCH STUDY INFORMATION SHEET

Data Linkage Between the Family Heart Health Program: Randomized Controlled Trial
and the Ottawa Neighborhood Study
HI Protocol Number: #2010059-01H

Please read this Information Sheet carefully and ask as many questions as you like before deciding whether to participate.

Introduction:

You are being asked to take part in a research study because you are a participant in the Family Heart Health Program: Randomized Controlled Trial. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background:

Physical inactivity and poor nutrition are risk factors for obesity and several chronic diseases, including heart disease. Engaging in regular physical activity and eating well is good for your health. Your neighbourhood influences your food and activity choices. It is important to understand the impact of your neighbourhood on health outcomes so that we can design programs and interventions according to what people need.

Purpose:

The purpose of this research study is to investigate the impact of the physical and social environment on physical activity and nutrition behaviour change.

Procedure:

If you agree to participate in the study, you will not be required to complete any additional questionnaires, surveys or appointments. We will use your existing data from the Family Heart Health Program and link it to the data from another study, the Ottawa Neighbourhood Study. The Ottawa Neighbourhood Study contains information about the social and physical characteristics of the different neighbourhoods throughout the City of Ottawa. For example, details such as residential density, presence of sidewalks, green space, and land use mix are included. We will look at how different neighbourhood characteristics influence physical activity and nutrition behaviours.

About 536 people from the University of Ottawa Heart Institute will be in the study. Everyone who is participating in the Family Heart Health Program: Randomized, Controlled Trial will be invited to participate.

Risks and Discomforts of Participation:

There are no risks associated with your participation in this study.

Benefits of Participation:

You will not receive any direct benefit from your participating in this study. Your participation in this research may allow the researchers to have a better understanding of how the social and physical environment influences physical activity and nutrition, which may be of benefit to future patients.

Compensation/Remuneration:

There will be no financial remuneration for participation in this study. By participating in the study, you are not waiving your legal rights that may be available to you.

Confidentiality:

All personal health information will be kept confidential, unless release is required by law. Representatives of the University of Ottawa Heart Institute Research Ethics Board, as well as the University of Ottawa Heart Institute, may review your information under the supervision of Dr.Reid's staff for audit purposes.

You will not be identifiable in any publications or presentations resulting from this study. No identifying information will leave the Heart Institute. All information which leaves the hospital will be coded with an independent study number. The link between your name and the independent study number will only be accessible by the principal investigator and/or his staff. The link and study files will be stored separately and securely. Both files will be kept for a period of 15 years after the study has been completed. All paper records will be stored in a locked file and/or office. All electronic records will be stored on a secure computer network and protected by a user password, again only accessible by the principal investigator and/or his staff. At the end of the retention period, all paper records will be disposed of in confidential waste or shredded, and all electronic records will be deleted.

Participation:

Participation in research is completely voluntary. You are free to choose to participate or not to participate in this research study. If you agree to participate in this study, you may choose to withdraw your participation at any time by contacting the investigator at the telephone number provided. This will not affect your present or future care.

Ethics:

This study has been reviewed and received ethics approval through the Human Research Ethics Board (HREB) of the University of Ottawa Heart Institute. This body considers the ethical aspects of research projects involving human subjects. If you have any questions about your right as a research subject you may contact the Chair of the Human Research Ethics Board at the University of Ottawa Heart Institute.

If you have any questions about this study, please feel free to contact the study coordinator.

APPENDIX P: Case Report Form - Data Linkage Between the Family Heart Health Program: Randomized Controlled Trial and the Ottawa Neighbourhood Study

FHHP-RCT ID: _____

Telephone Call 1:		Date: _____ Time: _____	Contacted: Yes / No
Call made by:		Call back date: _____ (dd/mm/yyyy)	
Telephone Call 2:	☐ N/A	Date: _____ Time: _____	Contacted: Yes / No
Call made by:		Call back date: _____ (dd/mm/yyyy)	
Telephone Call 3:	☐ N/A	Date: _____ Time: _____	Contacted: Yes / No
Call made by:		Call back date: _____ (dd/mm/yyyy)	
Telephone Call 4:	☐ N/A	Date: _____ Time: _____	Contacted: Yes / No
Call made by:		Call back date: _____ (dd/mm/yyyy)	
Telephone Call 5:	☐ N/A	Date: _____ Time: _____	Contacted: Yes / No
Call made by:		Call back date: _____ (dd/mm/yyyy)	
Telephone Call 6:	☐ N/A	Date: _____ Time: _____	Contacted: Yes / No
Call made by:		Call back date: _____ (dd/mm/yyyy)	
Telephone Call 7:	☐ N/A	Date: _____ Time: _____	Contacted: Yes / No
Call made by:		Call back date: _____ (dd/mm/yyyy)	
Telephone Call 8:	☐ N/A	Date: _____ Time: _____	Contacted: Yes / No
Call made by:		Call back date: _____ (dd/mm/yyyy)	

Telephone Call 9:	☐ N/A	Date: _____ Time: _____	Contacted: Yes / No
Call made by:		Call back date: _____ (dd/mm/yyyy)	
Telephone Call 10:	☐ N/A	Date: _____ Time: _____	Contacted: Yes / No
Call made by:		Call back date: _____ (dd/mm/yyyy)	

Additional Information Requested: Yes / No Date Sent: _____ (e-mail or mail)

Verbal Informed Consent
Received:

Yes / No Date: _____

Initials: _____

For telephone non-responders:

Participant Letter and Information Sheet
Mailed

Date: _____

Initials: _____

Final Telephone Contact:

Date: _____

Initials: _____

Participant
Status

Participant

☐

Refused

☐

Ineligible

☐

Unreachable

☐

	Baseline	3 Month	12 Month
Absolute Physical Activity			
Mild PA (minutes/week)			
Moderate PA (minutes/week)			
Vigorous PA (minutes/week)			
Dietary Behaviour Change			
Total Calories (kcal/day)			
Saturated and Trans Fat (g/d)			
Dietary Fat (% total calories)			
omega-3 poly unsaturated fats			
Cholesterol			
	Baseline	3 Month	12 Month
Fibre (g/d)			
Sodium (mg/d)			
Vegetable and Fruit Consumption			