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Robert J Petrella

Dawn P Gill
Western University, dawn.gill@uwo.ca

Marisa Kfrerer

Brendan Riggan

Melissa Majoni

See next page for additional authors

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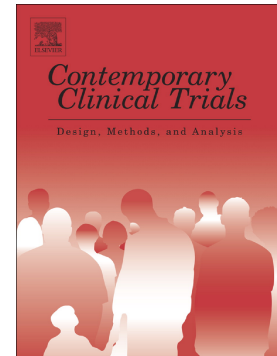
Authors

Robert J Petrella, Dawn P Gill, Marisa Kfrerer, Brendan Riggin, Melissa Majoni, Wendy Blunt, Brooke Bliss, Naron Cassio Boa Sorte Silva, Paul S Aspinall, Precious Adekoya, Matthew DiNunzio, Jacquelyn Marsh, Guangyong Zou, and Jennifer D Irwin

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Hockey Fans in Training (Hockey FIT): Rationale, Design, and Baseline Characteristics from a Cluster Randomized Controlled Trial in Men with Overweight or Obesity

Robert J. Petrella^{a,b}, MD, PhD

Dawn P. Gill^b, PhD

Marisa Kfrerer^b, MSc

Brendan Riggan^b, PhD

Melissa Majoni^a, MSc

Wendy Blunt^b, MPH

Brooke Bliss^b, BScFN

Narlon Cassio Boa Sorte Silva^b, PhD

Paul S. Aspinall^a, BSc

Precious Adekoya^b, BMSc

Matthew DiNunzio^b, BMSc

Jacquelyn Marsh^c, PhD

Guangyong Zou^d, PhD

Jennifer D. Irwin^e, PhD

^aDepartment of Family Practice, University of British Columbia, Vancouver, BC Canada

^bCentre for Studies in Family Medicine, Western University, London, ON Canada

^cDepartment of Physical Therapy, Western University, London, ON Canada

^dDepartment of Epidemiology & Biostatistics, Western University, London, ON Canada

^eSchool of Health Studies, Western University, London, ON Canada

Corresponding author:

Robert J. Petrella, MD, PhD

Email: robert.petrella@ubc.ca

Address: Department of Family Practice, 3rd Floor David Strangway Building, 5950 University Boulevard, Vancouver, BC Canada V6T 1Z3

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ABSTRACT

Background: Previous research highlights the need for effective lifestyle interventions for men. Hockey Fans in Training (Hockey FIT) was developed as a pragmatic healthy lifestyle program tailored to men with overweight or obesity. This paper overviews the rationale, program details, and design of a recently completed cluster randomized controlled trial (RCT) of Hockey FIT. Participant engagement and baseline characteristics are also described.

Methods: The RCT evaluated the effectiveness, cost-effectiveness, and implementation of Hockey FIT. Forty-two sites in Canada and the United States were randomized to either the Hockey FIT intervention group or wait-list control group. Participants were men, aged 35-65 years, with a body mass index (BMI) ≥ 27 kg/m². Hockey FIT is a group-based, off-ice, in-person healthy lifestyle program, including both a 5-month active phase and a 9-month minimally-supported phase. Outcomes were assessed at baseline, 3, and 12 months. The primary outcome was weight loss at 12 months.

Results: The design of the cluster RCT incorporates evaluations of participant health outcomes, program implementation, and broader healthcare system impact. In the RCT, 1,397 participants were assessed for eligibility and 997 were enrolled. Most participants heard about the program through social media or hockey team emails. Participants averaged 49 years of age, had BMI values of 35.3 kg/m², were predominately white, and had varying levels of education.

Conclusion: The intended audience for Hockey FIT was recruited successfully, however, targeted recruitment to better engage diverse populations is warranted. This paper affords a useful outline for evaluating future lifestyle interventions tailored to men.

This trial was registered on August 17, 2018 with ClinicalTrials.gov (identifier: NCT03636282).

Keywords: Cluster RCT; lifestyle intervention; men; obesity; physical activity; healthy eating

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INTRODUCTION

Excess weight, physical inactivity, and unhealthy eating are key risk factors contributing to chronic disease burden [1,2]. In 2018, the total percentage of adult Canadians with overweight was 36.3%, with an additional 26.8% having obesity [3]. Obesity rates in Canadian adults are higher in men compared to women (28.0% vs. 25%) [4] and in the United States (U.S.), burden is greater, with 41.9% of adult men having obesity [5]. Men are also more likely to report adverse health behaviours (including physical inactivity and unhealthy eating) that increase chronic disease risk [6,7]. The COVID-19 pandemic has further exacerbated chronic disease burden through social and physical distancing, as well as decreased preventative care [8].

The increasing rates of obesity among men in Canada and the U.S., coupled with increased adverse health behaviours, are of considerable concern for additional chronic disease burden now and in the future [1,9]. When addressing obesity and chronic disease risk in men, it is important to acknowledge the confounding societal factors that underscore men's experience with efforts to lead a healthy lifestyle. Men are more likely to view traditional lifestyle interventions as inherently feminine [10], working against the masculine ideals of independence, self-reliance, and invincibility [11,12]; making recruitment of men into lifestyle interventions more difficult. Men are also less likely to proactively seek health services and, when they do, are typically further along in the disease trajectory or in their risk for disease [13]. These findings underscore the need for effective chronic disease prevention programs tailored to men.

In recent years, there have been an increasing number of lifestyle-focused interventions for men [14,15]. Interventions successful in engaging men have utilized a gender-sensitized approach, targeting recruitment in group-based settings [11], and providing information and activities to fit masculine norms and ideals [16]. Some researchers have turned to sport as a way to recruit men into health promotion programs [17–21]; evidence indicates that bringing together individuals with similar interests can generate a positive and cohesive group dynamic, especially when the group is focused on a common goal (i.e., improved health) [22].

Hockey is embedded deeply within Canadian and American identities, with between one-half to two-thirds of Canadians and at least 13 million Americans identifying as a hockey fan [23,24]. In capitalizing on the strong male fan connection with hockey, Hockey Fans In Training (Hockey FIT) was developed as a pragmatic healthy lifestyle program tailored to men with overweight or obesity [25]. Through a previous pilot randomized controlled trial (RCT), we demonstrated the potential effectiveness of Hockey FIT for weight loss, increased physical activity, improved healthful eating, and decreased blood pressure (BP), after three months [26]. We also demonstrated feasibility to engage an at-risk population of men and findings from an exploratory analysis showed the potential for long-term sustainability of improved health outcomes. Together with results indicating program acceptability [27], this pilot study informed program optimization and evidence to proceed with a full-scale trial with longer follow-up.

The purpose of this paper is to: 1) provide an overview of the rationale, program details, and design of a recently completed cluster RCT of the Hockey FIT program; and 2) report participant engagement and baseline characteristics, with a view toward informing future healthy lifestyle interventions aimed at men at risk for chronic disease.

METHODS

Study Aims and Design

The overarching purpose of the RCT was to evaluate the effectiveness, cost-effectiveness, and implementation of Hockey FIT. The primary aim was to conduct an outcome evaluation to determine whether participants who receive Hockey FIT (relative to a wait-list control group) have greater absolute weight loss 12 months later (primary outcome), greater percentage weight loss from baseline, and improvements in other health behaviours/indicators, 3 and 12 months later. Secondary aims were to: 1) conduct an economic evaluation to estimate the cost to implement the program from different perspectives and the cost-effectiveness of Hockey FIT (vs. wait-list control); and 2) conduct a process evaluation to assess program fidelity (i.e., whether program delivery is adhered to as intended), program reach (i.e., understand who is attracted to Hockey FIT and why they take part), and program acceptability from participant, coach, and partner perspectives. Findings from the RCT are forthcoming in a separate paper.

Forty-two sites were randomly assigned to either the Hockey FIT intervention group or wait-list control group. Outcomes for examining effectiveness were assessed at baseline, 3, and 12 months; a healthcare resource use (cost) diary was completed at 3, 6, 9, and 12 months for the economic evaluation; and process evaluation measures were collected alongside the trial. The Health Sciences Research Ethics Board at Western University approved this study and all participants provided written informed consent.

Description of Sites

Sites were located in 37 cities across Canada and three cities in the U.S., spanning seven provinces (Ontario, British Columbia, Alberta, Saskatchewan, Nova Scotia, Prince Edward Island,

New Brunswick) and two states (Michigan, Oregon). Overwhelming interest from individuals within two Canadian cities resulted in two independent sites within each of those cities. After applying the population centre approach used by Statistics Canada [28], cities (including U.S. cities), were classified as follows: 18 as large urban population centres, 18 as medium population centres, and 4 as small population centres (see **Supplementary File 1**).

Sites were selected based on the availability and interest of both a major junior/professional hockey team and an implementation partner. Thirty-nine major junior hockey teams (from the Canadian Hockey League, including three teams located in the U.S.; British Columbia Hockey League; and Alberta Junior Hockey League) and one professional team (from the American Hockey League) were involved in this study, primarily assisting with recruitment and retention of participants. Thirty-seven implementation partners and three hockey teams facilitated the Hockey FIT program, providing staff to be trained as coaches and space to run the program. Of the 37 implementation partners (distinct from the hockey teams), 24 were YMCAs, five were universities, four were city recreation departments, three were private fitness facilities, and one was a health clinic.

Sites were grouped into two strata, which were used for randomization. Stratum 1 included sites located in Ontario (18 sites) while stratum 2 included sites from other provinces and states (24 sites). Each stratum was divided into phases, originally intended to group sites nearby (for ease of coach training, implementation, assessments, and to promote healthy competition among sites in similar regions with known rivalries), and later also focused on readiness of sites. Stratum 1 was divided into two phases (9 sites per phase), grouped by geographic location; randomization of these sites occurred prior to the onset of the COVID-19

pandemic. In stratum 2, the initial planned two phases (12 sites per phase, grouped by geographic location) was modified into six phases following the onset of the pandemic to accommodate site readiness (i.e., local COVID-19 burden and public health guidelines).

Participant Recruitment and Screening

Participant recruitment began in November 2018 with the first intervention period beginning in March 2019. The final group of sites launched participant recruitment in July 2021, with the intervention period beginning in November 2021. Recruitment materials promoted Hockey FIT as a program for middle-aged men who are fans of the local hockey team and looking to make changes to their lifestyle. Participants were recruited primarily through the local hockey team's social media, email blasts, and websites; Facebook ads were also used to reach individuals, along with other traditional recruitment methods (i.e., radio, newspaper, posters at local businesses, word of mouth).

Interested individuals were referred to the Hockey FIT website and asked to complete a brief contact form or call the study office. The research team followed up via email, providing the Letter of Information-Consent document and a link to a secure online data collection portal. Potential participants then provided written (digital) consent to participate and completed a stage 1 screening questionnaire where they self-reported their gender, age, height, weight, how they heard about Hockey FIT, and answered general health questions from the 2018 Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) [29].

Study inclusion criteria were as follows: identified as a man; between 35 and 65 years of age; objectively-measured BMI greater than or equal to 27 kg/m^2 ; and deemed safe to participate in an exercise program. Individuals were excluded if they were advised by a health

care provider to not participate in the study. If “Yes” was indicated for any of the PAR-Q+ general health questions, a research team member phoned the individual to complete the remainder of the questions; responses were reviewed by the Study Physician, who either cleared or required the individual to seek local external health care provider approval. Following successful stage 1 screening, an in-person stage 2 screening/baseline assessment was scheduled where individuals had their height and weight measured by trained assessors; other measurements completed as part of the baseline assessment will be reported on in the data collection section. Study eligibility was determined following the stage 2 screening.

Cluster Randomization

Participants received the intervention to which their site was assigned. Sites were randomized to either the intervention or control group, after stratification by location (Ontario vs. all other provinces/states). Stratified randomization was conducted to ensure sites in Ontario would be balanced in both arms of the trial. The study statistician generated the randomization sequences (one for each stratum); within each stratum, randomization was done in randomly varying blocks (2 and 4) to ensure balance between study arms throughout allocation. An independent researcher stored the randomization sequences and retrieved these only when the Study Manager had finalized site ordering within a specific stratum-phase, based on *a priori* criteria.

Interventions

Intervention Group (Hockey FIT program)

The intervention group received the Hockey FIT program shortly after baseline assessments, which consisted of a 3-month active phase followed by a 9-month minimally-

supported phase. Hockey FIT is a group-based, off-ice, in-person healthy lifestyle program, adapted from Football Fans in Training [17] and integrates aspects of the HealthSteps® lifestyle prescription program [30]. Hockey FIT is designed to appeal to hockey fans by featuring team engagement and including factors that attract men to lifestyle programs including: friendly group-based competition [31]; using humour to discuss sensitive health issues [32]; and being with like-minded and -sized men [33,34]. Behaviour change techniques are a key part of the Hockey FIT curriculum and delivery. These are related to control theory, social cognitive theory, and self-regulation and include activities such as self monitoring and shared goal setting among coaches and participants [35–37].

During the 3-month active phase, participants engaged in 12, 90-minute sessions (once per week), led by certified Hockey FIT coaches (approximately 1:10 coach to participant ratio). Most program sessions were delivered at the implementation partners' facilities, however, up to three sessions were held at the hockey teams' facilities, where other incentives to participate could be incorporated (e.g., tour of the dressing room). Sessions included two main components: 1) interactive, non didactic style, classroom-based education focusing on healthy eating, physical activity, and behaviour change skill development; and 2) group-based exercise comprised of aerobic, bodyweight strength, and flexibility training. See **Table 1** for an overview of the weekly sessions, **Supplementary File 2** for additional information on the Hockey FIT program, and **Supplementary File 3** for an overview of coach training.

Table 1: Overview of the Hockey FIT Program – Weekly Sessions in 3-Month Active Phase

EDUCATION COMPONENT	EXERCISE COMPONENT
Session 1: Introduction to Hockey FIT & Physical Activity Prescription	
<p><i>75 minutes:</i></p> <ul style="list-style-type: none"> • Introductions, program overview, and ground rules • Influences on food choices and barriers to being active • Locus of control (eating habits) • Introduction to and setting physical activity (step count) prescription (Rx) • Introduction to goal setting and healthy living tracking • Introduction to Hockey FIT Locker Room app 	<p><i>15 minutes:</i></p> <ul style="list-style-type: none"> • Light aerobic exercise (e.g., group walk)
Session 2: Healthy Eating Overview & Healthy Eating Prescription	
<p><i>65 minutes:</i></p> <ul style="list-style-type: none"> • Reintroduce Hockey FIT coaching team • Hockey Fans In Training Locker Room App check-in • Review healthy living goals and set new physical activity Rx • Eating well (introducing Canada's Food Guide) • Formal introduction to S.M.A.K.T. goal setting • Introduction to and setting healthy eating Rx 	<p><i>25 minutes:</i></p> <ul style="list-style-type: none"> • Light aerobic exercise
Session 3: Meal Planning & Weight Loss	
<p><i>60 minutes:</i></p> <ul style="list-style-type: none"> • Review participant healthy living goals • Set new physical activity Rx • Avoiding compensation/trade off behaviour • Healthy eating planning • Health benefits & calculating 5-10% weight loss • Importance of support from others 	<p><i>30 minutes:</i></p> <ul style="list-style-type: none"> • Introduction to principles of FITness • Warm-up exercises (e.g., slow fast walk) • Light aerobic exercise • Cool down/static stretching

EDUCATION COMPONENT	EXERCISE COMPONENT
Session 4: Becoming Fit & Exercise Prescription	
<p><i>75 minutes:</i></p> <ul style="list-style-type: none"> • Review participant healthy living goals • Facts about exercise and being more active • Overcoming barriers to exercise • Importance of target heart rate (THR) • Introduction to and setting exercise Rx • Simple fitness test (STEP Test) 	<p><i>25 minutes:</i></p> <ul style="list-style-type: none"> • Warm-up/dynamic stretching • Aerobic exercise (e.g., high knees, shadow boxing) • Target heart rate and rating of perceived exertion • Cool down/static stretching
Session 5: Alcohol & Weight Gain	
<p><i>50 minutes:</i></p> <ul style="list-style-type: none"> • Review participant healthy living goals • Alcohol facts • Myths about alcohol and standard drink sizes • Planning drinking and cutting back on sugary drinks 	<p><i>40 minutes:</i></p> <ul style="list-style-type: none"> • Warm-up/dynamic stretching • Aerobic exercise (e.g., jump rope, side shuffle) • Cool down/static stretching
Session 6: Stages of Change	
<p><i>45 minutes:</i></p> <ul style="list-style-type: none"> • Review participant healthy living goals • Stages of change • Shared experiences (dealing with setbacks) • Private weigh-in 	<p><i>45 minutes:</i></p> <ul style="list-style-type: none"> • Warm-up/dynamic stretching • Strength/muscular endurance exercise (e.g., push ups, lunges, sit ups) • Cool down/static stretching
Session 7: Weight Loss	
<p><i>45 minutes:</i></p> <ul style="list-style-type: none"> • Review participant healthy living goals • Examining weight loss to date • Weight loss targets • Motivation and confidence • Reflection on how things are going so far 	<p><i>45 minutes:</i></p> <ul style="list-style-type: none"> • Warm-up/dynamic stretching • Strength/muscular endurance exercise • Aerobic exercise • Cool down/static stretching
Session 8: Food Labels	
<p><i>45 minutes:</i></p> <ul style="list-style-type: none"> • Review participant healthy living goals • Understanding food labels and nutrition facts • Better eating (including eating breakfast) 	<p><i>45 minutes:</i></p> <ul style="list-style-type: none"> • Warm-up/dynamic stretching • Strength/muscular endurance exercise • Aerobic exercise • Cool down/static stretching
Session 9: Eating Out	
<p><i>45 minutes:</i></p>	<p><i>45 minutes:</i></p>

EDUCATION COMPONENT	EXERCISE COMPONENT
<ul style="list-style-type: none"> Review participant healthy living goals Favourite meals (making them healthier) Eating out Takeout & fast food (making them healthier) 	<ul style="list-style-type: none"> Warm-up/dynamic stretching Strength/muscular endurance exercise Aerobic exercise Cool down/static stretching

Session 10: Avoiding Setbacks & New Exercise Prescription	
<p><i>75 minutes:</i></p> <ul style="list-style-type: none"> Review participant healthy living goals Exploring myths Triggers for eating, drinking, and exercising less Things going wrong? (setbacks) STEP Test and set a new exercise Rx 	<p><i>30 minutes:</i></p> <ul style="list-style-type: none"> Warm-up/dynamic stretching Strength/muscular endurance exercise Aerobic exercise Cool down/static stretching
Session 11: Energy Balance & New Healthy Eating Prescription	
<p><i>45 minutes:</i></p> <ul style="list-style-type: none"> Review participant healthy living goals Set new healthy eating Rx Eating plans revisited Energy balance revisited Locus of control revisited 	<p><i>30 minutes:</i></p> <ul style="list-style-type: none"> Warm-up/dynamic stretching Strength/muscular endurance exercise Cool down/static stretching
Session 12: Celebrating Achievements & Next Steps	
<p><i>50 minutes:</i></p> <ul style="list-style-type: none"> Celebrating achievement Next steps Feedback Wrap-up 	<p><i>40 minutes:</i></p> <ul style="list-style-type: none"> Warm-up/dynamic stretching Ball hockey game OR Strength/muscular endurance exercise Cool down/static stretching

Control Group (Wait-list)

The wait-list control group continued with usual daily activities for 12 months. Following allocation, participants were provided with links to publicly available resources for healthy living and were encouraged to follow Hockey FIT on social media. Over the 12-month period, participants were contacted to: report any adverse events (monthly basis); schedule their 3-

and 12-month assessments; and complete online questionnaires at 3, 6, 9, and 12 months.

After 12-month assessments, participants in the wait-list control group started the 12-week Hockey FIT program with the rest of their teammates at their given site (i.e., when all sites within a given stratum-phase had completed 12-month assessments, sites allocated to the wait-list control group had now completed their control period and were offered the Hockey FIT program).

Data Collection

A combination of in-person assessments, online questionnaires, and focus groups were used to collect data from participants to inform outcome, economic and process evaluations.

Table 2 provides an overview of the complete measurement schedule for participants.

Table 2. Measurement Schedule for Study Participants

Measurement	Screen Stage 2	Baseline	3-Month	12-Month
Objective Measurements				
Weight	X	X	X	X
Height	X	X	X	X
Waist circumference		X	X	X
Blood Pressure		X	X	X
Finger prick sample		X	X	X
STEP™ test		X	X	X
Steps		X	X	X
Questionnaires				
Demographics & history with weight loss	X	X		
Medical conditions and medications ^a	X	X	X	X
IPAQ-SF		X	X	X

Measurement	Screen Stage 2	Baseline	3-Month	12-Month
Marshall Sitting Questionnaire		X	X	X
2016 CCHS (fruit and vegetable consumption; smoking behaviour)		X	X	X
2017 BRFSS (sugar-sweetened beverage intake)		X	X	X
Starting the Conversation Food Frequency Questionnaire		X	X	X
7-day recall diary for alcohol intake		X	X	X
PSQI		X	X	X
EQ-5D-5L		X	X	X
WHO-5		X	X	X
Abbreviated (10-item) DSSI		X	X	X
Healthcare resource use (cost) diary ^b			X	X
Program experience ^c			X	
Focus Group ^{d,e}			X	
Social impact of Hockey FIT ^e				X

Abbreviations: BRFSS = Behavioral Risk Factor Surveillance System; CCHS = Canadian Community Health Survey; DSSI = Duke Social Support Index; EQ-5D-5L = European Quality of Life 5 Dimensions Questionnaire; IPAQ SF = International Physical Activity Questionnaire – Short Form; PSQI = Pittsburgh Sleep Quality Index; STEP = Step and Exercise Prescription; WHO-5 = World Health Organization – Five Well-Being Index.

^aIncludes PARQ+

^bAlso completed by participants at 6 and 9 months

^cCompleted by participants in both groups directly following the active phase of Hockey FIT

^dProgram completers were invited to attend a focus group with participants from other sites

^eCompleted by participants from the intervention group only

In-person assessments were conducted by assessors not involved in delivery of the intervention. At baseline, 3 and 12 months, participants were invited to an in-person assessment to have their weight, height, waist circumference, BP, and glycated hemoglobin

(HbA1c) measured. Participants also completed a simple, self-paced fitness (STEP™) test [38,39] and were provided with an accelerometry-based step counter (New Lifestyles NL-800) to track steps for seven days. Participants submitted their step counts via the online portal, where they were also asked to complete questionnaires focused on physical activity, sedentary time, healthy eating, alcohol consumption, smoking, sleep quality, health-related quality of life, wellbeing, social connectedness, current health, and demographics. At 12 months, intervention participants also completed a questionnaire related to the social impact of Hockey FIT. Outcome measures and corresponding procedures/instruments are described in **Table 3**.

Table 3. Overview of Study Outcomes and Measurement Details

Outcome	Equipment or Instrument	Measurement Details
Objectively-Measured Outcomes		
Weight (absolute and % of baseline weight)	Seca 874dr digital scale	<ul style="list-style-type: none"> ▪ Participants are asked to wear light clothing, empty pockets, remove shoes and belts, and then stand evenly on both feet on centre of scale without support ▪ Weight is measured in kg (to the nearest 0.01 kg)
Body mass index (BMI)	Seca 217 stadiometer (integrated with Seca C/4dr digital scale)	<ul style="list-style-type: none"> ▪ Height measured in cm (to the nearest 0.1 cm) ▪ Participants are asked to remove shoes; stand with back, buttocks, and heels against rod; and stand with feet together and flat at the base of the scale ▪ Head is positioned in Frankfort plane for accurate measurement ▪ Participants are asked to take a deep breath and hold it – measurement is recorded at end of the deep inward breath ▪ Weight measurement detailed above ▪ Body mass index is calculated as kg/m^2

Outcome	Equipment or Instrument	Measurement Details
		(to two decimal points)
Waist Circumference	Tape measure	<ul style="list-style-type: none"> ▪ Participants are asked to clear abdominal area of clothing, belts, or accessories; stand upright with their feet shoulder-width apart and to relax their stomach ▪ Bottom edge of measuring tape is aligned with uppermost part of hipbone on both sides ▪ Participants are asked to take two normal breaths and then tape is comfortably tightened thereafter by the assessor for the first measurement. This process is repeated for the second measurement ▪ Waist circumference is measured in cm (to nearest 0.1 cm)
Blood Pressure	Automated blood pressure monitors: OMRON HEM 907XL and BP Tru BPM-100	<ul style="list-style-type: none"> ▪ Participants are asked to attend assessment with an empty bladder and sit quietly for 5 minutes prior to measurements begin taken (three in total) ▪ Participants are instructed to refrain from talking or chewing gum, to have their feet flat on the floor and their arm free of clothing (left arm preferred) and resting on the table or chair ▪ Assessors' ensure that participants are fitted with the correct cuff size ▪ Cuffs are placed at the level of the heart with the centre over the brachial artery; cuffs are tightened (enough to be able to slip two fingertips through) ▪ Systolic and diastolic blood pressure readings are recorded separately for all 3 readings, with 2 minutes rest given between readings ▪ Systolic and diastolic blood pressure is measured in mm Hg

Outcome	Equipment or Instrument	Measurement Details
Glycated Hemoglobin (HbA1c)	Siemens DCA Vantage Analyzer	<ul style="list-style-type: none"> ▪ Participants' finger is cleansed with alcohol wipe and then a finger prick is performed using a capillary holder (requires 1μ of blood) ▪ The capillary holder is inserted into the reagent cartridge and then scanned with the barcode scanner as part of the DCA Vantage Analyzer ▪ HbA1c measurements are recorded as a % (to the nearest 0.1%)
Predicted Maximal Oxygen Uptake (pVO ₂ max)	Step and Exercise Prescription (STEP) Test™	<ul style="list-style-type: none"> ▪ Assessors provide a demonstration of the self-paced STEP Test™ (i.e., walking up and down a set of two stairs, 20 times) [38,39] ▪ Participants are instructed to complete the test at a comfortable pace ▪ Upon completion, assessors record time taken to complete (in seconds) and heart rate (beats in 10 seconds) ▪ A predictive VO₂max score is calculated following the scoring protocol and measured in mL/kg/min (to the nearest two decimal points)
Steps (average steps/day)	New Lifestyles NL-800 accelerometry-based (piezo-electric) step counter	<ul style="list-style-type: none"> ▪ Waist-worn piezo-electric device that is not impacted by obesity or tilt angle, compared to spring-levered pedometers [40] ▪ New Lifestyles device has been used as criterion measure (gold standard) for examining free-living activity (vs. 10 different wearable tracking devices) [41] ▪ Participants are provided with a step counter and paper log to track their total number of steps per day; after the 7-day period, participants enter step counts into the online data collection platform ▪ At least three days of step data are needed to calculate average steps per

Outcome	Equipment or Instrument	Measurement Details
		day [42] and daily step counts of <500 steps were excluded from calculations
Online Self-Administered Questionnaires		
Physical activity (vigorous, moderate, walking and total physical activity scores)	International Physical Activity Questionnaire – Short Form (IPAQ-SF)	<ul style="list-style-type: none"> ▪ The IPAQ is designed for use with young and middle-aged adults (15-69 years) and measures self-reported physical activity over the last 7 days [43] ▪ Extensive reliability and validity testing in 12 different countries [44] and evidence for sensitivity to change following a weight loss intervention [45] ▪ Following the IPAQ-SF scoring protocol, scores are calculated in Metabolic Equivalent (MET)-minutes/week
Total time spent sitting (on a weekday)	Marshall Sitting Questionnaire	<ul style="list-style-type: none"> ▪ Questionnaire assesses sitting time on weekdays and weekend days in five domains: travelling to and from places; at work; watching TV; using a computer at home; and for leisure [not including TV] ▪ Questionnaire was adapted by Marshall and colleagues [46] from the work of Miller and Brown [47] ▪ Acceptable reliability and validity for questions that assess structured domain-specific and weekday sitting time (in minutes)
Fruit and vegetable intake	2016 Canadian Community Health Survey (CCHS)	<ul style="list-style-type: none"> ▪ The CCHS initiative began in 2000 and is a joint effort of Health Canada, the Public Health Agency of Canada, Statistics Canada, and the Canadian Institute for Health Information ▪ Six questions from the 2016 CCHS are used to assess fruit and vegetable consumption in the past month (participants are able to report

Outcome	Equipment or Instrument	Measurement Details
		consumption per day, per week, or per month)
Sweetened sugary beverages intake	2017 Behavioral Risk Factor Surveillance System (BRFSS)	<ul style="list-style-type: none"> ▪ The BRFSS began in 1984 in the United States and is administered via the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services ▪ Two questions from the 2017 BRFSS are used to assess sugar-sweetened beverage intake in the past month (participants are able to report consumption per day, per week, or per month)
Total healthful eating score	Starting the Conversation Food Frequency Questionnaire	<ul style="list-style-type: none"> ▪ Starting the Conversation is an eight-item simplified food frequency questionnaire that measure eating habits over the past few months, with evidence for reliability, validity, and sensitivity to change [48] ▪ A total healthful eating score (range 0-16) is calculated, where a lower score indicates a more healthful diet
Total alcohol intake (weekly)	7-day recall diary	<ul style="list-style-type: none"> ▪ A brief 7-day recall questionnaire is used to calculate total weekly alcohol consumption [49] ▪ Participants record the number of alcoholic drinks that they had each day over the past week, starting with the most recent day and working backwards ▪ Reporting is done by category (beer, cider/cooler, wine, distilled alcohol, other) and guidance on drink size is provided
Smoking status	2016 Canadian Community Health Survey (CCHS)	<ul style="list-style-type: none"> ▪ A brief set of questions from the CCHS were used to measure smoking behaviour (focused on cigarette

Outcome	Equipment or Instrument	Measurement Details
		<p>smoking)</p> <ul style="list-style-type: none"> ▪ The initial question measures frequency of smoking (daily, occasionally, or not at all); if daily or occasionally are selected then follow-up questions ask about number of cigarettes smoked (per day or per month)
Sleep quality (global score)	Pittsburgh Sleep Quality Index (PSQI)	<ul style="list-style-type: none"> ▪ Sleep quality is measured using the PSQI, which asks questions related to sleep habits in the past month [50] ▪ A global PSQI score (range 0-21) is calculated using the first nine items on the scale and following the PSQI scoring protocol, with higher scores indicating worse sleep quality
Health-related quality of life (VAS score)	European Quality of Life 5 Dimensions Questionnaire - 5 level version (EuroQol)	<ul style="list-style-type: none"> ▪ The EQ-5D-5L is a widely-used health status instrument that is used to measure, compare, and value health status across disease areas [51] ▪ For the outcome evaluation, the EQ-visual analog scale (EQ-VAS) score is being used as a simple measure of health-related quality of life [52] ▪ For the EQ-VAS score, participants rate their health on a scale from 0 (worst health imagined) to 100 (best health imagined)
Well-being (Overall score)	World Health Organization – Five Well-being Index (WHO-5)	<ul style="list-style-type: none"> ▪ The WHO-5 consists of five simple questions that measure current general well-being within the last two weeks, using positively phrased questions [53] ▪ Evidence has accumulated for using this questionnaire to assess well-being over time or for comparison between groups [54] ▪ A raw score of each individual item (range 0-5 for each item) is summed and then converted to a percentage

Outcome	Equipment or Instrument	Measurement Details
		score, where 100 represents the best quality of life
Social connectedness (Social support score)	Duke Social Support Index (DSSI)	<ul style="list-style-type: none"> ▪ The DSSI was originally designed to measure subjective social support in older adults; the shortened 10-item version of the DSSI has been evaluated in a large, diverse adult population [55,56] ▪ The DSSI total score is calculated as the sum from all 10 items following the scoring protocol (range 10-30), with higher scores indicating a stronger perception of social support

A cost diary was administered online at 3, 6, 9 and 12 months (Canadian sites only). This self-reported diary captured direct healthcare system costs (e.g., emergency department visits, hospitalizations, family physician visits), out-of-pocket costs (e.g., healthcare or medications not covered by public or private insurance, parking, transportation, equipment, resources used in Hockey FIT), healthcare covered by private insurance, and indirect costs (e.g., time involved with program participation, healthcare appointments and resulting time off employment).

During the active phase of the program, attendance data were collected by Hockey FIT coaches at each intervention site. To encourage attendance, participants were contacted by the research team if they missed two or more consecutive sessions without prior notice. Following the active phase of the program, participants were invited to complete a brief questionnaire asking about their experience with Hockey FIT. In the intervention sites, participants deemed program completers (i.e., attended at least 50% of sessions including at least one session in the final six weeks) were also invited to take part in a focus group (conducted via Zoom with

members of the research team) to further discuss what originally attracted them to participate in Hockey FIT, as well as their experience working through the program with their coach and other participants.

Data were also collected from Hockey FIT coaches and program partners. Coaches completed an online feedback questionnaire following coach training and weekly online post-session reflections during program delivery, to reflect on: whether they felt they delivered each of the key tasks as designed; what went well; and what they would do differently to improve their delivery of key tasks. Coaches were also invited to complete an interview to discuss their experience delivering Hockey FIT and what adaptations they may have made to the program design during local implementation at their site. Program partners (i.e., hockey team and implementation partner leads) were invited to participate in an interview to discuss their experience with the program and potential for sustainability. Coach and partner interviews were only conducted in the intervention group sites.

Adverse events (AEs) were defined as any injuries, illnesses, medication changes, day surgeries, newly diagnosed health conditions, changes in pre-existing conditions, visits to the emergency room (not resulting in hospital admission), or any other changes to normal health status. Starting at baseline assessments, participants were asked to report any AEs occurring during the study, regardless of whether it was related to study participation. Serious adverse events (SAEs) were defined as those that required hospitalization, prolonged medical attention, were immediately life threatening, or fatal. Standardized emails were sent to participants asking them to report any new AEs or to provide updates to previous AEs via the online portal;

emails were sent weekly during the active phase of the program or monthly otherwise.

Participants were asked to call the study office if they experienced an SAE.

Journal Pre-proof

Participant Appreciation

Participants who attended the baseline assessment received a Hockey FIT toque and at the first program session, participants received a Hockey FIT handbook, pen, and water bottle. To assist with study retention, participants in both groups had a chance to win one of ten \$100 gift cards to their site's hockey team, following the 3- and 12-month assessments. Participants in the control group also had a chance to win a pair of season's tickets to the hockey team following the 12-month assessments.

Sample Size

Sample size estimation was based on comparison of mean weight loss at 12 months between intervention and control groups using the two-sample t-test, adjusting for correlation among observations within the same site, commonly referred to as clustering effects. To detect a difference of 3.6 kg, with 80% power at 5% significance level, assuming a standard deviation of 18.9, a total of 866 participants would be required. This calculation indicates that a trial using these estimates will be able to detect a standardized effect size of 0.19, corresponding to a small effect size [57]. To account for the clustering effects, the sample size was inflated by 1.39 (based on assumptions of 40 participants/site and an intra-cluster correlation coefficient of 0.01), indicating the need to recruit 1204 participants from 32 sites [58–60].

Once recruitment closed across all sites, including recruitment within 24 sites that occurred during the COVID-19 pandemic, statistical power was re-evaluated. In total, 997 participants had been enrolled across 42 sites. After accounting for 30% lost to follow-up and using a revised clustering effect of 1.23, the total number of participants calculated as required was 1524. Assuming a within-participants correlation between baseline and follow-up weights

of 0.8, the total number of participants required was reduced to 549, providing 80% power at the 5% significance level to detect a small effect. This calculation may be regarded as conservative since data will be analyzed using a mixed model approach that accounts for clustering effects by site and baseline data. This approach is well-known to be more powerful than an adjusted t-test [61].

Planned Analyses

Outcome Evaluation

Analyses will be performed following intent-to-treat principles (i.e., all participants will be included according to the randomization scheme and regardless of compliance with the intervention). Differences between groups in weight loss (absolute) at 3 and 12 months will be examined using a linear mixed effects model, with group, time, group x time interaction, and baseline value of outcome included as fixed effects, while sites will be treated as random effects to account for clustering with the Kenward-Roger method used to estimate denominator degrees of freedom [62,63]. The primary comparison will be the contrast between groups (intervention vs. control) at 12 months using the method of least square means to account for unequal cluster sizes. The model may also include other participant-level characteristics (e.g., age, comorbidities) as explanatory covariates, as well as the stratification factor for randomization. Residuals from models will be examined and subject to assumptions checks.

A similar analysis approach will be used for secondary outcomes whereby linear and generalized mixed models will be used. Per protocol analyses including only participants deemed as completers will also be conducted as a sensitivity analysis. Significance tests will be

based on least-squares means using a two-sided significance of 0.05. Interpretation of results will primarily be based on estimation and associated 95% confidence intervals. Analyses will be performed using R version 4.2.0 and SAS version 9.4 (SAS Institute, Cary, NC, USA).

Economic Evaluation

Through a cost description analysis, we will estimate the cost to implement the Hockey FIT program for various stakeholders. To determine the cost of providing the program, total time involved for each participant and coaches will be recorded. Resources required to deliver the program such as equipment, personnel, facility, and other program-related costs will also be recorded. Associated salary costs of all staff and coaches to value time required for implementation and delivery will be used.

Cost-effectiveness analyses from a healthcare payer (Ontario Ministry of Health) and a societal perspective will be conducted using data from the cost diary. Both weight loss (primary outcome) and quality adjusted life years (QALYs) will be used as the measure of effectiveness for the cost-effectiveness analysis. QALYs incorporate both length of life and quality of life into a single measure and are the product of a participant's utility score (calculated from EQ-5D scores) and the corresponding health state duration. The incremental cost-effectiveness ratio (ICER) will be calculated and cost-effectiveness will be estimated using the net benefit regression, which will be used to estimate the incremental net benefit (INB) of the Hockey FIT program [64] using a variety of willingness to pay values. The following covariates will be included in regression models: age, baseline BMI, and comorbidities. To characterize the statistical uncertainty around the INB estimate, 95% confidence intervals will be calculated along with a cost-effectiveness acceptability curve [65].

Process Evaluation

Focus group, interview, and questionnaire data will be analyzed to build an understanding of participants', coaches', and partners' overall experiences with the program to inform reach, acceptability, fidelity, and opportunities for improving Hockey FIT beyond the trial. Recordings from focus groups and interviews will be transcribed verbatim. Transcripts and open-ended responses from questionnaires will have identifiers removed prior to analysis, which will be conducted by hand through a process of both deductive analysis by question and inductive content analysis by response [66].

Research team members (greater than two) will independently read the transcripts and open-ended responses several times to ensure familiarity and immersion in data and will meet to discuss and confirm themes. Exemplar quotes supporting each theme will be identified resulting in a final list of themes/quotes. A contextual form of data saturation will be sought whereby the addition of new data does not reveal information that is novel to the research questions asked [67]. The research team will discuss whether saturation has been reached or further collection would be justified. Member-checking, multiple coders, peer briefing, and detailed/rich descriptions are among the tools used to ensure data trustworthiness and the accuracy in data collection, content analysis, and interpretation [68]. For additional fidelity reporting, coach post-session reflections will also be assessed to examine the consistency of key tasks delivery across sites (i.e., to understand which components were more likely to be delivered and/or commonly missed).

RESULTS AND DISCUSSION

The Hockey FIT program aims to help men make positive changes to their health, by providing them with easily accessible information to eat healthier, become more physically active, and create sustainable lifestyle habits. The overall design of the cluster RCT of the Hockey FIT program presented in this paper incorporates evaluations from micro, meso, and macro levels, including from the perspectives of participant health outcomes, program implementation, and broader healthcare system impact.

Hockey teams led recruitment of participants from the target population using their social media platforms and email blasts to their fans. Across the 42 sites, 2,094 individuals expressed interest and 1,397 were assessed for eligibility. Of those assessed for eligibility, 147 did not meet inclusion criteria and 253 either did not attend the in-person stage 2 screening or attended, but later declined participation. The most common reason for ineligibility was having a BMI less than 27 kg/m^2 , followed by age younger than 35 or older than 65 years. In total, 997 participants were enrolled (497 intervention; 500 control) and site-level sample sizes ranged from 8 to 53, with a median of 22 participants per site (see **Figure 1** for the participant flow diagram). Of those enrolled, 411 (41%) heard about Hockey FIT through social media and 286 (29%) heard about Hockey FIT through hockey team email blasts. The next largest sources of recruitment were word of mouth and local paper/online news, followed by hockey team websites, hockey games, radio/TV, and other.

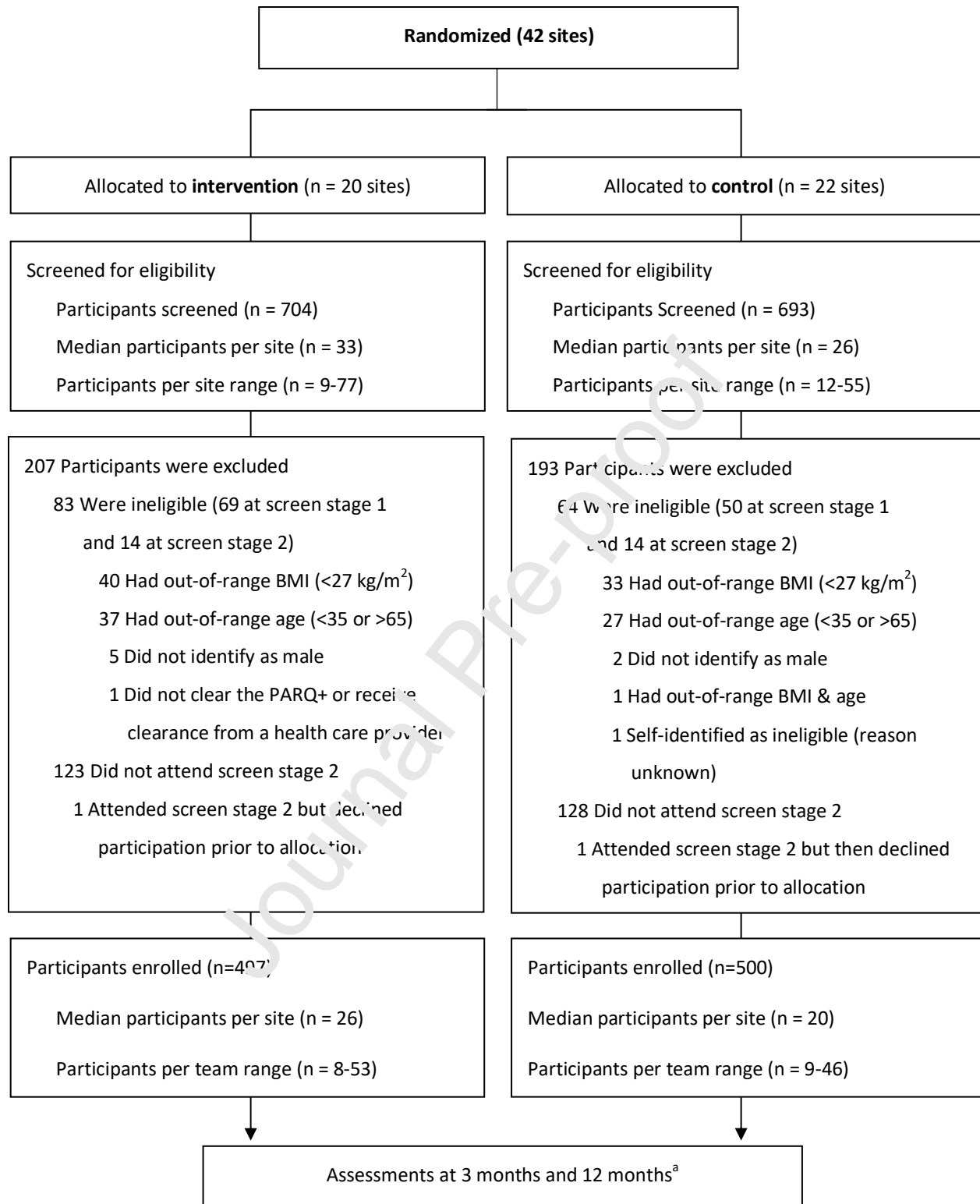


Figure 1. Participant Flow from Screening to Enrollment

^aHealthcare resource use diary also administered at 6 and 9 months

Baseline participant characteristics are presented in **Table 4**. Most characteristics were well-balanced between groups as expected due to randomization. An unexpected finding was that while average BMI values corresponded to the obese class II category (range 35.0 to 39.9) [69], reported average steps/day indicated a *somewhat active* lifestyle [70] and average predicted maximal oxygen uptake values corresponded to fitness categories ranging between poor and good for men within this age group (35 to 65 years) [71]. Despite the range of education and occupation, as well as the diverse set of cities included, the sample was predominately white.

Table 4. Characteristics of Participants at Baseline^a

Variable	Intervention Group	Control Group	Overall
Sites			
No. of sites	20	22	42
Participants			
No. of participants	497	500	997
Age, yr	48.9 ± 8.1	48.2 ± 8.5	48.6 ± 8.3
Race ^b , n (%)	n=480	n=480	n=960
White	445 (92.7)	459 (95.6)	904 (94.2)
Indigenous	16 (3.3)	11 (2.3)	27 (2.8)
East Asian	5 (1.0)	2 (0.4)	7 (0.7)
South Asian	5 (1.0)	0 (0.0)	5 (0.5)
Southeast Asian	3 (0.6)	3 (0.6)	6 (0.6)
Latin American	2 (0.4)	1 (0.2)	3 (0.3)
Black	1 (0.2)	1 (0.2)	2 (0.2)
Middle Eastern	1 (0.2)	0 (0.0)	1 (0.1)
Other – not specified	2 (0.4)	3 (0.6)	5 (0.5)
Marital status, n (%)	n=483	n=479	n=962
Legally Married or Common-law	427 (88.4)	422 (88.1)	849 (88.3)
Other	56 (11.6)	57 (11.9)	113 (11.7)
Highest level of education, n (%)	n=480	n=474	n=954
≤High school (or equivalent)	109 (22.7)	113 (23.8)	222 (23.3)
Certificate, diploma, or CEGEP	189 (39.4)	202 (42.6)	391 (41.0)
Bachelor's degree	108 (22.5)	115 (24.3)	223 (23.4)
>Bachelor's degree	74 (15.4)	44 (9.3)	118 (12.4)
Occupation, n (%)	n=482	n=480	n=962

Variable	Intervention Group	Control Group	Overall
Professional, scientific, technical	80 (16.6)	72 (15.0)	152 (15.8)
Finance, insurance, real estate	45 (9.3)	43 (9.0)	88 (9.2)
Trade (e.g., carpentry)	33 (6.9)	48 (10.0)	81 (8.4)
Small business & retail	37 (7.7)	47 (9.8)	84 (8.7)
Public administration	45 (9.3)	39 (8.1)	84 (8.7)
Retired	38 (7.9)	30 (6.3)	68 (7.1)
Manufacturing	32 (6.6)	35 (7.3)	67 (7.0)
Transportation & warehousing	29 (6.0)	29 (6.0)	58 (6.0)
Construction	23 (4.8)	29 (6.0)	52 (5.4)
Education	26 (5.4)	23 (4.8)	49 (5.1)
Other	94 (19.5)	85 (17.7)	179 (18.6)
Self-reported medical conditions, n (%)			
High blood pressure	n=452 109 (24.1)	n=441 129 (29.3)	n=893 238 (26.7)
High cholesterol	n=424 70 (16.5)	n=407 74 (18.2)	n=831 144 (17.3)
Type 2 diabetes	n=454 43 (9.3)	n=448 50 (11.2)	n=912 93 (10.2)
Arthritis/joint problems	n=461 117 (25.4)	n=449 98 (21.8)	n=910 215 (23.6)
Depression or anxiety	n=444 77 (17.3)	n=443 93 (21.0)	n=887 170 (19.2)
Body weight, kg	111.2 ± 22.4	112.4 ± 20.0	111.8 ± 21.2
Body Mass Index, kg/m ²	35.0 ± 6.2	35.7 ± 6.0	35.3 ± 6.1
Waist circumference, cm	118.3 ± 14.6	119.7 ± 14.2	119.0 ± 14.4
Blood pressure, mm Hg	n=496	n=499	n=995
Systolic	131.8 ± 14.9	131.5 ± 15.1	131.7 ± 15.0
Diastolic	83.8 ± 9.6	84.4 ± 9.4	84.1 ± 9.5
Glycated hemoglobin (HbA1c), %	n=496 5.8 ± 1.0	n=500 5.8 ± 1.2	n=996 5.8 ± 1.1
Predicted VO ₂ max, mL/kg/min	n=488 37.4 ± 6.5	n=494 37.9 ± 7.4	n=982 37.7 ± 6.9
Average steps per day	n=469 8027.6 ± 3138.7	n=470 7424.2 ± 2876.1	n=939 7725.6 ± 3023.6
Self-rated health (EQ-VAS)	n=483 66.5 ± 18.7	n=475 67.3 ± 16.8	n=958 66.9 ± 17.8

^aPlus-minus values are means ± SD. Percentages may not total 100 due to rounding.

^bOriginal question and responses were based on the 2016 Canadian Community Health Survey [72]. Due to changes in collection of race-based data, we have reclassified the original response options to be congruent with current classifications [73].

Note: HbA1c = Glycated hemoglobin; VO₂max = Maximal oxygen uptake; EQ-VAS = EuroQol Visual Analogue Scale

Utilizing a cluster RCT design minimized the risk of experimental contamination among cluster members [74], thereby allowing individuals in the same community to participate together. Recruiting men with similar interests into a group-based program enables social connection, which in turn, can positively impact health, through enhanced feelings of social integration and identity [75]. Hockey FIT aims to build sustainable lifestyle changes through these social connections, as well as the sport fandom one feels toward specific hockey teams.

The mixed methods process evaluation incorporates triangulation of data from various sources and from perspectives of coaches, participants, and partners. This evaluation will provide a comprehensive understanding of program acceptability and inform future program improvement. The process evaluation will also add greater context to the RCT results, allowing the research team to anticipate and develop solutions to potential program implementation and delivery barriers, to optimize the program based on the findings, to ensure the program is sustainable. The economic evaluation will estimate the cost to implement the Hockey FIT program, as well as showcase impacts on direct and indirect healthcare utilization, which will add further, more comprehensive support in determining the overall impact of Hockey FIT. Following these evaluations, the pragmatic nature of the Hockey FIT program (i.e., no specialized equipment; ability to tailor to local delivery environments) will allow for easier scale-up within the real-world.

The COVID-19 pandemic produced challenges to recruitment and implementation in this trial. Participant recruitment was paused and re-started several times during the period of March 2020 to July 2021, resulting in the inclusion of additional sites and a revised sample size calculation to ensure the trial was adequately powered. Site groupings and implementation timelines had to be modified based on site readiness and public health mandates. Despite these challenges, Hockey FIT was delivered in all sites in collaboration with local partners, ensuring core components were included but tailored as appropriate in response to the local community needs and working within a variety of delivery environments.

For future offerings of Hockey FIT, it will be critical to understand what recruitment methods will better engage more diverse populations who are traditionally challenged by poor access to health care and preventive health programs, while also experiencing higher rates of chronic disease burden. These priority populations for future research could include new immigrants, racialized communities, Indigenous Peoples, and people experiencing low socioeconomic status.

Conclusion

We have described the rationale, program details, and design of a cluster RCT of the Hockey FIT program – a community-led, healthy lifestyle program utilizing the power of sport fandom to engage and enable men with overweight or obesity. The intended audience for Hockey FIT was recruited successfully, however, targeted recruitment to enhance diversity is warranted for future offerings of Hockey FIT. This paper affords a useful outline for evaluating future lifestyle interventions tailored to men at increased risk for chronic disease.

AUTHOR STATEMENT

The authors have no competing interests to declare. **Robert Petrella:** Funding acquisition, Conceptualization, Supervision, Project administration, Writing – Reviewing and Editing. **Dawn Gill:** Conceptualization, Supervision, Project administration, Writing – Original draft preparation, Reviewing and Editing. **Marisa Kfrerer:** Investigation, Writing – Original draft preparation, Reviewing and Editing. **Brendan Rigglin:** Investigation, Supervision, Project administration, Writing – Reviewing and Editing. **Melissa Major:** Investigation, Writing – Reviewing and Editing. **Wendy Blunt:** Investigation, Project administration, Writing – Reviewing and Editing. **Brooke Bliss:** Investigation, Writing – Reviewing and Editing. **Narlon Boa Sorte Silva:** Investigation, Formal analysis, Writing – Reviewing and Editing. **Paul Aspinall:** Investigation, Writing – Reviewing and Editing. **Precious Adekoya:** Investigation, Writing – Reviewing and Editing. **Matthew DiNunzio:** Writing – Reviewing and Editing. **Jacquelyn Marsh:** Conceptualization, Writing – Reviewing and Editing. **Guangyong Zou:** Conceptualization, Writing – Reviewing and Editing. **Jennifer Irwin:** Conceptualization, Investigation, Writing – Reviewing and Editing.

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Declaration of interests

X The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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