



Letter of Information and Consent - Participant

Project Title: Hockey Fans in Training (Hockey FIT): A Pragmatic Cluster Randomized Controlled Trial to Improve Men’s Health through the Power of Sport

Principal Investigator:

Dr. Robert Petrella, MD, PhD

Professor, Department of Family Medicine, Western University

1465 Richmond St.

London, ON N6G 2M1

Phone: 519.661.2111 Ext. 22119

1. Invitation to Participate

You are receiving this letter of information as you expressed interest in participating in the Hockey Fans in Training (Hockey FIT) research study. This letter provides you with information to help you make an informed decision regarding your participation in the Hockey FIT research study. It is important for you to be aware of why the study is being done and what it will involve. Please take the time to read this letter carefully and contact us with questions if anything is unclear or if there are words or phrases you do not understand. The funding for this study is being provided by the Canadian Institutes of Health Research and the Public Health Agency of Canada. There are no conflicts of interest to declare in this study.

Hockey FIT Program

The Hockey FIT program is divided into two phases, the “active” phase (which lasts three months) and the “minimally-supported” phase (which lasts nine months). During the active phase, you will attend a group-based weight loss and healthy lifestyle program led by trained Hockey FIT coaches. The program consists of 12 weekly sessions (one 90-minute session per week) and includes: a) classroom-based learning (focusing on topics related to successful weight management, such as healthy eating, reducing alcohol consumption and increasing daily physical activity); and b) coach-led exercise sessions, which will gradually increase in intensity across the 12 weeks. The program will begin with walking and gradually move onto strength exercises using your body weight (i.e., push-ups, and sit-ups), aerobic activities (i.e., skipping, jumping jacks), and flexibility activities (i.e., stretching). Groups will consist of approximately 20 male fans with 2 coaches per group. The program sessions and assessments will take place at either the team/club facility or at the local YMCA/fitness centre.

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During the active phase of the program, you will be asked to download and sign-up for the free Hockey Fans in Training (Hockey FIT) Locker Room mobile app and Carrot Rewards. Both the Hockey FIT Locker Room App and Carrot Rewards are optional to download, but contain important information about the program and allow you to connect with fellow fans, your coach and the research team. Both apps require an email address and your first name in order to register, as well as an indication of what Canadian Hockey League (CHL) team you are a fan of. In order to download the apps, you must have access to a smartphone device (i.e., Apple iPhone or Android smartphone).

Following the completion of the active phase of the program, you will enter the minimally-supported phase. During this time, you will be encouraged to sustain any positive lifestyle changes; however, you will not be attending any weekly sessions. The program coaches will send occasional emails to you encouraging you throughout this phase and you may continue to use the Hockey FIT Locker Room App and Carrot Rewards for further support. You will also be invited to attend a Booster session 9 months after baseline.

Hockey Fans in Training (Hockey FIT) Locker Room App

The Locker Room app is a tool intended to support you throughout the duration of the program and after it has concluded. The app has a Hockey FIT team calendar allowing you to indicate your attendance at Hockey FIT program sessions; a built-in pedometer where you can set step goals and track your progress; and a competitive function, which compares your teams' step counts to Hockey FIT teams throughout Canada. The app also has a social network where you can connect with your Hockey FIT teammates; post progress stories; and connect privately with your coach or other teammates. Lastly, the app has a library of healthy eating and physical activity resources that will be available for you to access during and after the in-class program (active phase). Data will be collected from the app at the aggregate level across your team (no individual data will be analysed). This data includes the number of times participants used the app and the duration of time that they used the app.

Carrot Rewards

Carrot Rewards (<https://www.carrotrewards.ca/home/>) uses incentives (i.e., reward points) to encourage individuals to increase their physical activity levels and offers quizzes, testing user knowledge on different health-related topics. Through a partnership with Carrot Rewards Inc., Hockey FIT participants will get special access to the Carrot Rewards app including an offering of Carrot Rewards quizzes pertaining to different Hockey FIT program topics. In order to receive this special offering of Carrot Rewards, you will be asked to download the app prior to the first session and will receive a code at this session to link you into the Hockey FIT version of the app.

Booster Session

The purpose of the booster session is to bring participants together again, after having been on their own for six months, to reflect on their successes and challenges. The session will be an

opportunity for participants to discuss barriers and setbacks since the program has ended and identify ways they can be overcome. A portion of the classroom material will be refreshing concepts that were introduced in earlier sessions (i.e., S.M.A.R.T. goals and the stages of change) before participating in a friendly ball hockey game.

Hockey FIT Research Study

The Hockey FIT program is delivered within a pragmatic cluster randomized controlled trial. This means the program is delivered in real-world setting (i.e., local team/club facility or local YMCA/fitness centre) and after all baseline measurements (i.e., measurements at the start of the study) are completed, sites will be randomly assigned to receive the Hockey FIT program right away (referred to as the immediate delivery group) OR to wait 12 months and then receive the Hockey FIT program (referred to as the delayed delivery group). Both immediate and delayed delivery groups will receive the Hockey FIT program. The reason we randomly assign sites to receive the intervention right away or after a 12-month delay is so we can compare results between groups and see if and how the health of those receiving the Hockey FIT program compares to those who are not receiving it. This helps us evaluate the effectiveness of the program. We will be recruiting 1,280 participants across Canada from 32 different sites, with a goal of recruiting 40 participants at each site.

2. Study Purpose

The purpose of the study is to determine whether the Hockey FIT program can help men become more active, eat better, and lose weight. We also want to collect your feedback on the program itself including what you liked and did not like. This will help us to improve the program for future delivery across a greater number of communities and teams.

3. Study Locations

This study is occurring across Canada at participating sites that partner Canadian Hockey League (CHL) teams with local YMCA branches.

4. Study Length

The study length is dependent on your site's assignment to immediate delivery (begin Hockey FIT program after baseline assessments are complete) or delayed delivery (begin Hockey FIT program 12 months after baseline assessments). The active phase of the Hockey FIT program will be 12 weeks in length (3 months), with program sessions occurring on the same evening each week. Two to four weeks have been allocated for completion of baseline and follow-up measurements and questionnaires. Follow-up measurements and questionnaires will be completed both 3 and 12 months after the start of the study, regardless of your site's assignment. If your site is assigned to the delayed delivery group then additional assessments (i.e., measurements and questionnaires) will occur 15 and 24 months after the study start (i.e., coinciding with the end of the active and minimally-supported phases of the Hockey FIT program for delayed delivery groups). Therefore, if your site is allocated to the immediate

delivery group, then the study length is 12 months and if your site is allocated to the delayed delivery group, then the study length is 24 months.

5. Inclusion & Exclusion Criteria

In order to participate in this program, you must fit the following *inclusion* criteria:

- Be male
- Between 35 and 65 years of age
- Have a body mass index (BMI) of at least 27 kg/m²
- Be deemed safe to participate in exercise (i.e., clear the Physical Activity Readiness Questionnaire + [PAR-Q+] or alternatively receive clearance from a health care provider)

If you fit the following *exclusion* criteria you will not be able to participate:

- Advised by a health care provider to not participate in the program

6. Study Procedures

The study activities will be conducted before, during, and after the Hockey FIT program is complete. If you agree to participate in this study you will be asked to complete pre-screening questionnaires, attend in-person measurement sessions, and complete questionnaires. All questionnaires will be completed online using PRIVIT® - a secure, web-based data management platform. You will be asked to set up a profile in PRIVIT (using the same email address that you have provided to the Research Team), where you can access questionnaires and information about the study (including a copy of this letter of information). See Section 11 below for greater detail on privacy and confidentiality of the PRIVIT® platform. All questionnaires and measurements are optional aside from those required to assess eligibility for the study (i.e., weight, height, gender, age, and Physical Activity Readiness Questionnaire + (PAR-Q+)).

1. **Pre-screening:** Pre-screening is the first step in helping us determine whether you are eligible to participate in the Hockey FIT program. Reading through this Letter of Information and providing consent is one part of the pre-screening process to ensure you are aware of what is required of you as a participant in the Hockey FIT program and study activities. If you do consent to being a participant in this study, you will be asked: how you heard about the study, your age, and your estimated height and weight. We will also collect your contact information including your name, address including postal code, phone number, and e-mail to get in touch with you in the future. The final item of the pre-screening is the Physical Activity Readiness Questionnaire + (PAR-Q+). This questionnaire helps us determine whether you are ready to participate in a physical activity program. In the case that you require further medical clearance based on your responses to the PAR-Q+, you will be contacted by a member of the Hockey FIT Research Team. If further medical clearance is required beyond the Hockey FIT Research Team, the research team will contact your health care provider to request this clearance.

2. **Screening and Baseline Measurements:** Based on the information you provide in the pre-screening survey, you will be contacted by a member of the Hockey FIT Research Team and asked to attend an in-person measurement session to further assess your eligibility for the study. During this measurement session, a trained Hockey FIT Assessor will measure your weight, height, waist circumference, fitness level (simple step test), A1c glucose (small finger prick), and blood pressure. You must meet the study eligibility criteria outlined above in section 5 to continue in this study. You will also be given a step count tracking form and an accelerometer-based step counter (small device that you wear on your waist) to track your step counts over a 7-day period. At the end of the 7 days you will be sent an email asking you to log into your PRIVIT® account (described in detail below), where you will be asked to input your step counts for each day of tracking.
3. **Baseline Questionnaires:** After completing your baseline measurements, you will be sent an email with an online link to create a profile in PRIVIT®. This profile will allow you to access the baseline questionnaires that will collect information related to your medical history, current medical conditions, and medications, as well as your current physical activity levels, healthy eating habits, alcohol intake, self-esteem, wellbeing, health-related quality of life, sleep habits, concussion history, and demographic questions (i.e., your ethnicity, occupation, marital status, and education). You must complete these online questionnaires within 7 days in order to remain eligible to participate in the study.
4. **Assessments & Questionnaires During the Program**

Global Cognitive Functioning: As a part of this study we are also looking at cognitive functioning. Approximately 4 weeks into the Hockey FIT study you will receive an email from the Hockey FIT Research Team containing a link to a third-party site to complete a series of 12 games called the Cambridge Brain Sciences (CBS) neurocognitive test battery (www2.cbstrials.com). These games will take approximately 30 minutes to complete. As an example, in the Digit Span Task, you will view a sequence of numbers on the computer screen and then you will be required to remember and repeat this number sequence by entering them. You may choose to use your own personal email account or create a new email account that does not identify you for the purposes of the study. You only have to complete this once throughout the entire study. Of note, CBS stores data by IP address and therefore your IP address can be identified by a third party, regardless of the email used to sign up for the games.

During your participation in the Hockey FIT program you will receive monthly emails reminding you to update your profile on PRIVIT with any changes to your health status (i.e., report any Adverse Events). In the case of a serious change to your health status (i.e., a Serious Adverse Event), you will be directed to call the Hockey FIT Research Team (phone: 519-661-2111 Ext. 22124 or email: HFIT@uwo.ca) within 24 hours of onset of the event. Once you move into the minimally-supported phase of the Hockey FIT program, you will

continue to receive regular reminders to keep the Hockey FIT Research Team up to date on all Adverse Events.

5. **3-Month Measurements:** Regardless of your site allocation, you will be contacted to schedule a 3-month measurement session (i.e., occurring 3 months from study start). Measurements taken will be the same as those taken at the baseline screening (i.e., weight, waist circumference, fitness level, A1c glucose, and blood pressure). You will also be asked to track your step counts for 7 days after this measurement session. At the end of the 7 days you will be sent a link through PRIVIT® (described in detail below) where you will be asked to input your step counts for each day of tracking.
6. **3-Month Questionnaires:** Similar to the baseline questionnaires, you will be sent an email to complete the online questionnaires through PRIVIT® (i.e., occurring 3 months from study start). These questionnaires are similar to those completed at baseline, except you will not be asked to provide your demographic information again (i.e., ethnicity, occupation, marital status, education) and some of the questions related to your medical history will not be asked again. To inform the study's economic evaluation, we will also ask you to complete a questionnaire detailing your use of health services. You will have 7 days after you receive the email to complete the questionnaires.

***Please note:** If your site has been allocated to the delayed delivery group, you will be asked to repeat these same 3-month measurements and questionnaires (which coincides with the end of the Hockey FIT program active phase in the immediate delivery groups) after 15 months in the study (which coincides with the end of the Hockey FIT program active phase in the delayed delivery groups).*

7. **3-Month Focus Group:** You may be asked to participate in voluntary video or audio-recorded focus group with other Hockey FIT participants. This focus group is important for exploring your experience with the program, components that worked or did not work, and identify areas where the program can be improved for future delivery. Information that you provide at baseline (your age; occupation; education; type of area where you live (urban & rural); your self-rated health; body mass index; and your average steps/day) will be used to determine whether you will be asked to participate in this focus group. By providing your consent, you understand that this information and all data collected will be kept private and confidential.

The focus group will be conducted by the Research Team through Zoom teleconference platform. You can download Zoom through a computer with video and/or audio to participate. If you take part in the focus group and access Zoom via computer, you will be required to sign up for a free account. As part of the sign-up process, you will have to provide an email address; Zoom will then send you an email and you can register with your

name and create a password. If you do not want to access the meeting via computer, there is a telephone number that you can use instead and no personal information will be required.

8. **6 & 9-Month Questionnaire:** As a part of the economic evaluation being conducted for the study, we will also ask you to complete the same questionnaire that you completed at 3 months, at month 6 and 9, asking about your use of health services. This will be the only questionnaire you will be required to complete at month 6 and 9 and will be completed online using through the PRIVIT® platform.
9. **12-Month Measurements:** Regardless of your site allocation, you will be contacted to schedule a 12-month measurement session (i.e., occurring 12 months from study start). This session will take the same measurements as done at 3 months (i.e., weight, waist circumference, fitness level, A1c glucose, and blood pressure). You will also be asked to track your step counts for 7 days after this measurement session. At the end of the 7 days you will be sent a link through PRIVIT® (described in detail below) where you will be asked to input your step counts for each day of tracking.
10. **12 Month Questionnaires:** Similar to the 3-month questionnaires, you will be sent an email to complete the online questionnaires through PRIVIT® (i.e., occurring 12 months from study start). These questionnaires will be the same as those administered at 3 months. You will have 7 days after you receive the email to complete the questionnaires.

***Please note:** If your site has been allocated to the delayed delivery group, you will be asked to repeat these same 12-month measurements and questionnaires (which coincides with the end of the Hockey FIT program minimally-supported phase in the immediate delivery groups) after 24 months in the study (which coincides with the end of the Hockey FIT program minimally-supported phase in the delayed delivery groups).*

11. **12 Month Focus Group:** You may be asked to participate in a voluntary video or audio-recorded focus group with other Hockey FIT participants exploring your experience maintaining your health behaviour changes post-Hockey FIT. This will be conducted by the Research Team through Zoom teleconference platform. We will use data you provided at baseline and also data you provided at 3 months to determine whether you will be asked to participate in the focus group (i.e., your age; occupation; education; type of area where you live (urban & rural); self-rated health (baseline and 3 months); body mass index (baseline); weight change (change in weight from baseline to 3 months), and average steps/day (baseline and 3 months)).
12. **Ongoing Changes in Health Status:** Any Adverse Event or Serious Adverse Event that has been reported and is ongoing at the time you complete the Hockey FIT program will be

followed up until resolution, or until the event is judged chronic or stable in the opinion of the Principal Investigator (PI), Dr. Robert Petrella. The Hockey FIT Research Team will make every effort to obtain follow-up information on the outcome of the event from you or your health care provider.

- 13. Program Non-Completer Questionnaire (only for those who do not complete the Hockey FIT program):** If you do not finish the program for any reason, we would like to ask you about reasons why you were not able to complete the program through a questionnaire; however, your response is completely voluntary.

7. Possible Risks / Harms

It is very unlikely that you will come to any harm as a result of taking part in this research study. Precautions will be put in place to ensure your safety, including the completion of a PAR-Q+ prior to study enrollment. If necessary, the Principal Investigator may review and provide clearance for you to participate OR refer you to another health care provider. All Hockey FIT coaches will be trained in First Aid and CPR and facilities will have AEDs on-site.

During the study, specifically the exercise sessions, there is potential for injury. Sessions are geared to start slowly with walking and gradually work up to more intensive strength and aerobic exercise to reduce potential for injury. Potential injuries of beginning a new exercise program include muscle soreness from over-exertion; cramps in lower limb muscles; tendon injuries (sprains) to ankle or knees; joint pain; hip and lower back pain due to increased activity and lack of flexibility; upper body injuries to shoulders; and flare-ups of past injuries. Coaches are trained on how to prevent injuries such as this (i.e., ensuring participants drink water during sessions and wear appropriate footwear to sessions). Coaches and you, the participant, will be asked to report these injuries (as Adverse Events) in a timely manner to the Hockey FIT Research Team.

We do not anticipate emotional distress and/or embarrassment. We recognize, however, that weight and waist circumference measurements can be especially sensitive, and therefore we will ensure that these measurements are done privately.

8. Possible Benefits

You may not receive any benefits from participating in the Hockey FIT research study. It is anticipated that as a study participant you may improve your health and health behaviours (i.e., lose weight, increase physical activity levels, and improve eating habits). We anticipate you will increase your knowledge regarding the benefits of exercise, physical activity, and healthy eating behaviours and how to successfully change and maintain healthy habits. You will also be given the opportunity to socialize, support and receive support from other men in the program.

9. Compensation

You will not receive any compensation for participating in the Hockey FIT program and research study. Any potential costs (i.e., parking) will be covered by the participating site (i.e., team/club or local YMCA/fitness centre).

10. Voluntary Participation

Your participation in the study is voluntary. You may decide not to be in this study. Even if you consent to participate, you have the right to not answer individual questions or to withdraw from the study at any time. If you choose to leave the study at any time it will have no effect on your future participation in research studies. We will provide any new information that is learned during the study, as that might affect your decision to stay in the study.

11. Confidentiality

Every effort will be made to keep your study records confidential. Your study data will be linked to a unique study ID. A master list linking your study ID with your name and contact information will be available to the Hockey FIT Research Team at Western University and kept in a secure place (i.e., stored on Western University's Network drives with institutional firewalls and within a locked cabinet on site, separate from your study data).

Your research results will be stored in the following manner:

- All paper-based data will be stored in a locked cabinet in a secure office at Western University (Western Centre for Public Health and Family Medicine). Only the Hockey FIT Research Team directly involved in this study will have access to these data.
- All electronic data (photos, videos, audio-recordings) will be stored on the Western University's network drives behind institutional firewalls. All photos and videos taken will be sent to the Research Team via OWL Secure File Transfer Program and will be deleted immediately off the camera/device from which they were taken. Only the Research Team will have access to original photos or video files.
- All questionnaires completed during pre-screening, and at baseline, 3 months, 12 months, 15 months, and 24 months, will be completed online through the PRIVIT® online platform. PRIVIT's health profile management platform enables organizations such as schools, sports leagues, and other institutions to securely collect and manage access to health-related information for its members. Multiple levels of security in the PRIVIT® platform ensure that access to a participant's health information is restricted to those people with the credentials authorizing such access.
- Cambridge Brain Sciences is stored on the Amazon/EC2 server, which is hosted internationally; the back-up for this is at The Brain and Mind Institute at Western University. Due to the nature of this data storage method we cannot guarantee complete confidentiality. Please consult the Cambridge Brain Sciences privacy statement if you have any concerns.

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- Zoom (www.zoom.us) is a secure video conferencing platform, which uses encryption software to securely protect data from outside sources. All video and audio recordings will be encrypted using Advanced Encryption Standard (AES) software, deleted from Zoom platform immediately after the focus group is complete, and stored securely on the Western University's network drive.
- Data from Carrot Rewards and the Hockey Fans in Training Locker Room App are stored in the Amazon Web Service (AWS) ecosystem (Cloud). AWS is a secure hosting platform (<https://aws.amazon.com/security/>) with built-in firewalls to protect and encrypt data.

Study data will be kept for a minimum of 7 years in accordance with Western University regulations. Upon request from the Hockey FIT Research Team, data will be appropriately disposed of by Western Archives at the end of the 7 years. Western Archives has a contract with a private-sector records disposal company that carries out the actual destruction. This company, which has been approved to provide similar services to the federal government, operates a large off-site confidential records destruction facility. Paper records are shredded, and other media forms are shredded or disintegrated, as appropriate. Representatives of the Western University Health Sciences Research Ethics Board may contact you or require access to your study-related records in order to monitor the conduct of the research.

While we do our best to protect your information, there is no guarantee that we will be able to do so. If data is collected during the project, which may be required to report by law, we have a duty to report. A description of this study is available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

12. Contacts for further information

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Research Ethics at Western University (phone: 519-661-3036 or email: ethics@uwo.ca). If you have any questions about the study or have a research-related injury, please do not hesitate to contact:

- Dr. Robert Petrella, Professor, Department of Family Medicine – Centre for Studies in Family Medicine, Western University (phone: 519-661-2111 Ext. 22119 or email: petrella@uwo.ca)
- Dr. Dawn Gill, Research Manager/Scientist, Department of Family Medicine – Centre for Studies in Family Medicine, Western University (phone: 519-661-2111 Ext. 20658 or email: HFIT@uwo.ca or dawn.gill@uwo.ca)

13. Publications & Presentations

The results of this study will be presented in various ways. This includes publishing results in peer-reviewed journals and presentations at national and international conferences. Your

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name will not be used in any publications and all direct quotes taken from focus groups will be de-identified.

This letter is yours to keep for future reference.