Piloting an online telescoaching community-based exercise intervention with adults living with HIV: protocol for a mixed-methods implementation science study

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ABSTRACT

Introduction Our aim is to evaluate the implementation of an online telescoaching community-based exercise (CBE) intervention with the goal of reducing disability and enhancing physical activity and health among adults living with HIV.

Methods and analysis We will conduct a prospective longitudinal mixed-methods two-phased intervention study to pilot the implementation of an online CBE intervention with ~30 adults (≥18 years) living with HIV who consider themselves safe to participate in exercise. In the intervention phase (0–6 months), participants will take part in an online CBE intervention involving thrice weekly exercise (aerobic, resistance, balance and flexibility), with supervised biweekly personal training sessions with a fitness instructor, YMCA membership providing access to online exercise classes, wireless physical activity monitor to track physical activity and monthly online educational sessions on topics related to HIV physical activity and health. In the follow-up phase (6–12 months), participants will be encouraged to continue independent exercise thrice weekly. Quantitative assessment: Bimonthly, we will assess cardiopulmonary fitness, strength, weight, body composition and flexibility, followed by administering self-reported questionnaires to assess disability, contextual factor outcomes (mastery, engagement in care, stigma, social support), implementation factors (cost, feasibility, technology), health status and self-reported physical activity. We will conduct a segmented regression analyses to describe the change in level and trend between the intervention and follow-up phases. Qualitative assessment: We will conduct online interviews with a subsample of ~10 participants and 5 CBE stakeholders at baseline (month 0), postintervention (month 6) and end of follow-up (month 12) to explore experiences, impact and implementation factors for online CBE. Interviews will be audiorecorded and analysed using content analytical techniques.

Ethics and dissemination Protocol approved by the University of Toronto Research Ethics Board (Protocol # 40410). Knowledge translation will occur in the form of presentations and publications in open-access peer-reviewed journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Strengths of this study include our evaluation of the process and outcomes piloting the implementation of an online community based exercise (CBE) intervention for adults living with HIV using an Implementation Science approach with the Reach-Effectiveness-Adoption-Implementation-Maintenance Framework.
⇒ The online CBE intervention may facilitate study participation, offering accessible rehabilitation approaches to adults living with HIV who may face barriers accessing traditional exercise environments within the context of the COVID-19 pandemic.
⇒ This study involves a community-engaged approach involving people living with HIV, representatives from community-based organisations, clinicians working in HIV care, researchers and recreation fitness providers.
⇒ Our pilot approach will assess the process of implementation with the aim to inform feasibility for a future broader scale-up evaluation.
⇒ Potential challenges include recruitment and retention of participants across the yearlong study, access to technology and burden of assessments.

INTRODUCTION

HIV is a chronic illness where individuals can experience health-related consequences of HIV, ageing and multimorbidity, known as disability.1-3 The Episodic Disability Framework, derived from the perspectives of adults living with HIV defines disability as physical, cognitive, mental and emotional symptoms,
difficulties carrying out daily activities, challenges to social inclusion, and uncertainty about future health.\(^4\) These dimensions of disability may be exacerbated or alleviated by intrinsic (personal attributes) and extrinsic (environmental) factors over time.\(^5\) Disability is associated with worse adherence to antiretroviral therapy, poor physical and mental health, and lower retention in care for people living with HIV.\(^6\) Exercise in combination with antiretroviral therapy is a specific rehabilitation self-management intervention that can address health challenges among people living with HIV. Exercising three or more times per week can lead to improvements in cardiopulmonary fitness, strength, body composition and mental health among adults living with HIV.\(^7,8\) Benefits of exercise also have been shown with women living with HIV and older adults living with HIV,\(^9,10\) and physical activity also has been associated with enhancements to physical health,\(^10\) metabolic outcomes,\(^11-13\) cognitive health,\(^14-16\) social support and quality of life among adults living with HIV.\(^17,18\)

Despite the benefits, engagement in regular physical activity varies among adults living with HIV. Systematic review evidence reported that 51% of adults living with HIV achieved recommended guidelines of ≥150 min of moderate to vigorous aerobic physical activity per week and were less active than others with chronic illness.\(^19\) Older adults, women and members of the transgender community living with HIV and other intersecting identities are less likely to be physically active and can face specific structural and interpersonal discomforts and barriers to physical activity in traditional gym environments.\(^20-23\) Environmental (location, physical accessibility, cost), personal (multimorbidity, physical health, lack of knowledge about exercise, lack of self-efficacy, fatigue, anxiety, body image concerns) and social factors (competing priorities, caregiver responsibilities and fear of social stigma exercising in fitness facilities with ‘healthy’ individuals), can pose barriers to adults living with HIV engaging in exercise.\(^24-30\)

Community based exercise (CBE) is a strategy to improve health among people living with HIV within a self-management framework.\(^31\) CBE involves a group of individuals exercising under the assistance of an instructor with the goal of promoting regular exercise in the community.\(^32-34\) CBE can foster social interaction, peer support, encouragement to exercise, and can promote emotional, cognitive and behavioural self-management strategies to help independently manage chronic health challenges.\(^33,35\) In earlier work, we evaluated a CBE intervention in which adults living with HIV were expected to engage in thrice weekly exercise for 6 months, with weekly in-person supervised personal training at the YMCA in Toronto, Canada.\(^36-39\) Few women (<10%) and even fewer from the trans community participated in the study,\(^36\) citing barriers including geographical and childcare barriers, and social and interpersonal barriers to exercise in traditional cisnormative gym settings.\(^38\) Physical distancing and the risk of COVID-19 pose further barriers to exercising in gym environments and can place additional risk of social isolation and physical inactivity.\(^40\)

Telerehabilitation, involving the delivery of programmes and services via web-based platforms, and specifically, online physical activity have emerged as a telerehabilitation approach and way for people living with chronic conditions to engage in physical activity.\(^41\) Online telecoaching has been well established for individuals living with neurological conditions,\(^32,33,42-45\) persistent pain,\(^43\) chronic obstructive pulmonary disease,\(^45-47\) renal disease,\(^48\) and inactive adults,\(^49\) and offers viable alternatives for engaging in exercise.\(^50\) However, it is unclear how online exercise interventions translate to the HIV context; and the role of online approaches in addressing the complex environmental, personal and social barriers to exercise experienced by people living with HIV is unknown.

Our aim is to evaluate the implementation of an online telecoaching CBE intervention among adults living with HIV. Using the RE-AIM (Reach-Effectiveness-Adoption-Implementation-Maintenance) Framework,\(^51\) specific objectives are as follows: (1) To determine the extent to which adults living with HIV participate in the intervention (Reach); (2) To assess the impact of the intervention on physical activity, health and engagement in the care cascade (Effectiveness); (3) To assess engagement in exercise among adults living with HIV over time (physical activity, adherence) (Maintenance) and (4) To evaluate the (A) process (strengths, challenges, accessibility, cost, fidelity) and (B) feasibility of sustainability of the implementation, from the perspective of adults living with HIV, representatives of community-based organisations (CBOs), health and fitness centres, health providers and policy stakeholders (Implementation and Adoption).

METHODS AND ANALYSIS

We will use the RE-AIM Framework, to evaluate the implementation of online CBE, assess the long-term engagement in exercise, the ability to integrate online CBE into the community, and the ability of adults living with HIV to integrate exercise into their daily lives over time (figure 1). The RE-AIM Framework considers multiple aspects of an intervention beyond clinical efficacy.\(^51\) Hence, this approach is useful for physical activity interventions that can be challenging to implement due to the complexity of the intervention.\(^52\) This is a pilot study involving a complex multi-component online exercise intervention, hence our outcomes of interest are focused on process related to recruitment and retention of participants, engagement in exercise and fidelity of implementation of the online intervention.\(^53\)

Study design

We will conduct a prospective longitudinal mixed-methods intervention study to evaluate the implementation of an online telecoaching CBE intervention with adults living with HIV. We will implement a 6-month telecoaching intervention (phase 1), followed by a 6-month follow-up
phase (phase 2). We will use a qualitative longitudinal design using interviews to assess process and outcomes at baseline (0 months), postintervention (6 months) and postfollow-up (12 months) \(^\text{54}\) (figure 2). We initiated the intervention in October 2021, with rolling enrolment and intervention initiation, and expect to complete data collection in February 2023.

We will assess the Reach (Obj 1—extent adults living with HIV participate) and Maintenance (Obj 3—engagement in CBE over time) using quantitative methods. Impact (Obj 2) will be assessed quantitatively (change in physical activity, disability, health outcomes, engagement in care cascade); and qualitatively (perceived impact of the intervention) from the perspective of adults living with HIV. Adoption and Implementation (Obj 4), which concern organisational aspects of the evaluation, will be assessed using qualitative interviews with participants living with HIV and CBE stakeholders to determine the strengths and challenges of implementation; and the feasibility, and long-term sustainability in community (figure 1).

**Patient and public involvement**

This research involves a community-academic-clinical partnership derived from foundational work on CBE in the context of HIV with the Toronto Central YMCA, Toronto, Ontario, Canada.\(^\text{29} \text{30} \text{37} \text{39}\) Collaborating partners include the Toronto Central YMCA, community-based organisations, community HIV clinic in collaboration with the Ontario HIV Treatment Network Cohort Study (OCS), and Realize, a national organisation focused on advancing education, practice and policy on HIV and rehabilitation. Our team includes people living with HIV, representatives from community-based organisations, clinicians working in HIV care, researchers, recreation fitness providers and policy stakeholders who advise on all stages of the research. An Engagement Coordinator living with HIV will engage in communication, and provide support with participants throughout the study.

We will recruit ~30 adults (18 years and older) living with HIV who consider themselves medically stable and safe to participate in exercise as determined by the self-administered Physical Activity Readiness Questionnaire.\(^\text{55}\) Individuals will need access to: (1) a smart phone, tablet, laptop or desktop computer; (2) Wi-Fi or data internet plan; (3) a web-cam and willingness to use the web-cam for group exercise classes, fitness sessions, assessments and (4) a space in their home to take part in exercise. We will use the Information and Communication Technologies (ICT) Development Index to discuss digital access, connectivity, use and literacy.\(^\text{56} \text{57}\) We will use the index as a guide to discuss indicators of

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**Figure 1** Overview of study objectives with the RE-AIM framework. RE-AIM, Reach-Effectiveness-Adoption-Implementation-Maintenance.  

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access to information and technology (mobile telephone, computer, internet and type of internet), use of technology and skills (literacy). This will inform our assessment of ‘Reach’ (accessibility) of the intervention among adults living with HIV (Obj1).

We will recruit participants through the Ontario HIV Treatment Network Cohort Study (OCS) in Toronto and via community-based organisations with a recruitment poster. Participants in the OCS at the Maple Leaf Medical Clinic, Toronto, Ontario will be administered a supplemental questionnaire to identify eligible and interested OCS participants who agree to be contacted about exercise education and opportunity to exercise; problem- and goal attainment. As a result, we will approach women to engage in exercise for 60 min 3x/week. Intervention will include: 1) personal online coaching session bi-weekly by a fitness instructor who will monitor and progress exercise intensity accordingly; 2) weekly online group-based exercise classes; 3) online monthly self-management education sessions; and 4) Wireless Physical Activity Monitor (WPAM) (Fitbit®) to track physical activity.

Research procedure

Prior to the intervention fitness instructors will take part in a knowledge exchange workshop on topics including HIV, rehabilitation and exercise for people living with HIV, goal setting, research procedures, antipression and transclusion. Participants will be provided with exercise equipment to engage in the home-based exercise and fitness assessments, including a wooden step, measuring tape, body weight and composition scale, Therabands and a wireless physical activity monitor (WPAM) (Fitbit Inspire 2). We will set up and pilot the technology, including (but not limited to): Zoom software, web-cam, YMCA membership (including Sweat for Good App), web-based questionnaire software and Fitbit App, with participants and fitness instructors. See figure 2 for an overview of the study and data collection timeline.

Phase 1: online exercise intervention (6 months)

Participants will meet the fitness instructor to assess their goals and establish an individualised tailored home-based exercise programme involving aerobic, resistance, balance and flexibility training (~60 min, 3X/week for 24 weeks. The intervention includes: framing and explanation of the exercise through educational sessions; participants will have the opportunity to choose activities of interest and ability, to enhance engagement and adherance to exercise; problem-solving support where participants will have access to staff to assist with goal setting and overcoming barriers to exercise; and communication among participants, fitness instructors and study staff to ensure participants receive feedback on their progress and goal attainment.

The intervention will include: (component 1) biweekly 60 min personal online coaching with a certified trainer
from the YMCA (13 sessions) who will monitor and progress exercise intensity; (component 2) weekly online group-based exercise classes ~60 min each led by a trainer at YMCA; (component 3) monthly online evidence-based self-management education sessions, focused on topics related to self-management and health, and physical activity living with HIV and (component 4) a WPAM to self-monitor steps, distance, calories burned and active minutes. The combination of group and individualised exercise will ensure the intervention will be tailored to the individual, while promoting benefits of efficacy and social support that come from group activity. We will use Zoom as our telecoaching platform.

Our online telecoaching intervention builds on lessons learnt from our in-person CBE study, the American College of Sports Medicine guidelines, qualitative consultation with community (adults living with HIV and fitness instructors), and qualitative work that identified factors to consider in developing and implementing online CBE with the HIV community, specifically (1) person-specific considerations (episodic nature of disability, stigma, HIV disclosure), (2) accessibility (physical space to exercise, reliable internet, access to devices, digital literacy), (3) programme delivery and technology (live vs prerecorded online classes, multiple online platforms for delivery, physical activity tracking, troubleshooting technology), (4) attributes of CBE personnel (working with CBOs, relatable instructors, diverse staff), (5) programme content and design (tailored exercise classes, educational sessions) and (6) building community (shared experiences, peer support, social opportunities).

Phase 2: postintervention (6 months)
Participants will be encouraged to continue with independent exercise three times per week. Participants will continue to have their YMCA online membership, and encouraged to engage in online YMCA group-based exercise classes over Zoom.

Data collection
We will assess outcomes bimonthly, at seven time points across the intervention (months 0, 2, 4, 6) and postintervention (months 8, 10, 12) phases using objective fitness assessments and self-reported questionnaires via Zoom. Qualitative interviews will be conducted remotely online via Zoom. Through phase 1 and 2, participants will be asked to track their physical activity using their WPAM (Fitbit Inspire 2) to self-monitor steps, distance, calories burned and active minutes. Participants also will be asked to respond to a brief (2 min) weekly physical activity questionnaire (CBE-PAQ) to document the nature and extent of activity during both exercise phases (12 months) to assess sustained engagement in exercise (Obj3).

Objective 1 (Reach)—To determine the extent to which adults living with HIV participate in the intervention: We will measure the number, proportion and characteristics of individuals who: (A) express interest to participate; (B) are eligible but do not agree to be contacted about the study; (C) are eligible and agree to be contacted about the study; (D) are eligible, agree to be contacted and consent to participate; (E) consent to participate but do not initiate the intervention, (F) initiate but do not complete; (G) complete the intervention but not the follow-up self-monitored exercise and (H) complete the intervention and follow-up self-monitored exercise. We will describe how many participants withdraw, when and why. We will similarly monitor any participants lost to follow-up. We will assess the ICT access, use and skills of those who express interest to participate, and differences between those who self-select to and complete versus withdraw from the study.

Objective 2 (Effectiveness)—to assess the impact of the online CBE intervention: Our primary outcome is physical activity. We will assess physical activity, disability, health and engagement in care outcomes bimonthly using self-reported and objective measures at baseline (0 months), during (2, 4 months), postintervention (6 months) and post follow-up (8, 10, 12 months), extrinsic contextual factors (stigma, social support) and intrinsic contextual factors (eg, mastery, personal characteristics) (figure 2). Bimonthly assessments are needed to estimate the change in trend (slope) of outcomes between the intervention and follow-up phases over time. We will assess goal attainment at the end of the intervention and follow-up phases of the study.

Part 1: quantitative assessment: self-reported questionnaires
Outcomes will include physical activity (primary); and disability, health and care cascade outcomes (secondary) to assess implementation and effectiveness outcomes respectively (Obj2). We will administer patient-reported outcomes using web-based questionnaires bimonthly (months 0, 2, 4, 6, 8, 10, 12) for the following constructs:

Physical activity
We will administer a CBE-PAQ weekly via email asking participants (1) whether they achieved the weekly recommended Canadian Physical Activity Guidelines and (2) days in the past week engaged in ≥30 min of moderate to vigorous aerobic physical activity. The latter single physical activity item possesses reliability, concurrent construct validity and responsiveness to evaluate change among adults 18 years and older. Participants will use their Fitbit Inspire 2 provided to fill out their CBE-PAQ. The weekly CBE-PAQ will take approximately 2 min to complete.

Disability
The HIV Disability Questionnaire (HDQ) measures the presence, severity and episodic disability across six domains: physical, cognitive and mental-emotional health symptoms, difficulties with daily activities, challenges to social inclusion and uncertainty. The HDQ is valid and reliable for use with PLWH in Canada and internationally.
We recently developed a short-form version of the HIV Disability Questionnaire (SF-HDQ) to improve feasibility. Scores range from 0 to 100 with higher scores indicating greater presence, severity and episodic nature of disability. Requiring half the time to administer, this will be the first intervention study to use the SF-HDQ. We chose the SF-HDQ over other generic measures of disability as the questionnaire was developed for, and validated for use with adults living with HIV, it measures the episodic nature of disability, includes uncertainty, a key dimension of disability experienced among adults living with HIV, and is consistent with the disability measure used in our prior CBE intervention study.

**Health status**
The EQ-5D-5L (5 level EQ-5D) is a generic health status questionnaire comprised of five domains (mobility, self-care, usual activities, pain, anxiety/depression). The EQ-5D-5L is widely used and has demonstrated responsiveness with people living with HIV.

**Mental health**
The Patient Health Questionnaire (PHQ-8) is an eight item measure of depression severity. Items are rated using a Likert-type scale from 0 to 3, with a total score range of 0–24. A score of 10 or greater is considered major depression, 20 or more is severe major depression. The PHQ-8 has been used and is reliable and valid among people living with HIV.

**Engagement in care**
The HIV Index of Engagement considers the complexity of social contextual factors such as stigma, racial, sexual and addiction issues that may influence engagement in care for some people living with HIV. The Index of Engagement in HIV Care consists of 10 items. Higher scores are associated with antiretroviral adherence, appointment attendance and increased likelihood of viral load suppression. Validation has been demonstrated with over 3000 people living with HIV in the USA.

**Extrinsic contextual factors**
The Short Form SF-HIV Stigma Scale is a 12-item self-administered questionnaire that measures stigma in people living with HIV with four subscales (personailised stigma, disclosure concerns, concerns about public attitudes and negative self-image). Each item is measured using a Likert-type scale with four response categories ranging from 'strongly disagree' to 'strongly agree'. Higher scores reflect a higher level of perceived HIV-related stigma. This scale possesses construct validity and reliability with persons living with HIV. The MOS-Social Support Scale (MOS-SSS) is a 20-item measure that describes five dimensions of social support among patients with chronic illness emotional/informational support, tangible support, positive social interaction and affectionate support. Higher overall scores are indicative of higher levels of social support. The MOS-SSS possesses construct validity and reliability with people living with HIV.

Intrinsic contextual factors (living strategies and personal attributes)
We will measure mastery (living strategy) and personal attributes including demographic and clinical characteristics. The Pearlin Mastery Scale is a seven-item self-administered questionnaire that assesses sense of personal control over important life forces or outcomes. Each item in the scale is measured using an ordinal scale with four response options, and summary scores are generated indicating level of mastery (limited, moderate, great). This scale has demonstrated construct validity and reliability for caregivers of persons living with HIV, individuals with Alzheimer’s and dementia. The Demographic Questionnaire will capture personal attributes (age, gender, sex, living situation, employment status, race, smoking history, substance use), clinical characteristics (viral load, time since HIV diagnosis, antiretroviral use and adherence, multimorbidity) and COVID-19 factors (experience with COVID-19, impact of COVID-19 on housing, family, employment, personal safety, finances, social interaction and access to and engagement in care in the context of COVID-19). We will readminister items from this questionnaire every 2 months (medication adherence, smoking history, substance use, comorbidity, health events) and ask whether any events influenced participants’ ability to exercise since the last assessment.

The bimonthly self-reported questionnaire assessment will take approximately 45–60 min to complete.

**Goals**
We will administer the Goal Attainment Scale (GAS) at three time points: online CBE initiation (month 0) and completion (month 6) and end of study (month 12) to measure the motivation and impact of exercise based on the needs of the individual. Goal Attainment Scaling is a method of scoring the extent to which participants’ individual goals are achieved in the course of an intervention. Goals are stated by the participant at baseline, and the participant will score each goal based on the importance, difficulty of achievement and previous ability with the goal prior to the intervention. Following the intervention, the participant will report whether the goal was achieved (yes or no) and to what extent the goal was achieved or not achieved. Each goal is scored based on goal difficulty, importance, prior level of ability and achievement level. We will administer the GAS via Zoom at the time of the above questionnaire administration, taking ~15–20 min to complete. The GAS will be shared with participants and fitness instructors to provide feedback and inform progression of physical activity throughout the study.
Part 2: quantitative assessment: performance measures

Physical fitness and health
Trainers at the YMCA will conduct the following objective assessments bimonthly (months 0, 2, 4, 6, 8, 10, 12) with participants at their home remotely online via Zoom.60 The fitness assessment will include: (A) cardiopulmonary fitness; (3 min bench step test; heart rate measurement); (B) muscle strength and endurance (maximum plank duration, and maximum number of push-ups to failure); (C) physical function (30 s sit-to-stand test); (D) weight and body composition and anthropometrics; (body weight (kg), body fat %, hip and waist circumference (cm), waist: hip ratio) and (E) flexibility (sit and reach; cm).106 The fitness assessment will take approximately 1 hour to complete and staff will document outcomes using a web-based questionnaire.

Part 3: qualitative assessment: interviews
We will conduct a series of online interviews via Zoom63 with a subsample of ~10 adults living with HIV at CBE initiation (month 0), completion (month 6) and end of follow-up (month 12) to explore experiences, level of engagement in, and impact of exercise. Using a semi-structured interview guide, we will explore (A) experiences with exercise, (B) anticipated benefits of exercise (initiation), (C) perceived impact of online CBE (pertaining to: exercise, support from trainer, Fitbit Inspire 2), (D) self-management sessions) on physical activity and health over time (post) and (D) maintenance in exercise (end of study). We will explore the influence of extrinsic factors (social support, stigma) and intrinsic factors (sex, gender, age) and the use of technology on the impact and engagement in exercise. All interviews will be audiorecorded and transcribed verbatim.

Our outcomes and approaches to inquiry for impact are derived from the Episodic Disability Framework that considers dimensions of disability (physical, cognitive, mental-emotional health, daily function, social inclusion and uncertainty about future health) and contextual factors that include extrinsic (social support; stigma) and intrinsic factors (living strategies; personal attributes) that may influence disability and engagement in exercise.45

Objective 3 (Maintenance)—To assess engagement in exercise among adults living with HIV over time: Maintenance will be measured by assessing physical activity and adherence to the online CBE intervention over 12 months.71 We will measure physical activity by administering the Rapid Assessment of Physical Activity (RAPA) Questionnaire bimonthly (seven time points) and objectively using the WPAM Fitbit Inspire 2.62 We will measure adherence by (1) documenting attendance to the biweekly fitness sessions in the 6-month intervention (total 15 sessions) and (2) administering the weekly web-based CBE-PAQ.

Physical activity
The RAPA is a nine-item self-reported questionnaire that measures physical activity.108 RAPA 1 score uses items 1–7 and the score is representative of aerobic exercise engagement, classifying participants as sedentary, under-active, underactive regularly (light activities), underactive regular or active. RAPA 2 score uses items 8–9 and is representative of engagement in strength, flexibility, both or neither.109 Higher RAPA scores indicate greater level and intensity of engagement in physical activity. The RAPA demonstrates construct validity with adults living with HIV.109 The RAPA questionnaire will be administered with the other bimonthly web-based questionnaires.

We will use a WPAM, specifically the Fitbit Inspire 2 to objectively measure physical activity.62 Participants will be instructed to wear the Fitbit Inspire 2 daily to capture their steps and physical activity minutes.62 Participants will be asked to sync their Fitbit Inspire 2 with their Fitbit Account (via an electronic device or laptop/computer) weekly and to complete questions about physical activity as reported on the Fitbit65 in the CBE-PAQ.

Adherence
We will measure adherence by (1) documenting attendance to the biweekly fitness sessions in the 6 month intervention (total 13 sessions) and (2) documenting engagement in exercise as determined by responses to the weekly web-based CBE-PAQ.

Objective 4a (Implementation)—To evaluate the process (strengths, challenges, accessibility, cost, fidelity) of the implementation: We will explore implementation and adoption using interviews with the same subsample of ~10 adults living with HIV above (same interview for Obj2 and Obj4) and with ~5 CBE stakeholders involved in implementation (instructors), representatives from CBOs and health providers at CBE initiation (month 0), completion (month 6) and end of study (month 12).

Implementation process
We will explore (A) anticipated concerns (initiation), (B) strengths and challenges implementing CBE (tele-coaching, online classes, self-management sessions, Fitbit Inspire 2 use), (C) accessibility and feasibility of the intervention (including technology) and (D) mechanisms for long-term sustainability (post) and (E) reflections implementing telecoaching across the broader Ontario HIV community (end of study). All interviews will be audio recorded and later transcribed verbatim. The qualitative interview at each time point with participants living with HIV and CBE stakeholders will be approximately 60 min.

Cost
We will determine costs of the intervention from individual and system perspectives. We will calculate the direct intervention costs, predominantly related to labour, through YMCA wages. We will determine out-of-pockets costs for personal coaching, exercise clothing, footwear and technology and will allocate costs to the intervention by asking participants if they incurred incremental costs compared with baseline (eg, there may be no internet-related costs if individuals already have unlimited Wi-Fi or...
data plans). We will use a unit-cost approach (ask about the number of units used and assign an average cost to each unit), which we anticipate will be easier for participants to recall than actual costs. Items related to out-of-pocket costs of the intervention will be included in the bimonthly demographic questionnaire to minimise recall bias. This demographic questionnaire with inclusion of cost items will be administered with the other bimonthly web-based questionnaires.

Fidelity

Fidelity of implementation (FOI) refers to the degree to which an intervention or programme is delivered as intended. We will assess the following components of fidelity as part of the interviews with participants living with HIV: (1) adherence; (2) dose or amount of intervention delivered and (3) quality of delivery (eg, telecoaching). We will pose a single open-ended question asking participants to walk us through their most recent coaching session and most recent independent exercise session from start to finish. Additionally, we will assess FOI with the following: (1) fitness coaching log documentation—we will document the frequency, intensity, time and type of physical activity as recorded in the biweekly fitness instructor ‘coaching logs’ for each participant (total of 13 sessions), (2) brief open-ended interview ~10 min FOI Check-In when participants complete midway (2 months) and at the end of the intervention. We will ask participants to walk us through their mostIntrinsic contextual factors (list recent coaching and independent exercise session (start to finish). We will complete an FOI Check-List based on responses to guide assessment and rate whether fidelity criteria were met.

Objective 4b (Adoption)—To evaluate the feasibility of sustainability of the implementation: Using a semi-structured interview guide with adults living with HIV and CBE stakeholders, we will explore insights on (A) strengths and challenges of implementation (postintervention), (B) accessibility and feasibility of the intervention (post) and (C) readiness for sustainability across the community (end of study). We will specifically explore adoption of the technology, feasibility and usability of the online intervention guided by the WHO Framework for Implementation of a Telemedicine Service, and the Fit between Individuals, Task and Technology (FITT) Assessment, developed to assess the adoption of eHealth interventions based on the ‘fit’ between attributes of the user (demographics, comfort, use of technology), technology (efficiency, effectiveness, learnability, functionality, satisfaction) and task (engagement in physical activity). This model was used to assess adoption of eHealth interventions for people with chronic disease and HIV.

Feasibility

We will assess feasibility of the telecoaching intervention using telehealth indicators. Specifically we will use Key Performance Indicators for Evaluating Video-to-Video Services in eHealth to capture usability (ease of use, navigation), satisfaction (Telehealth Satisfaction Scale (10 items) and reliability of online video exercise sessions (type of device (computer, tablet, phone); number of interruptions/dropped sessions, audio and video quality of connection, bandwidth issues–Wi-Fi vs roaming). Participants and coaches will complete a questionnaire midway (2 months) and at intervention completion (6 months). Results will inform ways to improve the intervention and future programming for adults living with HIV. The telehealth indicators questionnaire will take approximately 5 min to complete.

Data analysis

Objective 1 (Reach)

We will report the number of individuals who express interest to participate in the intervention and the proportion interested, based on the number of eligible adults living with HIV. We will compare the characteristics of participants who engage in telecoaching with epidemiological data about persons living with HIV in Canada from the Public Health Agency of Canada. We will report the number, proportion and characteristics of participants who are eligible and agree to participate, technology access, use and skills, the number who withdraw, and the reasons for withdrawal over time. We will assess differences in characteristics (eg, gender) of those who complete vs withdraw from the study.

Objective 2 (Impact)

Quantitative analysis

We will compare patterns of responses to physical activity, disability and health outcomes during (0–6 months) and after the intervention (6–12 months) using linear mixed effects models. Using a segmented regression model, we will estimate the change in level (amount) and trend (slope) between the intervention and follow-up phases. We will define a clinically important change in physical activity as measured by an increase of 2 days in the past week engaged in ≥30 min of moderate to vigorous aerobic physical activity as measured by the single physical activity item. Goal attainment data will be analysed descriptively to measure the number (percent) of goals achieved over time.

Objective 3 (Maintenance)

Physical activity

We will calculate the time engaged in moderate to vigorous aerobic physical activity each week and the proportion of participants classified as ‘underactive’ versus ‘active’ by the RAPA across all time points. We will use descriptive statistics to describe scores for the Aerobic Scale and Strength and Flexibility Scale, steps, distance, calories burned, and active minutes as measured by the Fitbit weekly summary. We will use linear mixed effects models to test for differences in outcomes across the two phases. Beneficial changes in activity will be determined by transition from ‘underactive’ to ‘active’. We will
define maintenance as the ability to sustain similar RAPA classification (active) postintervention.

Adherence
We will calculate the proportion of biweekly individual and weekly group-based exercise sessions attended. Adherence will be defined as engaging in ≥75% p of the three weekly exercise sessions throughout.122 We will document reasons for lack of adherence, and reasons for rescheduling of coaching sessions to capture the episodic nature of exercise.

Objective 4a (Implementation)
We will use coaching logs to determine if participants received the prescribed time, type and intensity of intervention. We will describe responses to the telehealth indicators questionnaire (feasibility) by reporting the frequency and percent of each criterion met.129 We will qualitatively analyse data from the open-ended questions in the interviews using content analytical techniques.125

Objective 2 (Impact) and Objective 4a and b (Implementation and Adoption)
Qualitative analysis
We will use longitudinal qualitative analytical techniques to explore perceptions of participants living with HIV on the impact of CBE (Obj 2) and perceptions of participants living with HIV and CBE stakeholders on the process of implementation and its sustainability over time (Obj 4).34 123 We will analyse transcripts cross-sectionally and longitudinally to identify (A) experiences with exercise; (B) anticipated benefits and (C) perceived impact of online CBE on health outcomes to identify changes over time.124 Transcripts will be analysed using line-by-line coding and codes clustered into broader categories.126 We will use NVivo software to facilitate analysis.126 Quantitative and qualitative data pertaining to impact (Obj 2) will be analysed separately but concurrently and combined at the point of interpretation with team. When all interview data are analysed, we will formulate a summary of perceived impact (Obj 2) and strengths and challenges associated with the intervention and recommendations for long-term implementation (Obj 4).

Quantitative analysis
Cost
Our cost analyses will be descriptive using both a societal perspective (public and private costs) and a health system perspective (public health-related costs). Our analyses will follow Canadian recommendations for best practices in economic evaluation (Obj 4).127

Sample size
Our sample size is based on feasibility. We will recruit 40 participants with the aim to have 30 adults living with HIV complete the intervention (≥30% cisgender and transgender women) and a subsample of 10 adults living with HIV (≥5 cisgender and transgender women) and 5 CBE stakeholders to participate in the interviews. Our quantitative analyses will be exploratory to obtain knowledge of the distribution of outcomes in order to inform future sample size estimates feasibility for broader scale-up. Our prior work suggests this number will enable us to achieve our objectives related to the strengths and challenges of implementing CBE.37 38

Team and roles
This study is an academic-clinical-community-policy partnership involving over 20 team members including people living with HIV, representatives from community-based organisations, clinicians working in HIV care, researchers, trainees, recreation fitness providers and policy stakeholders. The lead investigator is responsible for the overall implementation and coordination of the study. A core team will meet regularly to discuss recruitment and retention, implementation of the intervention, data collection, analysis and interpretation of study findings. The full team (see authorship) will meet approximately quarterly to advise on all aspects of study implementation including the online CBE intervention, recruitment strategies, data collection, analysis, interpretation of study findings and evidence-sharing activities. Individual consultation with team members will occur throughout. Two research coordinators will be responsible for ongoing communication with the fitness personnel, communication with participants and administration of questionnaires. Two fitness personnel from the YMCA will conduct the fitness assessments and two fitness personnel will conduct the online biweekly personal training sessions with participants. One trainee will conduct the interviews. An engagement coordinator living with HIV will communicate with and provide support with participants throughout the study.

DISCUSSION
Results will lead to the first known online health promotion intervention tailored and evaluated for long-term engagement in physical activity with adults living with HIV. At the individual level, engagement in CBE may help to improve physical and mental health of adults living with HIV, which may have downstream implications for adherence to medications and engagement in HIV care. At the organisational level, results will yield the first known HIV online CBE intervention evaluated for translation and organisational level, results will yield the first known HIV online CBE intervention evaluated for translation and sustainability with community providing evidence on the impact of CBE on health and disability outcomes. Results may help to inform policy and programming on optimal forms of online CBE implementation that can be adopted by fitness centres and community-based organisations.

This research builds on results from our in-person CBE study,36–38 two Cochrane systematic reviews,7 8 and trainee research assessing readiness to engage in exercise among adults living with HIV.39 128 129 This study directly addresses key research priorities in HIV, ageing and rehabilitation,130 131 and the recent call to add a fourth ‘90’ of mental health and wellness to the global target for HIV control with the care cascade.132 133
This study emerged from a longstanding, productive community-academic-clinical partnership between researchers, community members and organisations, clinics and health centres. Team members have built a strong foundation of HIV, implementation science and exercise research. Strengths of our approach include: (1) our self-management and health promotion approach, tailored to the potentially episodic nature of HIV in contrast to earlier interventions, involving highly structured, prescriptive protocols; (2) our biweekly (opposed to weekly) supervision is accessible and less costly; (3) the 6-month CBE intervention and follow-up surpasses previously common 3-month interventions to evaluate long-term implementation; (4) the intervention was derived and will be implemented using a community-engaged approach; (5) adults living with HIV will tailor the intervention to their needs, provide unique insights into strengths and challenges of online telecoaching, and suggest ways to promote its sustainability; (6) outcomes for evaluating the impact of CBE are person-centred, derived from goals articulated by participants in the in-person CBE study. We will also assess fidelity of implementation, to determine the extent to which the intervention is delivered in the way and intensity in which it is intended, and feasibility of implementation by assessing indicators of telehealth implementation (Obj4a) to establish recommendations for future implementation of online telehealth-based services. (7) We will assess cost to inform the feasibility of long-term sustainability of the intervention with the community. (8) Involving the community in the evaluation will enable tailoring of CBE to meet the diverse needs of populations affected by HIV in different contexts and (9) our online telecoaching platform while timely, will have impact beyond the pandemic offering potential future transferability to other or remote geographic regions.

Limitations
We recognise some adults living with HIV may not meet the information technology eligibility to participate in the study. Potential challenges include recruitment and retention of participants across the yearlong study and burden of assessments. Given the pilot nature of the study design, our analysis is descriptive and exploratory in nature and will inform feasibility for a future broader scale-up evaluation.

Ethics and dissemination
This protocol was approved by the University of Toronto Research Ethics Board (REB) (Protocol #: 40410) (online supplemental file 1). We will inform potential participants of the study purpose, research procedure, eligibility criteria, potential risks of participation, and time commitment involved in participation (see online supplemental files 2 and 3, eg, consent forms for participation in the intervention study and interviews with adults living with HIV and for CBE stakeholders). Verbal consent to participate in the online telecoaching intervention and the interview will be obtained by the research investigator online via Zoom who will sign and date the consent form confirming verbal consent.

Compensation
Each participant living with HIV will receive a 12-month open access YMCA membership with access to online YMCA group exercise classes, and 6 months of biweekly online personal telecoaching with a YMCA fitness instructor for their participation in the study. The membership will be provided in two waves, the first membership will be for 6 months (intervention phase) and the second membership will be for 6 months (follow-up phase). Participants need to remain in the study for the intervention phase (0–6 months) and complete the bimonthly assessments to receive the second 6 month membership. Participants will be able to keep the Fitbit Inspire 2 and the exercise equipment (Therabands, body weight and composition scale, wooden step and tape measure) as a token of appreciation for participating in the study.

Potential risks
It is possible that participants will experience injury with the exercise sessions and fitness assessments. If injury does occur, the fitness instructors will follow appropriate emergency procedures (in accordance with the YMCA general safety procedures and guidelines). Participants also may find some of the questions on the questionnaires or in the interview to be personal or sensitive in nature or too burdensome, and can choose not to complete the physical assessments, choose not to answer questions and may end the interview, assessments or intervention at any time. Additionally, given the requirement for participants to turn on their web-cams during the fitness coaching sessions, fitness assessments and the online monthly self-management information sessions, it is possible that participants may feel a loss of privacy while participating in parts of the intervention. During the screening and consent process, we will indicate to participants that they must have access to, and be comfortable and able to use their web-cam for online sessions, and that all individuals involved in this study including other participants, fitness instructors and assessment staff at the YMCA, will know that participants in this study are HIV positive.

Confidentiality and data management
All information will be confidential and available only to study investigators, research staff and the University of Toronto REB. Participant records will be identified by a coded number to maintain confidentiality. We will store a master list of participants with their respective participant numeric codes and contact information on a password-protected computer file at the University of Toronto. Participants will be assigned to a YMCA fitness instructor who will have access to the participants’ contact information in order to directly liaise with their respective participants about scheduling their fitness sessions.

Data collected by YMCA fitness instructors will be uploaded to a password-protected and encrypted file share system (Sharefile) and subsequently transferred to the University of Toronto for storage on a secure server. All self-reported questionnaires will be administered electronically using Qualtrics Software, an online secure e-survey software that uses Transport Layer Security encryption. Data will be downloaded from Qualtrics to the University of Toronto and stored on a secure server. The Word document GAS will be stored on a password-protected folder on the University of Toronto server and uploaded to Sharefile in order to share with the YMCA fitness instructors. As per the REB approval, participant-level data will not be publicly accessible. Members of the public who wish to access the full protocol and statistical code may contact the corresponding author with their request.

Dissemination
We will translate knowledge with persons living with HIV, community-based organisation, fitness centres, HIV clinics, health centres and policy stakeholders. We will devise key messages for community forums and collaborator websites, presentations, fact sheets and social media. Our evidence-sharing plan will translate knowledge and establish pathways for long-term programming with stakeholders including people living with HIV, representatives from HIV and fitness community-based agencies, health centres and clinics, and policy makers. We will host a Forum in collaboration with the Canada-International HIV and Rehabilitation Research Collaborative to foster knowledge translation and strengthen partnerships to establish a coordinated response for the access and delivery of sustainable evidence-based CBE programming with the HIV and fitness communities. Further knowledge translation will include peer-reviewed open-access publications, conference presentations, webinars and education of trainees.

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Contributors KKO’B co-led the conceptualisation of the study objectives, and drafted the protocol, led the application for acquisition of funding, and is the lead investigator on the study. KKO’B, FL, C, SCC, AMB, AT and PS are coinvestigators on the research team, and were involved in the conceptualisation of the study design, development of the protocol and acquisition of funding. MRL is a coinvestigator on the research team, involved in the refinement of the protocol and facilitation of recruitment with the Maple Leaf Medical Clinic. DAB and LA are collaborators on the research team and were involved in the conceptualisation of the study design, and development of the protocol. SL, JL and CP are knowledge users and community experts who were involved in the review and refinement of the protocol. PA is a community collaborator and knowledge translation expert who will be involved in the knowledge translation. MZ, ZP and II were involved in the development and refinement of the study protocol and implementation procedure in collaboration with the YMCA. KM (PT, Research Coordinator), TJ (Postdoctoral Fellow), GDS (Engagement Coordinator) and BT (PT, Research Coordinator) are members of the research team involved in the start-up activities, recruitment of participants, implementation of the intervention, data collection and contributed to the refinement of the protocol. All authors have read and approved the final protocol manuscript.

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Disclaimer
Study funders and sponsors did not have a role in the study design and will not have authority of activities including data collection, management, analysis, interpretation of data, writing of the report, and submission for publication.

Competing interests
None declared.

Patient and public involvement
Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication
Not applicable.

Provenance and peer review
Not commissioned; externally peer reviewed.

Supplemental material
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REFERENCES


Huggins AC, Ritzhaupt AD, Dawson KM. Measuring information and communication technology literacy using a performance assessment: validation of the student tool for technology literacy (ST2L). *Computers & Education* 2014;77:1–12.


Zoom health care video communications [program], 2020.


101 Adams KB, Smyth KA, McClendon MJ. Psychosocial resources as moderators of the impact of spousal dementia caregiving on depression. *J Appl Gerontol* 2005;24:475–89.


133 Webster P. Unaid survey aligns with so-called 90 for HIV program. *Lancet* 2019;393.


135 Qualtrics [program]. Provo, Utah, USA.
RIS Protocol
Number: 40410
Approval Date: 12-Apr-21
PI Name: Miss Kelly O'Brien
Division Name:

Dear Miss Kelly O'Brien:

Re: Your research protocol application entitled, “Tele-Coaching CBE Study: Evaluating the Implementation of an Online Community-Based Exercise (CBE) Intervention using Tele-coaching to Enhance Physical Activity among Adults Living with HIV”

The Health Sciences REB has conducted a Full Board review of your application and has granted approval to the attached protocol for the period 2021-04-12 to 2022-03-18.

If this research involves face-to-face (F2F) in person research, please note that REB approval alone is not sufficient to commence research. You must wait for an approval letter from the F2F COVID-19 Review Committee. The approval letter will be sent to the Principal Investigator’s email address once the Committee has deemed the F2F in-person research ready to start.

Please be reminded of the following points:

- **An Amendment** must be submitted to the REB for any proposed changes to the approved protocol. The amended protocol must be reviewed and approved by the REB prior to implementation of the changes.

- **An annual Renewal** must be submitted for ongoing research. Renewals should be submitted between 15 and 30 days prior to the current expiry date.

- **A Protocol Deviation Report** (PDR) should be submitted when there is any departure from the REB-approved ethics review application form that has occurred without prior approval from the REB (e.g., changes to the study procedures, consent process, data protection measures). The submission of this form does not necessarily indicate wrong-doing; however follow-up procedures may be required.

- **An Adverse Events Report (AER)** must be submitted when adverse or unanticipated events occur to participants in the course of the research process.

- **A Protocol Completion Report** (PCR) is required when research using the protocol has been completed. For ongoing research, a PCR on the protocol will be required after 7 years, (Original and 6 Renewals). A continuation of work beyond 7 years will require the creation of a new protocol.

- If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your research.
Supplemental File 2 - Evaluating an Online Tele-Coaching Community-Based Exercise Intervention with Adults Living with HIV: Protocol for a Mixed Methods Implementation Science Study

Informed Consent Form to Participate in Online CBE Intervention Study

**Title of Study:** Tele-Coaching CBE Study: Evaluating the Implementation of an Online Community-Based Exercise (CBE) Intervention using Tele-coaching to Enhance Physical Activity Among Adults Living with HIV

**Principal Investigator:**
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**Sponsor:** Ontario HIV Treatment Network (OHTN) HIV Endgame Funding Program – Breaking New Ground

CBE Tele-Coaching Study – Info Letter and Consent Form - Adults Living with HIV
Date Last Revised: March 12, 2021

Page 1 of 11
You are invited to participate in a research study to evaluate an online Tele-Coaching Community-Based Exercise (CBE) intervention to improve health and enhance physical activity among people living with HIV. This study is being conducted in collaboration with the Greater Toronto YMCA and is a sub-study with the Ontario HIV Treatment Network (OHTN) Cohort Study (OCS). In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision.

**WHY IS THIS RESEARCH BEING DONE?**
Exercise is one activity that can help people living with HIV address their health-related challenges and improve their overall health. Older adults, women and members of the transgender community living with HIV are less likely to participate in exercise and can face structural and interpersonal barriers to physical activity in traditional gym environments. Online tele-coaching community-based exercise (CBE) is an ideal model to enhance physical activity and offers a viable alternative for people living with HIV to engage in exercise. Online physical activity platforms have emerged as a way for those living with chronic conditions to access services, when unable or unwilling to in person due to long travel time, HIV-related stigma or the COVID-19 pandemic. However, the ways in which an online tele-coaching physical activity is carried out in the HIV context, and the role of online CBE to address barriers to exercise adults living with HIV may experience is not yet known.

**WHAT IS THE PURPOSE OF THIS STUDY?**
The purpose of this research is to evaluate an online tele-coaching community-based exercise (CBE) intervention with adults living with HIV within the community.

**WHO CAN PARTICIPATE IN THIS STUDY?**
You are eligible to take part in this study if you are 18 years of age or older living with HIV in Toronto, have access to internet and technology to engage in online coaching, have a space in your home to engage in exercise and consider yourself medically stable and safe to participate in a Community-Based Exercise program. Because this is a sub-study of the OCS, our aim is to recruit individuals who are participants in the OCS.

If you are interested in the study you will be asked to complete a Physical Activity Readiness Questionnaire. Your responses to this questionnaire will help determine your ‘readiness’ to exercise and whether you will need to talk with your physician to confirm your ability to take part in physical activity that is involved with this study. We encourage all interested individuals to discuss their participation in this study with their physician (although written documentation from a physician is not required for participation in the study).

To participate in this study, you will also need access to an electronic device (smart phone, tablet, laptop or computer), data or Wi-Fi plan, web-cam and a space in your home to exercise. You will also have to be willing to commit to participating in a one-year tele-coaching study, whereby you will exercise 3x per week for 60 minutes, participate in bi-weekly fitness coaching sessions, weekly online exercise classes, and bi-monthly health and fitness assessments. You will also be required to commit to wearing a Fitbit® Inspire 2 on your wrist while exercising and syncing this Fitbit weekly. Because this study is a sub-study of the OCS, you also will be asked to agree for your study information in the tele-coaching study to be linked with your OCS data.
WHAT IS INVOLVED BY TAKING PART IN THE STUDY?
If you decide to participate in this study, you will be asked to take part in a 12 month study that is broken up into two phases. In order to take part you must commit to take part in both phases of the study.

Start-up Activities: Prior to beginning the exercise portion of the study, we will work with you to set up the and online platform including materials such as your web-cam and Zoom software (a tele-conferencing software to engage in video and audio calls), Fitbit, (a wireless physical activity monitor), and YMCA membership that will be needed to take part in the study.

Phase 1 (6 months): Tele-Coaching Exercise Intervention – In Phase 1, you will be asked to participate in an individually tailored home-based exercise program of approximately 60 minutes, three times per week for 24 weeks. The exercise sessions may include a combination of aerobic, strength, flexibility, and balance training and may be done at home either individually or via online group exercise classes through the YMCA on Zoom. A YMCA fitness instructor will meet with you online via Zoom and determine an ideal exercise program specifically individualized for you. During this time, you will be asked to take part in the following:

- Personalized one-on-one online exercise coaching sessions via Zoom with a YMCA Fitness Instructor every 2 weeks (total of 13 sessions). Your YMCA Fitness Instructor will document your personalized exercise program in a coaching log on your Virtuagym Sweat for Good App.
- Online group-exercise classes via Zoom with a YMCA Fitness Instructor.
- Online group educational sessions (one per month; 6 total) about topics related physical activity and healthy living with HIV.
- You will also be provided with a Fitbit® Inspire 2, which is a small wireless activity device you wear on your wrist to measure your physical activity.

Phase 2 (6 months): Post-Intervention Self-Monitored Exercise - In Phase 2 you will be encouraged to continue to take part in the home-based exercise sessions individually or through online group exercise classes on the YMCA via Zoom, three times per week for 6 months (24 weeks). However, this time the exercise will no longer include individualized personalized fitness instruction every two weeks.

During the 12 month study (Phase 1 and 2), you will be asked to complete physical health assessments and questionnaires every 2 months (total of 7 times):

- The physical health assessment will include a fitness test conducted at home, online via Zoom with a YMCA Fitness Instructor to assess your cardiopulmonary fitness, strength and endurance, weight and body composition, flexibility and physical function. The physical health assessment will take approximately 1 hour.
- You will also be asked to fill out a series of questionnaires within 7-10 days of your fitness assessment, remotely (at-home) on your computer or electronic device, asking you about your health. These questionnaires ask about health challenges, quality of life, mental health, social support and stigma. These questionnaires also include a demographic questionnaire that asks about your age, gender, health status, costs associated with taking part in exercise, and physical activity (including the impact of COVID-19 on health and your physical activity). You will receive the link to a web-based questionnaire administered through Qualtrics, a secure
Supplemental File 2 - Evaluating an Online Tele-Coaching Community-Based Exercise Intervention with Adults Living with HIV: Protocol for a Mixed Methods Implementation Science Study

web-based questionnaire platform, through your email, whereby you will fill out the questionnaire anonymously. The total time to complete the series of questionnaires will be approximately 45-60 minutes.

During the 12 month study (Phase 1 and 2), you will be asked to complete a weekly web-based CBE Physical Activity Questionnaire to track your overall physical activity during the study. This questionnaire will take approximately 2 minutes to complete and will be sent with a link to a questionnaire using Qualtrics, a secure web-based questionnaire platform.

During the 12 month study (Phase 1 and 2), you will be asked to sync your Fitbit® weekly to your electronic device/home computer. You will be asked to share your Fitbit® login information with the research team so they can download your physical activity data, as well as sync your Fitbit® weekly to your electronic device/home computer and the Fitbit® information can be used to help you fill out your weekly exercise log.

You will be asked to meet with the Research Coordinator (via Zoom) to complete a Goal Attainment Scale (GAS) at the start of the exercise portion of the study (Month 0) to state your health and function goals. You will then re-visit your goals at Month 6 (end of Phase 1) and Month 12 (end of study) to report whether your goals were achieved and to what extent, and have the opportunity to set new goals. The GAS will take approximately 15-20 minutes to complete.

You will also participate in a brief Zoom open-ended interview to assess the fidelity of the exercise study (how well you are sticking with exercising) at 2 time points: mid-way through the Phase 1 exercise portion of the study (Month 2) and at the end of the Phase 1 exercise portion of the study (Month 6). The research coordinator will ask you to walk through your most recent coaching and independent exercise session from start to finish. The total brief-open ended interview will take approximately 10 minutes to complete. Your responses will not be audio-recorded.

WHAT HAPPENS IF I HAVE AN EPISODE OF ILLNESS?
Sometimes the changing or fluctuating nature of HIV challenges may cause situations where your health status may change, which can affect your ability to safely engage in a fitness or questionnaire assessment and affect your ability to continue with the study. If any point during the study, the YMCA staff feels that it is not safe for you to start or continue a fitness assessment, they will stop the assessment. In these situations, you will be asked to talk with your physician by phone or in person to discuss your ability to safely engage in physical activity and to continue your participation in the study. You will be asked to report this information to the Research Coordinator and YMCA instructor who then may reschedule the assessments at a time that will be safe and feasible for you.

Level of Commitment – Since this study is 12 months long, we expect participants to remain committed to attending the exercise sessions and assessments. We understand the changing nature of living with HIV and health challenges and therefore understand last minute cancellations may occur due to health reasons and will be flexible in rescheduling assessments or session when necessary.

Commitment to this study includes:

CBE Tele-Coaching Study – Info Letter and Consent Form - Adults Living with HIV
Date Last Revised: March 12, 2021

Page 4 of 11
Participate in the bi-weekly (once every 2 weeks) online fitness sessions with your YMCA instructor (during Phase 1) and at least once weekly online YMCA group exercise classes with the YMCA Sweat for Good App (during Phase 1 and 2).

Turn your web-cam on during your fitness assessments, coaching sessions, and online YMCA exercise classes. This is for YMCA safety reasons.

Attend the 6 online monthly educational sessions in Phase 1 to the best of your ability.

Wear the Fitbit® Inspire and sync your Fitbit® data to your electronic device weekly.

Share your Fitbit® Login information with the research team.

Complete at least three of the four assessments (Fitness and Questionnaire Assessment) during Phase 1 and continue on to Phase 2.

Provide at least 24 hours’ notice of cancellation for any Fitness Assessments or online exercise coaching sessions with your fitness instructor throughout the study.

WHAT ARE THE POSSIBLE RISKS?
There is an element of physical and social risk to participating in this study including injury with exercise and you may perceive the type of questions in the self-reported health questionnaires as ‘probing’. It is also possible that you may find some of the questions in the bi-monthly self-reported health questionnaires to be personal or sensitive. During the study, researchers can refer you to personnel at a community organization (see below) to talk about your feelings, or will recommend you discuss any feelings with your physician, counsellor, or local support group, if available.

<table>
<thead>
<tr>
<th>Community Health Sites</th>
<th>Email / phone number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casey House</td>
<td>(416) 962-7600</td>
</tr>
<tr>
<td>Health Centre at 410</td>
<td>416-867-3728</td>
</tr>
<tr>
<td>AIDS Committee of Toronto</td>
<td>416-340-2437 <a href="mailto:ask@actoronto.org">ask@actoronto.org</a></td>
</tr>
<tr>
<td>Toronto People with AIDS Foundation</td>
<td>416-506-1400 ext. 205</td>
</tr>
<tr>
<td>Alliance for South Asian AIDS Prevention</td>
<td>416-599-2727, <a href="mailto:engagement@asaap.ca">engagement@asaap.ca</a></td>
</tr>
</tbody>
</table>

To participate in this study it is required for you to turn on your web-cam during the fitness coaching sessions, fitness assessments and YMCA online group exercise classes for safety reasons as you exercise and you may therefore experience a loss of privacy. During the YMCA group exercise classes, it is important to be aware that other members of the group exercise class (including potentially other CBE participants) will be able to see you on camera, however they will not know you are part of the CBE study.

If injury occurs during the fitness coaching sessions, fitness assessments or online group exercise classes, a YMCA staff will follow appropriate emergency procedures (in accordance with the YMCA general safety procedures and guidelines) and you will asked to follow-up with your physician.

When participating in the online self-management sessions with other CBE participants, you will be required to turn on your web-cam on to take part in the session. Given the nature of the online self-management sessions, other participants in this study will also know that you are HIV positive. All participants in the study will be required not to discuss or disclose what goes on during the group-based sessions including who is participating in the study, however we are unable to guarantee this.
Supplemental File 2 - Evaluating an Online Tele-Coaching Community-Based Exercise Intervention with Adults Living with HIV: Protocol for a Mixed Methods Implementation Science Study

The researchers, research coordinator and YMCA fitness instructors doing the online one-on-one coaching sessions and fitness assessments with this study will be aware that you are HIV positive.

The Fitness Instructor (Coach) who you are paired with at the YMCA will be provided with your Physical Activity Readiness Questionnaire (PARQ), Goal Attainment Scale as well as your phone number and/or e-mail address. The Fitness Instructors (Coaches) will use this information to help inform the program that they develop for you as well as will be in touch with you throughout the study regarding scheduling appointments.

There is a small risk of skin irritation from wearing the Fitbit® Inspire 2, if this is the case, you may wear the Fitbit® Inspire 2 on clipped onto your clothes.

WHAT ARE THE POSSIBLE BENEFITS?
Exercise is a beneficial strategy to address health challenges among people living with health conditions as well as enhancing health promotion and disease prevention. CBE programs also have the potential to promote peer support and social interaction in a group context under the supervision of an exercise instructor who can provide ongoing support and encouragement to exercise and independently manage challenges associated with their chronic condition.

WHAT IF I DO NOT WANT TO TAKE PART IN THE STUDY?
You are free to decide if you want to take part in this study or not. If you decide not to take part, you can withdraw at any time. Withdrawing from this study will not affect any of the services that you currently receive at the participating sites in this study. Withdrawing from the study means that the study investigators may still include information collected before you withdrew unless you request for investigators to remove or destroy your information. If you decide to withdraw, we will ask you to complete a study ‘exit’ and demographic questionnaire, but you can choose not to complete them.

WHAT INFORMATION WILL BE KEPT PRIVATE?
Computer files containing electronic consent forms, Qualtrics questionnaire responses (bi-monthly questionnaires and weekly physical activity questionnaires), downloaded Fitbit® data, word documents such as the Goal Attainment Scale will be stored on a secure server hosted at the University of Toronto. Any papers files will be kept in a locked filing cabinet in a locked office (Episodic Disability Lab) in the Rehabilitation Sciences Building (500 University Avenue). Only researchers and advisors directly involved with the study will be able to access these files.

The questionnaire information (bi-monthly questionnaires and weekly physical activity questionnaires) will be administered using Qualtrics Survey Software. This software collects data on a secure server in Canada. The information from the questionnaires will be downloaded from Qualtrics to the secure server at the University of Toronto.

The initial screening, eligibility and consent meeting with the Research Coordinator, bi-weekly online exercise personalized coaching sessions, bi-monthly online fitness tests, YMCA online exercise classes, Goal Attainment Scale administration, brief open-ended interviews to assess fidelity and monthly educational sessions will take place over Zoom with either the research coordinator or fitness instructor. To ensure privacy during Zoom interviews with the research coordinator or fitness instructor.

CBE Tele-Coaching Study – Info Letter and Consent Form - Adults Living with HIV
Date Last Revised: March 12, 2021
instructor: i) all Zoom sessions will require a password; ii) the waiting room will be enabled for all
sessions requiring the administrator to manually ‘admit’ participants into a session, and iii) we will
‘lock’ the meeting after the participant has entered the meeting preventing others from joining the
session. We will remain updated with the most recent Zoom security software and best practices to
ensure the security of the online platform.

Unique identifiers (participant ID numbers) will be used to match questionnaires, Fitbit® data and
fitness assessment data with participants. Only pooled data will be presented in final publications to
ensure participant anonymity. It is important to realize that the researchers, Research Coordinator
and YMCA Fitness Instructors with this study will be aware that you are HIV positive. The YMCA
Fitness Instructor who you are paired with will be provided your Physical Activity Readiness
Questionnaire (PARQ), Goal Attainment Scale (GAS) and contact information (phone or e-mail
address). This information will be shared between researchers and the YMCA fitness staff via
ShareFile, a secure file sharing system. This information will be shared with your YMCA fitness to help
inform the program that they develop for you as well as will be in touch with you throughout the
study regarding scheduling appointments.

The Fitbit® Inspire involves collecting data on physical activity onto servers in the United States and
therefore are subject to U.S. laws, including the U.S. Patriot Act, 2001. As a result, there is a
possibility that this information may be accessed by the U.S. government, in compliance with the
Patriot Act, without your knowledge or consent. To participate in this study, you will have to consent
to wearing a Fitbit® Inspire, and syncing your Fitbit® data to an online profile for the duration of the
study.

As a participant in this research study you will receive a membership to the YMCA which includes
access to the YMCA Sweat for Good App, where you can book your fitness coaching sessions and
access group online exercise classes. The Sweat for Good App is a Virtuagym application (Dutch
personal training online platform) used by members of the YMCA. As part of registering for the Sweat
for Good App, the App collects your first name, last name, email address, preferred language, age,
length, weight, sex and place of residence. The data collected on Sweat for Good App and Virtuagym
are stored onto servers in the Netherlands are in compliance with US and European information
protection laws. The Sweat for Good App is used by all YMCA members and there will be no
reference to your being linked to the CBE study in the App.

As part of the regular YMCA membership process, the YMCA collects personal and emergency contact
information from all of its members (including name, mailing and email address, phone number,
birthday, allergies or health concerns, gender, emergency contact name and phone number). This will
be collected and stored at the Toronto YMCA as part of their general membership process, but is not
part of the research study. The YMCA does not provide information about their members to others.
However, they do communicate with members regarding YMCA promotions and newsletters. All
communication with YMCA members is within the new Canadian Anti-Spam Legislation. Any other
information as it relates to the research study will be stored at the University of Toronto. All
electronic files stored will be destroyed 10 years after the study is completed.
For OCS participants, at the end of the study, anonymized data from the tele-coaching study will be transferred / linked with the OCS using a unique OCS generated ID code that links the OCS and tele-coaching study data using Sharefile (a secure encrypted transfer system).

**WILL I BE PAID TO PARTICIPATE IN THIS STUDY?**
You will not be paid to take part in this study; however as a study participant, you will receive an open access membership to the Toronto YMCA which provides access to the YMCA Sweat for Good App (access to online classes) during the 12 month exercise phase of the study, valued at approximately $900. The first membership will be for 6 months (exercise portion phase 1) and the second membership will be for 6 months (independent exercise phase 2). To receive the second membership for 6 months, you will need to remain in the study for the exercise portion phase 1 (6 months) and complete the bimonthly assessments in this phase. If you withdraw during the Phase 1, you can still retain the 6 month YMCA membership (Sweat for Good App) access until the end of Phase 1. If you withdraw from the study during the Phase 2 follow-up phase, you can still retain the 6 month YMCA membership (Sweat for Good App) access until the end of Phase 2.

You will also receive personalized fitness instruction every 2 weeks during the Phase 1 exercise portion (13 sessions) approximately $450. If you withdraw from the study you will no longer have access to the personalized fitness instruction.

You will not be paid to take part in the monthly educational sessions.

You will be able to keep the Fitbit® Inspire 2 wireless activity monitor for your participation in the study (approximately $120). If you withdraw during Phase 1 or 2 of the study you will be able to keep your Fitbit® Inspire 2.

You will also receive exercise equipment take part in the home-based fitness assessments, and training sessions such as: Thera bands, a body weight and composition scale, wooden step, and flexible tape measure. The total cost of this equipment is approximately $175 and you will be able to keep this equipment at the end of the study.

**WILL THERE BE ANY COSTS?**
Your participation in this research project will involve costs associated with the technology necessary to participate in this study (electronic device or laptop/computer, Wi-Fi or data internet access, Web-Cam) and equipment necessary to engage in exercise (clothing, footwear, space in your home to exercise). As part of the bi-monthly demographic questionnaire, we will ask you about any additional costs you pay out of pocket to participate in Tele-Coaching CBE such as internet, electronic device, exercise closing, footwear, or transportation. This is because one of the study objectives is to determine the costs of people taking part in online exercise programs.

**WILL THE RESULTS BE PUBLISHED?**
Results of this study will be presented at conferences and published in a scientific journal. We will also develop a fact sheet summary of the results that will be available at participating Community-Based Organizations, Casey House, Realize, the Ontario HIV Treatment Network (OHTN), and the YMCA. The investigators will not include personal information such as your name in the summary so
that any publication of results will not identify you. If you are interested in receiving a copy of the study summary, you can contact Kelly O’Brien at kelly.obrien@utoronto.ca.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?
If you have any questions about the research now or later, please contact Kelly O’Brien (Principal Investigator at the University of Toronto at 416-978-0565. If you have any questions regarding your rights as a research participant, you may contact the Office of the Research Ethics of the University of Toronto at 416-946-3273 or email at ethics.review@utoronto.ca.
CONSENT TO PARTICIPATE

Tele-Coaching CBE Study: Evaluating the Implementation of an Online Community-Based Exercise (CBE) Intervention using Tele-coaching to Enhance Physical Activity among Adults Living with HIV

I have read and understood all of the above. In no way does signing this form waive my legal rights nor relieve the investigator, sponsors from their legal and professional responsibilities.

By signing or giving verbal consent below I am agreeing that:

- I understand the information provided for the above study.
- I have been able to consider the information, ask questions, and have had them answered thoroughly.
- I understand that my participation is voluntary and that I am free to stop the study at any time without any penalty.
- As per the PAR-Q, or consultation with my doctor, I consider myself safe to participate in exercise.
- I have access to an electronic device or laptop/computer, a strong Wi-Fi or internet data connection, a web-cam and space in my home to do exercise and the ability to use these tools to engage in the study.
- I will download the Sweat for Good App and Zoom app on my electronic device or computer / laptop.
- I will participate in bi-monthly health assessments (questionnaire assessments and fitness assessments).
- I will take part in exercise as prescribed by my fitness instructor for a minimum of 3x/week for 60 minutes each session, to the best of my abilities.
- I will participate in bi-weekly one-on-one online fitness sessions, weekly YMCA online group exercise classes (via YMCA Sweat for Good App) and monthly educational sessions.
- I will wear my Fitbit® Inspire 2 when exercising and sync the Fitbit® Inspire to my Fitbit® account weekly.
- I will share my Fitbit® login information with the research team so they can access and analyze my physical activity data.
- I understand that the data collected during the study may be looked at by individuals from the research team, or the regulatory authorities where it is relevant.
- I give permission to these individuals to have access to the information I provided.
- I give permission to link my data collected during the tele-coaching study with my information in the OHTN Cohort Study (OCS).
Supplemental File 2 - Evaluating an Online Tele-Coaching Community-Based Exercise Intervention with Adults Living with HIV: Protocol for a Mixed Methods Implementation Science Study

Provision of written consent

____________________________ __________________________         ___________________
Participant’s Name (please print)   Participant’s Signature   Date

Provision of verbal consent

____________________________  ____________________________ ___________________
Investigator’s Name (please print) Investigator’s Signature   Date

Preferred method of contact during the study (e.g. for weekly physical activity questionnaire)

☒ Email:_________________________________________________
☒ Text (cell phone number): ______________________

I am willing to be contacted regarding future phases of research by email or phone.

☐ Yes, Contact:__________________________________________
☐ No

I would like to receive a copy of the summary of results by email following the completion of the study.

☐ Yes, Contact:__________________________________________
☐ No

I am willing to be contacted by an engagement coordinator regarding a HIV and exercise quarterly (4 times per year) Community of Practice (HIV in Motion):

☐ Yes, Contact:__________________________________________
☐ No

This study has been reviewed by the Research Ethics Board at the University of Toronto. The REB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Research Ethics of the University of Toronto at 416-946-3273 or email at ethics.review@utoronto.ca.
Supplemental File 3—Example Consent Form – Evaluating an Online Tele-Coaching Community-Based Exercise Intervention with Adults Living with HIV: Protocol for a Mixed Methods Implementation Science Study

Informed Consent Form to Participate in Interviews - CBE Stakeholders

Title of Study: Tele-Coaching CBE Study: Evaluating the Implementation of an Online Community-Based Exercise (CBE) Intervention using Tele-coaching to Enhance Physical Activity Among Adults Living with HIV in Ontario

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Sponsor: Ontario HIV Treatment Network (OHTN) HIV Endgame Funding Program – Breaking New Ground.

CBE Tele-Coaching Study-Info Letter & Consent Form – Qualitative Interview (CBE Stakeholders)
Date Last Revised: December 21, 2020
You are invited to participate in a research study to evaluate an online Tele-Coaching Community-Based Exercise (CBE) intervention to improve health among people living with HIV. This study is being conducted in collaboration with the Greater Toronto YMCA. In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision.

WHY IS THIS RESEARCH BEING DONE?
HIV is now considered a chronic illness where more individuals are living longer and aging with the health-related challenges of HIV, comorbidities (co-existing health challenges) and potential side effects of treatment. Exercise is one intervention that can help people living with HIV address their health-related challenges and improve their overall health and community-Based Exercise (CBE) is a promising model in which to enhance physical activity and health outcomes among people living with HIV. Telemedicine and online physical activity platforms have emerged as a way for those living with chronic conditions to access services, when unable or unwilling to in person due to long travel time, HIV-related stigma or the pandemic. However the ways an online tele-coaching physical activity intervention translates to the HIV context, and the role of online approaches to address barriers to exercise adults living with HIV may experience is not yet known.

WHAT IS THE PURPOSE OF THIS STUDY?
The purpose of this research is to evaluate an online tele-coaching community-based exercise (CBE) intervention with adults living with HIV within the community. We are interested in learning about the extent adults with HIV participate in a tele-coaching CBE program, the effect of tele-coaching CBE on the health of adults living with HIV, the adherence to and long-term uptake of exercise. In this part of the study, we are interested in learning about the process (including strengths and challenges) of implementing a tele-coaching CBE intervention and perspectives on long-term sustainability of tele-coaching CBE programming from the perspectives of adults living with HIV and CBE stakeholders (fitness instructors and managers, representatives of community based organizations and health centres, and policy representatives) involved in CBE implementation.

WHO CAN PARTICIPATE IN THIS STUDY?
You are eligible to take part in this study if you are a stakeholder involved in CBE implementation (e.g. fitness instructor or manager, representative of community based organization or health centre, policy representative). You are one of approximately 5 CBE stakeholders being recruited to this part of the study.

WHAT IS INVOLVED BY TAKING PART IN THE STUDY?
If you decide to participate in this part of the study you will be asked to take part in a series of 3 remote online interviews through Zoom at three different phases of the study: prior to the exercise intervention (month 0), at the end of exercise intervention (month 6) and at the end of the study (month 12). The Research Coordinator will meet with you remotely, online through Zoom to conduct the semi-structured interviews.
Interview Process: In these interviews, you will be asked about a) anticipated benefits of exercise (at initiation), c) perceived changes or impact of CBE (pertaining to: exercise, peer-support, Fitbit®, self-management sessions) on physical activity and health over time, d) your feedback on the strengths and challenges of implementing CBE, d) how well you believe exercise in a tele-coaching CBE intervention can be maintained over time, e) your feedback on accessibility and feasibility for participants to engage in CBE post-intervention and in the final phase of the study, f) readiness and mechanisms for long-term sustainability across the community including adoption of technology.

We will also ask about the influence that external factors such as social support or stigma and internal factors such as concurrent health conditions, age, gender and coping strategies might have on impact of and engagement in exercise and the use of technology. We are interested in learning about what you think makes it easier or harder to access and participate in community based exercise and whether there should be any refinements made to the online CBE program. Results from this interview will be used to refine an accessible, feasible, safe, and sustainable online CBE program for people living with HIV.

Each interview session will take approximately 60 minutes to complete.

If there are some questions that you do not wish to answer for any reason, you are free to do so, and you may stop at any time. If the interviewer feels that you are too uncomfortable with the questions being asked, they may also stop the discussion. The discussion will be audio recorded and then typed out. The typed report will be stored as a computer file at the University of Toronto and printed onto paper. Your name or other information that could identify who you are will never appear on the audio file, in the computer file or on the printed pages.

WHAT ARE THE POSSIBLE RISKS?
There are no obvious risks from taking part in the interview phase of this study.

WHAT ARE THE POSSIBLE BENEFITS?
Taking part in these interviews will not give you any health benefits. However, it may help to develop methods to improve accessible and sustainable online (tele-coaching) Community-Based Exercise (CBE) programs for people living with HIV.

WHAT IF I DO NOT WANT TO TAKE PART IN THE STUDY?
You are free to decide if you want to take part in this interview phase of the study or not. You can withdraw from participating in the interview at any time. Withdrawing from the interview means that the study investigators may still include information collected before you withdrew unless you request for investigators to remove or destroy your information.

WHAT INFORMATION WILL BE KEPT PRIVATE?
The investigators will keep all of the information in strict confidence. All of the audio files and computer data will be kept in computer files that are protected by a password. Your name or other information that could identify who you are will not be recorded on the audio files or computer. All of the transcript data will be destroyed ten years after the results of the study are published. Audio files from the interviews will immediately be transferred from the recording device to a secure, online

CBE Tele-Coaching Study-Info Letter & Consent Form – Qualitative Interview (CBE Stakeholders)
Date Last Revised: December 21, 2020
storage site with password protection. The files on the recorded device will then be deleted. Audio files will be deleted from the online storage site after the study is published, and all electronic files will be destroyed 10 years after the study is completed.

The one-on-one interview will take place remotely, online via Zoom. To ensure privacy during Zoom interviews: i) all Zoom interview sessions will require a password; ii) the waiting room will be enabled for all sessions requiring the administrator to manually ‘admit’ participants into a session, and iii) we will ‘lock’ the meeting after the participant has entered the meeting preventing others from joining the session. We will remain updated with the most recent Zoom security software and best practices to ensure the security of the online platform.

The computer files will be labelled with a code made up of numbers. Only the investigators and research staff will be able to see what the code means. When the investigators present the results of this study, they will never use your name or any other information that could tell others who you are. All information will remain strictly confidential and available only to study investigators and research staff, members of the University of Toronto Research Ethics Board that reviewed this protocol.

**WILL I BE PAID TO PARTICIPATE IN THIS STUDY?**
We will offer you a $30 E-Gift Card as a token of appreciation for your participation in each interview for this portion of this study (total of $90 E-Gift Cards for 3 interviews). If you decide to withdraw from interview, you can still receive the gift card token of appreciation.

**WILL THERE BE ANY COSTS?**
Your participation in this research project will not involve any additional costs to you.

**WILL THE RESULTS BE PUBLISHED?**
Results of this study will be presented at conferences and published in a scientific journal. We will also develop a summary of the results that will be available at participating Community-Based Organizations (Toronto People with AIDS Foundation, AIDS Committee of Toronto), Casey House, Realize, the Ontario HIV Treatment Network (OHTN), Alliance for South Asian AIDS Prevention (ASAAP) and the YMCA. The investigators will not include personal information such as your name in the summary so that any publication of results will not identify you. If you are interested in receiving a copy of the study summary, you can contact Kelly O’Brien at kelly.obrien@utoronto.ca

**IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?**
If you have any questions about the research now or later, please contact Kelly O’Brien (Principal Investigator at the University of Toronto at 416-978-0565. If you have any questions regarding your rights as a research participant, you may contact the Office of the Research Ethics of the University of Toronto at 416-946-3273 or email at ethics.review@utoronto.ca.
CONSENT TO PARTICIPATE – Interviews CBE Tele-Coaching Study

Tele-Coaching CBE Study: Evaluating the Implementation of an Online Community-Based Exercise (CBE) Intervention using Tele-coaching to Enhance Physical Activity Among Adults Living with HIV

I have read and understood all of the above. In no way does signing this form waive my legal rights nor relieve the investigator, sponsors from their legal and professional responsibilities.

By signing or giving verbal consent below I am agreeing that:

- I understand the information provided for the above study
- I have been able to consider the information, ask questions, and have had them answered thoroughly
- I understand that my participation is voluntary and that I am free to stop the study at any time without any penalty
- I understand the interview will be audio recorded.
- I understand that the data collected during the study may be looked at by individuals from the research team, or the regulatory authorities where it is relevant
- I give permission to these individuals to have access to the information I provided.
- I give permission to allow a research staff at University of Toronto conduct this interview.

- Provision of written consent

____________________________ __________________________         __________________
Participant’s Name (please print)   Participant’s Signature   Date

- Provision of verbal consent

____________________________  ____________________________ ___________________
Investigator’s Name (please print)   Investigator’s Signature      Date

This study has been reviewed by the Research Ethics Board at the University of Toronto. The REB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Research Ethics of the University of Toronto at 416-946-3273 or email at ethics.review@utoronto.ca.