

BMJ Open Piloting an online telecoaching 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 telecoaching 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

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.

of presentations and publications in open-access peer-reviewed journals.

Trial registration number NCT05006391.

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,^{32,33,42,43} persistent pain,⁴⁴ chronic obstructive pulmonary disease,^{45–47} renal disease⁴⁸ 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

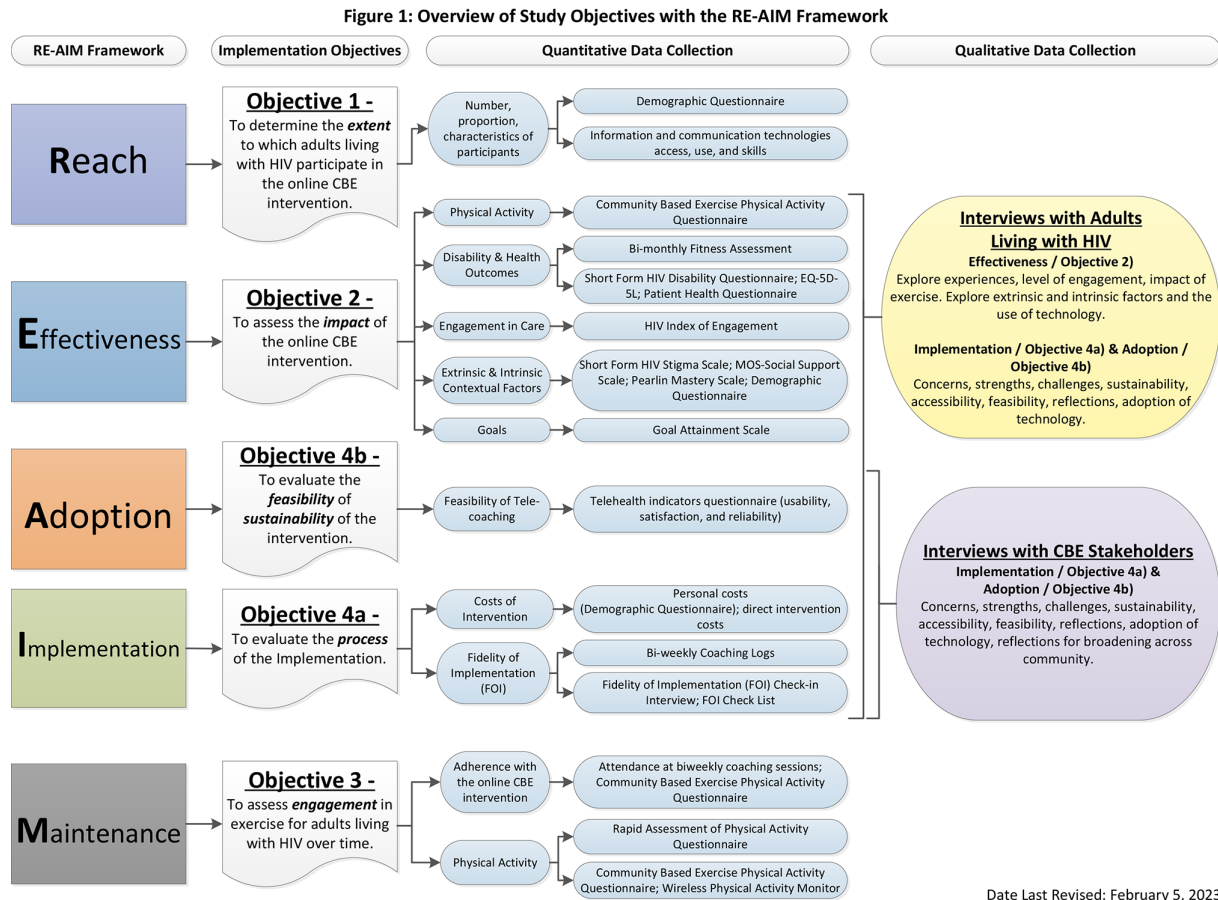


Figure 1 Overview of study objectives with the RE-AIM framework. RE-AIM, Reach-Effectiveness-Adoption-Implementation-Maintenance.

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)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 (Obj1—extent adults living with HIV participate) and Maintenance (Obj3—engagement in CBE over time) using quantitative methods. Impact (Obj2) 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 (Obj4), 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.^{29 30 37–39} 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.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 educational sessions 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.^{56 57} We will use the index as a guide to discuss indicators of

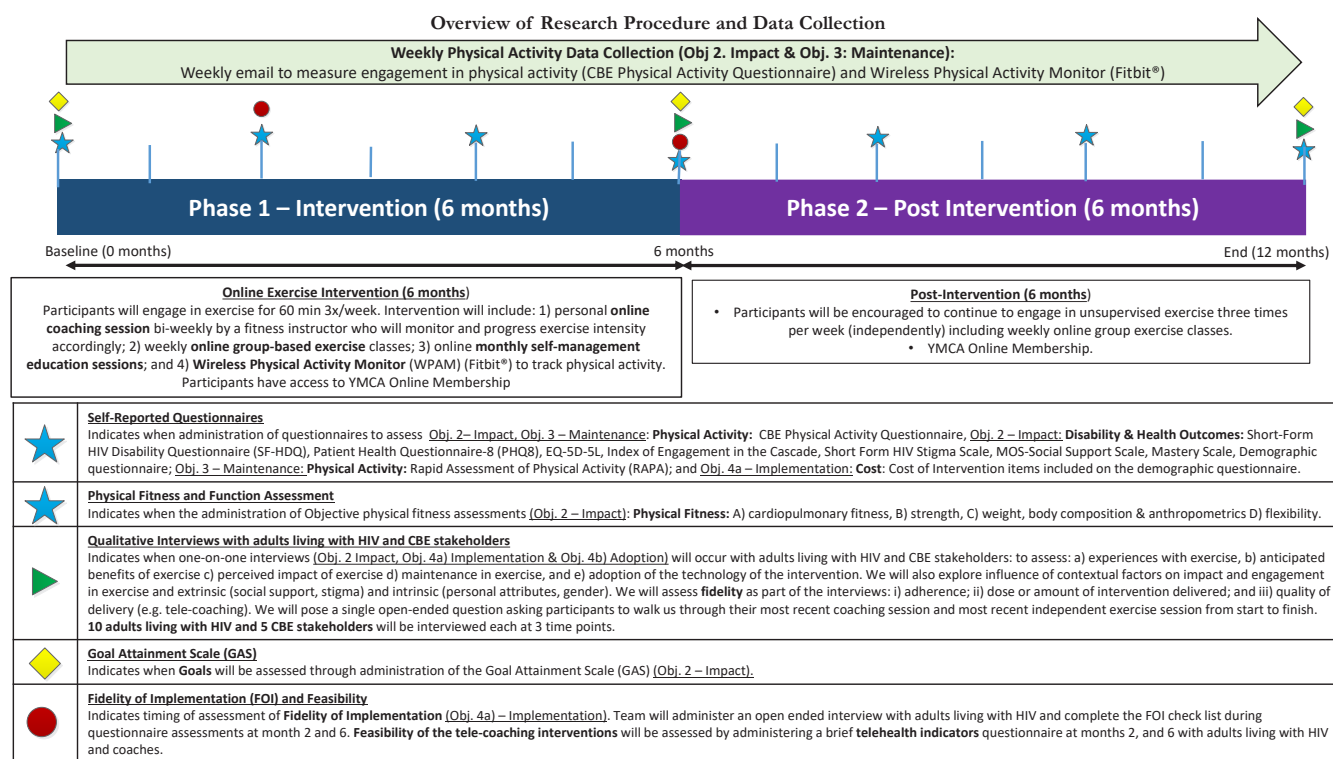


Figure 2 Overview of research procedure and data collection.

access to information and technology (mobile telephone, computer, internet and type of internet), use of technology and skills (literacy).⁵⁸ 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.⁵⁹ 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 the study. We will specifically aim to recruit individuals who self-identify as facing geographical, personal or structural barriers to exercise in traditional gym settings. We will recruit $\geq 30\%$ cisgender and transgender women to achieve proportional gender and geographical representation in the study.⁶⁰ As a result, we will approach women from our in-person CBE study who were interested but unable to participate due to geographical or childcare reasons.^{36–38}

To evaluate Adoption and Implementation (Obj4), we will recruit CBE stakeholders, defined as representatives from fitness centres (managers, instructors), community-based organisations, and health centres; health providers; and policy stakeholders with a role in implementing, referring to, or promoting CBE in care.

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,⁶¹ goal setting, research procedures, antioppression and transinclusion. 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).⁶² We will set up and pilot the technology, including (but not limited to); Zoom software,⁶³ web-cam, YMCA membership (including Sweat for Good App), web-based questionnaire software and Fitbit App,⁶² 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 adherence 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 progression and goal attainment.⁶⁴

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.^{62 65} 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.⁶⁶ We will use Zoom as our telecoaching platform.⁶³

Our online telecoaching intervention builds on lessons learnt from our in-person CBE study,³⁹ the American College of Sports Medicine guidelines,⁶⁷ qualitative consultation with community (adults living with HIV and fitness instructors),^{30 37} 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).⁶⁸

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.⁶³

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.⁶³ Qualitative interviews will be conducted remotely online via Zoom.⁶³ Throughout 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.⁶² 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).^{69 70}

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.⁵⁷

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 Guidelines⁷¹ 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.^{72 73} Participants will use their Fitbit Inspire 2 provided to fill out their *CBE-PAQ*.⁶² 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.^{74 75} The HDQ is valid and reliable for use with PLWH in Canada and internationally.^{76–80}



We recently developed a *short-form version of the HIV Disability Questionnaire (SF-HDQ)* to improve feasibility.⁸¹ 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^{82 83} 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,^{84 85} and is consistent with the disability measure used in our prior CBE intervention study.³⁶

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).⁸⁶ The EQ-5D-5L is widely used and has demonstrated responsiveness with people living with HIV.^{87–90}

Mental health

The *Patient Health Questionnaire (PHQ-8)* is an eight item measure of depression severity.⁹¹ 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.⁹¹ The PHQ-8 has been used and is reliable and valid among people living with HIV.^{92 93}

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.⁹⁴ 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.⁹⁴ Validation has been demonstrated with over 3000 people living with HIV in the USA.⁹⁴

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 (personalised stigma, disclosure concerns, concerns about public attitudes and negative self-image).⁹⁵ 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.⁹⁵ This scale possesses construct validity and reliability with persons living with HIV.^{95 96} 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.⁹⁷ The MOS-SSS possesses construct

validity and reliability with people living with HIV.^{97 98}

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.⁹⁹ 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.^{100–102} The *Demographic Questionnaire* will capture personal attributes (eg, age, gender, sex, living situation, employment status, race, smoking history, substance use), clinical characteristics (eg, viral load, time since HIV diagnosis, antiretroviral use and adherence, multimorbidity) and COVID-19 factors (eg, 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.^{103 104} Goal Attainment Scaling is a method of scoring the extent to which participants' individual goals are achieved in the course of an intervention.^{103 104} 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.¹⁰⁴ We will administer the GAS via Zoom at the time of the above questionnaire administration, taking ~15–20 min to complete.⁶³ 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.⁶³ The fitness assessment will include: (A) cardiopulmonary fitness; (3 min bench step test; heart rate measurement)¹⁰⁵; (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)¹⁰⁶; (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).¹⁰⁷ 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 2,⁶² 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 13 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, underactive, 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.¹⁰⁸ 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 Fitbit⁶² 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 (telecoaching, online classes, self-management sessions, Fitbit Inspire 2 use),⁶² (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.¹¹⁰ 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).¹¹⁰ 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 most recent 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 semistructured 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*,¹¹¹ 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).¹¹² This model was used to assess adoption of eHealth interventions for people with chronic disease and HIV.^{112–116}

Feasibility

We will assess feasibility of the telecoaching intervention using telehealth indicators.¹¹⁷ 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).^{118 119} 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.⁶⁰ 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.¹²⁰ Using a segmented regression model, we will estimate the change in level (amount) and trend (slope) between the intervention and follow-up phases.¹²¹ 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.⁷³ 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.¹⁰⁸ We will use descriptive statistics to describe scores for the Aerobic Scale and Strength and Flexibility Scale,¹⁰⁸ steps, distance, calories burned, and active minutes as measured by the Fitbit weekly summary.⁶² We will use linear mixed effects models to test for differences in outcomes across the two phases.¹²⁰ 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 $\geq 75\%$ 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.¹¹⁹ We will qualitatively analyse data from the open-ended questions in the interviews using content analytical techniques.¹²³

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 (Obj2) and perceptions of participants living with HIV and CBE stakeholders on the process of implementation and its sustainability over time (Obj4).^{54 123} 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.¹²⁵ We will use NVivo software to facilitate analysis.¹²⁶ Quantitative and qualitative data pertaining to impact (Obj2) 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 (Obj2) and strengths and challenges associated with the intervention and recommendations for long-term implementation (Obj4).

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 (Obj4).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 ($\geq 30\%$ 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 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.^{29 128 129} 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^{7 8 64}; (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.⁶³

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 2⁶² 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 interviews 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.¹³⁴ All self-reported questionnaires will be administered electronically using Qualtrics Software, an online secure e-survey software that uses Transport Layer Security encryption.¹³⁵ Data will be downloaded from Qualtrics to the University of Toronto and stored on a secure server.¹³⁵ 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.¹³⁴ 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.¹³¹ 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, FI-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. SI, 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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