Supplemental File 1 – World Health Organization Trial Registration Data Set

Evaluating a Community-Based Exercise Intervention with Adults Living with HIV: Protocol for an Interrupted Time Series Study

Protocol Version

Date: June 1, 2016; **Version Identifier:** Version 1

Data Category	Information
Primary registry and trial identifying number	Clinical Trials.gov Identifier: NCT02794415
Data of registration in primary registry	June 1, 2016
Secondary identifying numbers	University of Toronto Research Ethics Board Protocol #32910
Source(s) of monetary or material support	Canadian Institutes of Health Research (CIHR)
Primary sponsor	Canadian Institutes of Health Research (CIHR)
Collaborators	YMCA
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Public Title	YMCA Community-Based Exercise Study
Scientific Title	Translating Exercise Into the HIV Community: Evaluating a Community-based Exercise Intervention to Improve the Health of Adults Living With HIV
Countries of recruitment	Canada
Health condition(s) or problem(s) studied	HIV

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Intervention(s) Active comparator	Intervention: Community-Based Exercise Intervention Phase (6 months): The HIV Community-Based Exercise (CBE) intervention is a 6-month exercise program at the Central Toronto YMCA. Participants will meet the fitness instructor to establish an individualized exercise program that will include a combination of aerobic, resistive, neuromotor and flexibility training. Participants will attend exercise sessions for ~1.5 hour, 3 times per week for 24 weeks. Sessions will be supervised weekly by a fitness instructor. Post-Intervention Phase (8 months): At the end of the 24 week intervention, participants will be encouraged to continue to engage in unsupervised exercise 3 times per week. As per usual practice at the YMCA, a fitness instructor will be available to monitor participants monthly.
Placebo comparator	Not applicable
Key inclusion and exclusion criteria	≥18 years
Sexes eligible for study	Both
Accepts healthy volunteers	No
Inclusion criteria	Adults (18 years and older) living with HIV in Toronto who consider themselves medically stable and safe to engage in exercise and who are willing to participate in a 22 month study involving a 14 month CBE intervention at the YMCA.
Exclusion criteria	Anyone not meeting above inclusion criteria
Study type	Interventional; single group assignment; open label; interrupted time series analysis;
Date of first enrolment	June 2016
Target sample size	120
Recruitment status	Recruiting
Primary outcome(s)	Maximum oxygen consumption (VO2max)
Key secondary outcomes	Physical health (cardiopulmonary fitness; strength; weight, body composition, anthropometrics; flexibility) Disability Quality of Life Mental health Cognitive health Coping Mastery Stigma Social support