Title: The physicAl aCtivity Counselling for young adult cancEr SurvivorS (ACCESS) trial: a protocol for a parallel, two-arm pilot randomized controlled trial

Authors: *Jennifer Brunet, PhD (University of Ottawa; Ottawa Hospital Research Institute, Institut du savoir Montfort), Jenson Price, MA (University of Ottawa), Amirrtha Srikanthan, MD, MSc (The Ottawa Hospital), Fiona Gillison, PhD (University of Bath), Martyn Standage, PhD (University of Bath), Monica Taljaard, PhD (Ottawa Hospital Research Institute), Mark R. Beauchamp, PhD (University of British Columbia), Jennifer Reed, PhD (University of Ottawa; University of Ottawa Heart Institute), Amanda Wurz, PhD (University of the Fraser Valley)

Background: Physical activity (PA) holds promise as a behavioural intervention to mitigate persistent side effects and improve quality of life following cancer treatment; yet, few young adults are active enough to incur these benefits. We developed a novel and theoretically-informed behaviour support intervention to promote PA via videoconference in young adults following cancer treatment, and are undertaking a parallel, two-arm pilot randomized controlled trial (RCT) to gather evidence to inform the design of a large, full-scale RCT.

Objectives: We aim to: (1) assess intervention and trial feasibility and acceptability, and (2) generate data on PA behaviour. We present the study protocol herein.

Methods: Young adults (18–39 years) who have completed cancer treatment are being recruited from across Canada. Recruits are randomized to the intervention group (i.e., a 12-week behaviour support intervention delivered via videoconferencing by trained PA counsellors) or usual care (i.e., no intervention). Several feasibility outcomes covering enrollment, allocation, follow-up, and analysis are tracked by study staff. Acceptability is assessed through interviews. PA is measured using accelerometers. Assessments occur pre-randomization, post-intervention period, and 24 weeks post-baseline.

Conclusion: Feasibility and acceptability data will help to determine which refinements, if any, are required to the intervention, implementation approach, and proposed evaluation methods prior to advancing to a large, full-scale RCT. PA behaviour data collected will inform the sample size calculation for a large, full-scale RCT.

Trial registration: The trial was registered with the ClinicalTrials.gov database (ID: NCT04163042).