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Feasibility and acceptability of a parallel, two-arm randomized controlled trial to evaluate an online physical activity behavior counseling intervention for young adults diagnosed with cancer: a mixed-methods pilot study

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Abstract

Background Physical activity (PA) benefits young adults living with and beyond cancer, yet participation remains low. This pilot randomized controlled trial (RCT) evaluated the feasibility and acceptability of a PA behavior counseling intervention for young adults post-cancer treatment and trial methods.

Methods A mixed-methods, open-label, parallel, two-arm pilot RCT was conducted with young adults recruited nationwide (Canada) by healthcare provider referral or advertising. Eligible participants were 18–39 years (with a first diagnosis of invasive, non-metastatic cancer at age 18–39 years), had completed active treatment for invasive, non-metastatic cancer < 5 years prior, self-reported < 150 min of moderate-to-vigorous intensity PA weekly, were fluent in English, and had access to/computer literacy for videoconferencing technology. Young adults were randomized to receive a 12-week individualized PA behavior counseling intervention delivered via videoconferencing technology by PA counselors or usual care. Informed by self-determination theory, the intervention emphasized autonomy support and applied motivational interviewing. Staff tracked feasibility and acceptability outcomes regarding enrollment, allocation, retention, adherence, and adverse events. Young adults and PA counselors were interviewed post-intervention (T1; primary endpoint) and at trial completion, respectively. Planned efficacy outcomes were assessed using accelerometers and online surveys at baseline (T0), T1, and follow-up (T2; secondary endpoint; 24 weeks post-baseline).

Results Seventy-four young adults were screened for eligibility (recruitment rate ~4/month over 18 months); 47 (63.5%) were eligible, of which 42 (89%) consented, completed T0 assessments, and were randomized. Most (75% [15/20]) allocated to receive the intervention completed all sessions. Retention rates were 85.7% (T0 to T1 [36/42]) and 71.4% (T0 to T2 [30/42]). Analyzable data for the primary efficacy outcome (PA behavior) were available for 57.1% (24/42) at T1. Content analysis of interviews with 35 (80.0%) young adults and both (100.0%) PA counselors yielded three themes reflecting factors that *positively* impacted intervention acceptability and one theme reflecting factors that *negatively* impacted the trial methods' acceptability, as well as recommendations to optimize the trial methods and intervention.

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Conclusions The trial methods and intervention were largely feasible and acceptable for young adults post-cancer treatment, although modifications are required to optimize recruitment strategies, enhance retention at follow-up, refine the intervention, and reduce missing data. A full-scale RCT to assess the efficacy of the intervention and estimate concomitant costs is warranted.

Trial registration ClinicalTrials.gov (ID: NCT04163042). Registered on November 14, 2019.

Keywords Randomized controlled trial, Feasibility, Behavior, Neoplasms, Exercise, Internet-based intervention, Young adults

Key messages regarding feasibility

1. What uncertainties existed regarding the feasibility?

There has been little in-depth exploration of relevant issues around the extent to which clinical trials featuring online physical activity (PA) behavior counseling interventions are feasible and acceptable for young adults living with and beyond cancer. There has also been a lack of research on the perspectives and experiences of young adults in such trials.

2. What are the key feasibility findings?

The criteria used to evaluate metrics as “successful” were met for 9 of 11 quantitative feasibility outcomes (including 7 of 9 trial methods and 2 of 2 intervention outcomes). Analysis of qualitative data gathered from young adults and PA counselors helped to identify important considerations for researchers planning PA behavior change interventions and trials.

3. What are the implications of the feasibility findings for the design of the main study?

The quantitative results largely support the feasibility of a future full-scale trial. Recommendations were offered to inform modifications to optimize recruitment strategies, retention at follow-up, the intervention, and data completeness.

for increasing and maintaining PA levels among adults diagnosed with cancer, regardless of age [1, 12]. As well as improving long-term survival [5, 13, 14], increasing light PA, MVPA, and total PA levels can alleviate the persistent and disabling cancer treatment-related side effects linked to quality of life deficits, mitigate against psychosocial and occupational functioning impairments, and reduce morbidity and mortality risks in this cohort [15–18].

Rationale for behavior counseling interventions for young adults

Healthcare systems are a natural setting for implementing interventions to increase PA levels among young adults diagnosed with cancer because: (1) repeated contacts typically occur over many years, increasing referral to intervention opportunities; (2) such systems can facilitate identification and access to specific groups that would otherwise be difficult to reach; and (3) survivors of cancer want to receive PA information and prefer to receive this information from their healthcare provider [19, 20]. However, while it would seem that healthcare providers are ideally placed to actively promote PA, only 19% of oncologists provide specific PA guidance to $\geq 50\%$ of their patients and 80% of healthcare providers do not know about PA guidelines for survivors of cancer [21]. Healthcare providers have reported various factors thwarting their efforts to address PA, including lack of time, knowledge, referral opportunities, and availability of supportive resources and/or behavior change specialist/PA counselors [21–23]. We therefore developed the *physicAl aCtivity Counseling for young adult canCER SurvivorS* (ACCESS) intervention to facilitate access to, either via provider- or self-referral, an intervention that is responsive to young adults’ individual goals, needs, strengths, and capacities after cancer treatment. The ACCESS intervention is a PA behavior counseling intervention—a practice in which people with specialized training work with participants to help them adopt, change, or maintain their PA behavior to affect health outcomes, whereby healthcare providers could refer their insufficiently active patients as part of routine care.

Introduction

Background

Insufficient physical activity (PA; defined as < 150 min of moderate-to-vigorous intensity PA [MVPA] weekly) is prevalent among young adults (18–39 years) diagnosed with cancer [1–4] and contributes to morbidity and mortality [5–9]. Compared to young adults without a history of cancer, those treated for cancer are at increased risk of not meeting PA guidelines and reporting insufficient PA levels [3]. Despite the importance of PA, it often goes unaddressed by healthcare providers [10, 11]. Referral to evidence-based interventions that target fundamental processes associated with PA behavior and use a patient-centered approach to PA promotion is recommended

Interventions involving PA behavior counseling are a promising approach for promoting PA in adults living with and beyond cancer [24]. There are many advantages to interventions involving PA behavior counseling. First, they are highly individualized, allowing them to be adapted according to young adults' goals, needs, strengths, and capacities; this is because counseling is a very active process that involves considerable input from young adults. Second, counseling interventions can be adapted over time based on young adults' experiences and any changes (e.g., physical impairments). Third, counseling interventions can be modified depending on young adults' varying levels of motivation and progress over time. For example, if a young adult is experiencing very low or poor quality motivation, a PA counselor may draw on several techniques that have shown to be effective in increasing motivation quality [25–27]. Last, counseling interventions can help young adults learn to integrate and understand different aspects of themselves (e.g., mind, body, relationships, thoughts, emotions). Together, this one-to-one approach may facilitate and maintain PA behavior change [28].

While the number of PA interventions being delivered to young adults diagnosed with cancer is slowly growing [29–32], interventions that target fundamental processes associated with PA behavior to increase PA levels (i.e., PA as the *outcome*) remain scarce [33], yet are needed to address physical inactivity in an accessible manner. Indeed, most published interventions involve PA as the *intervention*, wherein participants receive regular PA training sessions comprised of aerobic training, resistance training, stretching, or flexibility activities, or their combination over 6–12 weeks, without counseling to explicitly and comprehensively explore how to successfully and meaningfully incorporate PA into one's daily life [30]. Still, research suggests that interventions incorporating at least some elements of behavioral counseling (e.g., establishing a therapeutic alliance between counselors and participants, applying techniques empirically shown to affect behavior and current functioning) can facilitate PA behavior change among people diagnosed with different chronic diseases and health conditions [34–37]. Based on these promising findings and preliminary evidence from trials with young adults living with and beyond cancer that featured interventions utilizing similar components (e.g., motivational interviewing) [33], the ACCESS intervention may increase PA levels among young adults after cancer treatment.

Guiding framework

Although many people are initially motivated to engage in PA after cancer treatment [38], changeable health, disruptions of daily life (e.g., side effects, other

responsibilities), and lack of knowledge about how to initiate and maintain PA can interfere with, and sometimes erode, motivation and engagement in PA [38, 39]. The ACCESS intervention applies motivational interviewing—a patient-centered method that seeks to enhance people's motivation to change problematic behaviors by *expressing empathy* for people's experiences, *rolling with resistance* rather than confronting and escalating conflict, *developing discrepancy* between actual and desired behavior, and *promoting self-efficacy* (i.e., perceived capabilities to perform the desired behavior) that change is achievable [40]. Motivational interviewing is an approach within the context of PA behavior counseling interventions that has yielded positive outcomes for PA behavior [41, 42]. Indeed, the results of a review of interventions applying motivational interviewing to elicit change in health behaviors (i.e., PA, nutrition) suggest that its use has the potential to increase PA levels in various settings for individuals on different cancer care trajectories [43]. In addition to its basis in motivational interviewing, the ACCESS intervention [44] is informed by self-determination theory (SDT [45]), which has empirical support in relation to PA behavior change interventions for adults living with and without cancer [46–50]. SDT is an organismic-dialectical theory of human motivation and well-being that takes into account individual psychological factors and socioenvironmental influences. Notably, SDT aligns with the principles of motivational interviewing. Last, the ACCESS intervention embeds (motivational) behavior change techniques that align with SDT tenets owing to their established role in intervention success [25, 27, 51, 52]. As a whole, the intervention seeks to promote young adults' autonomous motivation for PA—a key driver of behavior change [46, 53, 54]—by fostering their psychological needs for competence, autonomy, and relatedness via motivational interviewing and (motivational) behavior change techniques.

Online interventions

When PA behavior counseling interventions are delivered in-person [55], people within a relatively short distance to the location or who have the means to travel are typically recruited; notably, this limits participant diversity and makes it difficult for PA behavior counseling to become a cornerstone for providing support for PA behavior change to all those who could benefit from it. PA behavior counseling interventions delivered synchronously (in real-time) via videoconferencing technology can exceed the reach of in-person interventions, and thereby allow young adults from different (and hard-to-reach) locations to participate. Some studies have demonstrated positive effects of interventions delivered via information and communication technologies (e.g.,

smartphone, web-platform, Internet, video-monitoring) on health behaviors (e.g., PA) in clinical and non-clinical populations [56–58]. As well, it has been evidenced that various forms of PA interventions delivered via such technologies, including those utilizing telemonitoring and telecoaching tools (e.g., phone calls, text messages, emails), can increase PA levels after cancer treatment [59]. Considering these findings and that young adults living with and beyond cancer prefer online PA interventions [60, 61], young adults who are inactive or insufficiently active after cancer treatment may also benefit from PA behavior counseling delivered via videoconferencing technology.

The current study

Prior to evaluating the efficacy of the novel ACCESS intervention in comparison to de facto usual care (or treatment as usual) in a full-scale trial, it remains vital to determine how well the proposed trial methods and intervention will be received by the target population and identify issues that could affect intervention and trial implementation, mechanisms of change, and/or trial outcomes. Thus, a mixed-methods, pilot randomized controlled trial (RCT) was conducted. The objectives of this study were to:

- (1) Assess the feasibility and acceptability of the ACCESS intervention and trial methods, including factors that may affect intervention and trial implementation, mechanisms of change, and/or assessment of trial outcomes;
- (2) Capture young adults and PA counselors' views on various components of the intervention and trial methods (including but not limited to the procedures, contents, and materials) to enable a more meaningful interpretation of the quantitative outcomes relating to the feasibility and acceptability of the trial methods and intervention and inform any required changes to the intervention and/or trial methods;
- (3) Explore young adults' perceptions about the benefits, barriers, and facilitators to intervention participation.

A separate publication will report on estimates of variance in objectively measured PA behavior (i.e., planned primary efficacy outcome) and consider processes affecting participants' PA behavior.

Methods and materials

Reporting and registration

The methods of the ACCESS trial are described in full in the published protocol [44] written in accordance

with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines [62]; minor amendments to the protocol were required. A high-level description of amendments is provided throughout the main manuscript, whereas a detailed description is provided in Additional file 1. This manuscript was written per the reporting standards for pilot and feasibility trials described in the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement for randomized pilot and feasibility trials [63] and the CONSORT guidelines for eHealth interventions [64], as shown in Additional files 2 and 3, respectively. The ACCESS trial was registered with the ClinicalTrials.gov database (no.: NCT04163042) on November 14, 2019.

Trial design

A single-center, open-label, parallel, two-arm pilot RCT was conducted wherein young adults were randomized to receive the ACCESS intervention or usual care (no intervention) after completing baseline assessments. A sequential explanatory mixed-methods approach with longitudinal quantitative data and embedded qualitative data was utilized. Trial staffs' records and PA counselors' records (maintained in separate electronic databases) documenting feasibility and acceptability outcomes, as well as quantitative and qualitative data that were collected from young adults enrolled in the trial and PA counselors, were used for analysis in this study. Figure 1 summarizes the ACCESS pilot trial design and the flow of young adults from enrollment to trial completion.

Ethics

Ethics approval for the ACCESS trial protocol was granted by the University of Ottawa's Office of Research Ethics and Integrity (file no., #H-12–19-5172; initial approval, December 12, 2020) and the Ottawa Health Science Network Research Ethics Board (file no., #20190643-01H; initial approval, January 24, 2021). Young adults provided informed consent to participate in the ACCESS trial digitally through a web-based form hosted on SurveyMonkey, and PA counselors provided informed consent verbally. All young adults continued receiving medical care as determined by their healthcare team and were free to continue concomitant treatments throughout the trial. The ACCESS trial had the following stopping or discontinuing rule: The trial may be terminated if safety or ethical concerns are raised regarding the trial processes and/or the intervention.

Participants, study setting, and recruitment

Young adults who had completed cancer treatment were recruited nationwide (Canada). Two recruitment strategies were used to maximize reach and access to a range

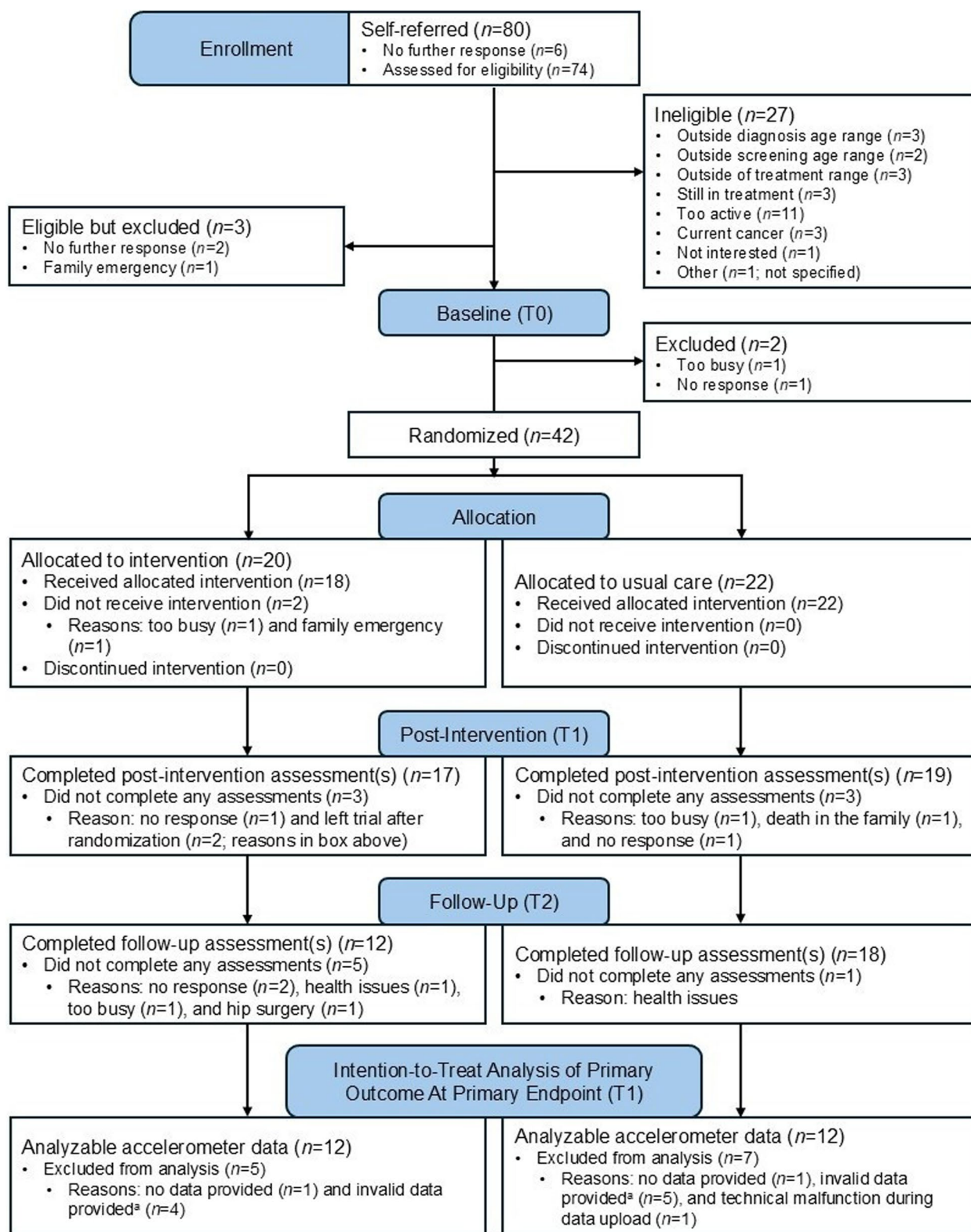


Fig. 1 CONSORT flow diagram detailing young adult participants' flow through the ACCESS trial

^aAccelerometer data did not meet inclusion criteria for analysis if the device was not worn ≥ 10 h/day for four consecutive days

of eligible young adults, and also yield invaluable insights into which recruitment approaches might be preferable for deployment in a full-scale trial. These include the following: (1) referral from healthcare providers at The Ottawa Hospital, and (2) self-referral in response to advertising (e.g., print, social media) or receiving a recruitment letter by mail. For the recruitment letter, potentially eligible young adults were identified using The Ottawa Hospital registry, and a random sample was mailed a one-page invitation letter containing study information; in response to an initial slow recruitment of males, mailed letters were subsequently amended to highlight their eligibility for the trial. Additionally, enrolled young adults were asked to share information about the ACCESS trial with others whom they believed might be interested in participating (i.e., through word of mouth). Young adults were consecutively selected as they met the eligibility criteria and agreed to enter the trial.

Young adults were eligible if they (1) were 18–39 years of age; (2) received a first diagnosis of invasive, non-metastatic cancer at age 18–39 years; (3) had completed primary cancer treatment within the past 5 years; (4) were fluent in English; and (5) had access to, and computer literacy for the use of, videoconferencing technology (e.g., Zoom, Microsoft Team). Exclusion criteria were as follows: (1) evidence of current cancer (i.e., recurrent, secondary, or relapse); (2) physical impairments precluding participation in PA; (3) self-report ≥ 150 min of aerobic MVPA weekly in the month prior to screening; or (4) non-ambulatory status.

Two self-identified women in their 20s (i.e., one MA student and one recent MA graduate from the School of Human Kinetics at the University of Ottawa) were recruited and trained as *PA counselors*. Neither were a part of the research team or had lived experiences of cancer at the time of recruitment. However, both had experience working with people living with and beyond cancer and had a special interest in PA behavior change.

Randomization and blinding

Randomization

The randomization schedule (1:1 allocation ratio) was generated using the National Cancer Institute online Clinical Trial Randomization Tool (<https://ctrandomization.cancer.gov/>) created using maximum tolerated imbalance randomization. Randomization was stratified by biological sex (male or female) to reduce a potential imbalance between the arms. A student not involved in the trial maintained the concealed schedule and revealed the next arm allocation to trial staff only after baseline assessments for an enrolled participant had been completed. Thereafter, trial staff informed the young adult of their arm allocation and the respective next steps.

Blinding

No blinding to arm allocation was performed, such that all persons involved in the ACCESS trial were aware of the arm assignment of young adults.

Sample size

Quantitative

No power calculation was performed for the efficacy outcome (PA behavior) in the pilot trial. Rather, the enrollment target was 30–40 young adults, which follows sample size recommendations for pilot studies using continuous outcome variables, as well as “rules of thumb” for pilot studies basing target sample size on anticipated effect size for a future full-scale trial [65]. Specifically, recruiting 15–25 participants per arm for a pilot study is recommended when planning for a future full-scale trial with 90% power and two-sided 5% significance anticipating a small-to-medium effect [66].

Qualitative

All young adults who provided consent to participate in the ACCESS trial and both PA counselors were invited to participate in an interview. The decision to invite *all* was chosen: (1) to avoid potential biases involved in interviewing only those who completed the intervention/trial; (2) because there was no strong reason to believe it would not be beneficial to hear from as many participants as possible; and (3) to enhance the potential richness of the data by maximizing the diversity and range of experiences.

Procedures

Young adults were screened by trained trial staff by phone. If eligible and interested, staff provided complete trial information, answered questions, and obtained verbal consent for email communication. Within 7 days of the call, young adults were emailed a web-link to SurveyMonkey for electronic consent and baseline (T0) survey completion. Consenting young adults were mailed an accelerometer to wear for seven consecutive days and asked to return it thereafter using the enclosed postage-paid return envelope. After baseline assessments were completed, the allocated arm was revealed to trial staff, and young adults were informed of their allocated arm by trial staff via email. Post-intervention (or post-usual care; T1) and 12-week follow-up (or 24 weeks post-baseline; T2) quantitative data were collected via accelerometers and electronic surveys administered through SurveyMonkey, with post-intervention selected as the primary endpoint. Qualitative data were collected via individual interviews from young adults post-intervention (or post-usual care; T1) and from PA counselors after all intervention sessions were delivered. Interviews were completed

online via Microsoft Teams. Throughout the trial, young adults who did not complete activities (e.g., provide consent, complete electronic surveys, wear the accelerometer) received three reminder emails or phone calls (depending on preference recorded during screening) 1 week apart. Follow-up communication emphasized the importance of their contributions to the trial and sought to address any barriers to protocol adherence; those who withdrew from the trial or could not be reached were considered lost to follow-up.

Trial arms

All young adults received treatment as usual from their healthcare team throughout the trial. While usual care is highly individualized to young adults, as well as to the institution or setting where they receive their care, it can involve the delivery of healthcare services directed toward preventing new (primary) and recurrent cancers and other late effects, surveillance for new cancer or recurrent cancer, intervention(s) for sequelae secondary to cancer and cancer treatment, and coordination between specialists and primary healthcare providers to meet young adults' needs.

Intervention arm: ACCESS intervention

Young adults received six free individual, real-time, biweekly, one-to-one 60-min videoconference sessions with the same PA counselor over 12 weeks. Sessions started within 1 week of completing baseline assessments. Sessions were scheduled via phone or email by the PA counselor, who accommodated young adults' schedules. Reminders were sent the day before sessions, and check-ins were made after missed sessions. Sessions were conducted according to a manualized protocol that included specific content to be covered, although discussions were tailored to young adults' goals, needs, strengths, and capacities.

The published protocol [44] provides full details of the structure and content of the intervention. Briefly, the overall goal of the intervention, based on its theoretical foundation (i.e., SDT), was to: (1) provide autonomy support, structure, and interpersonal involvement; (2) increase perceptions of autonomy, competence, and relatedness; and (3) foster autonomous motivation. Accordingly, several content and relational techniques aligned with SDT were implemented to support PA behavior change. To support the delivery of the content during sessions, PA counselors used (motivational) behavior change techniques and applied motivational interviewing techniques and principles that aligned with SDT. As well, young adults were supplied with worksheets to use during and in-between sessions as needed.

PA counselors Sessions were delivered by two trained PA counselors. As both had concurrent vocational commitments during the trial, both were assigned 2–3 young adults maximum at one time. PA counselors received specific literature to read, instructions to use the intervention manual and worksheets when delivering the intervention (i.e., keep manual handy during sessions, review the manual before sessions), and were trained by two authors (JB, JP) to deliver the intervention as specified in the intervention manual. The training consisted of a presentation, demonstrations and role-plays, didactic materials (i.e., describing the content and structure of sessions along with worksheets corresponding to topics/themes covered), and discussions. The training was reinforced with a mock session and biweekly meetings with JB and JP to ensure the intervention content, frequency, and duration were implemented as intended. To this end, PA counselors discussed sessions from the previous 2 weeks at each meeting, with a particular focus on adherence to content, frequency, and duration, as well as responsiveness (i.e., how young adults were engaged by or responded to the sessions) and any challenges that arose. Strategies to facilitate implementation were introduced as needed.

Control arm: no treatment

The control arm consisted of de facto usual care (or treatment as usual). Young adults in the control arm were asked to continue their normal activities of daily living and complete the data collection activities on a schedule identical to that of the intervention arm. To promote retention of control arm participants, they received a copy of the intervention materials after completing follow-up assessments (or leaving the trial for those lost to follow-up).

Measures

There were three categories of outcome measures relevant to this study: (1) quantitative outcomes related to the feasibility objectives (i.e., enrollment, allocation, retention, protocol adherence, and adverse events); (2) qualitative outcomes related to the acceptability objective (i.e., acceptability of the trial methods and intervention); and (3) quantitative outcomes related to the ability to measure the primary efficacy outcome (i.e., PA behavior), secondary outcomes (i.e., patient-reported outcomes), and potential mechanisms that may impact the effects of the intervention on the intended outcomes (i.e., targeted active ingredients; SDT constructs, [motivational] behavior change techniques). A separate publication will present data on outcomes and processes affecting participants' PA behavior change.

Quantitative feasibility outcomes

Table 1 presents the feasibility outcomes, including how they were operationalized, methods of data collection and analysis, and criteria used to evaluate metrics as “successful.” Criteria were set a priori based on relevant literature and the authors’ experiences.

Adverse events Adverse events (i.e., any unfavorable and unintended sign, symptoms, or disease temporally associated with PA) definitely, probably, or possibly related to engaging in the trial were monitored throughout the trial. PA counselors and trial staff were to record each event as it occurred and consult with the principal investigator (JB) immediately to evaluate the seriousness and relatedness of the event and take appropriate action as needed. Any adverse events were to be reported to the Research Ethics Boards per institutional guidelines.

Qualitative outcomes

Notes were taken during biweekly meetings with PA counselors, and semi-structured interviews were conducted with young adults (including those lost to follow-up) post-intervention (T1) to facilitate an in-depth understanding of the potential factors affecting feasibility and acceptability outcomes. Young adults were unknown to the interviewer (JP), a trained doctoral candidate in the School of Human Kinetics at the University of Ottawa. She self-identified as a woman, was in her 20s, had substantial knowledge of the trial and intervention, and was experienced in interviewing. An interview guide was used to focus on young adults’ opinions about the trial protocol (for intervention and control arms), and opinions about the intervention (i.e., content, materials, delivery mode, length, duration, PA counselor), SDT constructs, and (motivational) behavior change techniques (for intervention arm only). Semi-structured interviews were also conducted with PA counselors after they had delivered all intervention sessions, corresponding to the end of their contract. A separate interview guide was used to explore their experiences delivering the intervention, as well as their thoughts about its content, required training, ongoing supervision, using an intervention manual, conducting sessions using videoconferencing technology, maintaining fidelity to the manual, and their motivation and confidence to conduct the sessions. All interviews were audio-recorded, anonymized, and transcribed verbatim. No transcripts were returned to interviewees for feedback.

To enhance the methodological rigor and credibility of the qualitative data, recommended strategies [67–69]

that were used included the following: (1) interviews were recorded and transcribed; (2) ongoing discussions of results occurred among a small number of team members who collaborated to finalize the data interpretation; (3) interview guides were flexible to allow interviewees’ opinions to be explored in depth; (4) data were collected and managed transparently; (5) the method of analysis was appropriate for the data; (6) results are reported using direct quotes from interviews; and (7) the sample is described.

Quantitative primary efficacy outcome

The primary outcome for assessing the efficacy of the intervention in a full-scale RCT will be PA behavior as measured using accelerometers. At baseline (T0), post-intervention (T1; primary endpoint), and follow-up (T2, secondary endpoint), young adults were asked to wear an ActiGraph GT9X Link (ActiGraph; Pensacola, FL, USA) accelerometer for seven consecutive days (including \geq two weekdays and one weekend day), as recommended [70]. Young adults were instructed to wear the device on their non-dominant wrist and remove it only during sleep and water-based activities. The wear location was chosen based on evidence that wear compliance rates are higher in studies employing wrist-worn accelerometers relative to waist-worn accelerometers [71]. To facilitate protocol adherence, young adults were sent a two-page information guide by email, which reiterated verbal instructions given during the screening call and asked them to log their wear time on paper (by printing the provided log and filling it in with a pen or pencil). Young adults were encouraged to contact trial staff if they needed assistance. The acquisition of data was confirmed by trial staff upon receipt of accelerometers by importing the data into ActiLife v6.13.4 software and verifying wear time logs. Unit nonresponse and reasons for missing data were documented.

Sociodemographic and clinical variables

At baseline (T0), self-report data were collected on the sociodemographic and clinical characteristics of young adults within the electronic survey. The use of other resources (e.g., personal trainers, psychosocial support) was also collected in the electronic survey post-intervention (T1) and at follow-up (T2).

Data analysis

Quantitative analyses

Data were downloaded in SPSS (version 28). Quality checks were initially performed to identify errors and invalid entries. Descriptive statistics (i.e., number,

percent, mean [M], standard deviation [SD], median [Mdn], 95% confidence interval [95% CI], and range as appropriate) were computed on sociodemographic and clinical variables to characterize the sample at baseline and those who completed the trial. Further descriptive statistics were calculated for feasibility outcomes, and summary statistics were compared to benchmark criteria outlined in Table 1.

Qualitative analyses

Interview transcripts were uploaded to NVivo (version 15), checked for accuracy by two trainees, and segments pertaining to the aims of this study were analyzed deductively by JP and DW following Elo and Kyngäs' three-phased approach to content analysis [72]. During the *preparation* phase, JP and DW read interviews with an open mind to obtain an overall impression of the information provided by each young adult, and JB and JP created a categorization matrix for coding based on the aims of this study. During the *organization* phase, JP and DW coded interview segments independently using the matrix, discussed codes until consensus was reached, and classified codes into main themes. Also, meeting notes were read to identify possible codes to integrate into the reporting of results. Results were then reviewed by JB and discussion ensued until consensus was reached. During the *reporting* phase, a narrative summary of each main theme was created by JB and JP, and direct quotes were selected to support themes.

Mixed-methods analysis

The purpose of collecting both quantitative and qualitative data was to integrate these forms of data, bringing greater insight into the feasibility and acceptability of the intervention and trial methods than would be obtained by either alone [73]. Accordingly, the analysis involved cross-referencing quantitative results with qualitative insights to identify consistencies or discrepancies and connecting numerical trends with qualitative themes to explore factors that influenced the feasibility and acceptability of the intervention and trial methods. For example, missing data results for accelerometers were cross-checked with direct participant statements from the interviews, which captured concerns about the device. The integration of these multiple data sources helped to reinforce and expand upon quantitative results.

Patient and public involvement

No patients or members of the public were involved in the design, conduct, and interpretation of this study.

Results

Young adult participants' flow and data provided

The flow of young adults through the ACCESS trial is reported in a CONSORT flow diagram (Fig. 1). From

03/2021 to 08/2022, 74 young adults were screened for eligibility. Sending recruitment letters to The Ottawa Hospital registrants was more successful ($n=34$, 42.5%) than clinician referral ($n=17$, 21.3%) and self-referral from advertisements ($n=29$, 36.3%). Of the 74 screened, 47 (63.5%) were eligible. The most frequent reason for ineligibility was currently meeting PA guidelines ($n=11/27$, 40.7%). Of the 47 eligible, 42¹ (89.4%) provided informed consent (i.e., enrolled), completed baseline assessments, and were subsequently randomized (intervention arm, $n=20$ [47.6%]; control arm, $n=22$ [52.4%]). Of the 20 randomized to the intervention arm, 2 (10.0%) did not receive the intervention, 3 (15.0%) missed one session, and 15 (75.0%) completed all six sessions. Post-intervention (T1; primary endpoint), 85.7% (36/42) remained in the trial, and of those, 24 (66.7%; $n_{\text{intervention}}=12$, $n_{\text{control}}=12$) had analyzable data for the primary outcome (PA). At follow-up (T2; secondary endpoint), 30 of the 42 enrolled young adults completed the trial for a retention rate of 71.4%; the final follow-up assessment was completed 04/2023.

Young adult participants' characteristics

Detailed baseline values by arm are presented in Table 2 for the complete sample ($n=42$; i.e., those who enrolled and provided baseline data) and trial completers ($n=30$; i.e., those who completed post-intervention and follow-up assessments). Briefly, young adults were, on average, 33.1 years of age, 81.0% reported "female" as their sex (76.2% reported "women" as their gender), 78.6% were White/Caucasian, 95.2% had attended university, and 54.8% were employed full-time. Most were diagnosed with hematological (36.4%) or breast (22.7%) cancer. The median time since diagnosis was 6.08 years, and most had received chemotherapy (81.0%), surgery (73.8%), and/or radiotherapy (52.4%). At baseline, a third reported moderate impairments (i.e., interferes with normal activity, treatment is needed, and prognosis is good) in one or more of the body systems presented in the cumulative illness scale, and none were enrolled in another study.

Feasibility of trial methods

Of the 9 trial methods feasibility outcomes, 7 (77.8%) reached predefined success criteria (Tables 1 and 3). Notably, the goal of recruiting 30–40 young adults was met in 18 months. To meet this goal, 74 young adults were screened for eligibility ($M \sim 4$ monthly), with 42 of 47 eligible young adults enrolling and providing baseline data (enrollment rate, 89.4%; Fig. 1 presents reasons for exclusion). Of those 42, 36 completed surveys and/

¹ 42 was used as the denominator for calculating percentages throughout the results unless otherwise specified.

Table 1 Quantitative feasibility outcomes

Outcomes	Operationalizations	Criteria for "success" of feasibility	Methods of data collection and analysis	Results
<i>Trial methods</i>				
Recruitment, enrollment, and randomization	Number of months to reach target sample size	30–40 are enrolled \leq 20 months	Trial database/log Descriptive statistics	18 months ✓
	Number of young adults screened for eligibility	2–3 young adults are referred or self-refer per month and are assessed for eligibility	Trial database/log Descriptive statistics	M–4 monthly (range = 0–17; 74 across 18 months) ✓
	Number of young adults enrolled (i.e., who provided consent to participate)	\geq 70% of eligible young adults consent	Trial database/log Descriptive statistics	42/47 (89.4%) ✓
	Number of enrolled young adults randomized	\geq 70% of enrolled young adults are randomized	Trial database/log Descriptive statistics	42/42 (100.0%) ✓
Arm size	Number of enrolled young adults allocated to the intervention and control arms	Imbalance does not exceed $n \pm 3$	Trial database/log Descriptive statistics	$n_{\text{intervention}} = 20/42$ (47.6%) $n_{\text{control}} = 22/42$ (52.4%) ✓
Safety	Number and type of adverse events related to the trial methods	The trial methods are safe. No adverse events related to the trial methods are reported	Participant self-report Descriptive statistics	0 ✓
Retention and attrition	Number of young adults who completed some or all of the assessments at T1 and T2	Retention rates \geq 75% from T0 to T1 and from T0 to T2	Trial database/log Descriptive statistics	T0 to T1 retention rate: 85.7% (36/42) T0 to T2 retention rate: 71.4% (30/42)
	Number of young adults who did not complete any assessments at T1 and T2 ^a	Attrition rates \leq 25% from T0 to T1 and from T0 to T2		T0 to T1 attrition rate: 14.3% (6/42) T0 to T2 attrition rate: 28.6% (12/42)
Sample	Number of available for analysis of primary outcome (PA behavior) at T1	≥ 22 (≥ 11 per arm)	Trial database/log Descriptive statistics	24 ($n_{\text{intervention}} = 12$; $n_{\text{control}} = 12$) ✓
Missing data at the unit level	Percentage of unit nonresponse or unusable data at T0, T1, and T2 (excluding participants who left the trial at the respective timepoints): (a) for accelerometer data (primary outcome) (b) for survey data (secondary outcomes)	$\leq 10\%$ unit nonresponse at T0, T1, and T2	Trial database/log Descriptive statistics	T0: 19.0% (8/42) ^b T1: 33.3% (12/36) ^c T2: 36.7% (11/30) ^d T0: 0% (0/42) T1: 11.1% (4/36) ^e T2: 3.3% (1/30) ^f
Intervention	Percentage of enrolled young adults and PA counselors interviewed	$\geq 75\%$ of young adults and 100% of PA counselors are interviewed		Young adults: 83.3% (35/42) PA counselors: 100.0% (2/2)
Adherence	Percentage of sessions attended for the prescribed duration	$\geq 75\%$ of sessions for $M \geq 50$ min among those who received allocated intervention	PA counselors' records Descriptive statistics	97.2% (105/108) ✓
	Percentage of young adults who attended all sessions for the prescribed duration	$\geq 75\%$ who began the intervention completed all six sessions for $M \geq 50$ min	PA counselors' records Descriptive statistics	83.3% (15/18)
	Percentage of young adults who did not participate in any sessions or discontinued the intervention	$\leq 10\%$	PA counselors' records Descriptive statistics	10.0% (2/20) did not participate in any sessions
Safety	Number and type of adverse events related to the intervention	The intervention is safe. No adverse events related to the intervention are reported	Young adults' self-report Descriptive statistics	0 ✓

T0 baseline (prior to randomization); T1 post-intervention (primary endpoint); T2 follow-up (secondary endpoint; 24 weeks after baseline); M mean; ✓ successful; – unsuccessful

^a After the assessment window closed, if young adults asked to drop out of the study or did not complete assessments, they were marked as a loss to follow-up

^b $n = 1$ data not collected and $n = 7$ invalid data

^c $n = 2$ data not collected, $n = 9$ invalid data, and $n = 1$ technical malfunction

^d $n = 2$ data not collected, $n = 7$ invalid data, and $n = 2$ technical malfunction

^e $n = 4$ data not collected

^f $n = 1$ data not collected

Table 2 Young adult participants' characteristics self-reported at baseline by trial arm (complete sample and trial completers)

	Baseline assessment (n = 42)		Trial completers (n = 30)	
	Intervention (n = 20)	Control (n = 22)	Intervention (n = 12)	Control (n = 18)
Sociodemographic				
Age in years, <i>M</i> (<i>SD</i>), range [95% <i>CI</i>]	32.45 (4.11), 24–39 (30.53–34.37)	33.59 (5.44), 22–39 (31.18–36.0)	31.75 (4.56), 24–39 (28.86–34.64)	34.06 (5.03), 23–39 (31.55–36.56)
Female sex, <i>n</i> (%)	16 (80.0%)	18 (81.82%)	9 (75.0%)	14 (77.78%)
Gender, <i>n</i> (%)				
Man	4 (20.0%)	4 (18.18%)	3 (25.0%)	4 (22.22%)
Woman	15 (75.0%)	17 (77.27%)	8 (66.67%)	13 (72.22%)
Nonbinary	1 (5.0%)	1 (4.55%)	1 (8.33%)	1 (5.56%)
Ethnicity, <i>n</i> (%)				
White/Caucasian	15 (75.0%)	18 (81.82%)	11 (91.67%)	16 (88.89%)
Black/African Descent	1 (5.0%)			
Hispanic/Latino/Latina		1 (4.55%)		
West African		1 (4.55%)		
Southeast Asian	1 (5.0%)			
Chinese	1 (5.0%)			
Arab		1 (4.55%)		1 (5.56%)
Biracial (White/Caucasian and Aboriginal/Native)	2 (10.0%)	1 (4.55%)	1 (8.33%)	1 (5.56%)
Marital status, <i>n</i> (%) partnered (i.e., married, common law, committed relationship/ not living together)	10 (50.0%)	12 (54.55%)	6 (50.0%)	11 (61.11%)
Occupational status, <i>n</i> (%) working	12 (60.0%)	15 (68.18%)	8 (66.67%)	14 (77.78%)
Education, <i>n</i> (%)				
High school graduate	2 (10.0%)			
Some university or college degree	2 (10.0%)	2 (9.09%)	2 (16.67%)	1 (5.56%)
University bachelor's or college degree	12 (60.0%)	17 (77.27%)	8 (66.67%)	14 (77.78%)
Graduate school degree	4 (20.0%)	3 (13.64%)	2 (16.67%)	3 (16.67%)
Annual household income in CAD, <i>n</i> (%)				
< \$50,000	8 (40.0%)	3 (13.64%)	5 (41.67%)	3 (16.67%)
\$50,000–\$99,999	8 (40.0%)	7 (31.82%)	4 (33.33%)	5 (27.78%)
\$100,000–\$149,999	3 (15.0%)	4 (18.18%)	2 (16.67%)	4 (22.22%)
\$150,000–\$199,999		2 (9.09%)		2 (11.11%)
≥ \$200,000	1 (5.0%)		1 (8.33%)	
Do not know		3 (13.64%)		1 (5.56%)
Prefer not to answer		3 (13.64%)		3 (16.67%)
Clinical-related				
Body mass index in kg/m ² , <i>M</i> (<i>SD</i>), range [95% <i>CI</i>]	27.38 (7.93), 18.03–49.24 (23.67–31.09)	26.53 (7.56), 17.43–42.10 (23.18–29.88)	27.76 (8.28), 21.14–49.24 (22.50–33.02)	25.67 (7.28), 17.43–42.10 (22.05–29.29)
Cumulative illness rating (14 items) ^a , <i>M</i> (<i>SD</i>), range [95% <i>CI</i>]	* <i>n</i> = 18 17.11 (2.78), 14–23 (15.73–18.50)	* <i>n</i> = 19 18.79 (5.41), 14–33 (16.18–21.40)	* <i>n</i> = 11 17.18 (2.48), 14–23 (15.51–18.85)	* <i>n</i> = 17 18.65 (5.71), 14–33 (15.71–21.58)
Cumulative illness rating (13 items) ^b , <i>M</i> (<i>SD</i>), range [95% <i>CI</i>]	* <i>n</i> = 2 14.0 (0.0), 14.0–14.0 (n/a)	* <i>n</i> = 3 15.33 (2.08), 13–17 (10.16–20.50)	* <i>n</i> = 1 14	* <i>n</i> = 1 17

Table 2 (continued)

	Baseline assessment (n = 42)		Trial completers (n = 30)	
	Intervention (n = 20)	Control (n = 22)	Intervention (n = 12)	Control (n = 18)
Cancer type, n (%)				
Hematological	7 (35.0%)	8 (36.36%)	4 (33.33%)	7 (38.89%)
Breast	4 (20.0%)	6 (27.27%)	1 (8.33%)	5 (27.78%)
Sarcoma	1 (5.0%)	2 (9.09%)	1 (8.33%)	2 (11.11%)
Brain		1 (4.55%)		
Carcinoma	1 (5.0%)			
Gynecologic	4 (20.0%)	2 (9.09%)	4 (33.33%)	1 (5.56%)
Colorectal	1 (5.0%)		1 (8.33%)	
Melanoma	1 (5.0%)			
Testicular		1 (4.55%)		1 (5.56%)
Gastrointestinal		1 (4.55%)		1 (5.56%)
Other	1 (5.0%)	1 (4.55%)	1 (8.33%)	1 (5.56%)
Treatments received, n (%)				
Surgery	17 (85.0%)	14 (63.64%)	10 (83.33%)	11 (61.11%)
Chemotherapy	13 (65.0%)	21 (95.45%)	8 (66.67%)	17 (94.44%)
Radiation	9 (45.0%)	13 (59.09%)	3 (25.0%)	11 (61.11%)
Hormonal	5 (25.0%)	7 (31.82%)	2 (16.67%)	5 (27.78%)
Immunotherapy	2 (10.0%)	6 (27.27%)		6 (33.33%)
Other	5 (25.0%)	3 (13.64%)	3 (25.0%)	3 (16.67%)
Years since diagnosis, <i>Mdn</i> (<i>IQR</i>)	3.33 (1.44–4.33)	2.71 (1.38–3.83)	3.13 (0.96–4.40)	2.96 (1.42–4.19)
Perceived overall health ^c , n (%)				
Poor to fair	5 (25.0%)	5 (22.73%)	3 (25.0%)	4 (22.22%)
Good to very good	13 (65.0%)	16 (72.73%)	8 (66.67%)	13 (72.22%)
Excellent	2 (10.0%)	1 (4.55%)	1 (8.33%)	1 (5.56%)
Other				
Access additional PA resources (e.g., personal trainers, yoga/exercise programs), n (%)	8 (40.0%)	10 (45.45%)	5 (41.67%)	9 (50.0%)
Access emotional or psychological resources (e.g., support groups, counseling) or therapies (e.g., acupuncture), n (%)	10 (50.0%)	10 (45.45%)	8 (66.67%)	7 (38.89%)

CI confidence interval, *M* mean, *Mdn* median, *PA* physical activity, *SD* standard deviation, *IQR* interquartile range (mean excluded)

^a Cumulative Illness Rating Scale scores range is 0–56, where 0 indicates no health problems and 56 indicates severe failure in 14 different systems (e.g., cardiac, respiratory, gastrointestinal tract, psychiatric/behavioral)

^b Instances where responses for 13 of the 14 items were received

^c First question on RAND-36 (<https://www.rand.org/pubs/reprints/RP971.html>)

or accelerometry assessment(s) at T1 (retention rate at T1 [primary endpoint]: 85.7%). After removal of non-analyzable data due to dropout, missingness, or accelerometer data not meeting inclusion criteria threshold for analysis, 66.7% (24/36) had analyzable data for analysis for the primary outcome (PA behavior) at T1. When excluding young adults who withdrew from the trial or were lost to follow-up, there was < 10% missing values

on the electronic surveys at T0 and T2, whereas T1 had 11.1% missing values (4/36). However, when including all young adults enrolled (i.e., rates that are based on the would-be *n* = 42 at each timepoint if all who consented to participate had remained in the trial), the missing data rates became worse with increasing percentages of missing data across assessments (T0: 0% [0/42], T1: 23.8% [10/42], T2: 30.9% [13/42]). Also, 35 of the 42 enrolled

Table 3 Trial methods and intervention feasibility data

<i>Trial methods</i>		<i>Intervention</i>	
Enrollment rate, % (n)	89.4% (42/47 eligible)	Did not receive allocated intervention, % (n)	10.0% (2/20)
Noneligibility rate, % (n)	36.5% (27/74)	Sessions attended, <i>M</i> (<i>SD</i>)	5.8 (0.4)
Nonresponse rate, % (n)	7.5% (6/80)	Attendance, % (n)	
Source of recruitment		Session 1	100.0% (18/18)
Clinician-referred	21.3% (17/80)	Session 2	100.0% (18/18)
Self-referral	36.3% (29/80)	Session 3	94.4% (17/18)
Registry ascertained	42.5% (34/80)	Session 4	94.4% (17/18)
		Session 5	100.0% (18/18)
		Session 6	94.4% (17/18)
Lost to follow-up (from T0 to T1), % (n)			
All	14.3% (6/42)		
Intervention arm	15.0% (3/20)		
Control arm	13.6% (3/22)		
Lost to follow-up (from T1 to T2), % (n)			
All	16.7% (6/36)		
Intervention arm	29.4% (5/17)		
Control arm	5.3% (1/19)		
Retention rate (from T0 to T1), % (n)			
All	85.7% (36/42)		
Intervention arm	85.0% (17/20)		
Control arm	86.4% (19/22)		
Retention rate (from T1 to T2), % (n)			
All	83.3% (30/36)		
Intervention arm	70.5% (12/17)		
Control arm	94.7% (18/19)		

n number of young adult participants, *M* mean, *SD* standard deviation, *T0* baseline, *T1* post-intervention, *T2* follow-up (i.e., 24 weeks after baseline)

young adults (83.3% [$n_{\text{intervention}} = 18$, $n_{\text{control}} = 17$]) and both PA counselors (100.0%) were interviewed. Notably, although wear time logs were not considered for feasibility outcomes, they were not submitted in many cases, and comparison of the log data with monitor data generally indicated that the log data were incomplete and inaccurate, precluding analysis of log data.

As shown in Table 1, 2, of the 9 predefined success criteria were not met (22.2%). Retention at T2 (secondary endpoint) was 71.4% (target $\geq 75\%$), with 5 in the intervention arm and 1 in the control arm not completing any T2 assessments. In addition, further inspection of accelerometer data revealed that missingness was an issue at the primary endpoint (T1; 33.3% [12/36]), as well as at baseline (T0; 19.0% [8/42]) and T2 (36.7% [11/30]). Beyond lost to follow-up, other reasons for missingness across all timepoints included data not meeting the inclusion criteria threshold (i.e., device was worn for < 10 hours per day and/or for < 4 consecutive days (74.2% [23/31]), forgetting to wear the device altogether (16.1% [5/31]), and technical malfunctions resulting in unrecoverable data

(9.7% [3/31]). Additional file 4 provides details on missing data for both electronic survey and accelerometer data, categorized by arm and timepoint.

Feasibility of intervention

All intervention feasibility outcomes (100% [2/2]) reached predefined success criteria (Tables 1 and 3). Of the 20 randomized to the intervention arm, 18 (90%) initiated the intervention and the average number of sessions attended for ≥ 50 min was 5.8 (range = 5–6, 95% CI 5.64–6.02). In total, 83.3% (15/18) attended all six sessions for ≥ 50 min. Nonetheless, PA counselors noted difficulties adhering to the timing guidelines in the protocol due to logistical and contextual issues. They highlighted the need to be flexible and schedule intervention sessions around young adults' schedules, travels, and commitments, although 3 scheduled sessions were missed ($n = 2$ forgot; $n = 1$ no reason) and requests to reschedule sessions went unanswered; after 1 week passed, the session was marked as missed, and the PA counselors proceeded to the next session to avoid compromising the timing of the intervention.

Adverse events

No adverse events related to the trial methods and intervention were disclosed to the trial team.

Individual interviews

Thirty-five young adult participants (83.3%) were interviewed for 13–105 min ($M=49.6$ min); as expected, the duration was longer for the intervention arm ($M=67.2$ min, range=31–105 min) than for the control arm ($M=32.0$ min, range=13–68 min) due to the longer interview guide. Interviews occurred, on average, 2.5 weeks after the 12-week intervention/de facto usual care (or treatment as usual) period (range=3 days–9.7 weeks). Of the 35 young adult interviewed, 29 (82.9%) completed T0, T1, and T2 assessments (i.e., trial completers), whereas the remaining 6 were lost to follow-up (17.1%; $n=1$ at T1 and $n=5$ at T2). Young adult interviewees' sociodemographic and clinical characteristics mirror the trial sample (based on visual observations). Additionally, both PA counselors were interviewed for 53 and 66 min.

Content analysis

Analysis of interviews yielded four main themes: three reflect factors that *positively* impacted intervention acceptability, and one reflects factors that *negatively* impacted the acceptability of the trial methods. Additionally, these data provided significant insight into key action items that would optimize the acceptability of the trial methods and intervention, which are presented throughout the four main themes. Themes are described below, accompanied by supporting quotes, which are labeled with unique alphanumeric identifiers to ensure anonymity.

Theme 1: experienced benefits

Young adult participants described several benefits from participating in the intervention, including enhanced PA confidence, competence, and capacity to participate in PA, increased participation in PA, and as a result, mentioned tangible improvements in sleep, energy, and strength. For instance, YA13 shared that the intervention was a powerful catalyst for becoming active and emphasized that it improved their sleep: “*I was barely moving before the program. [...] I was sleeping a lot. Now when I see my energy going down, I’m going for a walk.*” YA07 shared that they acquired the ability to engage in various physical activities confidently and competently:

“A big one was being able to go places [to walk] by myself. I was previously pretty nervous, and sometimes would need to have someone with me just to make sure I could make it back. I definitely saw a

huge improvement there. I’m very confident walking quite a bit further by myself. I also noticed a big difference in just like being able to clean and do things for myself. [...] I have this big file holder box that probably weighs like 15 pounds and when I was first trying to clean my room by myself, I’d have to get someone to come help me move that so I could vacuum under that spot. But now I can move it by myself. Another example would be like I can totally clean the floor by myself now. The first time I tried I had to stop and do like a 15-minute break and then do the second half of the floor. But now I can kind of do it all in one shot and finish that by myself.”

Additionally, the intervention was pivotal in fostering positive attitudes toward PA and learning to enjoy PA, enhancing motivation for an active lifestyle. YA03 illustrated this: “*It allowed me to incorporate PA into daily life without it being a burden or a task that I had to complete. It was something that I was able to make super enjoyable and something that I look forward to every day instead of a burden which really helped with visualizing not only the short-term goals, but the long-term goals.*” Finally, feeling heard and talking to someone who can understand what they went through (during cancer) greatly empowered young adults to reflect on the challenges and setbacks they experienced, value their bodies, and embrace the future. YA16 explained: “*This intervention meant moving on from a really traumatic experience and repairing the relationship with my body. I felt my body betrayed me, but also did so much work to save my life, just so much work. I think repairing the relationship with my body, definitely that’s what it meant, it meant moving on and moving on together. Me and my body walking off into the sunset.*”

Theme 2: satisfaction with the intervention: content, design, and dose

Content – for PA counselors Overall, PA counselors considered the training helpful, especially the mock session as it provided an opportunity to receive critical feedback and gave them the confidence needed to deliver the intervention. PAC1 shared: “*While it was kind of scary in the moment, I liked that you asked us to practice in front of the four of us, delivering one of the behavior change techniques.*” Still, they acknowledged the importance of “*experience*,” and said they had become gradually more comfortable, flexible, and able to adapt to young adult participants after conducting several sessions. PA counselors thought that the detailed manual was useful too and clear. They described using it systematically, especially during the start of their contract. They identified

the need to review content and aims before each session, which they saw as critical to their ability to deliver sessions as intended. However, they disclosed that they gradually became less reliant on it after conducting a few interventions. As well, PA counselors viewed the biweekly meetings *together* as informative, adequate, and key to facilitating uniform delivery. Still, they emphasized uncertainty around navigating discussions of cancer symptoms and what they could and/or should do in terms of tailoring the intervention to avoid fidelity issues. They recommended having a priori training on these two items to understand this heterogeneous group of young adults who have completed treatment better and to ensure justifiable tailoring.

Content – for young adult participants Young adults were satisfied with the intervention content, order of the topics/sessions, and adaptations provided. They found the topics relevant and appreciated working actively through the content with a PA counselor who helped them reflect on their values, aims, and goals. YA04 shared: *“Having somebody who is knowledgeable in PA to talk to and the flexibility to kind of choose what I wanted to do. Through the intervention, I was able to figure out what works for me and then we just increased that. We just worked off of what works for me and then just went from there.”* Moreover, they described having autonomy—wherein they could voice their choices and receive validation—as an important factor contributing to their satisfaction because it made the intervention directly relevant to them. They highlighted the importance of being able to share their stories with an attentive listener with expertise in PA and take part in personal reflections and discussions to understand their motivation for PA, reasons for participating in PA, and what they enjoyed doing. Being able to share prior PA experiences and explore alternatives was also highlighted as particularly helpful. For instance, YA33 explained: *“I’ve always tried to fit working out into my schedule, like going to the gym and I do not like going to the gym. And it helped me realize there are other activity options out there that are things that I enjoy. So, it’s like [PA counselor] suggested possibly trying like bouldering and rock climbing and that’s something that is really close to me and I never even considered it and I feel like that’s a good option and is active.”* Nonetheless, young adults also described uncertainty around PA (e.g., high-intensity, long-duration, high volumes) and how to engage in PA as they navigate life after cancer. They conveyed that adding the following topics could promote further positive responses: (1) PA after cancer: focus on health considerations; (2) looking forward: life after the intervention; and (3) promoting self-compassion and understanding: PA is different after

cancer. Additionally, they suggested that supervised PA training during the intervention could be beneficial in offering additional PA support, advice, and encouragement, as well as increasing young adults’ confidence and competence in their ability to perform PA.

The responses to the corresponding worksheets were primarily positive—young adult participants and PA counselors viewed them as useful, informative, easy to understand, and beneficial to facilitate conversation. Nonetheless, young adult participants criticized the format (i.e., non-fillable, electronic PDF format) and considered that it limited their use. YA70 shared: *“I didn’t find the PDF booklet very [accessible]. I didn’t use it that often because it was in a PDF. I didn’t have it tangible in front of me so I didn’t find I was using it.”* Although young adult participants appreciated that their PA counselor used the worksheets during sessions, they provided suggestions for improvement, which were to provide worksheet printed (sent by mail) or in fillable, electronic PDF format.

Evaluation of the ACCESS intervention content also resulted in positive comments regarding the room for flexibility and individualization of the intervention to ensure it adequately met young adult participants’ goals and needs. From PA counselors’ perspectives, making individual adaptations (e.g., order of the topics described in the intervention manual) was key to delivering this intervention to a group of diverse young adults with respect to sociodemographic, clinical, and PA backgrounds. Accordingly, they recognized that having biweekly meetings to receive guidance throughout the trial was key to ensuring adaptations were acceptable and appropriate while aiming to maintain implementation fidelity. From young adult participants’ perspectives, witnessing their PA counselor adapt the intervention to their goals and needs after getting to know them fostered their interest in sessions and relationships with their PA counselor. Additionally, they believed that it made the sessions particularly interesting, useful, and appealing.

Design PA counselors saw using videoconferencing technology as a good tool to provide PA support to young adults and minimize barriers to in-person sessions (e.g., young adults’ geographical location and work commitments). Similarly, despite technological issues in a few cases (e.g., temporary difficulties with Wi-Fi connectivity), young adult participants were motivated to engage in the synchronous online sessions because they replicate important (verbal and non-verbal) communication strategies that occur within an in-person session. YA04 highlighted: *“The face-to-face was definitely important for me. [...] I need the personal. I need the non-verbal. I need to see what your face is doing and that kind of thing. Your*

reactions. [...] *In person, I don't feel that it's necessary. It could have gone just as well, I think, but I don't think it was needed to me. I don't think there was any reason for us to sit in a room together and go over it [the material] really.*" Furthermore, young adult participants offered that having online sessions (with their PA counselors able to accommodate their busy schedules as sessions could be scheduled weekdays and weekends from 7:00 am to 7:00 pm) offered flexibility and saved time, helping overcome barriers to in-person sessions (e.g., travel).

Dose The intervention comprised six 60-min individual sessions designed to be delivered over 12 weeks. PA counselors succeeded in covering the intended content during sessions and deemed the dose appropriate. Similarly, young adult participants found the number and duration of sessions relevant to cover the content and have engaging discussions. YA29 said: *"I think it was a perfect amount of time because even half an hour would have been us rushing through it or skipping through things but one hour and a half would have been a little bit too long because, for us, it's difficult to sit in one place for that long and I think it would just become too much."* Still, young adult participants expressed interest in "booster" sessions or follow-up contacts after the original intervention to receive additional information, monitor their progress, and troubleshoot challenges with their PA counselor. This is likely due to their concerns about their ability to maintain PA behavior after their last session. However, there was variation in the preferred parameters for the planning of booster sessions and follow-up contacts. For example, some young adult participants preferred multiple booster sessions with more spacing (i.e., 1 month apart), whereas others wanted a single booster session at 6 months.

Additionally, videoconferencing was not always seen as necessary for booster sessions and follow-up contacts, with some stating that they were comfortable with texting. Other considerations not discussed include whether to introduce new content versus reviewing previously covered content. Young adult participants' interest in booster sessions and follow-up contacts was supported by PA counselors who believed an expanded, longer-term intervention could help young adults maintain PA behavior changes made and perhaps further increase PA levels.

PA counselors indicated that biweekly sessions (as opposed to weekly) gave young adults enough time to reflect on, try out, and refine the behavior change techniques covered during sessions. PAC2 explained: *"I thought it [2 weeks] was a good amount of time. I liked that they [sessions] were spaced out every 2 weeks. I think 1 week would not have been enough time for them [young adults] to really implement behaviors and it [intervention]*

ends up being like 3 months and so it was enough time that we could actually start to see changes in their behavior." Young adult participants, however, were divided in their opinions of the timing. Some enjoyed having biweekly sessions as it offered sufficient time to implement weekly PA changes, reflect on progress, and adjust. Others, who initially said the overall timing was acceptable, then proposed either to have: (1) *gradually decreasing timing* (i.e., less time between sessions in the beginning [e.g., weekly] and more time at the end to gradually promote autonomy); or (2) *equally spaced sessions with more time* between each session to accommodate busy schedules and responsibilities. YA40 explained: *"I think ideally, I would have liked the 2 weeks [between sessions], but then I would like a couple more sessions where it goes to kind of like 3 weeks [between sessions]. And then after that 3 weeks, it is going to be 1 month [between sessions] to have a kind of a gradual end of the intervention,"* whereas YA33 shared: *"I found I had to schedule them in after my workday and then it took up a lot of time and then I felt like I had a lot to do."*

Theme 3: delivery agents

Young adult participants were very satisfied with PA counselors. They viewed their PA counselor as a critically important element of the intervention. The reasons were connected to the PA counselors': (1) knowledge and expertise; and (2) counseling skills. Regarding the former, young adult participants considered that their PA counselors had a high degree of knowledge and expertise because they could readily provide informational support, reorient them to PA that suited their needs, goals, strengths, and capacities, help them surmount anticipated and encountered barriers, enhance their PA goals and plans, and share appropriate resources. Regarding their counseling skills, young adult participants highlighted the non-judgmental, supportive listening skills, encouraging demeanor, level of interest, acceptance, and emotional support that their PA counselors offered. They believed their PA counselor was highly committed to them because of how their PA counselor interacted with them during the sessions, which boosted their motivation. YA75 explained: *"I really appreciated that collaborative intervention and the way she [PA counselor] approached it. It made me really get into it and want to participate and learn how do it [manage my PA behavior] by myself."* Notably, PA counselors and young adult participants enjoyed the professional relations they had developed during the intervention. PA counselors considered their training around motivational interviewing to have helped them to develop the necessary counseling skills.

Nevertheless, young adult participants had concerns about losing access to a motivated and committed PA counselor after the intervention. Consequently, recognizing the importance of social support for PA throughout the intervention, some young adult participants proposed developing and offering an online forum (e.g., peer-support group) for young adults involved in the intervention to promote peer support. They explained that connecting with peers could help them find a “*partner*” to support them in-between sessions and/or after the intervention. They also said that this could help them reach goals together and, in turn, strengthen their motivation to maintain PA behavior.

Theme 4: perceived inconveniences of trial methods

Randomization Young adult participants understood the main principle of the randomized design and thought it was acceptable, but many strongly preferred to be allocated to the intervention arm. Consequently, those allocated to the preferred intervention arm were appreciative, whereas those allocated to the control arm expressed some disappointment. YA38 shared: “*I was a little disappointed. I would have loved to have been in the other group. I think the PA counselor would have been awesome with the materials right away, but I am happy to be included in the study nonetheless.*” Notably, a young adult participant allocated to the intervention arm said that they initially wished they could have chosen the control arm because they perceived social pressure to make changes from individuals in their environment; however, they said they were happy that they were allocated to the intervention arm after they completed it.

Electronic surveys Overall, young adult participants appreciated the platform used for completing questionnaires online, i.e., SurveyMonkey. They described it as user-friendly and indicated that trial staffs’ directions to access surveys were clear and appropriate. The ease of access and convenience of online surveys also motivated them to complete the surveys. The ability to answer at a convenient time, take as much time as needed to respond, and complete surveys in multiple sessions were benefits young adult participants associated with the use of technology. Some young adult participants communicated that the length of surveys was acceptable. YA17 shared: “*It doesn’t take very long. I’m happy to do it three times. I forgot that I was going to do it a third time until you just said it, but it doesn’t take very long to do. I don’t mind doing it.*” Yet, others said “*shortening*” surveys should be considered to reduce response fatigue. Additionally, young adult participants had mixed views about the frequency of surveys; some considered baseline,

post-intervention, and follow-up surveys acceptable and necessary to measure change, whereas others thought this was too frequent.

In terms of survey content, young adult participants indicated that some questions were “*irrelevant*” (e.g., relating to immediate effects of cancer diagnosis and treatment) or “*repetitive*,” though they did not refer to a particular questionnaire. They said the absence of response options reflecting neutral/neither or non-applicable was a problem at times and linked this to item non-response. To reduce responder burden and enhance the relevance of survey questions and responses, young adult participants advised to: (1) reduce surveys on the basis of content validity and relevance to young adults; (2) include questions deemed important to young adults (i.e., sleep, PA enjoyment, self-control); (3) minimize redundant items to produce concise surveys; (4) provide anticipated minimum/maximum time required for answering surveys along with average completion time; and (5) offer more response options (e.g., not applicable, prefer not to answer).

Accelerometers Young adult participants generally had negative opinions about the design esthetics and utility of the GTX accelerometer. Despite being easy to put on and having a good battery life, young adult participants said it interfered with daily activities and was annoying to wear, primarily because of the placement site and bulkiness of the monitor. They felt that the monitor was “*too big*” and interfered with their regular watch. YA58 stated: “*It’s not cute. I dislike how large it was and I’m glad it was winter so I could put it in my sleeve.*” Other issues raised with the monitor were that it: (1) caught on clothing/backpack; (2) was poorly manufactured (e.g., the tracker would fall out of the manufacturer-provided adjustable wristband); (3) was easy to forget to remove it at night (causing some data loss); and (4) had limited functionality (i.e., no feedback was provided). Thus, although young adult participants maintained that it is acceptable to wear a PA monitor during free living, acceptability would be enhanced by changing the monitor for one that: (1) is less obtrusive and lightweight; (2) might be worn elsewhere than on the wrist; (3) possibly provides (at least) daily activity feedback and have regular watch features; and (4) prompts sitting breaks (e.g., notifications, vibrations).

Additional insights from PA counselors

PA counselors discussed three challenges. The first relates to balancing support and challenge during sessions to help young adults achieve PA behavior changes. For example, while acknowledging efforts and achievements was seen as essential, PA counselors were sometimes

unsure if they should support young adults with praise and empathy or challenge them with accountability and honest feedback when they had not achieved their goal or their general goals were “too” achievable. The second challenge relates to difficulties planning sessions due to young adults’ busy schedules, sessions missed without notice, and sessions attended by distracted/unmotivated young adults; this not only threatened the proposed frequency and timing of sessions but made maintaining the quality of the relationship with young adults more difficult. The third challenge PA counselors highlighted relates to navigating the profound and long-lasting impact cancer had on young adults as some had lost their sense of identity, faced setbacks, felt overwhelmed, or struggled with emotions. As PAC1 shared, “*They would be frustrated or sad because they couldn’t get back to that identity or they wanted to be that identity still when they really sort of needed to create this new post-cancer identity of ‘still active, but in different ways and has some restrictions, for now.’*” Nevertheless, PAC1 went on to explain that “*it was the grieving of that old identity and then the creation and acceptance of a new identity*” that afforded young adults the ability to experience joy and fulfillment from PA.

Integrated mixed-methods results

As criteria used to evaluate metrics as “successful” were met for 9 of 11 feasibility outcomes (including 7/9 trial methods and 2/2 intervention outcomes), the quantitative results largely support the feasibility of a future full-scale trial. Attrition from baseline (T0) to follow-up (T2, secondary endpoint) was higher than expected, which contributed partly to the missing data rates. Analysis of qualitative data gathered from young adult participants and PA counselors helped to identify important considerations for researchers planning PA behavior change interventions and trials. Based on these data, the benefits young adult participants experienced as a result of the intervention, their general satisfaction with the intervention (format, dose, content), and the delivery agents (PA counselors) *positively* impacted the overall feasibility and acceptability of the ACCESS intervention and trial methods. In contrast, perceived inconveniences *negatively* impacted the acceptability of the trial methods. Importantly, practical recommendations were made to optimize the acceptability of the trial methods, such as more relevant/shorter/less frequent survey data collection and a more esthetic/functional accelerometer. Recommendations were also offered for potential intervention modifications/additions, including additional training for PA counselors on how to navigate cancer symptom discussions, flexible and adaptive approach to scheduling (increasing timing in-between sessions or fading

schedule), more accessible worksheets, booster sessions or follow-up contacts, and opportunities to connect with peers (e.g., online support group).

Discussion

Despite robust evidence that PA provides numerous benefits after cancer treatment [5, 13–17], many young adults continue to report low levels [1–3–4]. Developing, implementing, and evaluating interventions designed to promote PA behavior are critical. Full-scale trials comparing new interventions to promote PA against the current standard treatment require substantial resources and participant commitment. Prior to undertaking such trials, it is prudent to ensure that proposed interventions and trial methods are robust and likely to lead to a successful randomized controlled trial. The ACCESS trial was designed to replicate, on a smaller scale, the main elements of a full-scale, well-powered efficacy trial among young adults. The aim of this study was to use quantitative and qualitative methods concurrently to assess the feasibility and acceptability of the ACCESS intervention and trial methods within this young adult cohort, and to identify aspects that might need modification or flexibility in a full-scale trial. The quantitative results indicate high feasibility and acceptability of the trial methods and intervention, as 9 of 11 pre-specified targets were met. No issues were experienced with main elements of the trial design (e.g., recruitment, randomization procedures, ability to deliver the intervention as intended, intervention acceptability, adherence, online surveys, retention at primary endpoint [T1]) and no adverse events occurred, except for completeness of primary outcome data and retention at secondary endpoint (T2). Findings collectively provide essential information to inform the design, conduct, and implementation of a successful full-scale version of the ACCESS trial that aims to evaluate if the ACCESS intervention is efficacious.

Discussion of findings

Recruitment of young adults into RCTs is critical to provide the strongest evidence of the efficacy (or effectiveness) of interventions. The problem of insufficient recruitment, common in oncology [74–77], has adverse consequences (e.g., premature trial closure, invalid or inconclusive results due to a reduction in statistical power, increased risk of Type II error, prolonged trial duration, and wasted/increased financial and other resources) [78]. The current results show that young adults want to participate in research based on recruitment and enrollment feasibility outcomes. This likely reflects a need for interventions for PA in this cohort. However, pilot testing of multiple recruitment methods showed that certain methods may yield better

recruitment rates. Herein, the most effective recruitment strategy was a more personal and active approach in which registry registrants from The Ottawa Hospital who consented to be contacted for research for which they may be eligible were directly contacted by mail. While it introduced burdensome administrative processes and costs, and resulted in letters being sent to some non-eligible young adults (as a detailed review of records containing basic sociodemographic and clinical history could not be performed), it nonetheless established a channel of communication between researchers and prospective participants. Researchers have identified direct mailing as a practical and effective approach for recruiting young adults diagnosed with cancer into research studies [79–81], and data show that direct mailings produce higher recruitment yields [79, 80, 82]. The higher rates may be explained, in part, by young adults being pleased to be contacted for a PA trial and the personal approach providing a perception that *they* are wanted and will be helpful to the research team. Their motivation to participate could have also stemmed from a desire to contribute to research for the “common good” and a sense of altruism [83, 84]. These findings imply that maintaining a research registry of all potential study volunteers is imperative for identifying and recruiting the required number of young adults within the stipulated timeframe. In turn, it is recommended that trialists consider advertising PA trials through targeted hospital-based research registries to ensure success for full-scale studies in this cohort and, hopefully, be able to overcome one of the most significant challenges facing trialists in oncology. Nonetheless, practical implications will need to be considered. Targeted direct mailing incurs costs, and the use of registries for recruitment purposes poses challenges owing to concerns about administrative burden (e.g., manually checking medical records, time to prepare mailouts) and issues of security, privacy, and confidentiality. This means that trialists should formulate their budget accordingly and that strategies to address such concerns are needed (e.g., training to use registries safely and effectively, institutional structure, personnel support, and policy). Moreover, where no registries are in place, or pathways to accessing registries are limited for researchers external to institutions where registries operate, opportunities to address this should be explored as this will have implications for recruitment practices from these contexts and in turn the transferability of the trial results to these contexts.

In contrast, social media and community initiatives (e.g., posters) were used to recruit young adults into the trial; however, their potential was not fully realized. With most young adults using online social media extensively, it is a suitable method to help maximize recruitment.

It offers a widespread, fast, and cost-effective means of informing the public about trials, ultimately increasing accrual to trials [85, 86], especially among otherwise underrepresented groups. Social media platforms are commonly employed to recruit young adults [83, 87–89] and noted as the most cost-effective method per participant recruited alongside direct mailings [90]. Poor recruitment rates from the distribution of trial advertisements herein could be due to advertisements not reaching a large pool/limited visibility, insufficiently attractive presentation, impersonal approach, or prejudiced views of trials publicized on social media. Still, successful recruitment via these methods may be possible, though it is necessary to make changes to ensure effectiveness. First, as there are many social media platforms, identifying those most used by young adults is essential so they can be reached. In addition, considering changing online behaviors, optimizing the content, communication, and dissemination of trial information to young adults in a trustworthy manner is critical. Thus, involving young adults and designers in co-creating and distributing materials to inform young adults about PA trials on social media may improve recruitment via this method.

Additionally, oncology-focused healthcare provider referral was not effective. This finding may seem at odds with previous studies indicating that healthcare provider referral is generally an effective recruitment method for young adults after cancer treatment [82]. Indeed, healthcare providers play an essential role in promoting patient participation in clinical research in this cohort [91], likely because physicians and nurses are among the most trusted sources for health information [92], and those who receive information about clinical trials from their healthcare provider are significantly more likely to participate [93]. It is difficult to identify the factors that undermined the effectiveness of this recruitment method in the ACCESS trial, as no data were collected from providers involved with recruitment to understand their decision-making process. Nonetheless, based on prior reports of barriers to referral [94], reasons for the low rate of referral observed in this trial are likely multifactorial and may include lack of time, lack of PA knowledge and skills, competing clinical priorities, competing actively enrolling trials, inadequate knowledge about the trial, and concerns about negative patient reactions [95]. Research with healthcare providers actively caring for young adults is needed to review the recruitment process from the perspective of oncology-focused healthcare provider recruiters and co-develop strategies to mitigate barriers to recruitment. Regardless, minimization of healthcare provider burden is prudent when envisioning how to potentially retain healthcare provider-referral; thus, the introduction of a patient liaison or research staff

into oncology settings may be an essential prerequisite for, and facilitator of, potential healthcare provider-referral for young adults. Moreover, these findings indicate the need to ensure recruiters are committed to the trial and understand their role as a recruiter, closely monitor healthcare provider-referral rates during the implementation of future PA trials, and prioritize training and support for recruiters.

Last, whereas the post-intervention (T1; primary endpoint) dropout rate points to the need to send email reminders to encourage retention, there was a higher than anticipated dropout rate at follow-up (T2; secondary endpoint), with the intervention arm experiencing the greatest attrition. While young adults are at increased risk for persistent psychological distress after cancer treatment [96] and this could potentially have influenced attrition, we do not have data to determine if psychological distress was prevalent in this sample. Indeed, some young adult participants recommended that mood-related conditions be addressed in future iterations of the intervention. This said, as PA counselors cannot directly provide counseling for mood-related conditions, this does point to an important role they have in being aware of and prepared to direct young adults to services that may be able to address such needs. Another factor possibly contributing to the dropout based on the synthesis of quantitative and qualitative results is that the data collection procedures—which included several questionnaires and having to wear an accelerometer—might have been burdensome. There were clear challenges to assessing PA using the GTX Actigraph accelerometer. Though young adult participants were willing to wear a monitor, they expressed preferences for a different model and there were multiple instances of invalid or missing data. Various wearable PA monitors are commonly employed to assess PA in various oncology settings [31, 97], including in young adults living with and beyond cancer [31, 98, 99]; thus, those planning to access PA using a monitor should consider engaging young adults to select the device. Additionally, training and support for device wear should be a key priority, as well as shortening the survey to reduce the burden on young adults—particularly for follow-up assessments. Incentives could also be used to encourage retention.

Strengths and limitations

Notable strengths of this study include the following: (1) trial preregistration; (2) training of the PA counselors and creation of a training manual to support fidelity in intervention delivery; (3) the use of a manualized intervention with a high adherence rate; (4) biweekly team meetings to discuss trial progress, intervention

fidelity, and feasibility; (5) online delivery of the intervention and collection of trial data (survey and interview data) allowing for flexibility around young adult participants and PA counselors' availability; (5) inclusion of a follow-up assessment (i.e., 24 weeks post-baseline) to assess longer-term impacts of the intervention; (6) mixed-methods approach to gain deeper insight through the inclusion of qualitative interview data to support and explain numerical trends; and (7) development of an intervention based on a strong theoretical foundation of SDT.

The main limitations of the trial are the high proportion of missing or invalid data for the primary outcome and the young adult sample's representativeness, including the low enrollment of *younger* young adults, defined by Arnett [100] as adolescents (15–18 years; $n=0$) and emerging adults (19–25 years; $n=4$), suggesting that the results of this research may be most pertinent to those defined as young adults (26–39 years; $n=38$). The results of this study may have limited generalizability because the participants were predominantly female (sex)/women (gender), White/Caucasian, and highly educated. Also, only one-third of the sample reported a moderate or higher impairment in one or more body systems presented in the cumulative illness scale, and while we did not exclude any young adult because of a lack of access to, and computer literacy for, videoconferencing technology, we cannot rule out the possibility that young adults without such access or literacy did not contact trial staff. Last, it is unknown what impact, if any, the COVID-19 pandemic had on the trial.

Implications for research

Informed by SDT, the ACCESS intervention is theorized to work by promoting psychological needs satisfaction to increase young adults' autonomous motivation for PA; this can then contribute to their increased engagement in PA. While there was evidence that the intervention contributed to enhanced psychological needs satisfaction and PA levels from young adult participants' accounts (e.g., see *Experienced Benefits* theme), providing some indirect evidence that changes in targeted SDT constructs and PA behavior might be plausible; these analyses herein offer limited insight into the intervention-related processes and consequences. The next step is to draw on quantitative and qualitative data collected within the ACCESS trial to develop a rich description of the intervention-related processes and consequences to formulate hypotheses about how the intervention might generate outcomes.

Conclusions

In this pilot RCT, we aimed to establish the feasibility and acceptability of the ACCESS intervention and trial methods to young adults who had completed cancer treatment and the PA counselors delivering the novel SDT-informed PA behavior counseling intervention via videoconferencing technology. Overall, the quantitative and qualitative results broadly support the feasibility and acceptability of the ACCESS intervention and trial methods, with no safety concerns noted. However, these findings should be interpreted with caution, as the quantitative results indicate that 2 of the 11 pre-specified targets were not met. Full-scale trials for young adults would benefit from adopting the recommendations outlined in this manuscript to optimize feasibility and enhance the participant experience (e.g., change the device used to measure PA, bolster recruitment and retention strategies). As low PA levels are prevalent in young adults who have completed cancer treatment^{1–4}, it is important to continue advancing research in this area and determine the efficacy of the ACCESS intervention in this cohort. In doing so, it is important to monitor digital equity to ensure inclusivity in future trials, and offer access points (e.g., public libraries, community centers) and support to those lacking access and computer literacy, respectively.

Abbreviations

ACCESS	Physical Activity Counseling for young adult cancer SurvivorS
CI	Confidence interval
CONSORT	Consolidated Standards of Reporting Trials
IQR	Interquartile range
M	Mean
Mdn	Median
MVPA	Moderate-to-vigorous intensity physical activity
PA	Physical activity
RCT	Randomized controlled trial
SD	Standard deviation
SDT	Self-determination theory
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s40814-025-01701-w>.

Additional file 1.pdf – Amendments to the Published Protocol

Additional file 2.pdf – CONSORT 2010 Checklist.

Additional file 3.pdf – CONSORT EHEALTH (V 1.6.1).

Additional file 4.pdf – Missing Data Details.

Acknowledgements

The authors thank Dr. Julia Hussien who helped manage data gathered for the *physical Activity Counseling for young adult cancer SurvivorS* (ACCESS) trial, analyzed data reported in this manuscript, and provided helpful suggestions. The authors also thank all individuals who supported trial activities, Darien Wrona who assisted with the analysis of the qualitative data, the young adults and physical activity counselors for their participation and generous sharing of time and insights, and The Ottawa Hospital for granting access to its registry. This

trial was conducted while JP was supported by a Joseph-Armand Bombardier Canada Graduate Doctoral Scholarship. JB holds a Tier II Canada Research Chair in *Physical Activity Promotion for Cancer Prevention and Survivorship*.

Authors' contributions

JB (corresponding author, principal investigator) conceptualized and designed the *physical Activity Counseling for young adult cancer SurvivorS* (ACCESS) trial and this study, co-created the intervention, implemented the trial, and drafted the manuscript. As the lead investigator, she was involved in all aspects of the trial conduct, including data collection and analysis. She also integrated the quantitative and qualitative results and wrote the first draft of the present manuscript. JP co-created the intervention, helped implement the trial, collected, analyzed, and reported on the qualitative data analysis. She also critically reviewed the results and supplied comments on the first draft. FG and MS provided expertise in the intervention design. MT provided statistical expertise in the trial design. MB provided expertise in the assessment protocol. JR offered input on the trial conception and design. AS contributed to the accrual for the trial. All authors critically reviewed the manuscript and approved the final version. No professional writers were used.

Funding

A Strategic Research Support Grant provided by the Faculty of Health Sciences at the University of Ottawa to JB supported the implementation of the *physical Activity Counseling for young adult cancer SurvivorS* (ACCESS) trial.

Data availability

The data analyzed for the current study are not publicly available nor available upon request to protect the privacy of the participants. Young adult participants did not consent to have their data shared with persons outside the research team. Trial materials (i.e., informed consent form, interview guides, surveys) will be made available upon reasonable request to the corresponding author up to 5 years after article publication. Requests should be directed to jennifer.brunet@uottawa.ca.

Declarations

Ethics approval and consent to participate

Ethics approval for the *physical Activity Counseling for young adult cancer SurvivorS* (ACCESS) trial protocol was granted by the University of Ottawa's Office of Research Ethics and Integrity (file no., #H-12-19-5172; initial approval, December 12, 2020) and the Ottawa Health Science Network Research Ethics Board (file no., #20190643-01H; initial approval, January 24, 2021). Young adult participants gave informed consent to participate in the ACCESS trial digitally through a web-based form housed on SurveyMonkey, and PA counselors gave informed consent verbally.

Consent for publication

The consent forms contained information about publication of results from the trial in anonymous form, and all young adult participants and PA counselors gave their consent.

Competing interests

The authors declare no competing interests.

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Received: 7 February 2025 Accepted: 22 August 2025
Published online: 04 November 2025

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