Excellent multi-stakeholder acceptability and reimbursable costs in a pilot pragmatic trial of an evidence-based physical activity counseling intervention for patients with type 2 diabetes

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Abstract

Background: Physical activity (PA) improves important health outcomes for patients with type 2 diabetes mellitus (T2D), including physical function. We iteratively adapted the implementation strategies of pragmatic and evidence-based PA counseling programs to meet primary care stakeholders' needs, resulting in the "Be ACTIVE" program. In a pilot randomized pragmatic trial, we evaluated the feasibility, acceptability and effectiveness of Be ACTIVE.

Methods: Formative activities involved engaging multi-level stakeholders (patients, clinicians, coaches) to tailor implementation strategies for Be ACTIVE to the primary care context, while taking care to preserve the core "functions" of Be ACTIVE. Be ACTIVE included: a PA tracker (FitBit©), six theory-informed PA counseling phone calls, and three in-person clinician visits. Sedentary patients with T2D from two academic primary care clinics were randomized to Be ACTIVE vs. enhanced usual care. We used mixed methods to assess implementation outcomes of feasibility and acceptability among multi-level stakeholders, including costs. Objective effectiveness outcomes included PA (primary outcome, steps/week), physical function (secondary outcomes, including Short Physical Performance Battery (SPPB)), and behavioral PA predictors.

Results: Multi-level stakeholders were engaged in formative activities to design a feasible pragmatic intervention. Fifty patients were randomized to Be ACTIVE or enhanced usual care. Acceptability was >90% for patients and clinic staff. In-person visits were fully reimbursed, and counseling costs of ~$90/patient would be reimbursable by Medicare. Pre-post PA increased by ~11% absolute in the Be ACTIVE group and by ~6% in controls (group difference: 1574 ± 4391 steps/week, p = 0.72) — less than the clinically important threshold of 4200 steps/week. Be ACTIVE participants' physical function improved more than controls (SPPB: +0.9 ± 0.3 versus -0.1 ± 0.3, p = 0.01, changes >0.5 points are clinically important for preventing falls), and for PA predictors of self-efficacy (p=0.02) and social-environmental support (p<0.01).

Conclusions: In this pilot trial, Be ACTIVE was feasible and highly acceptable to stakeholders and yielded significant improvements in objective physical function consistent with lower fall risk, while changes in PA were less than anticipated. Be ACTIVE may need adaptation or longer duration to clinically improve PA outcomes. Further optimizing the implementation strategies for sustainability is also needed.

Contributions To The Literature

- We report results from a pragmatic 12-week physical activity coaching program, termed "Be ACTIVE", for patients with type 2 diabetes that was designed to deliver effective coaching in a way that is reimbursable and feasible for primary care teams.
- Patients who received Be ACTIVE lowered their risk of falls as compared to those who had no coaching.
- Be ACTIVE was delivered with fidelity and highly acceptable to the patients and clinic staff — patients particularly liked the focus on setting goals to do enjoyable activities, the accountability of wearing a physical activity monitor, and the support of their coach.

Background

Adults with type 2 diabetes (T2D) are typically sedentary — sedentary behavior is a major driver of premature mortality, physical disability, and decreased quality of life in this population (1–5). The 2018 national report, "Diabetes in America", showed that 40% of women and 25% of men with diabetes experience major physical disability that is a barrier to increasing physical activity (PA)(6). Conversely, regular PA improves physical function, quality of life, glycemic control, and cardiovascular risk (7–14). However, changing sedentary behavior has been difficult for patients with T2D outside a formal PA behavioral intervention (7, 15–17). Prior PA behavioral interventions delivered in health systems were often too time and resource-intensive to be practical for clinical practices (7). To move towards integrating PA interventions into clinical practice, we need evidence-based PA interventions that are simple enough to be feasible, replicable, and effective.

Our recent systematic review identified several PA counseling programs that were delivered in health systems, improved PA for adults with T2D, and were rated as highly pragmatic for real-world health system use, hereafter termed "pragmatic evidence-based programs (EBPs)" (7). Key elements of these pragmatic EBPs included the use of simple tools to operationalize effective behavioral counseling, such as a checklist, motivational interviewing approaches, and use of a coach/care manager to guide patients to set and monitor PA goals. Our review also found that even pragmatic and effective programs were rarely sustained after grant funding ceased, thus identifying a pressing need for implementation strategies addressing costs and financial reimbursement (7). So, the key question emerging from this review was: how can pragmatic PA EBPs be adapted to work in real-world primary care?

To address this question, we conducted a formative pre-implementation phase of engaging patients and clinic staff to help us optimize the implementation strategies of the pragmatic PA EBPs identified in our systematic review into an integrated package, termed the "Be ACTIVE"

program. We then conducted a pilot pragmatic trial to determine the implementation outcomes and pilot measures of effectiveness of delivering “Be ACTIVE”. Briefly, Be ACTIVE includes: 1) phone PA counseling by non-clinician staff using brief motivational interviewing (18, 19); 2) a checklist to ensure counseling addresses key behavior change techniques (20); and 3) safety monitoring through in-person clinic visits and counseling phone calls (Fig. 1). Our overarching hypothesis was that Be ACTIVE would be highly feasible and acceptable to clinic and patient stakeholders, and would yield clinically important improvements in PA and physical function. The primary implementation outcomes were feasibility and acceptability to patient and clinic staff stakeholders, and secondary implementation outcomes were Reach, Implementation, and Maintenance (RE-AIM framework), including cost/reimbursement potential and fidelity of program delivery (21, 22). The primary effectiveness outcome was PA (steps/day and combined moderate-vigorous exercise) and secondary outcomes included physical function measures that predict fall risk and incident disability (23–25).

Methods

Design

The study design was a pre-implementation planning phase followed by a pilot hybrid type 2 effectiveness-implementation trial (26). This approach was important, as our pre-implementation phase identified a range of implementation and effectiveness outcomes that were important to our clinic and patient stakeholders, including implementation costs and physical function. We included a convergent mixed methods (27) approach to assess implementation outcomes with patient and clinic stakeholders qualitatively and quantitatively. We used 1:1 patient-level, parallel randomization of participants to Be ACTIVE vs. enhanced usual care (instead of cluster randomization) to enhance statistical power and because contamination of the intervention was not an issue.

Population

Pragmatic eligibility criteria for participants were intentionally developed to include the bulk of the U.S. population with T2D who are presently sedentary and could safely participate. These criteria included: diagnosis of T2D, age 50–85 years, performing < 3 days/week of moderate intensity exercise for at least 20 minutes (28), and the absence of conditions that would greatly limit the safety or effectiveness of the intervention (e.g., < 6-month life expectancy, moderate-to-high risk of fall (29), severely uncontrolled hypertension/blood glucose levels, or a clinical diagnosis of dementia). Potential patients were identified from the electronic health record by the presence of a diagnosis code for type 2 diabetes mellitus, and the absence of other exclusion criteria. Research assistants contacted primary care providers to confirm eligibility, and subsequently contacted patients by mail and phone to screen for interested participants who met our sedentary behavior criterion. Participants were consented between December 2015 - January 2019. All research processes were reviewed and approved by the Colorado Multiple Institutional Review Board.

As this was a pilot trial that required objective tests of function and fitness, we recruited from clinics in close proximity to the facility where these tests could be conducted — these included two moderately large academic primary care clinics (n = 15,000 patients total; ~1500 patients with T2D). These clinics serve a racially and ethnically diverse population of patients, and had no pre-existing programs of PA counseling. Participating clinics were National Committee for Quality Assurance-certified patient-centered medical homes (30) and had a pool of existing staff members to serve as coaches who had no direct patient care responsibilities, but instead conducted outreach calls to patients with unmet clinical goals.

Intervention

Enhanced usual care

The enhanced usual care intervention consisted of a series of printed educational materials, including the current U.S. physical activity guidelines at the time of study enrollment (31), and 3 monthly mailings on diet and other diabetes self-education topics.

Development of Be ACTIVE Intervention content in a Pre-Implementation phase

The pre-implementation phase required key patient, clinician, clinic leader, and coach stakeholder input. This process was informed by our recent systematic review (7) that identified four pragmatic EBPs that significantly increased PA (32), and were also rated as highly pragmatic by the Pragmatic Explanatory Continuum Summary (PRECIS-2) (33). The recent Patient Centered Outcomes Research Center (PCORI) guidance for complex behavioral interventions highlights the need for core components of a program to outline their key functions(34, 35). The key functions of the pragmatic EBPs we identified in our review were: 1) a checklist of PA behavioral counseling techniques to simplify the counseling approach for staff; 2) training in the use of brief motivational interviewing counseling approaches (training function); 3) repeated counseling encounters with patients to set and monitor PA goals that are enjoyable (patient-centered

counseling function: use of motivational interviewing and accountable tracking of patient progress towards appropriate PA goals); and 4) initial and subsequent monitoring for safety in this diseased population at-risk for injury with exercise (safe counseling function).

In a pre-implementation phase, we then engaged primary care clinicians, staff, and patients to iteratively guide the selection of implementation strategies that would deliver our key functions in a way that would meet clinic workflows and patient needs (36, 37). Initial stakeholder input identified key factors to address to make implementation strategies feasible (38) — selecting a clinic staff coach who has dedicated time to do patient outreach; provision of formal training for staff coaches in motivational interviewing for PA counseling; supporting coaches by embedding the counseling scripts in the electronic health record for ease of reference and documentation; and a resource binder for patients to track their PA. To maximize sustainability and dissemination, we also sought to identify approaches that would be sustainable and low-cost for delivery in primary care, as our review had identified this as a key gap. Clinic stakeholders identified a potential reimbursement approach of the Medicare Chronic Care Management billing code for care between clinic visits (39, 40). At the time of this intervention, this required charging a specific billing code (CPT 99490) for delivering ≥ 20 minutes per month of counseling/care management — this code was reimbursed by Medicare as 0.61 work relative value units, or $32.66/month in 2017 dollars for our region (39, 40). Of note, this billing code requires patients to have at least one other chronic disease other than diabetes, but > 95% of patients with T2D meet that criterion.

After beta-testing this Be ACTIVE delivery strategy with 5 patients with T2D, and debriefing with clinic staff, we learned we needed to share objective PA data with coaches to simplify their data review, so we added a PA tracker (FitBit©) and modeled the integration of FitBit© data with the electronic health record. Also, patients and coaches requested more specific information about motivations and methods to increase PA, so we added a “theme” to each coaching call (Fig. 1) from an evidence-based lifestyle PA program (41, 42). To pragmatically address participants’ functional limitations related to activity, we added simple multi-muscle resistance exercises recommended by the National Institute of Aging (14, 43). To capture key program costs of time, we added a field to the counseling script to capture the time spent with the patient by each coach and clinician. Ultimately, the stakeholder input in the pre-implementation phase guided the selection of several implementation strategies (38) and influenced the “form” of the Be ACTIVE intervention content and implementation strategies studied in this pilot trial to be more pragmatic, while preserving the “function” of the pragmatic EBPs that are its foundation (Fig. 1).

Outcome measures

Implementation outcomes and mixed methods analytic plan

We evaluated implementation outcomes with a convergent mixed methods approach (44) for the primary implementation outcomes of acceptability and feasibility (45) and secondary outcomes from the RE-AIM model that are related to acceptability and feasibility, including program costs. We sought to assess these outcomes among key stakeholders who completed the intervention: patients, Be ACTIVE coaches, and the clinicians who conducted the safety-focused in-person visits. In terms of qualitative data, we used semi-structured interviews to inform the acceptability of Be ACTIVE, and the areas where the program’s feasibility and acceptability were sub-optimal and could be further improved. We also qualitatively assessed key RE-AIM factors related to feasibility and acceptability: Reach (why patients chose to participate); Implementation (challenges with fidelity to program delivery and needs for adaptation related to factors such as delivery time and costs); and Maintenance (reasons why staff and patients recommend continuing/not continuing Be ACTIVE). To minimize response bias, patient interviews were conducted by a research staff member (KC) who did not deliver the intervention, and staff interviews were conducted by an independent qualitatively trained analyst (SL). Interview audio files were transcribed verbatim.

Our qualitative data analysis approach for these implementation outcomes used an iterative and team-based process guided by qualitative content analysis (46). A qualitatively trained analyst (SL) and the principal investigator (AGH) both inductively and deductively developed the codebook. Initial codes were based on themes related to Feasibility, Acceptability, interview guide domains, and the codebook was expanded based on codes emerging from the data. We used ATLAS.ti version 8 for data management. Transcripts were jointly reviewed and coded until reaching thematic saturation (i.e., no new codes identified) and strong code assignment agreement. Twenty percent of transcripts were independently read, double coded, and then merged prior to analysis. Overall, there was strong code assignment agreement among coders, and the few discrepancies in coding that emerged were resolved through discussion to consensus. Throughout the process, the analyst, principal investigator, and qualitative methodologist met regularly to check new findings, discuss emergent codes and themes, and assess the preliminary and final results.

For quantitative implementation outcome assessments, Feasibility included time spent on each counseling call, and the implementation costs per patient counseling call. We considered costs from the perspective of the clinic leader who would decide to adopt Be ACTIVE for a clinic (i.e., intra-organizational health system perspective)(47), and used a time-based activity micro-costing approach (48). Specifically, we aggregated the counseling time required across all participant coaching visits, and translated the time required to deliver a single coaching

session into costs as a pro-rated portion of each counselor's salary and benefits. Feasibility measures also included the percentage of counseling visits with fidelity to the counseling protocol based on chart review by an unblinded research assistant. Blinding to intervention group was impossible because no control participants had counseling notes — to minimize bias, fidelity was assessed by a research staff member who did not deliver the intervention. We measured the time for clinician safety visits, in order to assess whether visits exceeded their allotted time, as per the clinic leader adopter perspective. In keeping with the level of cost analysis recommended for pilot implementation studies(47), we did not estimate this clinician time in dollars, as these visits were fully reimbursed by insurance. Acceptability was assessed quantitatively as the percentage of patients who would recommend this study to a friend or family member, and the percent of staff who recommended the clinic continue to offer Be ACTIVE (i.e., Maintenance). Finally, we calculated Reach as another quantitative measure of acceptability (percent of individuals enrolled divided by the number of eligible participants).

Mixed Methods Analysis

To draw inferences from the qualitative and quantitative data on implementation outcomes, we integrated the quantitative data for feasibility and acceptability (including the RE-AIM constructs of Reach, Implementation, and Maintenance described above) with the qualitative themes, codes, and representative quotations from interviews with patients and clinic staff.

Effectiveness outcomes

All primary and secondary effectiveness outcomes were measured at baseline and immediately after the 12-week intervention. The primary outcome of objective PA was measured by the Actigraph GT3X + accelerometer (Actigraph, LLC, Pensacola, FL); analysis included ≥ 3 valid days of wear time ≥ 10 hours/day (as per standard methods); the use of linear mixed effects models allowed measurement of PA across all valid days to provide a weekly estimate of PA levels (49, 50). We considered steps/day and minutes of combined moderate-vigorous intensity exercise as the co-primary measures of PA, based on the clinical relevance of each of these PA domains to cardiovascular risk, insulin resistance/hyperglycemia, and physical function (51–54).

The secondary outcomes of physical function were selected to be clinically relevant to risk of mortality and disability/falls, and sensitive to change (23, 24, 55, 56). We included the Short Physical Performance Battery (SPPB, range of 0–12 where 12 is better function) that is sensitive to change for individuals with at least mild-to-severe baseline functional disability/frailty and the timed 400-meter walk assessment that is sensitive to change for individuals with either normal baseline physical function or mild-to-moderate impairment (23, 24, 55, 56). We also included leg extension power as a measure sensitive to change across patients with or without functional impairment (14, 57, 58). We assessed SPPB according to standard procedures, including the timed 4-meter walk, timed repetitive chair rise, and ability to stand for > 10 seconds with a tandem and semi-tandem stance (23). The standard timed walk procedure was conducted in a long corridor with a 20-meter path for patients to walk back and forth for 400 meters at maximal tolerated speed (59). The leg extension was conducted with a total of 10 trials for each leg on the Power Rig (57) and the best trial with either leg was reported. Post-intervention function assessments were not masked to intervention group for patients (who knew their intervention group assignment), or for research staff due to limited pilot funds — this lack of masking was partly mitigated by the use of objective data obtained directly from accelerometers (primary outcome), or from a stopwatch or Power Rig device (secondary outcomes).

Additional outcome measures included: glycemic control measured as Hemoglobin A1c (60), grip strength by hand-held dynamometer, cardiorespiratory fitness measured by modified Balke protocol (61) on a treadmill and MGC Diagnostics© metabolic cart (peak oxygen capacity, VO_2peak) – and Anaerobic Threshold (AT) as a measure of whether the intervention affected the threshold of sustainable exercise intensity, as measured by V-slope technique during VO2peak testing (61). VO_2peak tests were terminated for participant exhaustion or joint pain that limited endurance.

To better understand the potential mechanisms of Be ACTIVE, we also assessed behavioral predictors of improvements in PA and physical function outcomes. These included validated self-report measures of perceived social-environmental support for PA (62), self-efficacy for walking for incrementally longer durations without stopping (e.g., 5 minutes, 10 minutes, etc.) (63), self-efficacy to regularly make time for PA (64), and self-efficacy in persisting to be active despite chronic disease (65). We also measured depressive symptoms (Center for Epidemiologic Studies Depression scale, CESD (66)), cognitive function (behavioral dyscontrol scale (67)), and arthritis pain symptoms (68) according to the Western Ontario and McMaster Universities Arthritis Index (WOMAC), including separate subscales for pain (0–20, where higher numbers indicate greater pain), stiffness subscale (0–8), and physical function subscale (0–64).

There were no changes in the outcome assessment techniques or timing after the initiation of the research study testing procedures. In discussion with our exercise physiology study team member (JSL), after publishing the protocol on clinicaltrials.gov but before initiating testing procedures, we added leg extension power as a secondary functional outcome and eliminated grip strength as a secondary functional outcome, as leg power is typically more sensitive to change than grip strength (14, 57, 58).

Based on the effect size of prior PA counseling interventions (12), a fully-powered trial would need to complete n = 300 participants to demonstrate statistical significance for our primary outcome. Given the pilot feasibility nature of this trial, we aimed to enroll 50 participants to ensure stable effect size and an estimate of the clinical importance of observed changes in outcomes, and a relatively diverse population of participants. In lieu of interim safety analyses, we conducted annual evaluations of adverse events across the intervention/control group with a safety officer. No major adverse events occurred in either intervention group.

Parallel randomization of individuals was accomplished through a block-stratified randomization sequence to support balanced composition of age and sex. To maintain blinding to intervention allocation for all staff performing baseline assessments, the randomization key was kept in a secure drive by a staff member who did not participate in study visits, and who e-mailed the randomization code to the research staff member just prior to the randomization visit.

We used an intention to treat approach to analyze all baseline and post-intervention data from consented participants. Statistical analysis of all primary and secondary outcomes was carried out using linear mixed effects modeling to account for correlation within patients (69), allowing us to use all available data from each participant. Models for daily PA data only used data from "valid" days with ≥ 10 hours of accelerometer wear — these models contained a random intercept for subject and a random slope for visit, where possible; in the event of nonconvergence, model complexity was reduced by excluding the random slope term. Models for outcomes with only one measurement pre and post included only a random intercept for subject. Models contained fixed effect terms for visit (pre or post), treatment group (control or Be ACTIVE), and their interaction. The coefficient estimated for the interaction term represents the difference between treatment arms in mean change in outcome from pre to post, so hypothesis testing for the existence of a treatment effect is based on this coefficient. R statistical software was used to conduct all analyses (70, 71).

Results

We identified 259 participants who were approved to participate by their PCP and appeared sedentary/eligible by phone screening (Fig. 2). Among these, 204 declined to participate, and 55 patients consented, of whom 5 were subsequently deemed ineligible and were not included in the analysis (Reach = 50/254 = 20%). Demographics and baseline measures of the proposed outcome measures and key covariates were not significantly different between participants randomized to the intervention and control conditions (Table 1). Among the n = 50 who were enrolled, 47 completed the 12-week intervention (3 dropped out in the Be ACTIVE and 0 in the control condition).

The mixed methods evaluation results for Acceptability and Feasibility are shown in Tables 2 and 3, respectively. These tables display quantitative data on the left and qualitative themes and illustrative quotes related to these quantitative data on the right. Among intervention patients, Acceptability was 92%. Patients who found Be ACTIVE acceptable praised the program's deepening of their personal motivations to be active, liked setting PA goals that were personally meaningful, and appreciated meeting these goals without a formal "workout". They also found it important that the program kept them "accountable" through regular calls to review objective PA tracker data with coaches. Additional qualitative themes highlight the major perceived benefits of improved function and improved health. Among the 8% of participants who did not find Be ACTIVE acceptable, a major complaint was that the intervention activities were insufficiently intense for their functional level — a more vigorous intensity training approach would have been preferable.

In terms of Acceptability to clinicians and coaches, 100% of coaches/clinicians recommended that the clinic continue to offer the Be ACTIVE program (Table 2). Coaches found that Be ACTIVE met their population health mission, and found these phone calls to be more engaging than the "cold calls" they made in their typical clinical duties. Clinicians found their role of screening patients for safe participation to be highly acceptable and fitting to their expertise (Table 3). An important piece of feedback from clinicians in terms of program burden was that patients identified as low-risk for hypoglycemia, falls/balance problems, and foot ulcers in their initial in-person physician visit had no new concerning safety issues uncovered in future in-person visits. Some patients also commented that the three separate in-person safety visits seemed unnecessary, while others voiced appreciation of the ongoing clinical supervision. Coaches felt comfortable with screening for safety concerns during counseling calls, and had plans in place to coordinate close clinic follow-up if a safety issue arose.

In terms of feasibility, average call times for coaches were ~ 25 minutes per call (Table 3). Based on the prorated salary/benefits for coaches expressed in 2017 dollars, that equated to costs of ~$90/patient for 6 coaching calls over 12 weeks. If these clinics had enrolled a participant with Medicare insurance in the Medicare Chronic Care Management program over 12 weeks in this same timeframe, they would have been able to bill for $97.98 over that 3-month period, of which $19.60 would have been derived from patient co-payments and the remainder from Medicare. Delivering the program with fidelity was also feasible: there was 88% fidelity for the PA goal-setting chart documentation for coaches and 96% fidelity for the safety monitoring chart documentation for clinicians across all participant visits. Even though all clinicians/coaches recommended continuing Be ACTIVE, they provided some key suggestions to improve program feasibility, including simplifying chart note documentation for staff, and co-locating the coaching staff in clinics to allow better coordination between

coaches and clinicians. To improve feasibility for participants, additional methods of technical support for challenges uploading PA data to the clinic were suggested, including a video guide.

Effectiveness outcome data

Pre-post PA increased (Fig. 3a), albeit not significantly, ~ 11% absolute in the Be ACTIVE group and by ~ 6% in controls (group difference: 1574 ± 4391 steps/week, p = 0.72), where clinically important changes in PA are 4200 steps/week for diseased populations and ~ 7000 steps/week for healthy sedentary populations (51, 72). Changes in moderate-to-vigorous intensity exercise levels were not significantly different between groups (group difference: -2.1 ± 17.0 minutes/week, p = 0.90). Across the five phone calls where participants had PA goals to review with their coach, intervention participants' PA tracker data demonstrated that the average progress towards their goal in each call ranged from 60–79% (p > 0.05 for trend over time). There were 40% missing data for PA outcomes due to lack of wearing the accelerometer for the 10 hours needed to constitute a valid day, but 95% of participant data sets still met the threshold for ≥ 3 valid days needed to be included in the analysis.

Physical function, as measured by both the SPPB and the 400-meter walk, demonstrated clinically important improvements in the Be ACTIVE group as compared to controls (Figs. 3b and 3c). Specifically, SPPB scores increased by a clinically important > 0.5-point difference (25, 73) in the Be ACTIVE group (+ 0.9, 95%CI: 0.1,1.8) and decreased slightly (-0.1, 95% CI: -0.6,0.4) in the control group (p = 0.01 for group difference over time). In addition, the group difference in change in average walking time to complete the 400-meter walk was > 30 seconds faster in the intervention group as compared to control group (intervention group: -23.4, 95% CI: -46.5, -0.3; control group: +7.3, 95% CI: -17.6,32.3; p = 0.08 for group differences), where a change of ≥ 20 seconds is clinically important (25, 73). There was no significant group difference in leg extension power (p = 0.8), cardiorespiratory fitness (p = 0.75), anaerobic threshold (p = 0.80).

Changes in behavioral and glycemic control outcomes are summarized in Table 4, and are pertinent for statistically significant improvements in the intervention group as compared to control group in self-efficacy to walk longer distances without stopping (p = 0.01), and in self-efficacy for PA in the presence of chronic disease (p = 0.04), but non-significant improvements in self-efficacy to complete 150 minutes of weekly PA consistently (p = 0.19). In addition, reported social-environmental support increased significantly in the Be ACTIVE group as compared to controls (p < 0.01). There were modest improvements in arthritis pain, stiffness, and functioning subscales, cognitive function, glycemic control, and depressive symptoms that were not statistically significant between study groups.

Discussion:

In this pilot pragmatic trial, both patients and clinic staff found Be ACTIVE highly acceptable (> 90%) and feasible. Our mixed methods analysis also showed clinic staff unanimously recommended continuing to offer Be ACTIVE, that the program costs were modest and could be reimbursed by Medicare insurance and/or patient co-payments, and showed that patients changed their mindset about PA as they identified ways to be active that were personally enjoyable. In this pilot study, we also observed clinically important and statistically significant improvements in an objective measure of physical function linked to lower all-cause mortality and lower risks of fall and loss of functional independence. We observed these findings in a clinic population with T2D that was relatively frail at baseline: over 60% of individuals had at least some objective functional impairment (i.e., SPPB < 12). In contrast, the difference in PA increases between Be ACTIVE participants and the control group was nonsignificant and did not meet the minimal clinically important level of 4200 steps/week for individuals with disease (72). We also observed statistically significant improvements in behavioral constructs that predict PA improvement, including self-efficacy and social-environmental support.

T2D has been identified as a model of premature aging where functional impairment occurs earlier than in other populations and progresses over time (74); thus, pragmatic treatments to prevent functional decline are necessary. Be ACTIVE shares many evidence-based components with other interventions that have repeatedly demonstrated improved physical function, such as the OTAGO intervention (75) that also promotes regular physical activity and multi-muscle exercises used in Be ACTIVE (e.g., sit-to-stand exercises). Participants' qualitative feedback highlighted other ways in which their functional improvements benefited them, ranging from "keeping up with grandchildren" to the ability to accomplish yardwork and other tasks that they valued — this suggests that future evaluations of Be ACTIVE should also assess quality of life.

A major question is why there are discrepant findings between PA and the physical function/behavioral PA predictor outcomes. Specifically, we found a smaller relative signal for the effectiveness of Be ACTIVE on objective PA outcomes, as compared to the stronger signal observed for effects on both objective physical function outcomes and reported PA self-efficacy, both of which are typically closely linked to PA behavior. One explanation is a need for greater intervention "dose" — based on coach documentation, the participants' progress towards meeting their personal PA goals was fairly steady over the course of the 12-week intervention (range: 60–79% progress towards goal met in

each call), showing moderate progress among most but not all participants. Given that many participants were highly sedentary and functionally impaired, it is possible that a longer PA coaching intervention would be required to significantly increase PA, and other studies found behavioral interventions > 12 weeks are more likely to effectively increase PA than shorter programs (7). However, an insufficient "dose" of intervention does not necessarily fully explain these findings, as this 12-week "dose" was sufficient to lead to clinically important improvements in physical function (Fig. 2) and to significantly increase self-efficacy to walk longer distances ($p = 0.01$). Also, physical function improvements are typically linked to improvements in PA, but that was not the case here. A measurement issue may also partly explain the smaller relative intervention effect of PA outcomes: the large amount of missing data for the PA outcome. We were missing data from 40% of days that participants had their accelerometer. Thus, although > 95% of participants still met the threshold of ≥ 3 valid days needed to include their data in the analysis, these missing PA data widened the standard deviation and thus constrained the measured effect size for technical reasons. Future work using 24-hour accelerometry measures may mitigate this technical PA measurement challenge.

There are remaining challenges to sustainably implement/disseminate Be ACTIVE. One major challenge is aligning funding sources to offset the costs of the program. The cost of PA coaching over 12 weeks (~$90) would have been fully supported by Medicare Chronic Disease Management program billing ($98 over 3 months), but billing Medicare for this code also requires patients to pay a 20% co-payment of these fees. Acceptability of a co-payment varied, with a median co-payment of $15 per call being reported acceptable, but some participants could not afford any co-payment. Other sources of reimbursement would also be necessary for patients who are not covered by Medicare insurance. Telehealth visits are one promising avenue that are becomingly increasingly common in primary care, and that could be covered by Medicare and other insurers. As this was a pilot feasibility study, we also did not account for other initial 'fixed' costs, including the purchase of PA trackers by clinics and the integration of PA tracking data with the electronic health record. The qualitative multi-stakeholder input suggests that among patients designated as low-risk in their initial safety monitoring visit, it is safe to conduct further safety monitoring during coach phone calls and to forego additional in-person safety monitoring visits — this would minimize time and burden to patients and better preserve clinic access to other patients.

This was a pilot trial with several attendant limitations. Our findings of improved physical function must be replicated with more sites before proceeding with larger dissemination trials. Participants were racially/ethnically diverse (> 50% non-white) and are similar to the many U.S. primary care clinics that are patient-centered medical homes (e.g., fee-for-service billing system), but they were located in an academic health system and have population health staff available. Individual patient-level randomization could produce diminished effect sizes if clinicians are contaminated to deliver some portion of the intervention to control patients; however, the clinicians in this study only provided safety monitoring rather than PA coaching, so this should not have altered our effect size. Although a pilot, this pragmatic study also has a number of strengths including the integrated mixed methods evaluation, designing for dissemination and sustainment, application of form vs. function concepts (ref), multi-level stakeholder engagement, use of PRECIS-2 and the Enhanced CONSORT figure for transparent planning and reporting, and inclusion of cost analyses.

Conclusions:

This mixed methods pragmatic evaluation found that Be ACTIVE has substantial potential, as it is a relatively low-cost intervention that appears to deliver clinically important benefits to improve physical function for patients with T2D that is highly acceptable to patients and clinic staff. However, it is not yet ready for broad adoption. Staff and patients have recommended areas to improve its feasibility, including better technical assistance for sharing PA data. The effectiveness and implementation outcomes of Be ACTIVE under alternate intervention staffing models for clinics that do not have dedicated population health staff needs to be assessed. Nevertheless, this study represents an advance in developing and testing a pragmatic integrated PA coaching program derived from existing evidence based and pragmatic PA interventions. It is worth further efforts to refine and test Be ACTIVE as sedentary patients with T2D will greatly benefit from PA coaching to combat typically premature declines in function.

List Of Abbreviations

CESD (Center for Epidemiologic Studies Depression scale); EBP, Evidence-based program; PA, Physical Activity; PCP, Primary Care Provider; SPPB, Short Physical Performance Battery; T2D, Type 2 Diabetes; WOMAC, Western Ontario and McMaster Universities Arthritis Index; PRECIS-2, Pragmatic Explanatory Continuum Summary; PCORI, Patient Outcomes Research Institute; RE-AIM, Reach, Effectiveness, Adoption, Implementation, and Maintenance

Declarations

- *Ethics approval and consent to participate*: this study was approved by the Colorado Multiple Institutional Review Board (COMIRB# 15-1080).
- *Consent for publication:* all listed authors provided consent for publication.
- *Availability of data and materials:* study data and materials are available upon reasonable request to the corresponding author.
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Tables

Figures

Table 1. Baseline demographics and selected descriptive covariates of sample			
Demographic variable	Enhanced usual care (n=22)	Intervention (n=28)	P-value*
Age, years (mean, SD)	66.5 (7.1)	65.2 (7.5)	0.52
Gender (n, % female)	13, 59.1	12, 46.2	0.55
Race			0.35
White/Caucasian (n, %)	12, 54.5	13, 50	
Black/African American (n, %)	4, 18.2	9 (34.6)	
Asian (n, %)	1 (4.5)	2 (7.7)	
Alaskan Native/Native American	0	1 (3.8)	
Ethnicity (% Hispanic)	4 (20.0)	2 (8.7)	0.39
Weight (kg)	92.0 (21.4) kg	90.7 (22.5) kg	0.84
Body Mass Index (kg/m^2)	32.8 (6.0)	31.7 (7.0)	0.57
Hemoglobin A1c (%)	6.7 (0.8)	7.0 (1.4)	0.35
Systolic blood pressure (mm/Hg)	125.6 (10.5)	127.5 (9.3)	0.53
Diastolic blood pressure (mm/Hg)	80.0 (8.1)	84.0 (8.9)	0.11
Depressive symptoms by CESD	10.2 (8.3)	10.4 (8.4)	0.92
Endurance Self-efficacy to walk without stopping (range: 0-1200)	584.1 (288.9)	713.8 (380.5)	0.19
Self-efficacy: Motivation to conduct physical activity amidst competing demands (0- 60)	43.8 (2.0)	41.2 (1.9)	0.33
Self-efficacy for physical activity in presence of diabetes (0 - 800)	587.3 (36.9)	588.5 (33.9)	0.98
% participants with baseline functional disability (SPPB< 12)	17 (77.3)	16 (61.5)	0.39
Baseline fitness level (VO2peak, ml/kg/min)	18.3 (4.2)	19.1 (4.7)	0.56
Abbreviations: CESD (Center for Epidemiologic Studies Depression scale); Data reported as mean (SD) for continuous variables, and n (%) for categorical values; Missing <5% data for each variable reported			

Table 2. Quantitative and qualitative stakeholder perspectives on the Acceptability of Be ACTIVE

Quantitative Acceptability Data		Qualitative themes and representative quotations
Reach	20% of eligible patients joined	-
Would Recommend program (Patients)	92% of patients would recommend Be ACTIVE to a friend or family member High retention rates: 88%	<u>Support and accountability provided by the coach was invaluable</u> *"The most important thing was when you have a real person, when you sluff off on your Fitbit it doesn't bark back at you. (Coach's name) didn't bark, but having that personal interaction it rendered more accountability". (D29)* *"(Coach) was asking specifically what I wanted to accomplish and how to accomplish that, so it made me stop and think about exactly what I was going to do. It kind of gave me something to motivate me and hold me accountable." (D34)* <u>Valued the PA tracker to provide an accountable measure of progress</u> *"Before the program I would not walk but now I have a meter and I motivate myself to get up and walk. I don't have to do it I want to do it." (D5)* <u>Appreciated that clinicians/coaches guided them to be active safely</u> *"It was helpful because it reminded you what you should and should not do to be safe and healthy in doing your exercises." (D70)* <u>Many perceived functional improvements and a "healthy aging" mindset as a benefit:</u> *"…it allows you to do a lot of other things… I sawed off an apple tree limb that had been hanging there for a while, as an example. I don't know if I could do it before." (D4)* *"I'm able to move around in the house more. My walks …make me feel good generally." (D2)* *"I found that activity helps as opposed to hurt you. Others are like 'I'm old - I can't do this.' Where I'm like, 'I'm old - I better get out of here and do it.'" (D48)* <u>Some perceived benefits of improved overall health/diabetes care:</u> *"[I am motivated to be active for] keeping blood sugar at a lower level - it used to jump when I did not walk and did not do any exercise, but I noticed the more I walked the lower my sugar levels would go down and they stayed down." (D2)* *"I got off a couple medications since the study started." (D7)*
Would Not Recommend program (Patients)	8% of patients	<u>Felt the program was missing more intense exercise training options relevant for them</u> *"For me, this program didn't have what I needed. I would have needed a physical therapist or a personal trainer. For people who really aren't doing anything at all, maybe this program would help them." (D6)*
Would Recommend program (Coaches and Clinicians)	100% (n=4 coaches, n=2 clinicians) would recommend the clinic continue to offer Be ACTIVE	<u>All coaches and clinicians felt that their role of counseling (coach) and safety monitoring (clinician) aligned well with their clinical expertise, and was professionally rewarding.</u> *"[For] people that have maybe less of a social network to have them achieve their goals… that once every two-week call (with me) is really, that's a big anchor for them. I think that is rewarding." (CO2)* *"We got to build rapport with the patients, we really got to know them. They appreciated our outreach…a lot of our other programs we (were) cold calling patients." (CO4)* *"It was all pretty relevant. Stretching, strengthening, step counting - all basics of getting up and moving. Doing it safely and knowing how to prevent an injury. That's all necessary." (CL1)* <u>Coaches found these 3 themes most beneficial about the program:</u> **Overcoming negative perceptions of what "counts" as PA:** "I had a patient who told me on the first call I hate working out, I don't want to do it. … (I said) you don't need to go to the gym because that's what she hated the most… taking your grandson on a walk, playing with him at the park… can increase your step count. So, in that way she started loving it, and her attitude from call 1 to call 6 was completely different." (CO1) "…just trying to broaden the definition of activity. A lot of them thought they had to be in a gym. and heavily sweating… (I would say) no, it can be like walking around the block with your dog …." (CO3) **Accountability:**

	"…they were happy to report when they did well and a little embarrassed, even though that wasn't from me, when they didn't …hit the goal for themselves." (CO4) **PA tracker "raises awareness of current PA levels:** "I think the [PA tracker] certainly helped motivate them because it quantified their physical activity levels to a point where they could see it. It wasn't just "oh I walked a little bit longer" they could actually see how much…further they walked. (CO2)

Abbreviations: PA, Physical Activity; participant coding designated parenthetically after quotes uses D* to designate quotes from a patient; CO* to designate quotes from a coach, and CL* to designate quotes from a clinician

Figure 1. Summary of the Be ACTIVE Intervention Content and Implementation Strategies tested

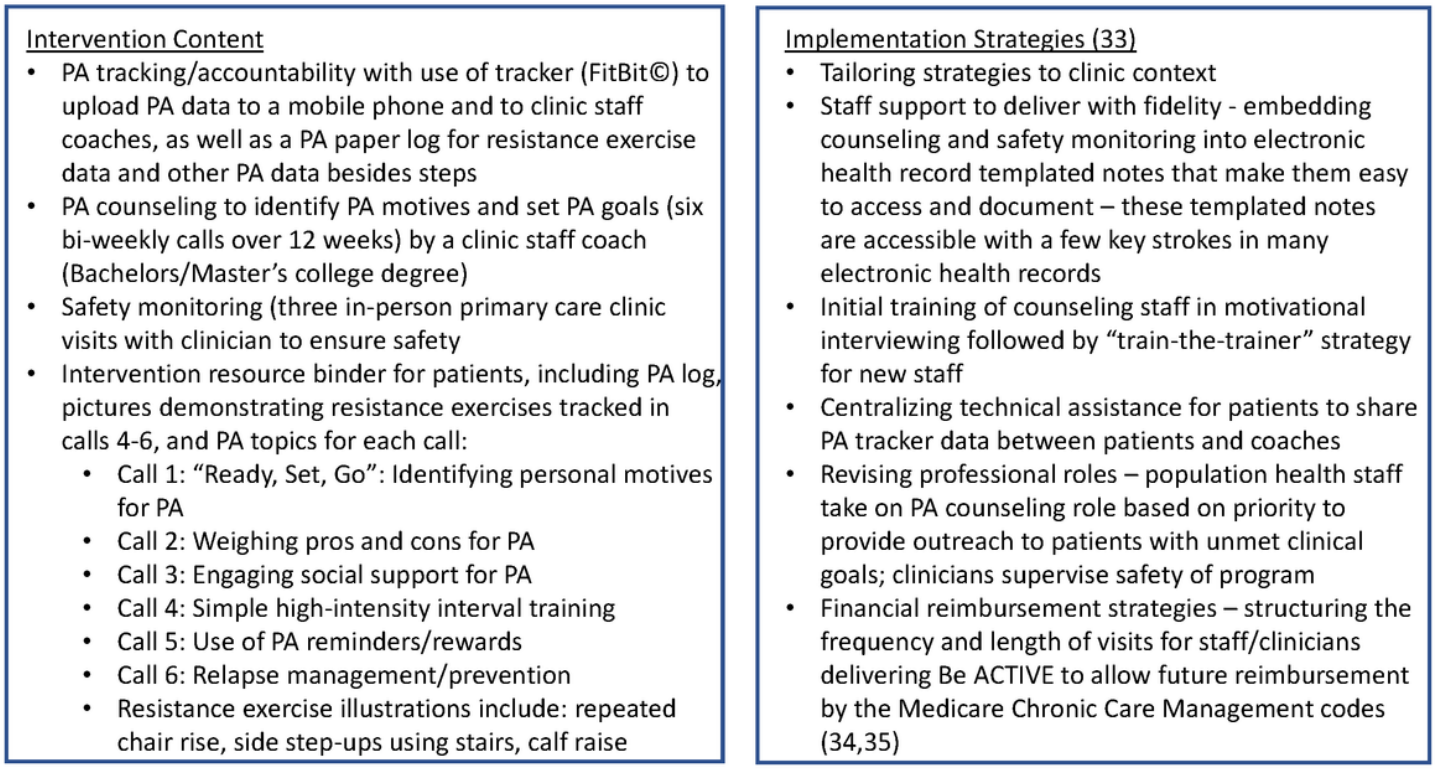

Figure 1

Summary of the Be ACTIVE Intervention Content and Implementation Strategies tested

Table 3. Quantitative and qualitative stakeholder perspectives on the Feasibility of Be ACTIVE, including Costs

Quantitative Feasibility data		Qualitative themes and representative quotations
Participant retention rate	92%	N/A
Participant rate of uploading PA tracker data†	94%	<u>Generally able to transmit PA data, but some had technical difficulties</u> *"I was excited about meeting my goals, so I checked it regularly." (D15)* *"Using the FitBit© was difficult for me... a video (guide) would be very helpful." (D41)*
Frequency of participants who used workbook regularly	50%	<u>Some found the workbook handouts and exercise tracking sheets useful</u> *"I did read all (the workbook handouts) and they were very helpful. I read them ahead of the next lesson… they were another thing to keep me on track..." (D39)* <u>Others found it redundant as compared to coach calls or forgot to use it.</u> *"I did not need to read anything in the binder because I knew what I needed to do. I saw the handouts as extra advice, but I did not need it." (D44)* *"That I did [have difficulty using tracking log in workbook]. Forgetting that I had to write it down. I'm always used to seeing (PA step data) on the phone and that was that - but I always forgot to write (strength exercises) down." (D07)*
Coach and clinician fidelity to protocol (based on chart review)	88% (Coach) 96% (Clinician)	<u>For charting, coaches found it time consuming to manually enter PA data – clinicians had no major issues but would like a separate chart note from the coach.</u> *"(if there was) a way that you could actually sync the FitBit© into a flowsheet in [the chart]. That would have been ideal…then you're not just copying over numbers" (CO3)* *"…it's (the same templated) phrase for the coaching call and for my visit… pages of stuff before I could do my portion which is much smaller…that was slightly annoying." (CL1)*
Major coach themes related to feasibility		<u>All coaches described frustration with the "warm transfer" from clinicians for the coaching calls due to clinician delays/long wait times</u> *"…it's just really hard to schedule your day when you're waiting on providers. Just inevitably the providers are always running late and but then sometimes they wouldn't. So…your schedule was basically open for two hours 'cause the provider might be on time and… transfer the call to you ten minutes after the visit (was supposed to begin)." (CO4)* <u>Motivational Interviewing (MI) training and "train-the-trainer" shadowing was very important</u> *"One of our colleagues did have a background in motivational interviewing – I did not have that background. So, the training was really key. And we also spent time …just listening to their (coaching calls), every call is going to go different… but just getting the understanding about how the whole flow works and everything like that. So, shadowing and the MI training was very beneficial." (CO2)*
Time costs of program **(Coaches and Clinicians)**	-Time per coaching session and clinician session: 24.9 ± 10.2 minutes and 21.2 ± 6.5 minutes, respectively	<u>Patients and coaches generally felt the length of coaching calls was appropriate</u> "Just right [length of call]. It was good." (D15) <u>Clinicians noted occasional problems with completing visits on-time when patients bringing up other health concerns</u> "Well, sometimes patients would bring up other things. Then you'd have to ask yourself, how important is this? Should it take priority over the study?" (CL1)
Financial Costs of program (Coaches)	- Cost per coaching session: $14.52 ± $5.95 – Potential Medicare reimbursement*: $32.66 (all costs in 2017 dollars)	<u>Patients valued the program according to their financial means, and reported an acceptable co-payment of $15.00 ± 22.95* (range: $2-100)</u> "I think it's important to be active and eat right, so I think $5-10/call would be reasonable." (D15) "I would have paid a co-pay to know someone was there for me." (D42)

Quantitative data presented as ranges and mean ± standard deviation except co-payment data presented as median ± standard deviation due to skewed distribution;†Rate of PA tracker uploads among the n=26 participants who used the PA tracker; n=2 participants were not included in the denominator as they selected PA goals not counted by PA tracker (e.g., swimming); * Medicare Chronic Disease Reimbursement CPT code 99490 reimbursed $32.66 per month in non-facility charges in 2017 for 20 minutes of counseling per month – this charge also includes a patient co-payment of $8.17 per month that may be covered by a patient's supplemental health insurance, if applicable.

Table 4. Pilot effects of Be ACTIVE program on factors related to physical activity behavior

	Enhanced Usual care			Intervention			
Outcome variable	Baseline (Mean, SD)	Post-intervention (Mean, SD)	Pre-post Difference (Mean, SD, 95% CI)	Baseline (Mean, SD)	Post-intervention (Mean, SD)	Pre-post Difference (Mean, SD, 95% CI)	P-value*
Social-environmental support	11.0 (1.3)	9.8 (1.1)	-1.3 (1.2)	6.8 (1.2)	11.3 (1.1)	4.5 (1.2)	<0.01
Endurance self-efficacy (0-1200)	584.1 (72.9)	523.9 (68.7)	-60.2 (63.6)	713.8 (67.0)	876.7 (66.8)	162.8 (62.4)	0.02
Self-efficacy to perform regular PA	43.8 (2.0)	40.4 (2.7)	-3.5 (2.2)	41.2 (1.9)	41.8 (2.6)	0.7 (2.2)	0.19
Self-efficacy for PA in chronic disease	587.3 (36.9)	540.4 (31.2)	-46.9 (32.9)	588.5 (33.9)	639.9 (31.0)	51.4 (32.5)	0.04
Hemoglobin A1c (%)	6.7 (0.2)	6.9 (0.2)	0.2 (0.1)	7.0 (0.2)	6.8 (0.2)	-0.1 (0.1)	0.14
Arthritis pain (WOMAC pain subscale, 0-20, higher is worse)	3.7 (0.8)	4.4 (1.0)	0.7 (0.9)	4.1 (0.7)	4.4 (0.9)	0.3 (0.8)	0.72
Arthritis joint stiffness (WOMAC joint stiffness subscale, 0-8)	2.3 (0.4)	2.6 (0.4)	0.3 (0.5)	2.6 (0.4)	2.2 (0.4)	-0.4 (0.4)	0.28
Arthritis physical function (WOMAC physical function subscale, 0-68)	12.8 (2.7)	14.0 (2.9)	1.2 (2.6)	12.3 (2.5)	10.5 (2.7)	-1.7 (2.4)	0.41
Depressive symptoms by CESD	10.2 (1.8)	11.9 (2.2)	1.7 (1.4)	10.4 (1.6)	11.5 (2.0)	1.1 (1.3)	0.77
Cognitive function	18.3 (0.9)	19.4 (0.7)	1.1 (0.6)	18.5 (0.8)	19.8 (0.7)	1.3 (0.6)	0.77

*Pre-post difference between Intervention and Enhanced Control group using intention-to-treat approach; Abbreviations: WOMAC, Western Ontario McMaster's Arthritis

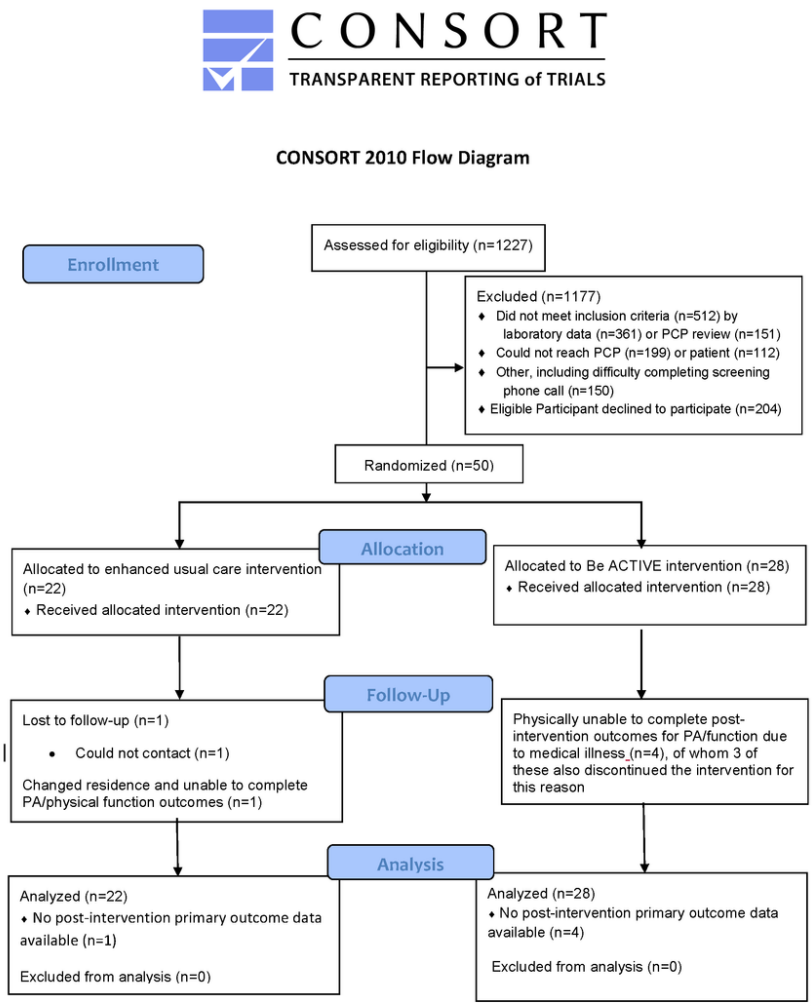

Figure 2

CONSORT diagram

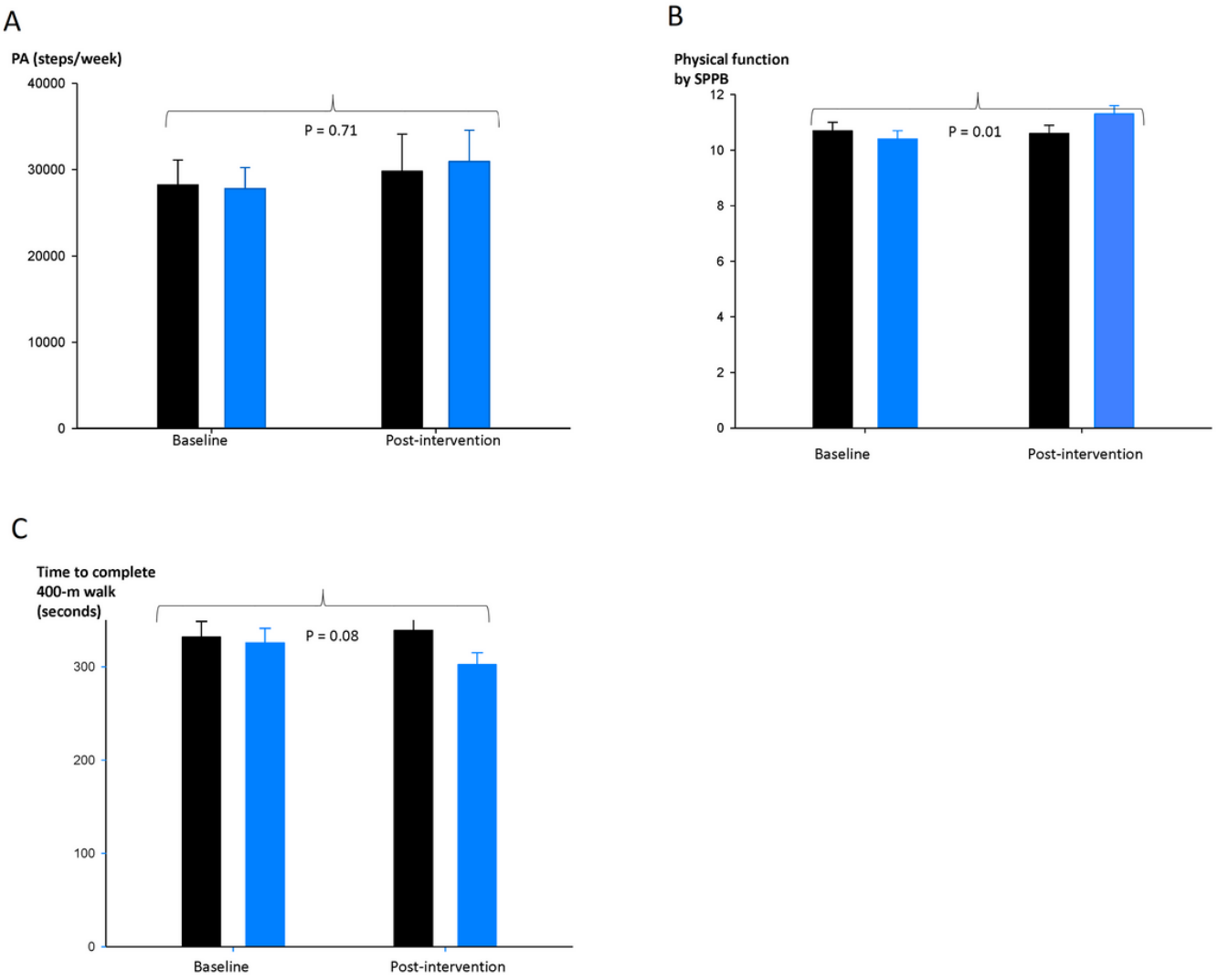

Figure 3

Be ACTIVE intervention increases Physical Function more than Physical Activity. Data shown compare group change over time between Be ACTIVE (Blue) vs. Enhanced Usual Care (Black) for outcomes of physical activity (Figure 3a), physical function by Short Physical Performance Battery (Figure 3b), and physical function by timed 400-meter walk (Figure 3c).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CONSORTextPilotTrialsChecklist152020.doc
- StaRIchecklist152020.docx