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Targeting physical health in schizophrenia: Results from the Physical Activity Can Enhance Life (PACE-Life) 24-week open trial

Julia Browne [a,b,c], Claudio Battaglini [d], L. Fredrik Jarskog [e], Paschal Sheeran [f], Ana M. Abrantes [g], Jessica McDermott [d], Tonya Elliott [e], Oscar Gonzalez [f], David L. Penn [f,h,*]

[a] Center of Excellence for Psychosocial and Systemic Research, Department of Psychiatry, Massachusetts General Hospital, Boston, MA, USA
[b] Harvard Medical School, Boston, MA, USA
[c] Geriatric Research, Education and Clinical Center, Durham VA Health Care System, Durham, NC, USA
[d] Department of Exercise and Sport Science, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA
[e] Department of Psychiatry, University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, NC, USA
[f] Department of Psychology and Neuroscience, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA
[g] Department of Psychiatry and Human Behavior, Brown University, Providence, RI, USA
[h] School of Behavioural and Health Sciences, Australian Catholic University, Melbourne, VIC, Australia

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ABSTRACT

Poor health and low cardiorespiratory fitness (CRF) contribute substantially to the shortened lifespan of individuals with schizophrenia spectrum disorders (SSDs). Increasing physical activity has demonstrated value; however, there are limited interventions that are accessible and adequately address motivational challenges. This paper reports on an open trial of Physical Activity Can Enhance Life (PACE-Life), a motivational theory-based manualized multicomponent walking intervention. The primary aim was to examine the feasibility of implementing PACE-Life through meeting the recruitment target (n = 14), attendance and adherence rates, and participant feedback. The secondary aim was to assess the impact of PACE-Life on intermediate targets (autonomous motivation and satisfaction of autonomy, relatedness, and competence needs), proximal outcomes (Fitbit steps/day and minutes spent walking), the primary outcome (CRF), and secondary outcomes (loneliness, symptoms, resting heart rate, blood pressure, weight, body mass index, and hip and waist circumference). Seventeen participants with SSDs enrolled in a 24-week open trial. Assessments occurred at baseline, mid-point, post-test, and one-month follow-up. The recruitment target was exceeded, the group attendance rate was 34%, Fitbit adherence rate was 54%, and participant feedback indicated satisfaction with the intervention as well as a positive group environment. There was a large improvement in the primary outcome of CRF with 77% of participants achieving clinically significant improvement at post-test. Small and medium effect size increases were observed in autonomous motivation and satisfaction of autonomy, relatedness, and competence needs. Fitbit data and secondary outcomes generally remained unchanged or worsened during the intervention. Results from this open trial indicate that PACE-Life leads to meaningful changes in CRF among people with SSDs.

1. Introduction

There continues to be a wide gap in life expectancy between those with schizophrenia spectrum disorders (SSDs) and the general population, which is largely due to physical health conditions that can be improved with lifestyle changes (Correll et al., 2017; Hjorthøj, Stürup, McGrath, & Nordentoft, 2017; Laursen, Munk-Olsen, & Vestergaard, 2012; Olfson, Gerhard, Huang, Crystal, & Stroup, 2015; Wildgust & Beary, 2010). Research has shown that increased exercise participation leads to improved mental and physical health outcomes, including cardiorespiratory fitness (CRF) in this population (Bartels et al., 2015; Daumit et al., 2013; Dauwan, Begemann, Heringa, & Sommer, 2016; Firth, Cotter, Elliott, French, & Yung, 2015; Rosenbaum, Tiedemann, Sherrington, Curtis, & Ward, 2014; Vogel et al., 2019). CRF, which is reduced in individuals with SSDs, is a critical health indicator given its relationship with cardiovascular and all-cause mortality (Kodama et al., 2009; Myers et al., 2002; Ozbulut et al., 2013; Stubbs et al., 2015; Stubbs, Williams, Gaughran, & Craig, 2016; Vancampfort et al., 2015;

* Corresponding author. Department of Psychology and Neuroscience, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA.
E-mail address: dpenn@ad.unc.edu (D.L. Penn).

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Vancampfort et al., 2017a; Vancampfort et al., 2015). Despite the capacity of exercise to promote improved CRF and health, many of the existing interventions for this population are unlikely to be widely disseminated due to cost and barriers to access (e.g., those that require gym access and/or delivery by a certified trainer).

In addition to issues with accessibility, motivation for initiation and long-term adoption of exercise remains a challenge in this population and should be targeted in interventions (Farholm & Sørensen, 2016; Firth et al., 2016). Self-determination Theory (SDT; Deci & Ryan, 2008; Ryan & Deci, 2000), a theory of motivation that has been applied to exercise interventions, emphasizes the importance of fulfilling the three basic psychological needs of autonomy, relatedness, and competence, which in turn, can promote autonomous motivation. Autonomous motivation for exercise (i.e., exercising for intrinsic rather than extrinsic reasons) is critical for initiation and maintenance of physical activity in the general population (Ng et al., 2012; Teixeira, Carraça, Markland, Silva, & Ryan, 2012) and in those with SSDs (Vancampfort et al., 2013; Vancampfort et al., 2015), which highlights its value as an important intervention target. Furthermore, implementation intentions (or "if-then plans") are a simple tool that can help individuals use their motivation and goals to make behavioral changes (Gollwitzer & Sheeran, 2006). If-then plans, which allow for identification of potential barriers and solutions for a given behavior (e.g., "if I feel too sad to exercise, then I will remind myself that my mood gets better with exercise"), have been shown to effectively increase levels of physical activity (Bélanger-Gravel, Godin, & Amireault, 2013; Brandstatter, Lengfelder, & Gollwitzer, 2001; Carraro & Gaudreau, 2013; Marquardt, Oettingen, Gollwitzer, Sheeran, & Liepert, 2017; Toli, Webb, & Hardy, 2016). As such, interventions that seek to impact autonomous motivation and incorporate implementation intentions have the potential to lead to increased and sustained exercise levels (Hagger et al., 2016; Koestner, Lekes, Powers, & Chicoine, 2002; Koestner, Otis, Powers, Pelletier, & Gagnon, 2008).

Walking interventions are not only compatible with SDT and implementation intentions but can also be delivered without the need for specialized equipment or significant staff training. Further, group walking provides opportunities for social interaction and support, which may be especially impactful for this population given the observed high levels of loneliness and social isolation (Bassilios, Judd, & Pattison, 2014; Gross, Vancampfort, Stubbs, Gorczynski, & Soundy, 2016; Johnstone, Nicol, Donaghy, & Lawrie, 2009; Leutwyler, Hubbard, Slater, & Jeste, 2014). Group walking can be enhanced by including activity trackers (e.g., pedometers, Fitbits), which are easy-to-use and helpful in promoting goal-setting and monitoring (Bravata et al., 2007; Browne, Penn, Battaglini, & Ludwig, 2016; Cobiac, Vos, & Barendregt, 2009; Soundy, Muhamed, Stubbs, Probst, & Vancampfort, 2014; Tudor-Locke & Lutes, 2009). Advanced devices that monitor heart rate also have the added benefit of providing an accessible method of tracking exercise intensity (i.e., how physically demanding the exercise is), which is valuable given the recommendations to engage in 150 min/week of *moderate-intensity* exercise (Haskell et al., 2007; Liguori & American College of Sports Medicine, 2020; Vancampfort et al., 2012).

Based on the accessibility of walking as a mode of exercise and the importance of targeting motivation to exercise, we developed Physical Activity Can Enhance Life (PACE-Life), a manualized multicomponent theory-based walking intervention for individuals with SSDs. The components of PACE-Life target the three basic psychological needs and autonomous motivation (intermediate targets) to facilitate increases in exercise behavior (proximal outcome) and ultimately, improved CRF (primary outcome) and psychological and biological measures (secondary outcomes; See Fig. 1).

The present study evaluated PACE-Life in a 24-week open trial. Given the pilot nature of the study, the primary aim was to examine the feasibility of implementing PACE-Life in a community mental health center setting. The secondary aim was to evaluate the impact of PACE-Life on (a) intermediate targets of autonomous motivation and the three basic psychological needs, (b) proximal outcomes of minutes spent walking and steps/day, (c) the primary outcome of CRF, and (d) secondary outcomes of loneliness, symptoms, resting heart rate, systolic/diastolic blood pressure, weight, body mass index (BMI), and hip and waist circumference during the intervention period (from baseline to mid-point and baseline to post-test) and at a one-month follow-up. We hypothesized that it would be feasible to implement PACE-Life in a community mental health center setting and that participants would experience improvements in all measures (intermediate targets, proximal outcomes, primary outcome, and secondary outcomes) during the intervention period and such improvements would be sustained through the follow-up timepoint.

2. Methods

2.1. Participants and setting

Participants were recruited from outpatient community mental health centers and were eligible if they: (1) had a DSM-V diagnosis of an SSD based on chart review, (2) were between the ages of 18–65, (3) had

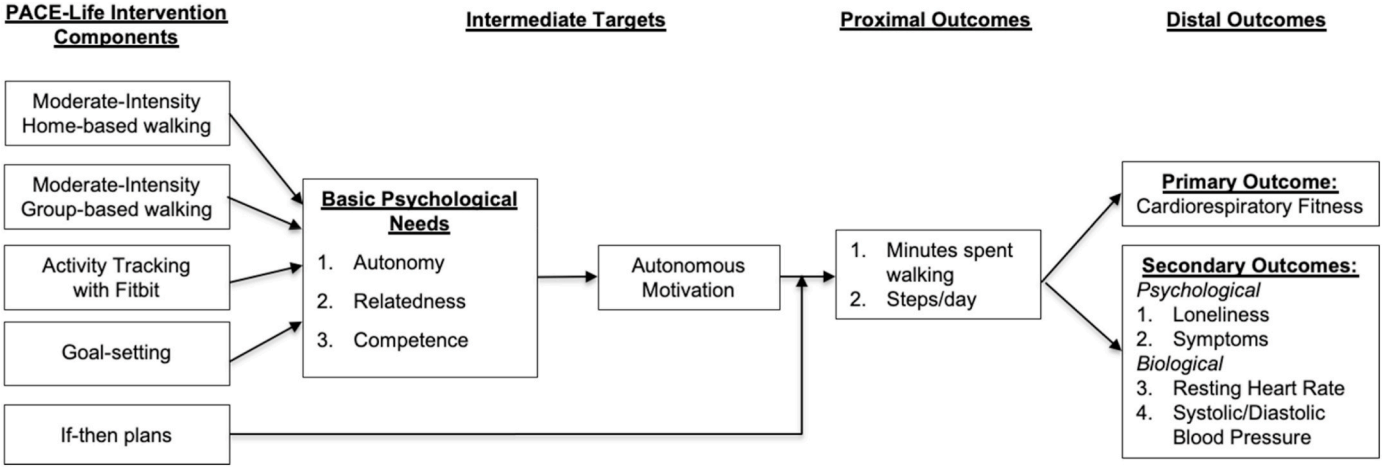

Fig. 1. PACE-life proposed model.
Figure caption. The figure above illustrates the proposed model for how PACE-Life engages the intermediate targets of basic needs (autonomy, relatedness, competence) and autonomous motivation to improve the proximal outcomes of physical activity (minutes spent walking and steps/day) to ultimately improve the primary and secondary outcomes. Only a subset of secondary outcomes is presented in this figure.

an IQ > 70 as measured by the Wechsler Abbreviated Scale of Intelligence (WASI; Wechsler, 1999), (4) had not been hospitalized for psychiatric reasons in the previous three months, (5) were clinically stable as defined by no psychiatric medication changes in the previous month, (6) were not already engaging in consistent moderate-intensity exercise (cutoff = 60 min/week for the past six months), (7) presented with no contra-indication to engage in regular moderate-intensity exercise based on completion of the Physical Activity Readiness Questionnaire (PAR-Q; American College of Sports Medicine & Pescatello, 2014) and a physical examination by the study physician with additional consultation with the treating primary care physician as needed, and (8) were willing and able to provide informed consent.

The study took place at two outpatient community mental health centers in [STATE] from December 2018 to September 2019. This study was approved by the [UNIVERSITY] Institutional Review Board and was registered on clinicaltrials.gov [NCT NUMBER].

2.2. Intervention

PACE-Life is a multicomponent theory-based walking intervention that targets the three basic psychological needs (autonomy, competence, relatedness) and autonomous motivation. The five intervention components are: (1) moderate-intensity group-based walking (targets relatedness need), (2) moderate-intensity home-based walking (targets autonomy need), (3) activity tracking with Fitbit devices (targets competence need), (4) goal-setting (targets competence need), and (5) if-then plans (targets the translation of autonomous motivation into action). Walking groups were held twice per week in the surrounding area of the community mental health center and led by graduate students from Psychology (n = 3) and Exercise and Sport Science (n = 2) departments as well as a masters-level community mental health clinician (n = 1). Undergraduate students from Psychology occasionally served as leaders if graduate student/clinician leaders were absent. Leaders provided recommendations for home-based walks (i.e., walks done independently by participants outside of groups) that slowly increased in number and intensity over the course of the 24 weeks to promote sustained exercise once the intervention ended (See Table 1). Intensity of exercise was monitored through heart rate (HR) and was increased in a stepwise manner over the course of the study to create a dose-response as an attempt to promote more pronounced physiological adaptations to participants. Specifically, individualized target HR zones were calculated using percentages of the heart rate reserve (HRR) through the Karvonen method (Díaz-Buschmann, Jaureguizar,), which takes into account age and resting HR. Target HR zones (minimum HR - maximum HR) were provided to participants each week on a notecard. Group leaders encouraged participants to check their HR consistently throughout group walks and modify their pace if they were not in the recommended range.

Once per week, goal-setting and if-then plans sessions were held after that day's walking group and were audiotaped. Participants set two types of goals: (1) how many steps/day they planned to walk during the upcoming week and (2) plans for completing home-based walks (e.g., how many, where/when they would complete them, and in what HR zone). Participants also identified their motivations and reasons for wanting to increase walking, identified potential barriers to achieving their goals, and identified solutions to those barriers. Barriers and solutions were recorded as if-then plans following the structure of "if (barrier), then (solution)." At the end of the session, all participants had set two goals, identified at least one reason for wanting to walk more regularly, and created an if-then plan. Group leaders checked in with participants during groups about their progress in reaching goals and assisted in modifying upcoming goals.

Table 1
PACE-life training schedule.

Weeks	# of Clinic-based (Group) Sessions	Duration of Group Sessions	# of Home-based Sessions	Duration of Home-based Sessions	Intensity
1–3	2	30 minutes	0	30 minutes	50–60% of HRR
4–6	2	30 minutes	0	30 minutes	50–65% of HRR
7–9	2	30 minutes	1	30 minutes	60–65% of HRR
10–12	2	30 minutes	1	30 minutes	65–70% of HRR
13–15	2	30 minutes	2	30 minutes	65–70% of HRR
16–18	2	30 minutes	2	30 minutes	65–70% of HRR
19–21	2	30 minutes	3	30 minutes	70% of HRR
22–24	2	30 minutes	3	30 minutes	70% of HRR

Note. HRR = Heart Rate Reserve.

3. Measures

Measures were administered at baseline, mid-point (after 12 weeks), post-test (after 24 weeks), and one-month follow-up except for the feedback form, which was administered only at follow-up.

Feasibility. Feasibility was defined by (a) our ability to meet our recruitment target (14 participants), (b) frequency of engagement in the intervention (group attendance and Fitbit adherence rates), and (c) participant feedback measured through Likert scale and open-ended responses to a questionnaire developed by the research team. The recruitment target of 14 participants was determined based on the sample sizes of our prior work (Browne et al., 2016; Orleans-Pobee et al., 2020) to facilitate successful implementation of two cohorts, which we found was valuable for evaluating feasibility of a group exercise intervention.

Intermediate targets. Satisfaction of basic psychological needs was assessed using two self-report questionnaires: The Basic Psychological Needs Scale – In General (BPNS; Deci & Ryan, 2000; Gagne, 2003) and The Basic Psychological Needs in Exercise Scale (BPNES; Vlachopoulos & Michailidou, 2006). Both measures yield subscale scores for the basic psychological needs of autonomy, competence, and relatedness. Autonomous motivation was also assessed with a self-report measure, the Behavioral Regulation in Exercise Questionnaire-2 (BREQ-2; Markland & Tobin, 2016), which yields subscale scores for the extent to which exercise is motivated by amotivation, external regulation, introjected regulation, identified regulation, and intrinsic regulation. Further, a relative autonomy index (RAI) can be calculated to provide a single value that measures the extent to which exercise motivation is autonomous. All subscales are reported; however, the RAI was used as the composite indicator of autonomous motivation in analyses.

Proximal outcomes. Exercise behavior was assessed objectively from Fitbits (Feehan et al., 2018). Specifically, steps/day were collected automatically by Fitbit whenever the device was worn and served as an indicator of overall physical activity. Minutes spent walking were defined as any physical activity automatically or manually recorded by the Fitbit device lasting for 15 or more continuous minutes. HR during these exercise bouts was also automatically recorded by Fitbit. Minutes spent walking served as an indicator of continuous exercise at different levels of intensity (based on intervention recommendations). Fitbit data were obtained daily from the start of the intervention until the end of the follow-up period. As such, the baseline timepoint reflects the first week of the intervention as compared to all other measures, which were administered prior to the start of the intervention. Weekly averages of steps/day were calculated for all weeks during the intervention and for the entire follow-up period; however, steps/day averages for week one, week 12, week 24, and follow-up were included in analyses to allow for comparison with the assessment timepoints (baseline, mid-point,

post-test, follow-up).

Primary outcome. CRF was estimated by the 6-min walk test (6MWT; Cahalin, Mathier, Semigran, Dec, & DiSalvo, 1996; Vancampfort et al., 2011). The 6MWT has been shown to be a valid functional test to estimate CRF (Ross, Murthy, Wollak, & Jackson, 2010) and has been used as such in prior large exercise trials of individuals with schizophrenia (Bartels et al., 2013, 2015). The 6MWT involves having participants walk back and forth continuously for 6 min on a flat, indoor surface with cones separated by a specified distance. The 6MWT was administered in hallways of outpatient community mental health centers in this study with cones separated by 50 or 100 feet depending on availability of space. The total distance covered was used in analyses.

Secondary outcomes. The Positive and Negative Syndrome Scale (PANSS; Kay, Opler, & Fiszbein, 1992), a semi-structured interview, was used to assess severity of total symptoms and specific domains of positive symptoms, negative symptoms, disorganization, excitement, and emotional distress symptoms of schizophrenia (van der Gaag et al., 2006). Raters were trained to gold standard reliability (intraclass correlation >0.80). All subscales are reported; however, the total score was used as the overall indicator of symptoms in analyses. The UCLA Loneliness Scale (Russell, Peplau, & Ferguson, 1978), a well-established self-report measure, was used to assess the severity of loneliness and yields a total score. In terms of biological outcomes, participants were first instructed to sit in a quiet room with the lights dimmed for 10 min prior to having their resting HR measured via palpation. After their resting HR was measured, their systolic and diastolic blood pressure (BP) was measured manually by trained research staff. Additionally, weight, waist circumference, and hip circumference were measured using the scale and measuring tape available at the clinic. Body mass index (BMI) was then calculated for each participant.

4. Procedure

Intervention procedure. All participants were provided with a Fitbit Charge HR device and instructions for use at their baseline assessment. Participants were encouraged to wear it during all waking hours except when showering. Each Fitbit device was paired with a Fitbit account and participants were taught how to sync the device on their own if possible. Participants were also provided with information about the overall training schedule and the use of HR to guide exercise intensity. Twice per week, participants and group leaders met at the community mental health center to walk together for 30 minutes in the surrounding area on sidewalks, paved trails, and residential streets. The group leaders and participants collaboratively determined the route prior to the start of each group and group leaders reminded participants of their target HR zones. Groups had at least two leaders (one who walked at the front and one who walked at the back) who encouraged social interaction among participants. Particularly for participants that were less talkative with other group members, group leaders made efforts to engage them in conversation with group leaders about salient topics (e.g., weather, surroundings, physical activity) and over time, focused on facilitating conversation between participants. Group leaders also reminded participants to check their HR during the walk and encouraged them to speed up or slow down based on how their HR compared to their target HR zone. At the end of the walk, the group met inside the clinic to reflect on how the group went and once per week, met longer for goal-setting and if-then plans sessions. Two cohorts (n = 11 & n = 6) were run simultaneously at two outpatient community mental health centers.

Group leader training and monitoring procedure. Group leaders were provided with the intervention manual (available upon request from the first author) and received a half-day training prior to the start of the study that involved a review of the intervention components and role-play practice of leading group walks and goal-setting sessions. Group leaders also participated in weekly supervision calls with the first author throughout the duration of the study. Walking groups and goal-setting sessions were rated for fidelity throughout the study using forms created by the research team and feedback was provided to group leaders during supervision. Specifically, a trained research staff member attended walking groups periodically over the course of the intervention and rated fidelity of walking groups through direct observation to assess whether the required elements were included before (reminding participants of their HR zones, determining the walking route), during (encouraging participants to check HR and adjust speed if not in HR zone, encourage social interaction among participants), and after (check-in with participants about how they felt) the group walk. The first author rated fidelity of goal-setting sessions by audiotape review to assess the inclusion of required elements (identification of goals for steps and home-based walks, plans for completing home-based walks, motivations for increasing walking, and if-then plans) and the extent to which group leaders facilitated a positive group environment.

4.1. Data analysis

Given the small sample size, both cohorts were combined for all analyses. With regard to feasibility, attendance rates at groups were calculated across participants by dividing the total number of attended groups by the total number of groups that participants were eligible to attend (e.g., to account for late enrollees). Similarly, Fitbit adherence rates were calculated across participants by dividing the total number of days that the Fitbit was worn (defined as having accumulated at least 300 steps in a given day) divided by the total number of eligible days.

For analysis of intermediate targets, proximal outcomes, primary outcome, and secondary outcomes, group means and standard deviations or medians were examined at each timepoint. To assess changes across the intervention period and maintenance of effects at follow-up, within-person mean changes and standard deviations were calculated for participants with complete data at the specified timepoints. Further, three within-person effect sizes (ES) were calculated for each outcome from: (1) baseline to mid-point, (2) baseline to post-test and, (3) post-test to one-month follow-up. ES were calculated by dividing the mean of the difference scores (time2 – time1) by the standard deviation of the difference scores (time2 – time1). ES were classified according to Cohen (1988) as small (ES = .20–.49), medium (ES = .50–0.79), and large (ES $\geq$ 0.80). For ES estimates, 95% percentile bootstrap confidence intervals (with 10,000 draws) were reported.

In addition to ES changes across all variables, the number of participants meeting pre-specified metrics of clinically significant change (established based on prior literature and physical activity guidelines) were examined for the proximal (steps/day: $\geq$2,000 steps/day increase during intervention period; (Bravata et al., 2007; Browne et al., 2016)); minutes spent walking: $\geq$150 min/week of walking during final six weeks of intervention period (Liguori & American College of Sports Medicine, 2020) and primary (6MWT: >50 m increase in 6MWT distance during intervention period (Bartels et al., 2013, 2015; Vancampfort et al., 2011)) outcomes.

5. Results

5.1. Participants

Out of the 70 referrals received, 63 persons were screened of which 23 declined to participate and 23 were ineligible. The remaining 17 participants were consented and enrolled in this open trial. One participant withdrew halfway through the study and did not complete any follow-up assessments. As such, this participant was removed from analyses leaving a sample size of sixteen (See Fig. 2). The sample was primarily male (62.50%) and on average 38.2 years (SD = 11.7) old. The majority of participants identified as white (56.25%) or Black or African American (18.75%) race and none identified as Hispanic or Latinx ethnicity. All participants had an SSD diagnosis with all but one participant taking antipsychotic medication (See Table 2).

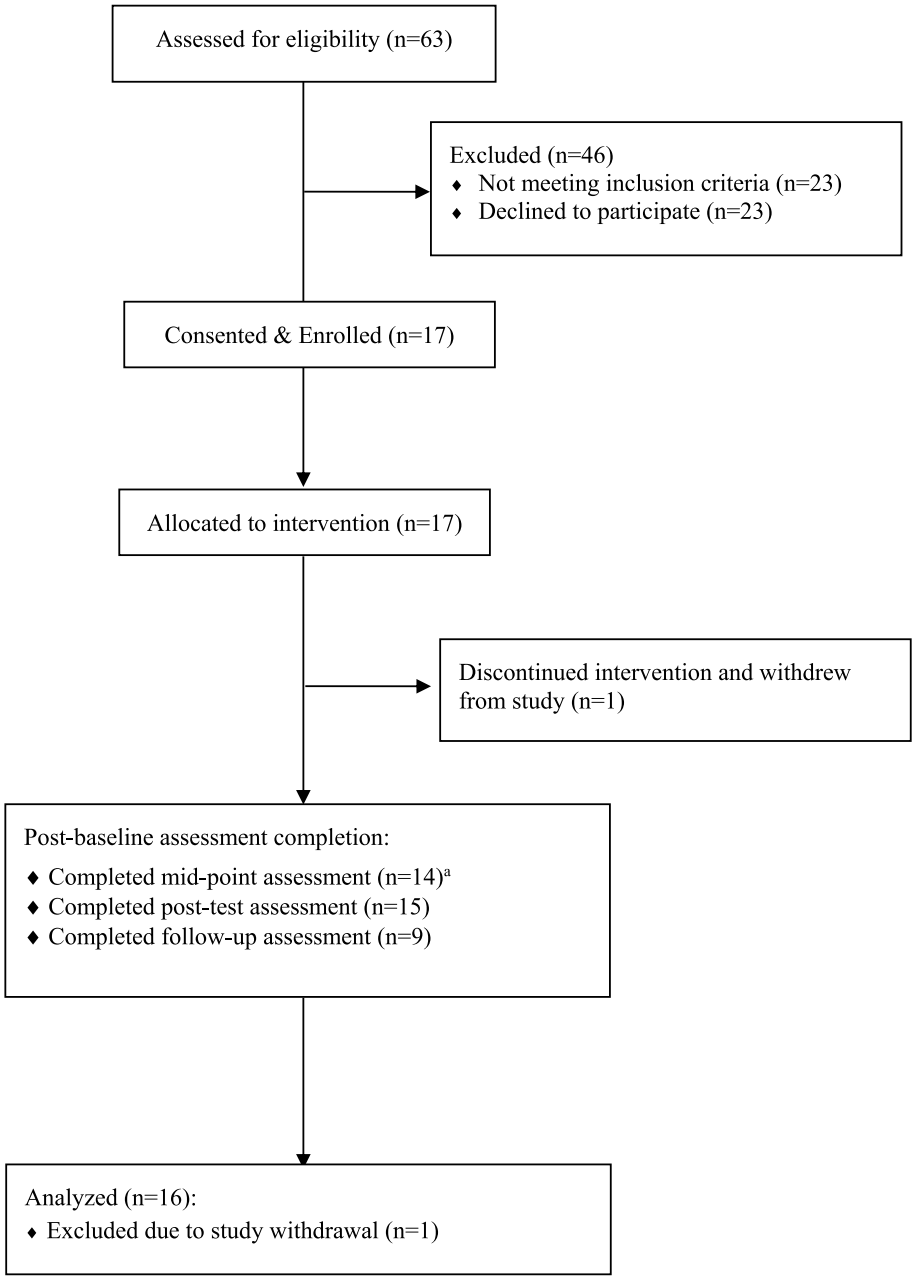

Fig. 2. PACE-life open trial consort diagram.

5.2. Feasibility

The overall group attendance rate was 34% (n = 16)[1] and Fitbit adherence rate was 54% (n = 15)[2] during the 24-week intervention. Rates were higher during the first half of the intervention for both attendance (Weeks 1–12: 46%, Weeks 13–24: 22%) and Fitbit adherence (Weeks 1–12: 63%, Weeks 13–24: 46%). Fitbit adherence was 35% during the four-week follow-up period. In general, Likert-scale responses on the feedback questionnaire (which was administered at follow-up to the nine participants that completed this assessment period) were positive suggesting a high level of satisfaction (Table 3). Additionally, responses from open-ended questions of barriers to group attendance and Fitbit adherence revealed the most common reasons for not attending groups were issues with transportation (n = 5) and the outside temperature being too hot (n = 5), and the most common reason for not wearing the Fitbit was forgetting to put it on after charging (n = 6).

5.3. Changes in outcomes during the intervention period

Fourteen participants had at least partial data from all three intervention timepoints (baseline, mid-point, post-test) and as such, were included in analyses of changes in outcomes during the intervention period (Table 4).

[1] Attendance was not taken at three groups in one cohort. As such, the attendance rate for participants in this cohort was calculated out of 45 (rather than 48) groups and further adjusted for late enrollees. Attendance in the other cohort was calculated out of 48 groups and adjusted for late enrollees.

[2] One participant was excluded due to substantial Fitbit malfunctioning issues.

Table 2
Demographic and clinical characteristics (n = 16).

Characteristic	Participants (n = 16)	
	n	%
Gender		
Female	6	37.50
Male	10	62.50
Race		
Caucasian	9	56.25
Black or African American	3	18.75
Asian	1	6.25
Native Hawaiian or other Pacific Islander	1	6.25
American Indian or Alaskan Native	1	6.25
Other	1	6.25
Ethnicity		
Hispanic or Latinx	0	0
Not Hispanic or Latinx	16	100
Primary Diagnosis		
Schizophrenia	8	50.00
Schizoaffective Disorder	6	37.50
Psychosis Not Otherwise Specified	2	12.50
Taking Antipsychotic Medication		
Yes	15	93.75
No	1	6.25
Current Smoker		
Yes	7	43.75
No	9	56.25
Education Level		
Some High School	1	6.25
High School Diploma or Equivalent	2	12.50
Some College	9	56.25
College Degree	2	12.50
Higher than College	2	12.50
	M	SD
Age (years)	38.2	11.7

Note. M = mean, SD = standard deviation. Table above summarizes demographic and clinical data from the sample included in analyses (i.e., excluding the single participant that withdrew from the study).

Table 3
Feasibility (n = 9).

Feedback Item	M	SD
1. I enjoyed being part of a group focused on physical activity and health.[a]	4.375	.916
2. Overall, I enjoyed goal-setting/if-then plan sessions once a week.[a]	4.375	.916
3. I felt included in conversations during group.[a]	4.750	.463
4. I had a good relationship with the other members of the group.[a]	4.375	.744
5. I was motivated to attend groups because of the social interaction.	4.000	1.118
6. I had a good relationship with the walking group leaders.[a]	4.625	.744
7. I felt motivated by group leaders during walking.[a]	4.625	.744
8. I was motivated to attend groups because of the health benefits I would gain from walking.	4.444	.527
9. I enjoyed using a Fitbit to track my physical activity.[a]	4.222	1.302
10. I found the Fitbit easy to use.	4.333	.500
11. I am likely to continue to use my Fitbit after the study ends.	4.000	1.414
12. I enjoyed tracking my heart rate during walks.	3.778	.833
13. I enjoyed receiving target heart rate goals throughout the study.	4.000	.866
14. I felt the target heart rate goals were attainable for me.	4.222	.972
15. I enjoyed setting goals for home-based intensity walks.	4.333	.707
16. I felt that my if-then plans helped me overcome barriers to walking.	4.222	.667
17. Overall, I feel that my health has improved since joining PACE-Life.	4.444	.882
18. If given the chance, I would join PACE-Life again.	4.333	1.118

Note. M = mean, SD = standard deviation. Feedback was collected at the follow-up assessment. Items were rated from 1 (not at all true) to 5 (very true).
[a] n = 8.

Table 4
Changes in outcomes during intervention period (n = 14).

Outcome Type and Measure	Timepoint	M	SD	ES	95% CI
Intermediate Targets					
BPNS – Autonomy[a]	BL	4.220	1.160	-	-
	MP	4.730	0.976	.940	.447,1.894
	PT	4.308	1.088	.072	-.359, 1.589
BPNS – Relatedness[a]	BL	4.712	0.921	-	-
	MP	4.875	1.072	.313	-.236, 1.165
	PT	4.779	1.042	.086	-.682, .550
BPNS – Competence[a]	BL	4.295	1.025	-	-
	MP	4.372	0.991	.082	-.647, .594
	PT	4.231	.873	-.064	-.659, .564
BPNES - Autonomy	BL	3.286	.955	-	-
	MP	3.625	.712	.312	-.192, 1.382
	PT	3.696	.666	.421	-.193, 1.374
BPNES - Relatedness	BL	2.381	1.204	-	-
	MP	3.190	.834	.726	.190, 1.776
	PT	3.333	.915	.620	.078, 1.603
BPNES - Competence	BL	2.964	.999	-	-
	MP	3.500	.665	.531	.038, 1.244
	PT	3.304	.900	.278	-.273, .840
BREQ-2 - Amotivation	BL	0.446	.680	-	-
	MP	0.482	.532	.046	-.422, .721
	PT	0.536	.712	.119	-.396, .609
BREQ-2 - External Regulation	BL	1.411	.858	-	-
	MP	1.036	.790	-.413	−1.031, .110
	PT	1.250	1.038	-.213	-.887, .312
BREQ-2 - Introjected Regulation	BL	1.619	1.280	-	-
	MP	1.738	.962	.109	-.381, .850
	PT	1.690	1.090	.089	-.424, .928
BREQ-2 - Identified Regulation	BL	2.696	1.015	-	-
	MP	3.036	.726	.670	.357, 1.203
	PT	2.946	.894	.431	-.067, 1.155
BREQ-2 - Intrinsic Regulation	BL	2.536	1.255	-	-
	MP	3.179	.682	.653	.279, 1.131
	PT	2.767	.775	.286	-.264, .808
BREQ-2 - Relative Autonomy Index	BL	7.220	6.470	-	-
	MP	10.351	4.831	.493	.010, 1.093
	PT	8.399	4.926	.211	-.354, .797
Proximal Outcomes					
Fitbit Steps/day[b,c]	BL	6581	-	-	-
	MP	8601	-	-	-
	PT	6231	-	-	-
Fitbit Minutes Spent Walking[b,c]	BL	91	-	-	-
	MP	41.5	-	-	-
	PT	79.5	-	-	-
Primary Outcome					
6MWT (meters)[a]	BL	376.623	123.652	-	-
	MP	471.469	116.184	1.167	.794, 1.886
	PT	482.953	125.126	1.224	.730, 2.389
Secondary Outcomes					
PANSS - Positive	BL	12.071	3.222	-	-
	MP	14.071	2.759	1.041	.576, 2.059
	PT	15.000	5.561	.883	.416, 1.570
PANSS - Negative	BL	12.000	5.533	-	-
	MP	15.286	4.890	.805	.305, 1.611
	PT	15.000	6.917	.561	.035, 1.304
PANSS - Disorganization	BL	13.071	2.165	-	-
	MP	17.357	4.236	1.189	.838, 1.879
	PT	18.286	4.890	1.095	.801, 2.266
PANSS - Excitement	BL	10.000	2.353	-	-
	MP	11.857	1.875	.699	.197, 1.633
	PT	11.428	2.848	.601	.107, 1.356
PANSS - Emotional Distress	BL	17.357	5.943	-	-
	MP	18.214	3.620	.232	-.277, 1.018
	PT	16.571	6.847	-.168	-.903, .351
PANSS - Total	BL	49.214	9.374	-	-
	MP	57.786	8.069	1.147	.637, 2.161

(continued on next page)

Table 4 (*continued*)

Outcome Type and Measure	Timepoint	M	SD	ES	95% CI
	PT	57.642	15.843	.699	.258, 1.404
UCLA Loneliness	BL	51.429	16.095	-	-
	MP	49.214	15.720	-.351	-.880, .185
	PT	50.500	12.690	-.109	-.838, .378
Systolic Blood	BL	108.643	12.144	-	-
Pressure	MP	107.786	13.542	-.083	-.855, .407
	PT	110.429	12.195	.165	-.415, .735
Diastolic Blood	BL	73.571	12.157	-	-
Pressure	MP	74.857	13.767	.128	-.393, .835
	PT	79.285	11.631	.434	-.057, 1.122
Resting Heart Rate	BL	81.071	16.964	-	-
	MP	85.714	15.046	.319	-.195, 1.152
	PT	81.428	16.749	.018	-.467, .686
Weight (kilograms)	BL	97.336	31.471	-	-
	MP	97.386	32.020	.022	-.663, .520
	PT	98.350	32.945	.211	-.333, .854
Body Mass Index	BL	32.750	9.436	-	-
	MP	32.850	9.646	.077	-.752, .513
	PT	33.014	9.849	.147	-.452, .661
Waist	BL	105.679	24.646	-	-
Circumference	MP	105.821	24.309	.013	-.433, .820
(centimeters)	PT	108.464	24.308	.292	-.203, 1.453
Hip Circumference	BL	117.536	20.819	-	-
(centimeters)	MP	115.714	15.921	-.190	-.572, .654
	PT	117.571	20.206	.003	-.397,1.275

Note. M = Mean, SD = Standard Deviation, ES = Effect Size, CI = Confidence Interval, BL = Baseline, MP = Mid-point, PT = Post-test, BPNS = The Basic Psychological Needs Scale – In General, BPNES = The Basic Psychological Needs in Exercise Scale, BREQ-2 = Behavioral Regulation in Exercise Questionnaire-2, 6MWT = 6-min walk test, PANSS = Positive and Negative Syndrome Scale. Effect sizes were calculated as changes from baseline.

[a] n = 13.

[b] Median was used for Fitbit steps/day and minutes spent walking due to distribution of variables. As such, standard deviation and effect sizes were not calculated. BL reflects the first week of the intervention (data from week 1, 2, or 3 were used), MP reflects the middle of the intervention period (data from week 11, 12, or 13 were used), and PT reflects the final week of the intervention (week 22, 23, or 24 were used).

[c] n = 6.

5.4. Intermediate targets

When measured using the general scale (BPNS), there was a large ES increase in autonomy from baseline to mid-point (ES = .94) but little to no change from baseline to post-test. There was a small ES increase in relatedness from baseline to mid-point (ES = .31) but little to no change from baseline to post-test. There was little to no change in competence from baseline to either timepoint. On the exercise-specific scale (BPNES), there was a small ES increase in autonomy from baseline to mid-point (ES = .31) and baseline to post-test (ES = 42). There was a medium ES increase in relatedness from baseline to mid-point (ES = .73) and baseline to post-test (ES = .62). There was a medium ES increase in competence from baseline to mid-point (ES = .53) and a small ES increase from baseline to post-test (ES = .28). On the BREQ-2 RAI, there was a small ES increase in autonomous motivation from baseline to mid-point (ES = .49) and baseline to post-test (ES = .21).

5.5. Proximal outcomes

Out of the six participants with complete Fitbit data at the three intervention timepoints, steps/day increased from week one (median: 6,581) to week 12 (median: 8,601) but then decreased from week 12 to week 24 (median: 6,231). Two participants (out of six with complete data) met the pre-specified threshold for clinically significant improvement (≥2,000 steps/day increase during intervention period) at week 12 and at week 24. Fitbit minutes spent walking decreased from week one (median: 91) to week 12 (median: 41.5) and increased from week 12 to week 24 (median: 79.5). Two participants (out of nine with any Fitbit minutes spent walking data during the final six weeks)[3] met the pre-specified threshold for clinically significant improvement (≥150 min/week of walking during final six weeks of intervention period).

5.6. Primary outcome

There was a large ES increase in CRF as measured by the 6MWT from baseline to mid-point (ES = 1.17) and baseline to post-test (ES = 1.22). Out of the 13 participants with complete data, eight at mid-point (61%) and ten at post-test (77%) met the pre-specified threshold for achieving clinically significant improvement (>50-m increase).

5.7. Secondary outcomes

In terms of psychological outcomes, there was a large ES increase in total symptoms from baseline to mid-point (ES = 1.15) and a medium ES increase from baseline to post-test (ES = .70). There was a small ES decrease in loneliness from baseline to mid-point (ES = -.35) but little to no change from baseline to post-test.

In terms of biological outcomes, there was little to no change in systolic blood pressure from baseline to either timepoint and in diastolic blood pressure from baseline to mid-point. There was a small ES increase in diastolic blood pressure from baseline to post-test (ES = .43). There was a small ES increase in resting HR from baseline to mid-point (ES = .32) and little to no change from baseline to post-test. In terms of weight and body composition outcomes, there was little to no change in weight from baseline to mid-point and a small ES increase from baseline to post-test (ES = .21). There was little to no change in BMI or hip circumference from baseline to either timepoint. There was little to no change in waist circumference from baseline to mid-point, but a small ES increase from baseline to post-test (ES = .29).

5.8. Changes in outcomes during follow-up period

Nine participants had at least partial data from the post-test and follow-up timepoints and as such, were included in analyses of changes in outcomes during the follow-up period (Table 5).

In terms of intermediate targets, there was little to no change in autonomy or competence when measured using the general scale (BPNS); however, there was a small ES decrease in relatedness (ES = −.46). Further, when measured using the exercise-specific scale (BPNES), there was a small ES decrease in autonomy (ES = -.45), relatedness (ES = -.31), and competence (ES = -.22). Additionally, there was little to no change in autonomous motivation as measured by the BREQ-2 RAI. Proximal outcomes of Fitbit steps/day decreased from week 24 (median: 7,987) to follow-up (median: 4,693) and Fitbit minutes spent walking decreased from week 24 (median: 79.5) to follow-up (median: 22.63). A small ES increase (ES = .20) in the primary outcome of CRF measured by the 6MWT was observed. In terms of secondary outcomes, there was a small ES decrease in total symptoms (ES = -.36) and loneliness (ES = -.21). All biological outcomes deteriorated during the follow-up period such that there was a large ES increase in systolic blood pressure (ES = .85), a medium ES increase in diastolic blood pressure (ES = .71), and a small ES increase in resting HR (ES = .20). In terms of weight and body composition outcomes, there was a small ES increase in weight (ES = .40), but little to no change in BMI. Finally, there was a small ES decrease in waist circumference (ES = -.28) and medium ES decrease in hip circumference (ES = -.60).

[3] Participants that completed at least partial assessments at BL/MT/PT and had any non-missing Fitbit minutes spent walking data during the final six weeks of the intervention period (weeks 19–24) were included in this analysis.

Table 5
Changes in outcomes during follow-up period (n = 9).

Outcome Type and Measure	Timepoint	M	SD	ES	95% CI
Intermediate Targets					
BPNS - Autonomy	PT	4.159	.629	-	-
	FU	4.238	.990	.075	-.441, 1.862
BPNS - Relatedness	PT	4.667	.910	-	-
	FU	4.513	1.013	-.456	−1.777, .181
BPNS - Competence	PT	4.278	.909	-	-
	FU	4.259	.440	.027	-.949, .720
BPNES - Autonomy	PT	3.778	.734	-	-
	FU	3.556	.596	−0.452	−1.414, .185
BPNES - Relatedness	PT	3.519	.884	-	-
	FU	3.185	.709	−0.308	-.883, .544
BPNES - Competence	PT	3.472	.814	-	-
	FU	3.278	.795	−0.222	−1.093, .434
BREQ-2 - Amotivation	PT	.417	.586	-	-
	FU	.444	.447	0.073	-.550, .765
BREQ-2 - External Regulation	PT	1.167	.810	-	-
	FU	.972	.701	-.225	-.816, .939
BREQ-2 - Introjected Regulation	PT	1.963	.790	-	-
	FU	2.037	.978	0.120	-.668, .833
BREQ-2 - Identified Regulation	PT	3.167	.829	-	-
	FU	3.056	.990	−0.215	−1.491, .392
BREQ-2 - Intrinsic Regulation	PT	2.889	.697	-	-
	FU	2.833	.770	−0.134	-.843, .712
BREQ-2 - Relative Autonomy Index	PT	9.454	4.397	-	-
	FU	9.296	4.672	-.066	-.786, .875
Proximal Outcomes					
Fitbit Steps/day[a,b]	PT	7987	-	-	-
	FU	4693	-	-	-
Fitbit Minutes Spent Walking[a,b]	PT	79.5	-	-	-
	FU	22.63	-	-	-
Primary Outcome					
6MWT (meters)[b]	PT	482.775	145.060	-	-
	FU	489.425	144.603	.204	-.590, 1.135
Secondary Outcomes					
PANSS - Positive	PT	14.667	5.523	-	-
	FU	13.222	5.495	-.487	−1.310, .153
PANSS - Negative	PT	14.333	5.315	-	-
	FU	15.333	6.185	.277	-.419, 1.061
PANSS - Disorganization	PT	16.111	3.180	-	-
	FU	13.556	3.087	−1.020	−2.667, −.378
PANSS - Excitement	PT	10.667	1.500	-	-
	FU	10.889	2.804	.087	-.843, .800
PANSS - Emotional Distress	PT	15.222	3.768	-	-
	FU	15.556	3.745	.094	-.479, 1.639
PANSS - Total	PT	53.111	12.015	-	-
	FU	50.333	11.757	-.363	−1.238, .329
UCLA Loneliness	PT	54.667	11.779	-	-
	FU	52.889	11.096	-.209	−1.416, .384
Systolic Blood Pressure	PT	110.000	13.444	-	-
	FU	121.111	7.817	0.848	.354, 1.964
Diastolic Blood Pressure	PT	77.444	9.939	-	-
	FU	82.778	8.700	0.705	.090, 2.052
Resting Heart Rate	PT	82.667	16.093	-	-
	FU	85.333	8.366	0.203	-.414, 1.988
Weight (kilograms)	PT	94.800	18.544	-	-
	FU	95.356	18.757	0.402	-.294, 1.131
Body Mass Index	PT	32.588	7.185	-	-
	FU	32.611	7.164	0.034	-.663, 1.014
Waist Circumference (centimeters)	PT	105.333	15.762	-	-
	FU	104.667	14.440	−0.277	−1.247, .411
Hip Circumference (centimeters)	PT	116.778	15.941	-	-
	FU	114.500	17.685	−0.601	−2.054, .033

Note. M = Mean, SD = Standard Deviation, ES = Effect Size, CI = Confidence Interval, BL = Baseline, FU = Follow-up, BPNS = The Basic Psychological Needs Scale – In General, BPNES = The Basic Psychological Needs in Exercise Scale, BREQ-2 = Behavioral Regulation in Exercise Questionnaire-2, 6MWT = Six-minute walk test, PANSS = Positive and Negative Syndrome Scale.

[a] Median was used for Fitbit steps/day and minutes spent walking due to distribution of variables. As such, standard deviation and effect sizes were not calculated. PT reflects the final week of the intervention (week 22, 23, or 24 were used) and FU represents the entire four weeks of follow-up. Minutes per week were calculated as a total over the four follow-up weeks then divided by 4 to reflect weekly minutes.

[b] n = 8.

6. Discussion

The present study was a 24-week open trial of PACE-Life, a manualized multicomponent theory-based walking intervention for persons with SSDs. The aims were to evaluate the feasibility of implementing the intervention and to examine its impact on intermediate targets of autonomous motivation and the three basic psychological needs, proximal outcomes of Fitbit minutes spent walking and steps/day, the primary outcome of CRF, and secondary outcomes of loneliness, symptoms, resting heart rate, systolic/diastolic blood pressure, weight, BMI, and hip and waist circumference during the intervention period and at a one-month follow-up. Overall, this open trial demonstrated high participant satisfaction, a large and clinically meaningful effect size improvement in CRF as well as small and medium increases in autonomous motivation and satisfaction of autonomy, relatedness, and competence needs. However, relatively low intervention engagement rates were also observed, and Fitbit data and secondary outcomes generally remained unchanged or worsened during the intervention.

With regard to feasibility, the recruitment target of 14 participants was exceeded (n = 17) and feedback indicated satisfaction with the intervention and group environment. It should be noted, however, that the feedback form was administered at follow-up to only the nine participants that completed that assessment timepoint and all Likert-scale items were framed positively, which may have contributed to the positive results. Though not pre-specified as a metric of feasibility for this open trial, the number of participants that were assessed for eligibility that did not meet inclusion criteria (36%) or that declined to participate (36%) raises concerns regarding feasibility of the recruitment methods. It may be that recruitment materials did not adequately describe the nature of the intervention and/or that recruitment efforts were not sufficiently targeted to the intended population. Further, engagement rates in this study were relatively low (group attendance: 34%; Fitbit adherence: 54%), particularly during the second half of the intervention. Although these rates and their declining pattern over time are consistent with other walking studies of participants with schizophrenia (Soundy et al., 2014), they were substantially lower than those observed in our

short previous pilot study of a 10-week version of PACE-Life (group attendance: 65%, Fitbit adherence: 81%) (Orleans-Pobee et al., 2020). The declining group attendance rate in this study was likely largely driven by the rising hot temperatures observed during the second half of the intervention, which occurred during the summer months. Participants also noted transportation difficulties and forgetting to put their Fitbit on after charging as additional barriers of attendance and adherence, respectively. Therefore, shortening the length of the intervention, avoiding the hot summer months, and including transportation resources and Fitbit reminders may increase engagement and adherence in future studies.

The most encouraging finding was the large ES improvement in the primary outcome of CRF as estimated by the 6MWT during the intervention and a continued small improvement at follow-up. Further, 61% and 77% of the sample achieved clinically significant improvement in CRF (>50-m increase on 6MWT) at midpoint and post-test, respectively. These results are important given that CRF is a predictor of cardiovascular health and all-cause mortality and is known to be reduced in persons with SSDs (Vancampfort et al., 2015; Vancampfort et al., 2017b; Vancampfort et al., 2015). Further, our study highlights that meaningful improvements in CRF can occur in a moderate-intensity walking intervention, which is noteworthy given that CRF has rarely been measured in walking interventions for this population (Soundy et al., 2014).

Small and medium increases in the intermediate targets of autonomy, relatedness and competence occurred during the intervention particularly when measured using the exercise-specific scale (BPNES), which suggests that participants experienced satisfaction of these basic psychological needs from the PACE-Life intervention. Moreover, small increases in autonomous motivation were observed during the intervention and sustained at follow-up. Although intermediate targets improved, the proximal outcomes of Fitbit steps/day and minutes spent walking generally remained unchanged or worsened over the course of the intervention and at follow-up. Yet, Fitbit data during the intervention were only available for a small subset of participants ($n = 6$) due to substantial missing data (resulting from low adherence and technology malfunctions), which likely impacted the validity of these outcomes. For this small subsample, Fitbit steps/day increased during the first half of the intervention but then returned below baseline during the second half, and only two participants achieved clinically significant change. Similarly, Fitbit minutes spent walking decreased during the intervention with just two participants meeting the threshold for clinical significance. These results are surprising particularly in light of research suggesting the increases in autonomous motivation are related to greater physical activity, particularly walking, among persons with schizophrenia (Vancampfort et al., 2013, 2015).

Secondary outcomes generally did not change or worsened over the course of the intervention. Psychologically, symptoms appeared to worsen from baseline to post-test; however, it is important to note that symptom severity remained on the low end. Loneliness improved slightly at midpoint but then returned to baseline at post-test, which may suggest that the social interaction provided during the group was not sufficient to meaningfully impact overall loneliness. The lack of improvement in biological and weight and body composition outcomes suggest that additional components, namely nutrition, are necessary to engender broader health results (Bartels et al., 2015; Daumit et al., 2013; Soundy et al., 2014).

The study was primarily limited in its open trial design and small sample size. Given the primary aim of assessing feasibility and lack of a control group, pre-post changes in outcomes should be interpreted with caution. Additionally, we did not collect a true baseline exercise level as Fitbit data were collected only once the intervention began. As such, initial exercise levels were likely inflated, and within-person changes do not reflect the impact of PACE-Life as compared to no intervention. Relatedly, Fitbit adherence was low resulting in substantial missing data, which likely impacted the validity of the exercise behavior measures. Further, the minutes spent walking variable may have included physical activity beyond walking as it was not possible to determine the type of exercise. Moreover, high variability within participants was observed in blood pressure ratings, which may indicate issues with validity of this assessment. Finally, post-test to follow-up results should be interpreted with caution due to a substantial amount of missing data.

Future studies should consider examining PACE-Life against a comparison condition, in a larger sample, and with Fitbit data collection beginning prior to the intervention. Moreover, given that the attendance and adherence rates were low and continued to decrease over the course of the 24 weeks in combination with large improvements in CRF observed after just 12 weeks, future studies may consider reducing the length and/or including additional strategies to sustain engagement. Additionally, it would be valuable for future work to include qualitative interviews with participants at the end of the intervention to obtain greater understanding of how the intervention was received, the group processes that impacted engagement and outcomes, and the relationship between physical activity and mental health. Gathering this type of data would allow for important follow-up mixed methods work that would add to the literature on how group-based exercise programs foster behavior change (Borek & Abraham, 2018; Borek, Abraham, Greaves, & Tarrant, 2018; Borek et al., 2019).

The present study adds to a small but growing literature on motivational theory-based physical activity interventions for persons with SSDs (Romain et al., 2020). PACE-Life was designed to target the three basic psychological needs (autonomy, competence, and relatedness) derived from SDT and autonomous motivation to promote increased physical activity and ultimately improve important physical and psychological health outcomes. Overall, the results are promising, particularly in terms of the proportion of participants (10/13 or 77%) that achieved clinically significant improvements in CRF after 24 weeks. However, relatively low engagement rates were observed, particularly during the second half of the intervention, which highlights the need for modifications to improve feasibility. In sum, this open trial serves as a valuable basis for future work aiming to improve CRF among persons with SSDs through theory-based walking interventions.

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Declaration of competing interest

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