Work out by Walking

A Pilot Exercise Program for Individuals With Schizophrenia Spectrum Disorders

Julia Browne, MA,* David L. Penn, PhD,*† Claudio L. Battaglini, PhD,‡ and Kelsey Ludwig, BS*

Abstract: The health benefits of exercise are well documented, yet annual health care costs related to physical inactivity are well within the billions. Furthermore, individuals with schizophrenia spectrum disorders (SSDs) are more likely to lead sedentary lives, exercise less than the general population, and die prematurely from preventable causes. Previous research examining the effects of exercise on individuals with SSDs has been encouraging yet limited in creating accessible and sustainable interventions. The current pilot study developed and evaluated the impact of Work out by Walking (WOW), a multicomponent group walking intervention on the health of 16 individuals with SSDs. Results indicated improvements in indicators of physical health, activity level, social support, and mental health and a high level of program satisfaction. Future research should examine multicomponent group walking programs for individuals with SSDs in larger samples and with the inclusion of a comparison condition.

Key Words: Schizophrenia, exercise, health, physical activity, walking

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ndividuals with schizophrenia spectrum disorders (SSDs) have a life expectancy up to 25 years shorter than individuals in the general population due to elevated rates of chronic physical and medical illnesses (Brown et al., 2000; Laursen, 2011; Laursen et al., 2012). Physical inactivity and elevated smoking rates (~90%) contribute greatly to increased rates of metabolic syndrome and subsequent development of cardiovascular disease (CVD) and other related illnesses (Blair, 2009; Wildgust and Beary, 2010). Despite reductions in mortality from CVD in the general population over the past two decades, rates in SSDs have remained high (Lawrence et al., 2010). Consequently, the potential benefits of interventions that address physical inactivity in this population are substantial.

Research examining the health impact of exercise interventions for individuals with SSDs is promising (Dauwan et al., 2016; Firth et al., 2015; Rosenbaum et al., 2014). But, given that the majority of previous studies examined interventions requiring gym access and equipment, the opportunity for individuals to sustain exercise upon study completion is limited (Acil et al., 2008; Beebe et al., 2005; Marzolini et al., 2009; Pelham et al., 1993; Scheewe et al., 2012; Skrinar et al., 2005). Exercise interventions targeting this population should not only emphasize efficacious protocols but also accessibility, feasibility, and sustainability to promote long-term adoption (Daumit et al., 2005; Vancampfort et al., 2015).

Walking is one of the most accessible and popular forms of exercise among those with SSDs (Daumit et al., 2005). Walking interventions have been shown to impact physical health, well-being, and weight loss (Bravata et al., 2007; Ogilvie et al., 2007; Richardson

*Department of Psychology and Neuroscience, The University of North Carolina at Chapel Hill, Chapel Hill, NC; †School of Psychology, Australian Catholic University, Melbourne Campus (St Patrick), Fitzroy, Australia; and ‡Department of Exercise and Sport Science, University of North Carolina, Chapel Hill, NC.

Send reprint requests to Julia Browne, MA, Department of Psychology and Neuroscience, The University of North Carolina at Chapel Hill, 235 E. Cameron Ave, Davie Hall, CB #3270, Chapel Hill, NC. E-mail: ibrowne@unc.edu.

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ISSN: 0022-3018/16/20409-0651 DOI: 10.1097/NMD.000000000000556 et al., 2008; Soundy et al., 2014) and reduce the risk of all-cause mortality (Kelly et al., 2014), premature death (Nelson et al., 2007), and cardiovascular disease (Manson et al., 2002). Though walking interventions employing groups, treadmills, or pedometers have been successfully utilized in the general population (Bravata et al., 2007; Ogilvie et al., 2007; Tudor-Locke and Bassett Jr., 2004; Tudor-Locke et al., 2011) and SSDs (Beebe and Harris, 2012; Beebe et al., 2011; Methapatara and Srisurapanont, 2011), less attention has been given to a combination approach that involves walking protocols and pedometers. A group-based program that incorporates activity tracking holds particular promise given barriers to participation, including social isolation, lack of an exercise companion, inaccessibility, and amotivation (Archie et al., 2003; Beebe et al., 2009; McDevitt et al., 2006).

The present study sought to develop and evaluate the impact of Work out by Walking (WOW), a multicomponent group walking intervention on the health of individuals with SSDs. The primary aim of the current study was to examine the impact of WOW on domains of physical health, activity level, social support, and mental health. Exploratory aims were (a) to examine the relationship between activity level and physical health indices at posttest to establish whether changes in physical activity were associated with physical health improvements, and (b) to examine participant feedback and satisfaction. We hypothesized that participants would experience increases in activity level through participation in WOW and improvements in indicators of physical health, social support, and mental health.

METHODS

Participants

The sample included 16 individuals with SSDs (see Fig. 1 and Table 1). Participants were primarily Caucasian (75%), male (69.75%), and middle-aged (mean = 43.3 years, SD = 7.8). All study subjects signed a written informed consent approved by the University's IRB.

Intervention

WOW is a multicomponent group walking intervention that employs engagement and motivational strategies to address the specific needs of this population including pedometers, goal-setting, daily contact, feedback on progress, and financial incentives (\$10.00/group). WOW was integrated into the local outpatient clinic as individuals with SSDs have frequent contact with mental health providers, thus limiting the need for additional transportation.

Pedometers were used to self-monitor daily steps and facilitate goal-setting for the upcoming week. Goal-setting groups were held weekly during which participants set individual step goals and received updates outlining their progress. Participants reported their upcoming step goal to the entire group (including the leaders) to foster cohesion and supportive accountability. This protocol, including supervised walking groups (2×/wk) and unsupervised pedometer-based walks (step count goals), met the minimum exercise recommendations for health promotion (Haskell et al., 2007).

To increase accountability and adherence to pedometer usage, the study coordinator provided reminders to wear pedometers and would request step count readings each morning via call, text, or email

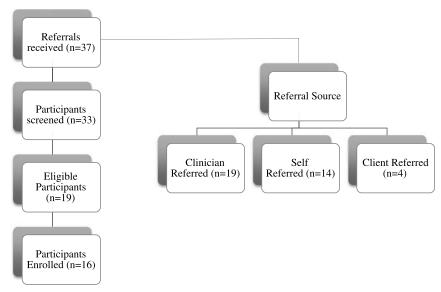


FIGURE 1. Flowchart of participant referrals, screening, and enrollment. During recruitment for WOW, 37 referrals were received of which 33 were screened for eligibility. Nineteen individuals were eligible for participation and 16 people enrolled. Referral source information indicated that clinicians referred 19 individuals, 14 were self-referred, and other clients referred four individuals.

(depending on participant access/preference). Pedometer readings were recorded based on participant self-report; however, the research team confirmed readings at weekly group walks.

To promote social interaction during group walks, group leaders would engage participants in conversation and promote conversation between participants. Group leaders identified potential conversation topics to aid in discussion with and among participants including weather, nature, music, movies, exercise, current events, and upcoming plans. Participants were free to discuss additional topics during the walk; however, symptoms were not discussed unless brought up specifically by the participant. Further, after each walk, the group would reconvene in the outpatient clinic for "after walk sharing" (Browne et al., 2016). After walk sharing would consist of open-ended questions regarding thoughts about the walk and how individuals felt after the walk. Finally, once per week, goal-setting groups would occur following "after walk sharing."

Measures

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Assessments were completed at baseline, posttest, and 1 month follow-up. Participants were paid \$20.00 per assessment. The Physical Activity Readiness Questionnaire (PAR-Q; American College of Sports Medicine and Pescatello, 2014), a 7-item yes/no screening tool, is the minimum recommended screening tool to be used by the ACSM with the goal of minimizing potential adverse events during participation in regular physical activity. Individuals were excluded from the study if they indicated any significant health concerns as evidenced by answering "yes" to any item and could not provide documentation of verbal consent from a doctor. Participants were not excluded on the basis of disclosing minor health problems (e.g., muscle soreness); however, doctor's permission indicating they were safe to participate in the study was required for issues impacting walking.

The Short Form-36 (SF-36; Leese et al., 2008) is a 36-item self-report measure of physical health that produces two summary scores: Physical Component Summary (PCS) and Mental Component Summary (MCS); however, only the PCS was utilized in the present study. The SF-36 has been validated in individuals with SSDs and demonstrated adequate psychometric properties for the PCS summary score (internal consistency: 0.88; Leese et al., 2008).

Weight was assessed using a digital scale located in the outpatient clinic. One participant exceeded the maximum weight of the scale (>400 lbs) and, as a result, weighed herself at her doctor's office and reported the weight to the research team. Body Mass Index (BMI) was used to assess change in body mass during the pilot study. Only overweight or obese individuals (BMI ≥ 25) were included in

TABLE 1. Demographic and Clinical Characteristics of Participants (n = 16)

Gender, $\%$ (n)	
% Female	31.25 (5)
Age	
M(SD)	43.3 (7.8)
Range	33–61
Race, $\%$ (n)	
Caucasian	75.0 (12)
African-American	25.0 (4)
Education, $\%$ (n)	
High school diploma	31.25 (5)
Some college	6.25 (1)
College degree	50.0 (8)
Higher than college	12.5 (2)
Employment status, $\%$ (n)	
Unemployed	81.25 (13)
Employed part-time	18.75 (3)
Diagnosis, $\%$ (n)	
Schizophrenia	31.25 (5)
Schizoaffective disorder	62.5 (10)
Psychotic disorder NOS	6.25 (1)
Baseline health parameters, M (SD)	
Weight (lbs) ^a	244.15 (68.53)
Body mass index (BMI) ^a	36.65 (9.86)

analyses of weight/BMI (n = 15). Blood pressure and resting heart rate (RHR) were assessed using the available equipment at the clinic only for the second cohort (n = 7).

The Six-Minute Walk Test (6MWT; Vancampfort et al., 2011) was used to assess changes in physical health resulting from increased physical activity. The 6MWT measures the total distance an individual can walk in 6 minutes. Consistent with test guidelines, participants completed this test individually, on a level course, and under supervision (American Thoracic Society Statement, 2002).

The Short Form International Physical Activity Questionnaire (IPAQ; Faulkner et al., 2006), a valid self-report measure, was used to assess changes in physical activity. The IPAQ Short Form is a 4-item scale that assesses the frequency and duration of walking, moderate-intensity exercise, vigorous-activity exercise, and sitting.

Yamax Corporation DW model pedometers were used to track steps (Basset Jr et al., 1996). Pedometer readings were recorded daily for the duration of the program, including the 1 month follow-up.

The Multidimensional Scale of Perceived Social Support (MSPSS; Zimet et al., 1990), a 12-item self-report questionnaire assessing the perceived adequacy of support from family, friends, and significant others, was selected due to strong psychometric properties and suitability for use with individuals with SSDs (Vaingankar et al., 2012). Items are rated on 5-point Likert scales, and subscale scores are obtained for family, friends, and significant others. Due to the nature of the study, the friends subscale score (internal consistency: 0.91), which consists of four items, was utilized in analyses (Vaingankar et al., 2012).

Symptoms were assessed with the Positive and Negative Syndrome Scale (PANSS; Kay et al., 1992). Four scaled scores are produced: Positive Symptoms, Negative Symptoms, General Psychopathology, and Total Score. Raters were trained to conduct the PANSS to a gold standard of reliability (*i.e.*, intraclass correlation > 0.80).

The Positive and Negative Affect Schedule Short Form (PANAS-SF; Thompson, 2007) is a 10-item scale used to assess changes in mood. Participants completed the 5-item Positive Affect scale before and after each group walk (possible total of 40 times). The PANAS-SF Positive Affect scale was selected due to its adequate psychometric properties (internal consistency: 0.78, test-retest reliability: 0.84) and its brevity (Thompson, 2007).

The World Health Organization Quality of Life Scale (WHOQOL-BREF; Skevington et al., 2004) is a 26-item self-report questionnaire that assesses quality of life in four domains: physical health, psychological health, social relationships, and environment. An overall score is also produced.

Attendance rates, pedometer adherence, and client feedback were used to assess participant feedback and satisfaction. The Client Satisfaction Questionnaire (CSQ-8; Larsen et al., 1979), an 8-item measure of client satisfaction (range 8–32; higher scores are better), was modified slightly to prompt feedback for the exercise intervention. The CSQ-8 has strong psychometric properties (internal consistency: 0.93) and is suitable for use as a brief overall measure of satisfaction (Attkisson and Zwick, 1982). Additionally, clients completed a feedback questionnaire developed by the research team with multiple choice and free response questions.

Procedure

We conducted walking groups for two cohorts of individuals (n=16) for 10 weeks. Cohort 1 (n=9) completed the program in the fall (September to November) and cohort 2 (n=7) completed the program in the spring (March to May). The study coordinator and a graduate student research assistant met the group at the clinic for each session, reviewed safety precautions, administered the PANAS-SF, and led individuals on a walk for 30 minutes in the area neighboring the clinic. Participants were encouraged to walk at a moderate pace,

defined as being able to speak without feeling out of breath, which is consistent with rating level of physical exertion around "3" (scaled 1–5) using the "Talk Test" (Persinger et al., 2004). After 30 minutes, the group returned to the clinic, had "after walk sharing," and completed the PANAS-SF a second time. Although the inclusion of exercise specialists has been associated with lower dropout across several interventions in this population, the evidence is less clear when considering solely walking-based interventions (Vancampfort et al., 2016). Further, given that these qualified professionals are rarely available at community mental health centers to deliver exercise interventions and WOW was designed with sustainability at its core, exercise specialists did not deliver WOW in this study.

Data Analysis

Given the small sample size and nature of the pilot study, formal inferential statistics are not appropriate (Lancaster et al., 2004). Instead, we computed within-group effect sizes for continuous outcome variables to evaluate the magnitude of pre-post and follow-up changes in physical health, activity level, social support, and mental health. Effect sizes were calculated by dividing the mean difference (baseline to posttest and baseline to follow-up) by the baseline standard deviation (Lakens, 2013). Effect sizes were evaluated according to Cohen's (1988) recommended ranges: small (d=0.20), medium (d=0.50), and large (d=0.80).

To assess the relationship between step count and physical health, we computed partial correlations between step count and 6MWT and BMI at both posttest and follow-up controlling for baseline scores. To assess program satisfaction and participant feedback, we calculated total walking group attendance, pedometer adherence, and total scores on the CSQ-8. Pedometer adherence was operationalized as the percentage of total days (out of 98 possible) participants reported their step count to the research coordinator.

Independent samples t-tests and chi-squared tests revealed cohorts 1 and 2 were not significantly different in regards to age, gender, baseline symptoms (PANSS Total Scores), and self-reported minutes spent walking (IPAQ). Thus, results from both cohorts (n = 16) were combined for all analyses.

Primary Outcomes

Table 2 provides means, standard deviations, and within-group effect sizes for key domains of physical health, activity level, social support, and mental health. From baseline to posttest, results indicated large effect size (ES) improvements in minutes spent walking each week (IPAQ walking) and daily steps. Moderate to large ES improvements were observed in all domains of PANSS symptoms. Participants experienced small to moderate ES improvements in resting HR, 6MWT, IPAQ sitting, overall quality of life, and physical health and psychological domains of quality of life. Finally, small ES improvements in social support and self-reported physical health (PCS) were detected. Little to no changes were observed in weight, BMI, and social relationships quality of life. Systolic and diastolic blood pressure appeared to deteriorate.

Between baseline and follow-up, analyses revealed a large ES improvement in IPAQ walking and a moderate to large ES improvement in daily steps. Small-to-moderate ES improvements were observed in 6MWT, social support, PANSS symptom domains (Positive, General, and Total), and quality of life domains (Overall and Physical Health). Small ES improvements were found in psychological and social relationship domains of quality of life. Little to no changes were observed in self-reported physical health (PCS), weight, BMI, diastolic BP, RHR, IPAQ sitting, and PANSS Negative symptoms.

TABLE 2. Means (M), Standard Deviation (SD), and Within-Group Effect Sizes (Cohen's d) for Outcomes (n = 16)

Outcomes and Measures	Baseline M (SD)	Posttest M (SD)	1-mo FU M (SD)	BL-PT d	BL-FU d
Physical health					
SF-36 PCS	49.93 (9.46)	51.55 (8.95)	50.30 (9.79)	0.17	0.04
Weight (lbs) ^a	244.15 (68.53)	242.85 (67.53)	244.21 (68.05)	0.02	-0.00
BMI^a	36.65 (9.86)	36.51 (9.92)	36.66 (9.92)	0.01	-0.00
Systolic BP ^b	123.29 (21.09)	134.71 (15.03)	129.29 (11.41)	-0.54	-0.28
Diastolic BP ^b	80.00 (17.41)	86.71 (10.45)	79.29 (10.27)	-0.39	-0.04
Resting HR ^b	90.43 (13.70)	86.57 (7.39)	90.00 (6.00)	0.28	0.03
6MWT ^a (ft)	1499.57 (404.10)	1631.78 (312.87)	1622.76 (301.61)	0.33	0.30
Activity level					
IPAQ walking (min/wk)	64.69 (78.83)	316.25 (418.42)	171.72 (234.30)	3.19	1.36
IPAQ sitting (hr/d)	5.41 (3.29)	4.31 (2.82)	5.34 (2.64)	0.33	0.02
Daily steps	4464.60 (2240.09)	6766.10 (3425.20)	5940.04 (3791.13)	1.03	0.66
Social support					
MSPSS—friends	21.75 (6.05)	22.44 (5.74)	23.25 (5.11)	0.11	0.25
Mental health					
PANSS Positive	18.81 (4.45)	16.38 (5.00)	17.00 (4.55)	0.55	0.41
PANSS Negative	18.81 (5.66)	15.38 (4.83)	18.81 (6.25)	0.61	0.00
PANSS General	38.56 (6.43)	35.31 (5.57)	36.50 (8.40)	0.51	0.32
PANSS Total	76.19 (12.71)	67.06 (12.17)	72.31 (16.59)	0.72	0.30
WHOQOL-Overall	7.16 (1.86)	7.88 (1.78)	7.69 (1.82)	0.39	0.29
WHOQOL-Physical Health	24.59 (4.64)	26.13 (5.89)	25.75 (5.50)	0.33	0.25
WHOQOL-Psychological	20.69 (4.94)	21.94 (5.81)	21.50 (5.57)	0.25	0.16
WHOQOL-Social Rel.	10.81 (2.95)	10.63 (3.07)	11.19 (3.15)	-0.06	0.13

A positive effect indicates improvement and a negative effect size indicates deterioration. One participant did not complete the 6MWT at PT and FU and was subsequently removed from analyses of this measure.

BL = baseline; PT = posttest; FU = follow-up; PCS = physical component score; BMI = body mass index; BP = blood pressure; HR = heart rate; 6MWT = Six-Minute Walk Test; MSPSS = Multidimensional Scale of Perceived Social Support; PANSS = Positive and Negative Syndrome Scale; WHOQOL = World Health Organization Quality of Life Scale, Brief Version.

Finally, PANAS scores from pre-walk (M = 17.80, SD = 4.64) to post-walk (M = 20.93, SD = 3.19) reflect medium to large improvements in positive mood experienced during the walk (d = 0.68).

Exploratory Outcomes

Table 3 provides partial correlations of step count with 6MWT, and BMI at post-test and follow-up while controlling for baseline scores. Significant positive correlations were found between 6MWT distance and step count at posttest and follow-up after controlling for baseline measures of these variables indicating that higher step count was associated with longer distances walked during the 6MWT. Partial correlations between step count and BMI at both time points were in the expected direction but were not statistically significant.

Walking group attendance and pedometer adherence rates were 84% and 86%, respectively. Scores on the CSQ-8 indicated a high level of satisfaction for WOW (M=30.6, SD=1.45; maximum score is 32). Additionally, participant responses on the posttest feedback questionnaire indicated that the health benefit, social interaction, walking different routes, and money were all motivating factors to attendance with health benefit and social interaction rated highest (Fig. 2). Feedback about pedometers and goal setting revealed moderate to high levels of acceptability. Finally, participants reported high levels of satisfaction with reporting steps daily and are moderately likely to attend walking groups without compensation (Table 4).

DISCUSSION

The purpose of the current study was to evaluate the impact of WOW on domains of physical health, activity level, social support, and mental health in individuals with SSDs. Exploratory aims were (a) to assess the relationship between activity level and physical indices at posttest to establish whether changes in physical activity

TABLE 3. Partial Correlations Between Step Count and Physical Health Indices

	PT Step Count	FU Step Count	
6MWT	0.720*	0.622**	
BMI	-0.481	-0.368	

Posttest scores of 6MWT and BMI were entered into correlational analysis with PT step count (not with FU step count). The same procedure was used for FU scores. Baseline measures were entered as covariates for all partial correlations.

 $^{^{}a}n = 15.$

 $^{^{\}rm b}$ *n* = 7.

^{*}Correlation is significant at the 0.05 level (2-tailed).

^{**}Correlation is significant at the 0.01 level (2-tailed).

PT = posttest; FU = follow-up; 6MWT = Six-Minute Walk Test; BMI = body mass index.

were associated with physical health improvements, and (b) to examine participant feedback and satisfaction. Participants experienced improvements in all of the key domains over the course of this 10-week intervention, including the Six-Minute Walk Test, a measure of physical health. Although, on average, participants experienced minor weight loss (~1.3 lbs), it varied drastically among participants. Finally, given that WOW was delivered over 10 weeks and at a moderate pace, it is likely that this intervention was not of sufficient duration or intensity to significantly impact blood pressure (Murphy et al., 2007).

Step count improvements were substantial with participants experiencing an approximate 2000 steps/day increase over the course of 10 weeks. Compared to one individual at baseline, eight participants (50%) were accumulating daily steps within the 6500 to 8500 range recommended for adults with chronic illnesses at posttest (Tudor-Locke et al., 2011). Moreover, by the end of the 10-week intervention, four participants were walking above 10,000 steps/day, which is considered the upper end recommendation for healthy older adults (Tudor-Locke et al., 2011). Participants reported increased minutes spent walking and fewer hours sitting, suggesting participation in WOW promoted lifestyle changes outside supervised walking groups.

Improved quality of life, social support, and symptoms suggest participation in WOW also impacted psychological outcomes. Though this sample consisted of clinically stable participants currently receiving outpatient pharmacological and psychological treatment, large improvements in symptoms were present from baseline to posttest. Consistent with previous research on exercise in SSDs (Dauwan et al., 2016), results from this study demonstrate the impact of physical activity on symptoms. Given the difficulty in treating negative symptoms, mental healthcare providers may consider a group-based exercise intervention as an adjunct to current treatment for individuals with SSDs.

Results from the current study suggest positive perceptions of WOW and overall program satisfaction as evidenced by high attendance/ adherence rates and participant ratings. Though pedometers have been successfully used in this population as the primary intervention (Kane et al., 2012; Lindamer et al., 2008), high pedometer adherence rates and participant acceptability ratings observed during WOW suggest that pedometers can be effectively used in combination with a walking group program. In addition, participants endorsed social interaction and health benefits as the primary rationale for group attendance, suggesting the importance of these domains in addressing

How much did each of the following motivate you to attend groups?

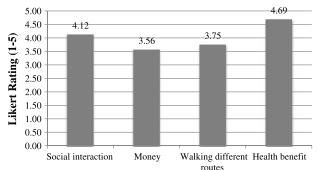


FIGURE 2. Participants (n = 16) rated how much each category (health benefit, social interaction, walking different routes, money) motivated them to attend walking groups on a scale from 1 to 5 (higher indicated more motivating). As noted in this graph, participants identified health benefit as the most motivating followed by social interaction, walking different routes, and, finally, money.

TABLE 4. WOW Participant Feedback

Feedback Category	M (SD)
Pedometer usage	
How much did you like using a pedometer?	4.0 (1.2)
How likely are you to continue using the pedometer after the study ends?	3.5 (1.4)
Goal-setting	
How much did you like setting weekly step goals?	3.6 (0.9)
How much did you like receiving weekly goal sheets?	4.0 (1.0)
WOW specific feedback	
How much did you like reporting your steps each day?	3.9 (1.1)
How likely is it that you would attend groups without pay?	3.6 (1.3)

Participants rated all feedback questions on a scale from 1 (not at all) to 5 (extremely).

motivational barriers in this population (Archie et al., 2003; Beebe et al., 2011).

Limitations of the current study include a small sample size and lack of a comparison condition. Due to the small sample size and lack of a control condition, it is important to interpret the results with caution. Additionally, because participants were compensated for attendance in the walking groups, attendance rates may not reflect those obtained in their absence. Given that this study was supported with seed funds, the study coordinator led all walking groups, conducted all assessments, and initiated all daily contact calls, texts, and emails. As a result, participants' responses during assessments may have been influenced by the presence and perceived goals of the study coordinator. Finally, it was not possible to conduct assessments of physical parameters (weight/BMI, RHR, and blood pressure) at consistent times of day or while controlling for diet. As a result, these outcomes may have been influenced by several external factors and should be interpreted with caution.

Despite these limitations, changes in the key domains are comparable to those reported in published randomized controlled trials of exercise interventions for individuals with SSDs (Beebe et al., 2005; Pelham et al., 1993). Yet, unlike the majority of previous research, WOW was integrated into the local outpatient clinic and did not require access to a gym, supervision by a professional trainer, or advanced equipment, thus promoting scalability of the intervention. Moreover, WOW includes strategies to promote accountability and motivation including self-monitoring, mood ratings, daily reminders, step count reporting (to a research assistant), goal-setting, and weekly progress updates. Social interaction was also a primary focus of WOW as participants were encouraged to talk with each other and with the group leaders during group walks and during the "after walk sharing" session.

CONCLUSIONS

Individuals in WOW increased their activity level throughout the program and seemed to have experienced benefits in symptoms, social support, and physical health. High group attendance and pedometer adherence rates in tandem with program satisfaction ratings suggest that WOW may not only impact important domains but also could serve as a viable adjunct to typical outpatient treatment. Overall, this pilot study has demonstrated the value of a comprehensive vet accessible, feasible, and sustainable exercise intervention for individuals with SSDs. Future research should consider evaluating WOW in the context of a randomized controlled trial with the inclusion of a comparison condition.

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DISCLOSURE

The authors declare no conflict of interest.

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