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Research Article

Results of a nine month home-based physical activity intervention for people living with HIV

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ABSTRACT

Background: The purpose of this investigation was to test the feasibility of a home-based moderate-intensity physical activity (MPA) program for people living with HIV/AIDS (PLWHA) currently taking antiretroviral therapy (ART).
Methods: 68 participants recruited for a 9-month home-based PA intervention aimed to reduce risk factors of cardiovascular disease for PLWHA taking ART. All participants received an educational weight loss workbook and a pedometer for self-monitoring of physical activity. The intervention group received elastic Therabands® for strength training in addition to telephone based behavioural coaching. Clinical assessments were conducted at baseline and each follow-up which also included psychometric questionnaires and PA levels via the SenseWear® armband accelerometer.
Results: Of the 57 completing the study, 29 of those were in the intervention group and 28 were in the standard care group. Results show that the home-based PA intervention was not successful in increasing the total amount of MPA for PLWHA. However there was a trend (p=0.08) of decreasing sedentary time. In a secondary analysis those who increased PA by >10% observed decreases in waist circumference and improved functioning at 18 weeks. None of the changes observed were significant after controlling for all potential confounders.
Conclusions: A home-based exercise approach with telephone-based coaching may not be a feasible method for increasing MPA among PLWHA. Slight decreases in sedentary time indicate some positive changes in activity habits. A possible strategy to improve studies similar to this is to incorporate a group based social interaction each week similar to that of a support group.

Keywords: Community intervention, Randomized clinical trial, HIV, Physical Activity, Exercise, Self-care

INTRODUCTION

With the success of antiretroviral therapy (ART) extending the life of people living with HIV/AIDS (PLWHA), there has emerged an aging HIV population and the long term consequences associated with ART toxicity. These consequences primarily affect metabolic processes often resulting in conditions similar to that of metabolic syndrome.[1,2] For example, protease inhibitors have been shown to increase circulating blood lipids (i.e. triglycerides, cholesterol, etc.) and cause a pattern of abnormal fat deposition known as lipodystrophy -

resulting in central fat accumulation. Other classes of antiretrovirals are known to cause gastrointestinal and metabolic consequences. Evidence has shown that the risk for cardiovascular and diabetes related complications increases significantly for every year a person is taking ART.[1,3]

Physical activity has been widely accepted as a way to reduce the incidence and risk of cardiovascular disease and diabetes in the general population as well as PLWHA.[4-6] Physical activity is especially important to PLWHA because the side effects associated with ART can have a synergistic effect on lifestyle choices such as sedentary living, unhealthy diets, and other determinants of chronic disease. Routine physical activity could be successful in reducing some of the side effects of HIV infection/treatment and help self-manage the disease while improving quality of life.

Routine physical activity has proven benefits in general and clinical populations.[4,7-13] Many of the physiological benefits of activity are a direct result of metabolic improvements (i.e. improved lipid panel, reduced waist circumference and body fat, etc.) with long-term improvements in cardiorespiratory health. Randomized controlled trials of physical activity interventions have shown decreases in body weight and visceral fat accumulation, increased HDL cholesterol, decreased triglycerides, and improved insulin sensitivity.[9,14,15] These studies are of various lengths with some lasting as little as 6-8 weeks and others showing benefits from year-long interventions. What is unclear, however, is whether PLWHA on ART intervention will benefit similarly from a physical activity intervention. Because the rate of HIV infection continues to increase in low-income populations, it is important that cost-effective interventions aimed at increasing physical activity are identified and implemented. The increased number of barriers to physical activity among many PLWHA requires the development of effective interventions that can be provided to large numbers at a low cost.

A number of studies demonstrate the effectiveness of community-based physical activity interventions.[8,12,16] These interventions range from group-based classroom activities that emphasize behavior modification and education all the way to simple home-based approaches that incorporate weekly or bi-weekly telephone calls from a trained health educator. These strategies have been shown to be effective in a range of populations. Similar home-based activity programs have targeted healthy populations as well as a variety of clinical populations such as those with heart failure, cancer, sporadic inclusion body myositis, chronic obstructive pulmonary disorder, and outcomes associated with various inflammatory responses.[12,13,17] To date, there have been no published investigations that incorporate a home-based exercise approach for PLWHA.

There is a growing body of evidence suggesting plwha can achieve similar benefits in routine physical activity commonly observed in the general population.[7,11,18-20] The use of a home-based physical activity intervention in other clinical populations has successfully increased the amount of daily physical activity accumulated when compared to a control group.[12,21,22] These programs incorporated moderate-intensity physical activity, which has been shown to be safe for clinical populations with functional limitations.[23,24] Similar physical activity interventions are needed that can improve self-management of metabolic conditions among PLWHA taking art. The purpose of this study was to evaluate the feasibility of a home-based physical activity intervention aimed to increase moderate intensity physical activity and reduce the incidence of cardiometabolic risk factors among PLWHA.

METHODS

Participants

Study participants were recruited from local physicians, clinics, and HIV/AIDS support groups in the greater Columbia and Charleston, SC areas. There were 68 participants enrolled in the study and randomized into one of two groups. For a complete list of the inclusion and exclusion criteria see Table 1. Out of the initial 68 participants who were randomized, 62 completed the 18 week data collection period, and 57 completed the full 36 week study. There were six outliers identified at baseline leaving a total of 62 participants for the final intent-to-treat data analysis. Outliers were determined according to baseline moderate-intensity physical activity values that were 3 standard deviations higher or lower than the total average. Figure 1 provides a schematic of participant involvement through randomization and 36 week follow-up. The detailed description of the study methodologies and participant recruitment for this study has been published previously.[25]

Randomization

After completion of baseline assessments all participants were randomized into one of two groups: 1) Home-based physical activity intervention or 2) standard care. Both groups received an evidence-based book on healthful eating and regular physical activity and a pedometer.[26] Those randomized into the intervention group received a one-on-one physical activity training session from a trained interventionist to further explain participant expectations. The training session provided an overview of what constitutes physical activity, benefits of physical activity, different types of physical activity, current physical activity recommendations, tips for starting a physical activity program and proper use of the activity log. Additionally, the session included a demonstration for use of the elastic Thera-bands® for strength training.

Intervention

Two interventionists were trained by a clinical psychologist with expertise in behavioral interventions to implement the Active Choices program (developed at Stanford University). Active Choices is a home-based physical activity program that uses theoretically-based strategies to help participants make lifestyle changes and is based on both social cognitive theory and the transtheoretical model.[27] The intervention began with a 60-minute individual face-to-face session in which rapport was established; the program and expectations were described; a physical activity and diet history was taken; explanation of realistic, specific, and measurable short-term and long-term goals was addressed; safety information was provided; instructions for wearing a pedometer was given; self-monitoring tools (pedometer and log) were distributed; and a schedule for follow-up telephone calls was set. In addition to the education session the health educator worked with each participant to help them establish reasonable short term goals that would eventually lead up to a common long term goal among the participants (> 150 minutes of routine moderate intensity physical activity per week).[25]

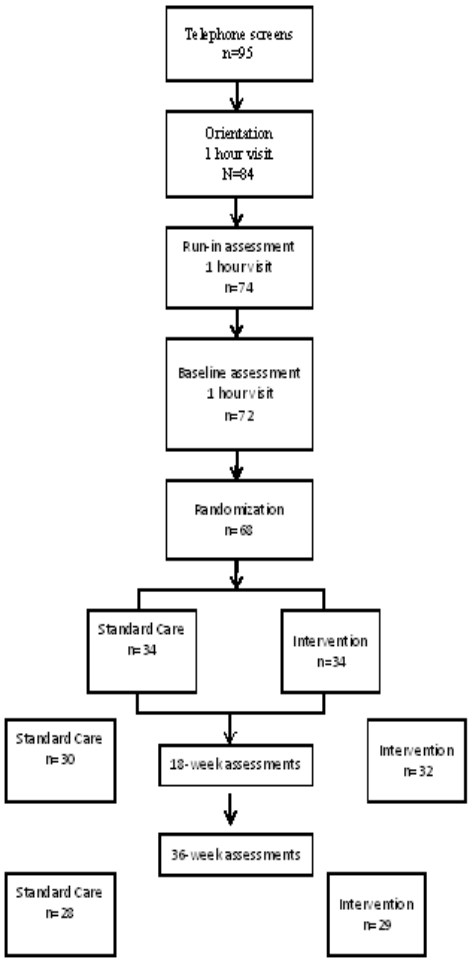

Figure 1: CONSORT flow diagram.

Non-exercise Standard Care Group

Participants in the standard care group received the same educational material and weight loss manual as those randomized to the physical activity group. Physical activity habits were monitored throughout the study for participants randomized to the standard care group in the same manner as for the intervention group using the SenseWear® armband. One potential problem in this group was the possibility of participants losing interest in the study because they were assigned to a "control" group. We have been successful in reducing standard care group dropout in previous studies by maintaining telephone contact with standard care group participants. In this study, we initiated contact with the standard care group participants by telephone every two weeks to update health status, maintain current contact information, and emphasized the importance of their participation for a successful study.

Outcome variables

The primary outcome of interest for this investigation was moderate-intensity physical activity as measured by the Sensewear® armband. This measurement was used as an index of program adherence and total accumulation of daily physical activity. Using tri-accelerometry technology augmented by 2 heat sensors (a thermistor-based skin surface sensor and a proprietary heat flux sensor), and a galvanic skin response sensor, the device is able to accurately measure and record total energy expenditure, and also measures activity intensity. The 4 internal sensors turn on the monitor when detecting skin contact and measures total time the armband was worn, daily energy expenditure, step count, sleep efficiency, and the intensity, duration, and frequency of physical activity bouts.

All arm band data were analyzed by computer-based software using demographic information (gender, age, height, and weight at prior assessment) and proprietary algorithms. Validity of armband energy expenditure estimates has been reported in several conditions including resting, exercise (i.e. treadmill and cycle ergometer), and free-living conditions (i.e. physical activity and exercise).[28,29] St-Onge et al. found that when comparing the armband to doubly labeled water daily energy expenditure had an interclass correlation of 0.81 ($P < 0.01$) between the two methods.[30] When comparing the armband to the Intelligent Device for Estimating Energy Expenditure and Activity (IDEEA) Welk et al. showed comparable results between the armband and IDEEA when estimating energy expenditure and PA.[29] Participants were required to wear the armband for a minimum of 10 hours on 4 separate days for the armband data to be considered valid. Secondary outcomes included physiological and psychological variables, such as cardiorespiratory fitness (VO2), body composition, full blood lipid panel, serum C - reactive protein (CRP),

interleukin-6 (IL-6), depression, anxiety, stress, and health-related quality of life.

Testing procedures

Graded exercise stress test: Following a medical examination including evaluation of family and personal medical history, resting blood pressure, and resting ECG evaluation, each participant completed a graded exercise treadmill test (GXT). The GXT was used to screen for abnormal physiological responses to exercise, including blood pressure and ECG responses, and for determining the participant's current level of cardiorespiratory fitness. The test was terminated either at volitional exhaustion or at observation of abnormal responses that are contraindications for exercise. This test has been found to be highly reproducible with a high sensitivity to changes in VO2 peak.[31]

Body mass index and visceral fat: Anthropomorphic measurements were made using standard laboratory equipment. Height and weight were used to determine body mass index (BMI, weight in kg/height in meters^2) as an index of total body fat. Waist circumference (WC) was measured as an index of visceral fat. Waist circumference is only an indirect measure of visceral fat, but budget constraints preclude more direct measurement of visceral fat.[32]

Self-report questionnaires

Perceived stress scale (PSS): The 10-item PSS assesses the degree to which an individual finds life events unpredictable, uncontrollable, or overwhelming.[33] Internal consistency has been demonstrated by a Cronbach's alpha of 0.78.[33] Validity of the PSS is supported by significant correlations with greater help-seeking, poorer health, more health service utilization, and poorer life satisfaction.[33]

MOS 36-item short-form health survey (SF-36): The SF-36 is a widely used and validated self-report measure of health-related quality of life.[34] It consists of eight health concepts including physical function, social function, pain, mental health, energy/fatigue, general health perceptions, role limitations due to physical problems, and role limitations due to emotional problems. The SF-36 can be divided into the two parts: the Mental Composite Score (MCS) and the Physical Composite Score (PCS). The internal consistency reliability coefficients are high for its eight scales and ranges from 0.78 to 0.93.[35]

Centers for epidemiologic studies-depression (CES-D): The 20-item CES-D is a widely used and validated self-report measure of depressive symptoms.[36] Components of the CES-D include depressed mood, feelings of guilt and worthlessness, feelings of hopelessness and helplessness, psychomotor retardation, loss of appetite, and sleep disturbance. The CES-D has a high internal consistency in both the general population (.85) and in patient populations (.90).[36]

Blood Sampling and Analyses

Blood draws were performed following an 8 hour fast at baseline, 18 weeks, and 36 weeks. Participants were asked to refrain from taking aspirin and other anti-inflammatory medications for 48 hours prior to the blood draw. Twenty milliliters of whole venous blood was drawn into standard vacutainer tubes by trained personnel. Standard separation procedures were used for collection of serum and plasma. Samples were stored at -80º C until ready for analysis. The blood components of interest were measured in duplicate by LabCorp® clinical trials division. All samples were analyzed by a LabCorp professional at a central location that undergoes rigorous quality assurance testing to deliver high accuracy and reliability in the results.

Statistical analyses

We conducted an intent-to-treat analysis to test the feasibility of this home-based study. Missing observations were imputed into the dataset by the last observation carried forward method. Outliers were identified as participants who accumulated more than 3 standard deviations from the sample mean of moderate intensity physical activity at baseline and removed from the dataset. All analyses were performed using SPSS statistical software. Treatment effects were evaluated using a two way ANOVA by conducting a repeated measure general linear model controlling for age, gender, VO2, and baseline measures. Analyses were performed on all outcome variables and accelerometer data. In a secondary data analysis to determine changes in secondary outcomes participants were divided into one of two groups according to changes in physical activity. Those in group 1 increased their average minutes per day of moderate intensity physical activity by more than 10%, whereas group 2 included the participants who stayed within 10% or less of their daily physical activity average measured at baseline and the 18 week follow-up. The same groups were then created according to changes in physical activity from baseline to 36 week follow-up. Differences within and between groups were conducted in a similar manner previously described but also controlled for group assignment (intervention or standard care).

RESULTS

At baseline there were no significant differences between intervention and the standard care group for any demographic, medical characteristics, or outcome variables. All participants were currently taking a combination antiretroviral regimen and none reported changes in medications throughout the study duration.

The majority of participants (54%) were females and African-American (82%), with a self-reported income

less than $30,000 (69%). The average age was 47.1±9.4 years. Table 2 shows the baseline values of each outcome variable. The mean duration of moderate intensity activity for all participants was 91.6±77.8 minutes per day and average sedentary time was 881.9±403.5 minutes per day. No significant differences were found within or between groups at the 18 week or 36 week time points for any of the measured variables as seen in Table 2.

Tables 3.1 and 3.2 show the results of the secondary data analysis in which participants were separated into groups according to changes in physical activity. Those who increased their activity levels by 10% or more showed a decreasing trend in waist circumference that barely reached significance ($p = 0.05$) at the 18 week time point, but not 36 weeks. Systolic blood pressure also significantly decreased ($p = 0.023$) for those who increased their daily physical activity at 18 weeks, but no difference was observed at 36 weeks. As expected there were also significant changes in moderate intensity physical activity and sedentary time for both groups at each time point. No significant differences were observed among the other physiological variables. No significant differences were observed in the psychological variables.

A decreasing trend was observed in role functioning and physical health of the intervention group at 18 weeks, but this did not continue at 36 weeks. A reduction in pain was seen at 36 weeks in the intervention group; role limitations due to emotional health at 18 weeks also exhibited a downward trend. After controlling for potential confounders, none of the trends were statistically significant.

Table 1: Inclusion and exclusion criteria.

Inclusion Criteria	
• Age 18 years and older • Medical diagnosis of HIV-1 positive serostatus • Sedentary lifestyle: not actively exercising ≥ 3 d·wk^{-1} for 20 min per session • Stable, DHHS-approved ART regimen for previous 3 months, with HIV viral load below 75 copies/mL • Capable of performing the required exercise regimen • Have daily access to a telephone for approximately 10 months • Capacity and willingness to provide informed consent and accept randomized group assignment	
Exclusion Criteria	**Temporary Exclusion Criteria**
• Individuals who have a clinical history strongly suggestive of Type 1 diabetes. • History of serious arrhythmias, cardiomyopathy, congestive heart failure, stroke or transient ischemic cerebral attacks, peripheral vascular disease with intermittent claudication, myocardial infarction, or CABG. • Malignancies in the past 5 years, except therapeutically controlled skin cancer. • Plans to be away > 4 weeks in the next 9 months • Score of 5 or greater on the DAST or MAST (signifying excessive use of drugs or alcohol). • Weight loss in excess of 10% body weight in previous 12 weeks. • Chronic or recurrent respiratory, gastrointestinal, neuromuscular, neurological, or psychiatric conditions. • Inflammatory-related conditions such as collagen disorders. • Any other medical condition or disease that is life-threatening or that can interfere with or be aggravated by exercise.	• Total cholesterol ≥240 mg/dl with LDL-C ≥160 mg/dl or TG levels ≥300 mg/dl. Note: Individuals on cholesterol lowering medications but meeting blood lipid requirements are eligible. • Resting blood pressure >160 systolic and/or 90 diastolic. Note: Individuals on blood pressure medications but meeting blood pressure criteria are eligible. • HbA1c ≥11%. Individuals whose HbA1c exceeds this level will be recommended to seek treatment immediately. Such individuals may be re-screened after three months to re-assess HbA1c eligibility. • Current opportunistic infection at the time of screening. • Participation in another intervention trial. • Other temporary intervening event, such as sick spouse, bereavement, or recent move.

Table 2: Results of measured outcomes.

Variable	Baseline	18 weeks	36 weeks	p value
Weight in pounds, Mean ± SD				
Standard Care	190.68 ± 49.79	195.65 ± 53.86	195.74 ± 53.42	0.94
Intervention	192.36 ± 40.25	193.16 ± 41.02	196.01 ± 41.72	0.96
BMI (kg/m^2), Mean ± SD				
Standard Care	30.88 ± 8.39	31.11 ± 8.73	31.33 ± 9.22	0.99
Intervention	30.29 ± 4.85	30.28 ± 4.43	31.43 ± 5.50	0.97
Waist circumference, Mean ± SD				
Standard Care	99.47 ± 18.70	100.63 ± 18.31	100.76 ± 18.77	0.97
Intervention	99.08 ± 12.43	96.31 ± 17.75	101.64 ± 14.28	0.55
Blood Pressure, Mean ± SD				
Systolic (mmHg)				
Standard Care	129 ± 15	125 ± 12	129 ± 19	0.66
Intervention	128 ± 15	124 ± 13	125 ± 14	0.58
Diastolic (mmHg)				
Standard Care	82 ± 11	82 ± 10	83 ± 12	0.95
Intervention	82 ± 9	78 ± 8	82 ± 10	0.35
Fasting blood analysis, Mean ± SD				
Cholesterol (mg/dL)				
Standard Care	172.82 ± 33.58	174.29 ± 36.43	183.94 ± 31.35	0.59
Intervention	199.94 ± 61.09	199.90 ± 40.08	205.69 ± 39.49	0.94
Triglycerides (mg/dL)				
Standard Care	116.18 ± 68.44	145.82 ± 122.64	138.63 ± 147.78	0.75
Intervention	179.94 ± 189.19	188.40 ± 123.30	168.23 ± 107.30	0.95
LDL (mg/dL)				
Standard Care	100.71 ± 28.64	99.06 ± 31.21	106.60 ± 29.15	0.76
Intervention	116.07 ± 39.78	122.89 ± 39.76	122.17 ± 34.75	0.88
HDL (mg/dL)				
Standard Care	48.76 ± 12.59	50.65 ± 13.36	51.81 ± 13.13	0.79
Intervention	44.50 ± 22.75	47.40 ± 19.84	48.69 ± 21.50	0.87
VLDL (mg/dL)				
Standard Care	23.35 ± 13.65	24.88 ± 17.69	20.87 ± 12.28	0.75
Intervention	27.07 ± 12.46	32.56 ± 18.86	29.75 ± 16.85	0.72
Glucose (mg/dL)				
Standard Care	116.41 ± 40.63	119.65 ± 89.02	100.75 ± 21.94	0.62
Intervention	116.31 ± 59.45	113.40 ± 63.47	85.52 ± 30.36	0.27
C-Reactive Protein (mg/L)				
Standard Care	6.62 ± 6.89	5.00 ± 4.75	4.04 ± 4.36	0.39
Intervention	4.53 ± 5.10	4.27 ± 3.23	5.29 ± 5.17	0.86
Interleukin-6 (pg/mL)				
Standard Care	4.77 ± 2.11	3.34 ± 2.45	4.30 ± 2.77	0.25
Intervention	3.00 ± 1.58	3.16 ± 2.10	11.86 ± 33.14	0.43
PA Outcomes (Average minutes per day)				
MVPA				
Standard Care	93.35 ± 92.51	89.59 ± 79.29	96.36 ± 80.33	0.96
Intervention	89.90 ± 63.14	83.16 ± 72.23	79.26 ± 64.15	0.88
Light PA				
Standard Care	221.23 ± 126.89	203.36 ± 84.41	230.82 ± 114.30	0.71
Intervention	190.62 ± 71.32	181.74 ± 74.79	198.16 ± 93.20	0.82
Sedentary				
Standard Care	838.32 ± 249.61	848.23 ± 231.70	808.05 ± 274.80	0.86
Intervention	925.48 ± 153.86	787.37 ± 232.04	816.26 ± 224.90	0.08
Steps (Average per day)				

Standard Care	5905.55 ± 2944.37	6179.47 ± 2865.38	6610.17 ± 3886.32	0.14
Intervention	5870.37 ± 2893.44	5285.38 ± 2483.99	5769.52 ± 3724.28	0.77
Sleep Metrics (Average hours per day)				
Total sleep time				
Standard Care	4.41 ± 1.64	4.32 ± 2.07	4.36 ± 1.75	0.99
Intervention	4.99 ± 1.69	3.92 ± 2.29	4.43 ± 2.45	0.29
Sleep efficiency (%)				
Standard Care	73.44 ± 10.72	73.96 ± 8.72	75.84 ± 8.61	0.64
Intervention	73.71± 13.30	72.75 ± 16.79	71.47 ± 12.49	0.87

Table 3.1: Physical activity changes from baseline to 18 weeks.

Variable	Baseline	18 Weeks	P value
BMI (kg/m^2), Mean ± SD			
Standard Care	30.92 ± 6.14	31.41 ± 6.15	0.12
Intervention	32.26 ± 5.14	31.99 ± 5.50	0.23
Waist circumference, Mean ± SD			
Standard Care	100.15 ± 15.23	99.35 ± 17.35	0.33
Intervention	104.11 ± 13.53	102.89 ± 12.68	0.05
Blood Pressure, Mean ± SD			
Systolic (mmHg)			
Standard Care	127 ± 16	124 ± 11	0.11
Intervention	130 ± 16	124 ± 80	0.03
Diastolic (mmHg)			
Standard Care	82 ± 4	80 ± 8	0.16
Intervention	84 ± 9	80 ± 10	0.09
Activity Monitor Outcomes, Mean ± SD			
Measured EE			
Standard Care	2280.87 ± 712.93	2094.54 ± 581.93	<0.001
Intervention	2289.42 ± 500.32	2244.55 ± 556.19	0.35
Steps			
Standard Care	6106.75 ± 4025.09	5236.41 ± 2684.68	0.004
Intervention	5540.08 ± 2839.96	6331.07 ± 2890.79	0.03
Sedentary Time			
Standard Care	855.05 ± 167.62	818.61 ± 200.87	0.04
Intervention	912.58 ± 133.39	785.05 ± 188.57	0.008
Light Activity			
Standard Care	180.81 ± 38.16	172.23 ± 44.47	0.25
Intervention	202.75 ± 60.87	215.06 ± 75.71	0.28
Moderate Activity			
Standard Care	82.16 ± 71.64	67.82 ± 54.37	0.001
Intervention	59.00 ± 58.10	89.16 ± 64.77	<0.001
Vigorous Activity			
Standard Care	5.27 ± 2.53	2.88 ± 1.39	0.06
Intervention	4.25 ± 2.39	5.43 ± 4.38	0.12
Sleep Hours			
Standard Care	4.38 ± 1.29	5.18 ± 1.53	0.17
Intervention	4.78 ± 1.23	4.05 ± 1.88	0.04
Fasting blood analysis, Mean ± SD			
Cholesterol (mg/dL)			
Standard Care	182.94 ± 30.29	180.10 ± 40.44	0.31
Intervention	194.25 ± 35.83	191.65 ± 35.08	0.34
Triglycerides (mg/dL)			
Standard Care	160.81 ± 93.83	142.39 ± 112.24	0.21
Intervention	140.70 ± 67.66	158.26 ± 119.70	0.24

LDL (mg/dL)			
Standard Care	104.03 ± 36.36	103.13 ± 37.17	0.38
Intervention	119.61 ± 38.54	111.13 ± 38.80	0.26
HDL (mg/dL)			
Standard Care	46.19 ± 13.89	49.23 ± 14.39	0.19
Intervention	46.48 ± 14.18	50.74 ± 14.05	0.09
VLDL (mg/dL)			
Standard Care	28.58 ± 18.89	27.68 ± 17.71	0.35
Intervention	28.26 ± 13.46	29.48 ± 17.12	0.13
Glucose (mg/dL)			
Standard Care	110.19 ± 69.27	110.26 ± 68.55	0.49
Intervention	109.09 ± 43.15	116.57 ± 93.59	0.28
C-Reactive Protein (mg/L)			
Standard Care	5.77 ± 6.24	5.72 ± 5.79	0.46
Intervention	4.85 ± 5.38	4.23 ± 3.07	0.17
Interleukin-6 (pg/mL)			
Standard Care	4.30 ± 1.27	4.46 ± 1.33	0.46
Intervention	4.20 ± 2.21	3.89 ± 2.08	0.16
Questionnaires			
Perceived Stress			
Standard Care	14.84 ± 2.54	15.66 ± 3.16	0.72
Intervention	16.59 ± 3.74	18.23 ± 4.25	0.16
CESD			
Standard Care	15.15 ± 6.25	14.13 ± 6.25	0.49
Intervention	11.85 ± 17.57	17.57 ± 4.98	0.06
SF-36 (Quality of Life)			
Physical Functioning			
Standard Care	81.32 ± 5.63	78.55 ± 6.41	0.32
Intervention	79.77 ± 3.20	65.31 ± 2.38	0.03
Role Limitations (Physical Health)			
Standard Care	76.97 ± 5.19	32.89 ± 4.12	0.08
Intervention	83.33 ± 5.57	34.38 ± 7.79	0.05
Role Limitations (Emotional Health)			
Standard	79.82 ± 5.83	25.43 ± 5.82	0.001
Intervention	79.17 ± 6.89	41.67 ± 7.84	0.005
Energy/Fatigue			
Standard	64.52 ± 3.27	62.57 ± 3.59	0.92
Intervention	62.29 ± 3.88	60.63 ± 4.04	0.86
Mental Health			
Standard Care	72.21 ± 3.09	70.92 ± 3.57	0.65
Intervention	70.92 ± 3.57	67.25 ± 3.92	0.07
Social Function			
Standard Care	76.97 ± 3.93	73.31 ± 4.44	0.24
Intervention	77.60 ± 4.05	66.67 ± 6.34	0.09
Pain			
Standard Care	75.21 ± 3.87	74.14 ± 4.20	0.72
Intervention	76.35 ± 4.47	65.31 ± 5.51	0.303
General Health			
Standard Care	64.21 ± 3.66	67.31 ± 3.45	0.11
Intervention	61.67 ± 4.94	60.21 ± 4.13	0.66

Table 3.2: Physical activity changes from baseline to 36 weeks.

Variable	Baseline	36 weeks	p value
BMI (kg/m^2), Mean ± SD			
Standard Care	31.47 ± 6.08	32.16 ± 7.35	0.23
Intervention	30.18 ± 5.23	30.11 ± 5.31	0.44
Waist circumference, Mean ± SD			
Standard Care	101.49 ± 13.02	102.24 ± 15.15	0.17
Intervention	99.30 ± 14.27	99.17 ± 15.48	0.47
Blood Pressure, Mean ± SD			
Systolic (mmHg)			
Standard Care	127 ± 18.82	126 ± 17.43	0.27
Intervention	130.00 ± 11.39	128.00 ± 20.49	0.38
Diastolic (mmHg)			
Standard Care	83 ± 10.5	82 ± 10.17	0.16
Intervention	83.00 ± 6.36	85.00 ± 11.37	0.27
Activity Monitor Outcomes, Mean ± SD			
Measured EE			
Standard Care	2273.37 ± 639.32	2142.65 ± 475.44	0.02
Intervention	2338.76 ± 543.88	2583.92 ± 547.50	0.004
Steps			
Standard Care	5734.45 ± 3464.75	5498.74 ± 2643.26	0.14
Intervention	6459.52 ± 2918.25	9214.95 ± 3915.20	0.02
Sedentary Time			
Standard Care	945.68 ± 152.83	895.74 ± 246.84	0.02
Intervention	890.00 ± 121.82	779.83 ± 145.64	0.035
Light Activity			
Standard Care	185.59 ± 59.75	193.61 ± 73.17	0.13
Intervention	207.33 ± 61.56	236.25 ± 86.83	0.07
Moderate Activity			
Standard Care	72.76 ± 67.59	65.53 ± 48.5	0.004
Intervention	74.33 ± 62.07	126.50 ± 79.31	0.001
Vigorous Activity			
Standard Care	5.17 ± 2.94	2.6 ± 1.2	0.03
Intervention	4.33 ± 68.55	4.50 ± 3.35	0.38
Sleep Hours			
Standard Care	4.46 ± 1.54	4.15 ± 1.98	0.07
Intervention	4.45 ± 1.03	4.58 ± 1.71	0.31
Fasting blood analysis, Mean ± SD			
Cholesterol (mg/dL)			
Standard Care	184.42 ± 38.52	194.5 ± 57.58	0.42
Intervention	203.27 ± 47.45	191.09 ± 40.24	0.19
Triglycerides (mg/dL)			
Standard Care	132.69 ± 81.78	143.41 ± 139.77	0.18
Intervention	240.27 ± 55.42	194.55 ± 178.79	0.15
LDL (mg/dL)			
Standard Care	110.84 ± 40.95	115.5 ± 47.75	0.19
Intervention	107.00 ± 41.35	102.11 ± 42.22	0.31
HDL (mg/dL)			
Standard Care	46.96 ± 12.37	50.2 ± 12.16	0.21
Intervention	45.55 ± 27.96	49.45 ± 23.85	0.16
VLDL (mg/dL)			
Standard Care	26.62 ± 16.4	27.41 ± 12.64	0.39
Intervention	25.56 ± 11.03	24.33 ± 21.86	0.35
Glucose (mg/dL)			

Standard Care	109.76 ± 64.75	97.73 ± 26.22	0.11
Intervention	104.09 ± 32.57	92.00 ± 14.51	0.09
C-Reactive Protein (mg/L)			
Standard Care	5.21 ± 5.22	5.03 ± 5.1	0.19
Intervention	5.09 ± 6.04	2.95 ± 2.70	0.11
Interleukin-6 (pg/mL)			
Standard Care	4.24 ± 2.25	7.25 ± 2.03	0.15
Intervention	3.93 ± 1.65	3.25 ± 1.07	0.07
Questionnaires			
Perceived Stress			
Standard Care	15.32 ± 1.08	15.24 ± 0.98	0.32
Intervention	16.17 ± 1.86	17.58 ± 2.58	0.12
CESD			
Standard Care	14.24 ± 1.65	12.96 ± 1.39	0.53
Intervention	12.33 ± 3.35	18.50 ± 4.67	0.13
SF-36 (Quality of Life)			
Physical Functioning			
Standard Care	78.37 ± 3.36	73.01 ± 3.89	0.08
Intervention	90.52 ± 4.03	75.74 ± 8.71	0.08
Role Limitations (Physical Health)			
Standard Care	76.02 ± 2.85	30.39 ± 4.66	0.45
Intervention	91.67 ± 2.43	25.00 ± 4.75	0.03
Role Limitations (Emotional Health)			
Standard	80.27 ± 7.34	35.33 ± 5.51	0.45
Intervention	75.00 ± 3.96	30.56 ± 10.43	0.21
Energy/Fatigue			
Standard	62.43 ± 2.94	61.60 ± 3.16	0.86
Intervention	68.75 ± 3.75	64.58 ± 5.55	0.57
Mental Health			
Standard Care	72.32 ± 2.70	74.82 ± 2.73	0.57
Intervention	75.00 ± 3.45	71.67 ± 5.33	0.23
Social Function			
Standard Care	76.96 ± 3.16	77.50 ± 3.94	0.23
Intervention	80.21 ± 6.61	68.75 ± 7.77	0.43
Pain			
Standard Care	73.25 ± 3.36	70.41 ± 3.76	0.19
Intervention	85.63 ± 4.67	61.25 ± 8.16	0.001
General Health			
Standard Care	62.61 ± 3.31	63.80 ± 2.92	0.49
Intervention	65.83 ± 6.42	71.25 ± 5.51	0.23

DISCUSSION

The purpose of this investigation was to test the feasibility and short-term effectiveness of a 9-month home-based physical activity intervention to increase moderate-intensity physical activity and reduce cardio-metabolic risk among PLWHA compared to standard care. We found that compared to standard care, a home-based walking intervention was not effective for increasing daily physical activity levels among PLWHA who were not regularly active prior to the intervention. Activity levels were measured at 18 and 36 weeks post randomization and neither time point showed a significant change in daily physical activity. Due to the lack of increases in physical activity, it was not surprising to observe no changes in cardio-metabolic risk factors. These findings are conflicting with similar home-based trials for different clinical populations such as breast cancer survivors reported by Matthews et al.[17]

Matthews et al. found significant increases in physical activity levels among breast cancer survivors completing a similar home-based exercise program as this one.[17] Similar to this study, Matthews and colleagues focused on increasing activity levels of a previously sedentary clinical population using a similar telephone-based coaching and behavior modification technique. The intervention resulted in a 12 MET-h/week increase among breast cancer survivors and 76% of the women in the intervention were active 5 days a week or more during the final 4 weeks of the intervention. A major difference between our study and the one by Matthews et al was the length of the intervention (12 weeks compared to 36). However when measured at 18 weeks, our

population did not show any increases in daily physical activity. Another possible explanation for the conflicting results could be the population itself. PLWHA are known to have inconsistent periods of good and bad health. Depression and anxiety are also very common when faced with a chronic condition like HIV making it that much harder to be active consistently.[12,37] In the study by Matthews and colleagues they recruited survivors of breast cancer. The women in that investigation were possibly more focused on improving their health and quality of life since they had just overcome a life threatening condition such as cancer.[12]

Analysis of Increased Physical Activity

In a secondary data analysis we separated the participants into one of two groups at both the 18 week and 36 week follow-ups: 1) those who increased daily moderate intensity physical activity minutes by more than 10% compared to baseline, and 2) those who accumulated 10% or less of moderate intensity physical activity compared to their baseline measurement. This was done in an effort to test the effects of increased activity particularly on markers of cardio-metabolic risk. What we found were significant changes in two variables, both of which are known risk factors for CVD. More specifically, those who increased daily physical activity saw a decrease in waist circumference and systolic blood pressure. Although not significant, some individuals experienced improved lipid profiles, such as increased HDL cholesterol and decreased LDL cholesterol. These findings are similar to what would be expected among healthy individuals and would further indicate the importance to identify simple and cost-effective interventions that successfully increase physical activity among PLWHA.

As presented in Table 3.1, there was a slight downward trend at 18 weeks in most of the psychological variables, including physical functioning, physical and emotional health, energy/fatigue, mental and social health, pain, and general health. At 36 weeks, a stronger downward trend was observed for pain and emotional health; however physical functioning, mental and social health, energy/fatigue, and general health did not show significant change. None of the changes observed were significant after controlling for all potential confounders. Various factors could have contributed to this lack of significance. For example the length of time between questionnaires and characteristics of the population are possible reasons. The participants completed the profile of mood states questionnaire a total of 3 times: baseline, 18 weeks, and 36 weeks. To observe a true relationship, this should be completed multiple times throughout the week and studied using an average of those results. Other researchers have observed a trend between pain and mood with exercise.[37,38] Neidig et al saw a decrease in depressive symptoms in HIV infected individuals after a 12 week exercise intervention using the CES-D and POMS depression subscale.[37] This group is known to have multiple comorbidities, side effects to medications, socioeconomic barriers, and psychosocial concerns.

A possible strategy to improve studies similar to this is to incorporate a group based social interaction each week similar to that of a support group. It also would be ideal to include a type of "buddy system" or asking participants to recruit a partner to exercise with them. Studies have consistently shown the importance of social support among physical activity and the social interaction will often increase the chances of success when someone is beginning a new workout program.[39] Many of the participants of this trial actually asked if such a system was in place. Since this was a single-person study design, it was explained to them that being paired with a partner was not part of the study protocol, but it was encouraged that they find a friend or loved one who might be able to exercise with them.

One of the most significant findings of this study was further evidence showing a strong inverse relationship between waist circumference and increased physical activity. In a previous article from this study, we showed moderate intensity physical activity to be a significant predictor for waist circumference.[7] Although the intervention itself was not successful in increasing physical activity, when the sample was divided into groups according to changes in physical activity, the data showed that regardless of group assignment those who significantly increased their daily physical activity significantly decreased their waist circumference at the 18 week time point.

Strengths and limitations of the current study should be taken into careful consideration and may explain some of our findings, or lack thereof. The strengths included recruiting an HIV population with almost equal numbers of males and females, which allowed for comparing possible gender differences of significant findings. It should also be noted that this clinical trial incorporated a randomized design of physically inactive HIV+ patients and an analysis plan that utilized intent-to-treat principles. The lack of significance of increased physical activity for those randomized to the intervention group would indicate that future studies should take a different approach to increase daily physical activity of similar populations. It should be noted that there are multiple barriers PLWHA face that need to be taken into consideration when developing future interventions including socioeconomic, personal, social, and environmental factors. Mgbere et al found numerous barriers that can adversely affect care access: negative perceptions of the health care system, longer wait time for appointments, lack of flexibility in clinic hours, unmet needs for child care, lack of access to a provider with expertise in treating HIV, strained patient–provider relationship, patient concerns about privacy, mandatory insurance coverage, and multiple funding sources with variable eligibility criteria. On the individual level, they noted multiple barriers which prevent or decrease

PLWHA from utilizing health care including mental health issues and drug addictions, HIV stigma, limited social support, unstable housing and transportation, incarceration, undocumented immigrant status, and avoidance and denial of HIV status.[40] When separated into groups according to change in physical activity, it was observed that health benefits could be obtained within 18 weeks for this specific population. In addition to a randomized design, this study also incorporated objective measures of physical activity and sedentary behavior using the Sensewear® armband.

Several limitations should be noted as well. This population was comprised primarily of African-Americans from lower socio-economic status and majority reported a yearly income less than $30,000. This does not allow us to generalize the findings across other races or individuals living with HIV with a higher yearly income who may have access to other means for physical activity such as gyms or home exercise equipment. Although this investigation examined numerous confounding variables, the lack of unmeasured covariates cannot be ruled out. Some of these include weekly, or even daily, health status and dietary intake. Another covariate could potentially be chronic pain and/or peripheral neuropathy which is very common among PLWHA and known to limit activity levels.[41] Other limitations include the lack of dietary data and exercise log to determine weekly adherence.

CONCLUSION

Increasing the daily amount of routine physical activity has been shown to lead to significant health improvements in multiple populations.[4,7,15,23] With increases in life expectancy due to the advances in treating HIV, daily physical activity is an important step in helping PLWHA self-manage the detrimental side effects often associated with pharmacological treatment, as well reduce the risk of developing chronic comorbid conditions such as CVD and diabetes. Since the antiretroviral regimen has because a necessity to halt viral replication it is critical that we discover better ways to improve the long term health for those living with HIV. Daily activity has shown promising results in other clinical populations, but with limited evidence among the HIV population. Additional research is needed to not only test the hypothesis that long term changes in physical activity behaviors would improve quality of life by helping self-manage the illness, but also to discover more cost-effective and practical ways to achieve this lifestyle change. With increased rates of new infections occurring in more rural areas and those of lower socio-economic status it is imperative that community-based programs tailored to these individuals are developed. Such programs will not be possible without first increasing efforts of bridging clinical-community linkages that in turn could help improve enrollment, adherence, retention, etc.[42]

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