

Pilot Studies to Evaluate Feasibility of a Physical Activity Intervention in Persons with Depression

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Abstract

Depressive disorders are associated with high disease burden and high rates of medical comorbidities. Exercise interventions have been shown to reduce depressive symptoms and help improve physical health outcomes in persons with depression. However, the interventions used in studies demonstrating exercise as an efficacious treatment for depression are unlikely to be adopted into clinical practice due to the significant resources (personnel, facilities, equipment) required to deliver these interventions. This suggests the need for more efficient interventions for increasing physical activity in persons with depression. Two pilot studies were conducted to determine the feasibility of a multi-component physical activity intervention in persons with depression. Components of the intervention included group educational sessions about increasing physical activity, a Fitbit, and access to on-site exercise facility. The results from these pilot studies show significant decreases in depressive symptoms post intervention (PA: $t(13) = 3.51$, $p = .004$; BC: $t(13) = 3.05$, $p = .009$). 100% of participants in the PA pilot and 85.7% of participants in the BC pilot responded that they benefited overall from the study. These results indicate that implementing a multi-component physical activity intervention is feasible and can reduce depressive symptoms and other psychosocial outcomes. Limitations and future directions for physical activity interventions are discussed.

Keywords (five)

Physical activity, depression, Fitbit, feasibility, exercise

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1. INTRODUCTION

Depressive disorders are chronic and associated with high disease burden. [1] The disproportionate prevalence of medical comorbidities contributes to this high disease burden. Persons with Major Depressive Disorder (MDD) are disproportionately affected by
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medical comorbidities, particularly coronary heart disease (CHD) and type 2 diabetes (DM2). [1, 2] A current MDD diagnosis increases the risk of CHD by 64% [3] and incident DM2 by 60%. [4] The significant medical burden experienced by persons with MDD underscores the need for interventions to optimize treatment outcomes, reduce disease recurrence, and improve the physical health of persons with depression.

Increasing physical activity among those with MDD has the potential to impact treatment outcomes and medical comorbidities. Depressive symptoms have consistently been associated with low levels of self-reported physical activity [5, 6] and poor cardiorespiratory fitness. [7, 8] Analysis of the National Health and Nutrition Survey (NHANES) indicates those with depression engage in approximately 50% less moderate-to-vigorous physical activity (MVPA) compared to those without depression. [9] Exercise has proven to be an efficacious stand-alone and augmentation treatment for MDD. [10-14] In addition to improved remission rates, exercise has been shown to decrease the risk of a relapse. A one-year follow up study found that patients who participated in supervised exercise sessions and achieved remission with exercise were less likely to experience a relapse than those who achieved remission with a SSRI. [15] Finally, higher cardiorespiratory fitness levels have been associated with a reduced mortality risk in individuals with depression.[16] In sum, these previous studies demonstrate the positive impact that physical activity has on both physical and mental health in persons with MDD.

This evidence demonstrating the benefits of exercise in persons with depression has not translated into clinical practice. In the research described above, the exercise interventions typically consist of one-on-one supervised exercise with an exercise professional. While effective in ensuring the participants achieve the targeted dose of exercise, these interventions are likely too resource intensive to be used in routine clinical practice. Evidence-based strategies for increasing physical activity that may require less resources, such as educational counseling, [17] utilizing self-monitoring devices, like a Fitbit [18], and exercise facility access [19, 20] have not been examined in persons with depression. In this paper we describe two pilot studies that were conducted to evaluate the feasibility of a multi-component intervention to increase physical activity. Feasibility data will support future studies to identify an optimized intervention for increasing physical activity in persons with MDD.

2. METHODS

Two pilot studies were conducted to assess the effects and feasibility of a multi-component intervention to increase physical activity in persons with depression (PA pilot) and breast cancer survivors with depression (BC pilot).

2.1 Participants

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A total of 28 participants ages 18-65 years were enrolled in the pilot studies (PA pilot n = 14, BC pilot n = 14). Eligible participants were depressed at screening using the Patient Health Questionnaire – 9 [21], a common depressive symptom scale (PHQ-9 score \geq 8, or current antidepressant use) and currently reported less than 150 minutes of moderate-to-vigorous physical activity (MVPA) per week assessed via self-report questionnaires. Participants in the BC pilot were 3 months to 5 years post active breast cancer treatment (surgery, radiation, or chemotherapy). Individuals from both pilots were excluded if they had a medical condition that contraindicated physical activity participation.

2.2 Intervention

Intervention components were chosen due to their proven effectiveness and their ability to be implemented and sustained in real-world settings. Participants were enrolled in group education sessions about ways to increase physical activity (Active Living Every Day), were provided a self-monitoring device for the 12 weeks of the study, and provided supervised access to the on-site exercise lab.

Participants were enrolled in the Active Living Every Day (ALED) [22] counseling program. This program consists of 12 weekly group educational sessions about ways to increase physical activity. The group sessions were conducted by project interventionists who were trained in the delivery of the ALED program. The weekly sessions involve a discussion of topic related to increasing physical activity including: identifying and overcoming barriers, setting goals, enlisting social support, and time management. The PA pilot sessions were held weekly and the BC pilot sessions were held bi-weekly.

Fitbit Flex devices were provided to facilitate participant self-monitoring of physical activity throughout the course of the study. Project interventionists instructed participants on the proper wear and use of the Fitbit devices. Participants were instructed to wear the device daily throughout the study. The devices were set up to be synced via the participant's phone or computer to the study Fitabase account.

Participants were also provided supervised access to the exercise lab at the UT Southwestern Center for Depression Research and Clinical Care (CDRC). Project interventionists were available to supervise participant to access the facility, which included treadmills and exercise bikes for aerobic activity.

Participants in the BC pilot also received a print copy of *Exercise for Health: An Exercise Guide for Breast Cancer Survivors*. [23] Topics covered within the book include benefits of exercise in breast cancer survivors; recommendations on type, duration, frequency and intensity of exercise; goal-setting; and advice on overcoming common barriers.

2.3 Measures

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Study data were collected and managed using REDCap (Research Electronic Data Capture) hosted at UT Southwestern Medical Center.[24] REDCap is a secure, web-based application designed to support data capture for research studies.

2.3.1 Screening

Demographics information including gender, race, ethnicity, and age were collected at the screening visit. Contact information was also collected at this visit. Current medication use was collected via participant self-report at the screening visit and updated throughout the study as needed.

The Physical Activity Readiness Questionnaire-Revised (PAR-Q)[25] asks 7 health related questions to determine whether a person needs to consult with their physician prior to engaging in an exercise program. The PAR-Q was administered at the screening visit. Any participant who scored greater than zero was asked to get medical clearance from their physician before engaging in any physical activity.

The Patient Health Questionnaire-9 (PHQ-9)[21] is a 9-item scale designed to measure depressive symptoms. Participants who scored 8 or higher on the PHQ-9, reflecting moderate depressive symptoms, at their screening visit were eligible to participate in the study.

2.3.2 Outcome Assessments

The following set of assessments were administered at the baseline. Assessments were repeated at Week 7 and Week 13 for the PA Pilot, and at Week 13 and Week 25 for the BC Pilot. Participant self-reported outcomes described below were completed in REDCap. [23]

All participants wore accelerometers (Actigraph 3GTX+) on their non-dominant wrist at three time points (baseline, half way through the intervention, and post intervention). Participants wore the accelerometers for 7 days at each assessment time point. Valid wear days were scored if there was at least 10 hours of wear time per day. Valid wear time for the week was operationalized as 5 days of at least 10 hours of wear time per day. Raw data from the Actigraph was processed using the GGIR R package.[26] Minutes were classified as moderate-to-vigorous physical activity using an epoch length of 5 seconds and an acceleration cut-point of 100mg.[26, 27] Only minutes in which 80% of activity exceeded the 100mg threshold were classified as MVPA.[26]

Quick Inventory of Depressive Symptomatology – Self-Rated (QIDS-SR)[28] is a 16-item questionnaire to assess severity of depression-specific symptoms.

Short Form 36 Health Survey (SF-36)[29] is a 36-item survey of participant-reported general health and quality of life across eight domains of well-being (physical functioning, social functioning, vitality, pain, general health, physical role functioning, emotional role functioning, and mental health).

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Pittsburgh Sleep Quality Index (PSQI)[30] is a 19-item scale designed to assess sleep quality and disturbances. If the response option for Other was left blank, this was coded as a 0 (e.g., 5j. During the past month, how often have you had trouble sleeping because you... Other reason(s) please describe).

Brief Fatigue Inventory (BFI)[31] is a 9-item scale designed to assess fatigue.

Snaith-Hamilton Pleasure Scale (SHAPS)[32] is a 14-item scale that measures anhedonia, the inability to experience pleasure.

Physical Activity Stages of Change Questionnaire. The 4-item scale assesses the current stage within the Transtheoretical Model framework (Pre-contemplation, Contemplation, Preparation, Action, Maintenance). [33].

Physical Activity Self-Efficacy Questionnaire. The 3-item scale assesses self-efficacy for physical activity. Activity-specific self-efficacy is highly correlated with activity change and psychosocial outcomes[33].

A Study Evaluation questionnaire was completed post-intervention for both pilot studies. Participants were asked to rate if they benefited from the group classes, were more physically active than when they began the program, and if they had fewer barriers to physical activity. Participants were asked to rate their experience with using the Fitbit device and their overall experience regarding their participation in the study on a 5-point Likert scale ranging from very poor (1) to very good (5).

2.4 Statistical Analysis

Data examining intervention feasibility included calculation of mean days of Fitbit wear and mean attendance of ALED session. For examination of intervention acceptability, we calculated mean response on the patient satisfaction surveys (1-5 Likert scales). Changes in MVPA were tested using a signed-rank test. For other outcome measures of interest (depressive symptoms, fatigue, anhedonia), paired sample t-tests were conducted to determine significance of the mean change scores.

3. 1 Results

3.1.1 Demographics Data. Demographic data for the two pilot studies are reported in Table 1.

3.1.2 Feasibility Data. Participants in the PA pilot had good total Fitbit wear-time during the intervention. Wear time was assessed for the thirteen weeks of the study. If the Fitbit device had any steps for the day, the day was scored as active. Days with step counts of zero were scored as inactive days. Mean Fitbit wear for observed days in the PA pilot was 94.22% (range 66.67-100%). In the BC pilot, mean Fitbit wear for observed days was 79.7% (range 43.70-100%). The mean attendance for ALED sessions was 89.87% (range 75-100%) in the

PA pilot and 82.13% (range 50-100%) for the BC pilot. No participants in either pilot chose to utilize the supervised access to the on-site exercise lab.

3.1.3 Acceptability Data. Participants in both pilots completed study evaluation questionnaires at their post-intervention assessment visit. 100% of PA pilot participants responded that they benefited overall from the study, had improved their amount of physical activity, and had fewer barriers to physical activity than before the intervention. Overall Fitbit ($\mu = 4.78$) and study experience ($\mu = 4.86$) was rated as very good. 85.7% of BC pilot participants responded that they benefited overall from the study and improved their amount of physical activity. 100% of participants responded that they had fewer barriers to physical activity post-intervention. Overall Fitbit ($\mu = 4.57$) and study experience ($\mu = 4.57$) was rated as good.

3.1.4 Physical Activity Data. In the PA pilot, 93% of participants had valid wear time for baseline, 93% had valid wear time for Week 7, and 78.6% had valid wear time for Week 13. In the BC pilot, 78.6% of participants had valid wear time for baseline, 64.3% had valid wear time for Week 13, and 78.6% had valid wear time for Week 25. There was a mean overall decrease in MVPA for the PA pilot ($\mu = -2.41$, $SD = 26.60$), but a mean overall increase for MVPA in the BC pilot ($\mu = 3.8$, $SD = 23.41$), (Figures 1a, 1b); however, these changes were not significant ($V = 32$, $p = 0.97$).

Participant responses on the stage of change questionnaire indicated that 100% of the participants in the PA pilot and 42% of participants in the BC pilot moved forward in their stage of change (i.e., Contemplation to Preparation). Self-efficacy for participating in physical activity was assessed at baseline and the end of the study. Participants in both pilots showed a mean overall increase in self-efficacy scores post-intervention (PA: $\mu = 0.46$, $SD = 1.26$; BC: $\mu = 0.18$, $SD = 0.69$).

3.1.5 Depressive Symptoms and Psychosocial Outcomes. Participants in both pilot studies showed a significant decrease in their depressive symptoms from baseline. 35.71% of participants in both pilots achieved remission after the intervention. We defined remission according to the QIDS-SR scoring recommendations of a post-intervention depressive symptoms score $< / 5$. Previous work has demonstrated that a two point overall decrease on the QIDS-SR is clinically significant even if remission is not achieved.[28] In the PA pilot, we observed significant decreases in depressive symptoms ($t(13) = 3.51$, $p = .004$), fatigue symptoms ($t(13) = 2.46$, $p = .029$), and anhedonia symptoms ($t(13) = 3.63$, $p = .003$; Table 2). Similarly, we observed significant decreases in depressive symptoms in the BC pilot ($t(13) = 3.05$, $p = .009$). In the BC pilot, there were no significant changes in fatigue symptoms ($t(13) = 1.98$, $p = .069$) or anhedonia scores ($t(13) = 1.88$, $p = .083$; Table 3).

4.1 Tables and Figures

Table 1 Demographics

	PA Pilot (N = 14)	BC Pilot (N = 14)
Age (years), mean (SD)	47.4 (12.61)	56.4 (8.10)
Gender, <i>n</i> (%)		
Female	11 (78.57)	14 (100)
Male	3 (21.43)	-
Race, <i>n</i> (%)		
Black/African American	2 (14.29)	-
White	11 (78.57)	14 (100)
Other	1 (7.14)	-
Ethnicity, <i>n</i> (%)		
Hispanic/Latino	1 (7.14)	1 (7.14)
Not Hispanic/Latino	11 (78.57)	13 (92.86)
Chose not to report	2 (14.29)	-
SSRI use at baseline, <i>n</i> (%)	12 (85.71)	8 (57.14)

SSRI – Selective Serotonin Reuptake Inhibitor

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Measure	Baseline		Post Intervention		<i>n</i>	95% CI for Mean Dif- ference	<i>t</i>	df
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>				
BFI	4.95	2.65	3.24	1.75	14	0.21, 3.22	2.46*	13
QIDS-SR	12.85	4.33	7.29	3.31	14	2.15, 9.0	3.51**	13
SHAPS	4.29	3.75	0.79	0.80	14	1.42, 5.58	3.63**	13
PSQI	7.69	3.57	6.31	3.90	14	-0.89, 3.66	1.50	13
SF-36 subscales								
Physical Functioning	76.07	25.81	75.71	28.00	14	-9.39, 8.68	0.078	13
Role of Health	64.29	33.56	72.32	33.03	14	-3.12, 19.19	1.14	13
Role of Emotion	40.48	28.47	64.88	22.45	14	12.86, 35.95	4.14**	13
Energy	25.45	20.43	54.46	15.78	14	18.38, 39.65	5.35***	13
Emotional	41.07	17.34	63.57	11.34	14	12.93, 32.07	4.61***	13
Social	33.93	27.92	66.96	21.15	14	21.96, 44.11	5.84***	13
Pain	66.96	28.00	70.53	29.66	14	-5.48, 12.63	0.77	13
General Health	54.29	20.18	62.86	22.34	14	1.96, 15.18	2.54*	13

* $p < .05$

** $p < .01$

*** $p < .001$

Table 2

Paired Samples t-test Comparing Baseline and Post-Intervention Psychosocial Outcomes in PA Pilot

Table 3

Measure	Baseline		Post Intervention		<i>n</i>	95% CI for Mean Difference	<i>t</i>	df
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>				
BFI	5.32	2.40	4.31	2.40	14	-0.91, 2.11	1.98	13
QIDS-SR	13.21	4.74	9.57	5.43	14	1.06, 6.22	3.05**	13
SHAPS	3.36	3.25	2.00	2.63	14	-0.21, 2.92	1.88	13
PSQI	10.08	4.03	8.00	3.41	12	-1.00, 5.17	1.68	11
SF-36 subscales:								
Physical Functioning	67.50	22.65	70.71	24.41	14	-3.65, 10.08	0.92	13
Role of Health	55.80	28.62	64.73	29.17	14	-3.50, 21.36	1.40	13
Role of Emotion	46.42	25.87	63.11	29.00	14	1.16, 32.17	2.11	13
Energy	22.77	17.34	42.41	21.68	14	10.49, 28.80	4.20**	13
Emotional	51.79	20.22	59.64	19.56	14	-2.95, 18.67	1.43	13
Social	55.36	27.74	66.96	29.66	14	-1.61, 24.82	1.72	13
Pain	51.79	29.68	62.50	29.82	14	-1.56, 22.99	1.71	13
General Health	49.29	19.00	59.29	21.38	14	1.85, 18.15	2.40*	13

* $p < .05$

** $p < .01$

Paired Samples t-test Comparing Baseline and Post-Intervention Psychosocial Outcomes in BC Pilot

BFI – Brief Fatigue Inventory

QIDS-SR – Quick Inventory of Depressive Symptomatology Self-Rated

SHAPS – Snaith-Hamilton Pleasure Scale

PSQI – Pittsburgh Sleep Quality Index

SF-36 – Short Form 26 Health Survey

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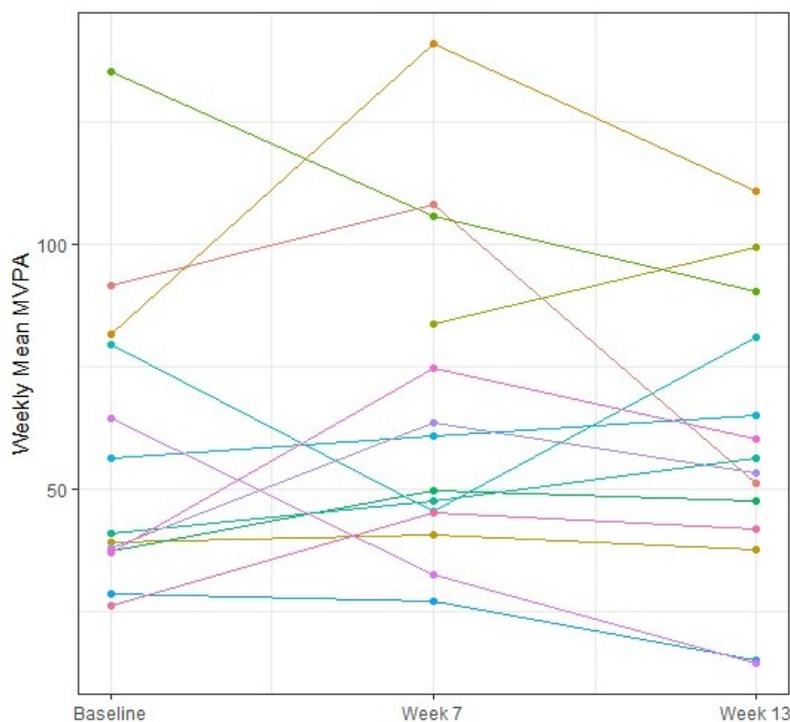


Figure 1a. Mean Weekly MVPA for PA Pilot

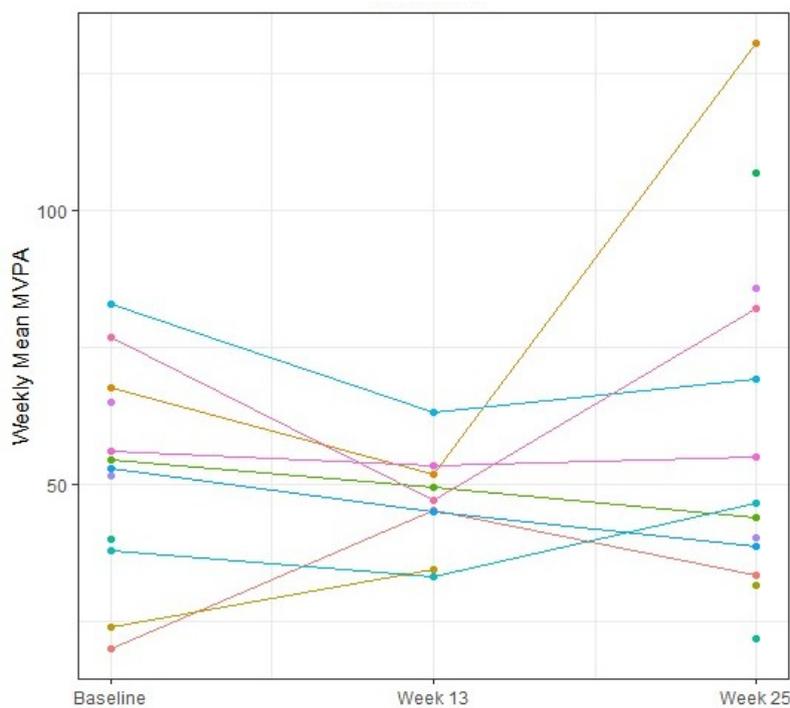


Figure 1b. Mean Weekly MVPA for BC Pilot

Note: Each line represents a participant's weekly MVPA for the length of the intervention

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5.1 Discussion

These pilot studies were conducted to determine the feasibility of a multi-component intervention to increase physical activity among persons with depression. The results from these pilots suggest that implementing a multi-component intervention for increasing physical activity in individuals with depression is feasible. Overall, participants responded well to the intervention and showed good adherence to the intervention components. While the preliminary results do not provide evidence for increasing physical activity, potentially due to the small sample size, we observed improvements in depressive symptoms and other psychosocial symptoms, like fatigue and sleep problems. This is important considering the significant amount of resources needed to implement traditional exercise interventions into clinical practice. The results from these pilot studies suggest that lifestyle counseling and education in group settings and physical activity monitoring devices can lead to clinically significant outcomes in symptom reduction.

Previous research has shown the ALED[22] program to be efficacious at improving physical activity among adults [34] but has not been examined in persons with depression. All of the participants in the PA pilot and 42% of participants in the BC pilot moved forward in their stage of change. These stages are highly correlated with change in physical activity over time [33]. This suggests that the ALED program is effective at helping participants move through the stages of change and can increase their physical activity levels. Previous research has shown that educational resources about the benefits of physical activity are effective among breast cancer survivors, [17] however approximately 50% of oncologists do not advise patients on physical activity habits. This suggests that educational programs, like ALED[22], could be effective at increasing physical activity and decreasing disease burden among breast cancer survivors. Both pilot studies showed favorable responses from the participants with the majority indicating that they benefited overall from the study. These results indicate that the program is feasible for use with these new populations and requires less resources than other traditional exercise interventions.

Our pilot studies had some limitations. We found significant changes in depressive symptoms within both pilots, however we had small sample sizes for both pilots. Both studies also lacked a comparison group. As a result, we cannot conclude that these changes observed were due to the intervention or reflect naturally occurring changes in depressive symptoms. Future research should attempt to isolate the effects of each intervention component in larger samples to determine which component are necessary. We only collected data at the end of their intervention and did not do any long-term follow up assessments, which would have allowed us to observe the impact of the interventions over time. No participants in either pilot utilized the exercise facilities at our center. This was generally due to participant's schedules and the location of our lab. Many participants lived far away from our center, which may have affected their preference to exercise at home. A more convenient location may increase the use of on-site exercise facilities.

These results suggest that interventions targeting physical activity among persons with depression are feasible and may help to reduce depressive symptoms, improve fatigue, and improve physical functioning. These studies suggest a less resource intensive physical activity intervention can be translated into clinical practice with positive changes to psychosocial outcomes. Future research should continue to investigate the optimal intervention strategies for increasing physical activity and decreasing depressive symptoms.

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