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A pilot randomized controlled trial of aerobic exercise as an adjunct to OCD treatment

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ABSTRACT

Objective: The purpose of the current study was to conduct a randomized controlled trial testing the efficacy of aerobic exercise for decreasing OCD symptom severity, other mental health outcomes, and increasing exercise behaviors and cardiorespiratory fitness among individuals with OCD.

Method: Fifty-six patients (64% female; mean age = 38.8 years) with OCD and a Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) score of 16 or greater despite engaging in OCD treatment were randomized to 12-weeks of supervised plus home-based moderate-intensity aerobic exercise (AE; n = 28) or to 12-weeks of health education sessions (HE; n = 28).

Results: Random intercepts mixed models examined differences between conditions at post-treatment. Though no difference between conditions on outcomes was observed, both AE and HE showed significant reduction in OCD symptom severity, depression and anxiety at post-treatment. Relative to HE, significant increases were noted in amount of exercise and cardiorespiratory fitness for those in the AE condition. At post-treatment, 30.4% of the AE condition (7 of 23) were treatment-responders (using the commonly accepted measure of 35% symptom reduction from baseline). In the HE condition, 7.7% of the sample (2 of 26) met this criterion at post-treatment.

Conclusion: The results of this preliminary study suggest that exercise and health-focused interventions may be beneficial adjuncts to existing OCD treatment. Future studies with larger samples are needed to more definitively answer questions the efficacy of AE for reducing OCD symptoms and improving related clinical outcomes.

1. Introduction

OCD is considered a chronic condition and existing treatment options (e.g., cognitive behavioral therapy (CBT) and pharmacotherapy) are effective but not without limitations. For example, even when behavioral and pharmacological treatments are delivered at therapeutic "doses", rates of non-response and partial remission remain high, such that a significant percentage of individuals with OCD continue to struggle with symptoms and impairment [1–4]. Therefore, interventions that can serve as adjuncts to existing treatments are needed to help improve symptom reduction, functioning, and wellness among patients with OCD [5]. Aerobic exercise as an intervention strategy for improving mental health outcomes among individuals with depression and anxiety has been increasingly examined and findings have been quite promising [6–10]. Therefore, based on the observed benefits in symptom reduction in these illnesses, which are closely related to OCD [11], it is possible that incorporating exercise in the context of OCD treatment may also prove effective.

Indeed, there may be several potential pathways by which aerobic exercise could impact improved OCD symptomatology. For example, vulnerabilities underlying OCD, common to anxiety and affective disorders, include the tendency to experience heightened negative affect...
[12] and lower levels of positive affect [13]. Poor regulation of affective states, in turn, influences the motivational processes of behavioral activation and behavioral inhibition [14], leading to avoidance behaviors and more severe symptomatology [15]. Exercise, on the other hand, has consistently been associated with decreases in negative affect [16,17] and increases in positive affect [18]. Thus, it is possible that improved regulation of affect and mood (e.g. depression and anxiety) could impact approach/avoidance behaviors in patients with OCD.

Therefore, while aerobic exercise may be a potentially beneficial approach to examine as an adjunct to OCD treatment, relatively little attention has been given to this population. For example, with the exception of several open pilot trials [19-21], there have been no well-controlled, randomized trials of aerobic exercise for symptom reduction in OCD. The purpose of this study was to conduct an RCT of aerobic exercise for patients with OCD who, despite standard treatments, remain clinically symptomatic. In addition, we examine intervention effects on depression, anxiety, and physical activity outcomes. We hypothesized that adjunctive treatment with structured aerobic exercise, compared to a control health education condition, would result in significant reductions in OCD symptom severity and improvements in all other outcomes.

2. Methods

2.1. Participants and procedures

This trial is registered with ClinicalTrials.gov (NCT01242735) and received institutional review board approval from Butler Hospital. An a priori power analysis was conducted prior to study initiation and the planned sample size for this trial was n = 102 (see [22]). Participants who initially expressed interest in the study (N = 351) did so from various sources including referral from our hospital’s OCD specialty clinic, community clinicians, and advertisements. Of these, 197 (56%) were screened for eligibility criteria while the remainder 44% lost interest in the study prior to being screened. See Fig. 1 for a CONSORT diagram of the recruitment flow.

We enrolled 56 adults between the ages of 18 and 65 with a DSM-IV diagnosis of OCD who were still experiencing clinically significant symptoms (Y-BOCS ≥ 16) despite currently receiving treatment for OCD with either pharmacotherapy or CBT. It was required that pharmacotherapy be at an adequate and stable dose for the past month, with a minimum drug trial length of 12 weeks and that CBT be for at least the past 13 weeks. Additionally, all participants were physically inactive over the past 3 months (i.e., < 60 min of aerobic exercise per week). Individuals were excluded from participation if they had a DSM-IV diagnosis of a substance use disorder, anorexia or bulimia nervosa, bipolar disorder, psychotic disorder, current suicidality or homicidality, current or planned pregnancy during the upcoming 12 weeks, or any other physical or medical problems with would be contraindicated with a moderate-intensity exercise intervention. Study staff obtained medical clearance for beginning a moderate-intensity aerobic exercise program from each participant’s primary care physician. Eligible participants were unrandomized [23] with the following blocking variables: sex (male/female), current OCD severity (low/high; 16–24 vs. > 24), current pharmacotherapy for OCD (yes/no), and current CBT for OCD (yes/no).

2.2. Assessments

All measures were completed at baseline and post-treatment (i.e., following the 12-week intervention). Additionally, the Y-BOCS was administered at weeks 3, 6, and 9 during the intervention.

2.2.1. Yale-Brown Obsessive-Compulsive Scale (Y-BOCS)

The Y-BOCS, is a 10-item evaluator-administered scale assessing severity of OCD symptoms over the past week [24,25].

2.2.2. Beck Depression Inventory-II (BDI-II)

The BDI-II is a 21-item self-report measure assessing depressive symptoms over the past two weeks [26].

2.2.3. Beck Anxiety Inventory (BAI)

The BAI is a 21-item self-report measure assessing general symptoms of anxiety over the past month [27].

2.2.4. Exercise outcomes

Consistent with the exercise as a “vital sign” literature [28], participants were asked: 1) Over the last 3 months, on average how many days/week did you exercise? and 2) On those days, on average how many minutes/day did you exercise? Time spent exercising was calculated based on the multiplication of these 2 responses. Cardiorespiratory fitness was also assessed using the 1-mile Rockport walking test modified for treadmill [29] at baseline and post-treatment, where a measure of VO₂ peak was calculated based on weight, age, gender, minutes of walk time, and heart rate.

2.2.5. Concurrent treatment

At the end of treatment, participants were asked to report on any therapy or counseling, as well as pharmacotherapy that they received during the course of the 12-week intervention. Treatments for both OCD as well as other psychological problems were assessed. Types of therapy/counseling included individual therapy, group therapy, couples therapy, therapy as part of medication management sessions, support groups/self-help, partial and inpatient hospitalization, religious/spiritual support, or case management.

2.3. Intervention conditions

2.3.1. The aerobic exercise (AE) intervention

Participants in AE attended 12 weekly exercise sessions, supervised by an exercise physiologist. Participants exercised on treadmills, elliptical machines, and recumbent bicycles. Participant heart rate was monitored to ensure moderate-intensity exercise. Participants were also instructed to exercise on their own between two and four days during the week (increasing from two days/week early in the intervention to four days/week later in the intervention period). By the last several weeks of the intervention, participants were given the goal of attaining a minimum of 150 min of moderate-intensity aerobic exercise per week. In addition, participants participated in a 20-minute session immediately prior to the supervised exercise session where cognitive-behavioral topics were discussed: physical health benefits of exercise, goal-setting, time management, identifying and overcoming barrier to exercise, and exercise and mental health (for full list of topics and descriptions, see [22]). Lastly, participants received $5 for each supervised exercise session attended. Continued attendance was also incentivized as participants were able to draw from a prize bowl (prize value ranging from $10–$50) for consecutively attended sessions.

2.3.2. Health education (HE) intervention

Participants in the HE condition received 12 weekly hour-long psychoeducation sessions. Sample topics included nutrition, sleep hygiene, caffeine, alcohol, and cigarette smoking, and coordinating your medical treatment. The last session of the 12-week intervention was on physical activity and included information on the public health recommendations for engaging in exercise. Participants in the HE and AE conditions were equated for time and incentives.

2.4. Data analysis

We examined the data for completeness and, where possible, single missing items were imputed with the participant’s mean on all other items in the scale. Data were examined for normality and data transformed if necessary. Then, we evaluated baseline group differences in
our primary outcome variable (Y-BOCS score), followed by other clinical outcome variables and exercise outcome variables: depression (BDI-II), anxiety (BAI), average time spent exercising per week, and VO2 peak. In these analyses, we used random intercepts mixed models, fit with restricted maximum likelihood estimation and an unstructured covariance matrix. Predictors included intervention condition, timepoint, and a condition by timepoint interaction. Model covariates included indicator variables for sex, and two separate indicator variables denoting whether or not a participant was currently in CBT, and whether or not a participant was currently on medication for OCD at baseline. Interactions were sliced to test for differences between conditions at each timepoint, with the between-condition comparison at post-treatment being our primary contrast of interest.

3. Results

3.1. Baseline characteristics

The final sample was comprised of 56 participants (n = 28 in the exercise condition; n = 28 in the wellness education condition) with a diagnosis of OCD. The sample was 64.3% female and had an average age of 38.8 (SD = 13.0) years. 83.9% of the sample identified as White and 14.3% as a racial minority (3.6% Black or African American, 1.8% Asian American, 8.9% as other minority or multiple races), with 1.8% unreported. In addition, 7.1% of the sample identified as Hispanic or Latino. Overall, the sample was highly educated with 60.7% of the sample having at least completed a college degree. 62.5% of the sample reported currently receiving CBT and 92.9% of the sample reported currently being on medication for OCD. Despite urn randomization, average OCD severity appeared different across conditions at baseline, though this difference was not statistically significant (t = −1.95, p = 0.056).

3.2. Concurrent treatment

As noted previously, this study examined AE as an adjunctive intervention to ongoing OCD treatment (i.e., medication, therapy, or both). At end of treatment, 46 of 48 participants endorsed receiving therapy or counseling for OCD or other emotional or psychological problem since baseline. 42 of the 46 reported receiving some type of therapy specifically for OCD. The proportion of the sample receiving some type of therapy during the intervention (either overall, or for OCD, specifically) did not differ between conditions (Fisher exact test p’s > 0.05). At end of treatment, 45 of 48 also reported receiving medication or OCD or any other emotional or psychological problems since baseline. Of the 45, 34 reported taking medications specifically for OCD. The proportion of the sample receiving medication during the intervention (either overall, or for OCD, specifically) did not differ between conditions (Fisher’s exact test p’s > 0.05).

3.3. Changes in OCD symptom severity

Both groups attended the majority of the 12 sessions, with participants in the AE condition attending an average of 9.7 sessions (sd = 2.6) and participants in the HE condition averaging 9.96 sessions (sd = 2.7). For our primary outcome, OCD symptom severity (i.e., Y-BOCS scores), results indicated no significant difference between AE and HE conditions at post-treatment. The time by condition interaction
was also not significant. Model results indicated a significant main effect of time for both depression (F(4,190) = 17.66, p < 0.001) such that Y-BOCS at all mid- and post-intervention timepoints was significantly lower than at baseline, irrespective of condition. At post-treatment, 30.4% of the AE condition who completed the post-treatment assessment (7 of 23) were treatment-responders (using the commonly accepted measure of 35% change in other clinical outcomes (p = 0.064). There was a trend toward greater treatment response among participants of 26) met this criterion at post-treatment. Based on Fisher’s Exact test, no significant differences on clinical outcomes was observed, both conditions showed significant reduction in OCD symptom severity, depression and anxiety. Whereas, relative to HE, those in the AE condition demonstrated significant increases in amount of exercise and cardiorespiratory fitness over the 12-week intervention.

The overall sample size in this study was lower than originally projected (56 vs. 102) [22]. Despite initial interest from a larger number of OCD patients, only 56% followed through with eligibility screening. As such, we were not powered to detect a statistically significant difference across conditions in our primary outcome of OCD symptom severity. Further, there was a significant main effect of time, such that both conditions showed reductions in OCD symptom severity from baseline to end of treatment. Yet, there was a trend toward a higher rate of treatment response in the AE condition. While this is promising, future studies employing larger samples are needed to fully understand the effect of AE on OCD outcomes. In addition, future research is needed to help develop strategies for increasing the interest, motivation, and engagement of patients with OCD in physically active, healthy lifestyles.

Similar to the Y-BOCS findings, there was also a significant main effect of time for depression and anxiety symptoms where improvements were observed for both the AE and HE conditions over the 12-week intervention for both the AE and HE conditions. All participants in the study were receiving pharmacotherapy or therapy/counseling during the course of the 12-week intervention, with no differences in the rates of each of these across the AE or HE conditions. It is possible that the participants in this study found the health information provided in the control condition and/or the social support received by attending weekly sessions with a research interventionist helpful such that mental health outcomes improved. This finding is consistent with previous research demonstrating smaller effect sizes for CBT when compared with a “placebo control” versus a waitlist control [3] in patients with OCD. In addition, participants in the HE condition may have changed their behavior as a result of the information learned, resulting in improved mental health benefits. Therefore, the results of this study suggest that integrating health-focused interventions among individuals with OCD who are still symptomatic despite treatment, could lead to beneficial clinical outcomes, including OCD symptom severity.

Though both the AE and HE conditions increased their exercise behaviors, greater increases in amount of exercise and cardiorespiratory fitness were observed over the course of the intervention in the AE condition. As such, the AE intervention appears to have achieved its intended behavioral outcomes. Independent of mental health benefits, physical activity is one of the best behavioral strategies for preventing and decreasing risk for many of these chronic physical health problems [31]. Individuals with psychiatric disorders are at risk for numerous physical health-related problems [32], including patients with OCD [33]. Yet, little attention has been given to addressing the physical health of patients with OCD. Future studies examining the role of AE versus other health behaviors in improving the overall physical health of individuals with OCD are necessary.

To date, only a few exercise studies have been conducted among patients with OCD. In our prior work [19] (N = 15), we found a promising effect of 12-weeks of moderate-intensity aerobic exercise on decreasing OCD symptom severity. These findings were consistent with an earlier work (N = 11) conducted by Lancer and colleagues [20] where 6 weeks of brisk walking was associated with significant decreases in OCD symptoms. More recently, Rector and colleagues [21] provided gym memberships and exercise prescriptions to 11 patients with OCD who were beginning CBT treatment for OCD and found

| Table 1 | Outcomes. |
|-----------------------------------|-----------------|-----------------|-----------------|
| | Aerobic exercise | Health education | Effect size (d) |
| n | M (SD) or median | n | M (SD) or median | |
| OCD severity (Y-BOCS) | | | |
| Baseline | 28 | 26.2 (5.32) | 28 | 23.5 (4.94) | 0.36 |
| Intervention week 3 | 27 | 21.3 (6.21) | 26 | 20.1 (6.82) | 0.07 |
| Intervention week 6 | 24 | 20.0 (6.75) | 25 | 19.2 (7.25) | 0.10 |
| Intervention week 9 | 23 | 20.9 (7.23) | 24 | 19.4 (6.06) | 0.36 |
| Post-treatment | 23 | 19.4 (6.40) | 26 | 19.9 (6.43) | −0.17 |
| Anxiety (BAI) | | | |
| Baseline | 28 | 20.4 (12.33) | 27 | 13.0 (7.48) | 0.54 |
| Post-treatment | 21 | 13.3 (11.39) | 26 | 10.2 (9.16) | 0.38 |
| Depression (BDI) | | | |
| Baseline | 28 | 26.2 (14.55) | 26 | 19.9 (14.56) | 0.22 |
| Post-treatment | 22 | 18.1 (16.27) | 27 | 15.5 (13.97) | 0.12 |
| Average min of exercise/week | | | |
| Baseline | 28 | 85.0 (216.96) | 28 | 71.5 (141.90) | 0.05 |
| Post-treatment | 21 | 133.1 (68.14) | 27 | 96.3 (117.75) | 0.58 |
| VO2 peak | | | |
| Baseline | 22 | 26.4 (7.36) | 24 | 27.0 (7.61) | 0.10 |
| Post-treatment | 16 | 31.7 (9.36) | 21 | 28.5 (7.49) | 0.44 |

* Reported means and standard deviations are based on raw, untransformed scores. Between group Cohen’s d effect sizes at each timepoint were calculated using the difference between model estimated means (AE-HE) divided by the pooled, weighted standard deviation of baseline raw scores of the dependent variable.
significant reductions in OCD symptoms after 12 weeks. While these preliminary studies demonstrated promising findings, each was an uncontrolled pilot study with a small sample. In the current study, we conducted a randomized controlled trial, which adds to the growing literature in this area by suggesting that both exercise and health-focused education programs may be beneficial as adjuncts to OCD treatment.

There are a number of study limitations worth noting. First, the randomization process was not optimally effective in producing balanced OCD symptom severity across conditions. Second, the assessment of outcomes was not blinded. Future trials that include blinded assessment and experience successful randomization will increase the validity of results. [34] Third, while we attempted to collect an objective measure of exercise, so few participants provided baseline and post-treatment data, that we do not report it. However, given the concerns with the validity of self-reports of physical activity [35], objective measurement is critical. Despite these limitations, the current study makes a number of contributions. To our knowledge, this is the first RCT of AE in this population. Also, the sample is focused on patients with OCD who, despite treatment, are still symptomatic – a subgroup of those with OCD who need additional interventions to improve outcomes. Therefore, future research that can build on these preliminary findings will be necessary to determine the efficacy of AE for OCD symptom reduction and improvement in associated clinical outcomes.

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