Published in final edited form as:

Ment Health Phys Act. 2012 December 1; 5(2): 155–165. doi:10.1016/j.mhpa.2012.06.002.

Design and Rationale for a Randomized Controlled Trial Testing the Efficacy of Aerobic Exercise for Patients with Obsessive-Compulsive Disorder

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Abstract

Background—Over the last two decades very few advances have been made in the development of new treatments for obsessive-compulsive disorder (OCD). While patients with OCD improve with available treatments (pharmacotherapy and/or cognitive-behavioral therapy), moderate levels of OCD symptoms often persist even with adequate doses and durations of these treatments. Building on the growing body of evidence for the efficacy of exercise in the treatment of other psychiatric disorders, interventions to increase aerobic exercise in patients with OCD represent a potentially useful yet relatively unexplored strategy in OCD.

Methods/Design—One hundred and two (102) patients with clinically significant OCD symptoms despite current engagement in recommended treatments (pharmacotherapy and/or CBT) will be randomly assigned to receive either a 12-week moderate intensity aerobic exercise (AE) intervention or a health education control (HEC) intervention. Follow-up interviews will be conducted at the end of treatment and at 3-, 6- and 12-months post-intervention. They will assess OCD severity, nonspecific anxiety, depression, quality of life, cardiorespiratory fitness and cognition (executive function).

Discussion—If efficacy is established, patients with OCD who have clinically significant residual symptoms despite current pharmacotherapy or CBT would gain a valuable and practical treatment augmentation option.

1. Background

1.1. OCD as a Public Health Concern

Obsessive-compulsive disorder (OCD) is an anxiety disorder characterized by recurrent intrusive thoughts and repetitive compulsive behaviors. The most recent data put its 12-

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month prevalence at 1% of the US adult population (Kessler, Chiu, Demler, Merikangas, & Walters, 2005). Lifetime prevalence estimates are in the range of 2% (Kessler, et al., 2005). The illness tends to be chronic. OCD is associated with significant impairments in employment, marriage and child bearing, family functioning, marital stability, and quality of life (Eisen et al., 2006; Grabe et al., 2000; Koran, 2000; Koran, Thienemann, & Davenport, 1996; Lochner et al., 2003). The Global Burden of Disease Study has identified OCD among the leading causes of disability in industrialized countries (Murray & Lopez, 1996). Direct and indirect economic burdens imposed by OCD are high, including healthcare costs and especially marked loss of earning capacity, posing a huge economic burden for patients, their families, and society (Greist et al., 2003; Mancebo et al., 2008).

1.2. Current State of OCD treatment

Generally effective treatments such as cognitive behavioral therapy (CBT including exposure with response prevention E/RP), and pharmacotherapy for treating OCD exist. The efficacy of serotonin reuptake inhibitors (SRIs) and CBT in OCD is established (e.g. Baer, 1993; Fisher & Wells, 2005; Franklin, Abramowitz, Kozak, Levitt, & Foa, 2000; Perse, 1988; Rasmussen, Eisen, & Pato, 1993; van Balkom et al., 1994). The American Psychiatric Association Practice Guidelines recommends CBT as a first-line treatment for patients willing and able to participate (Koran, Hanna, Hollander, Nestadt, & Simpson, 2007), with exposure with response prevention (E/RP) considered the treatment of choice for OCD (Foa, Franklin, & Moser, 2002; Koran, et al., 2007; March, Franklin, Nelson, & Foa, 2001; Steketee, 1997). Sixty-five to 85% of patients who complete E/RP improve immediately after treatment and maintain gains for 3 months to 6 years (Franklin et al., 1998). However, the availability of CBT, and particularly E/RP, is limited due to a lack of trained behavioral therapists and insurance reimbursement policies favoring pharmacotherapy (Greist & Baer, 2002; Mancebo, Pinto, Rasmussen, & Eisen, 2008). Also, many patients are too fearful to participate in E/RP (Mancebo, Pinto, et al., 2008). In one study, 25% of treatment-seeking patients recommended to engage in CBT by a mental health professional refused while 23% dropped out of CBT before completion (Mancebo, Eisen, Dyck, Pinto, & Rasmussen, 2006). Thus many individuals with OCD end up relying primarily on pharmacotherapy.

The APA Guidelines recommend selective SRIs fluvoxamine, fluoxetine, sertraline, and paroxetine as first line options. Guidelines recommend a trial of 10 to 12 weeks at a maximal tolerated dose. Importantly, only 40-60% of patients feel “much” or “very much” improved after an SRI trial; most patients report residual symptoms (McDonough & Kennedy, 2002). Further, a very high percentage (70-90%) of medication responders relapse within four to seven weeks after discontinuing SRIs (Stanley & Turner, 1995). Further, SRI doses needed for OCD are often higher than for depression, which can increase adverse effects. In one study, almost half (47%) of patients with OCD recommended serotonin reuptake inhibitors (SRIs) refused or were non-adherent, primarily due to side effect concerns (Mancebo, et al., 2006).

To examine the efficacy of each of these approaches (i.e., CBT, pharmacotherapy, and combined CBT+pharmacotherapy), Eddy and colleagues (2004) in a multidimensional meta-analysis found mean effect sizes ranging from 1.52 for psychotherapy, 1.18 for pharmacotherapy, and 1.72 for pharmacotherapy plus CBT. Despite a wide range across studies in how response to treatment was defined (25% to 50% reduction in scores utilizing the gold standard for measuring OCD symptom severity, the Yale-Brown Obsessive Compulsive Scale (Y-BOCS; Goodman, Price, Rasmussen, Mazure, Delgado, et al., 1989)), they found that only about half of patients in each treatment modality improved. Therefore, despite the demonstrated efficacy of both pharmacotherapy and CBT for OCD, the number of nonresponders to treatment is substantial. As such, alternatives are clearly needed for

patients who will not accept current treatments and for those who fail to benefit meaningfully from existing options.

1.3. The Existing Efficacy of Aerobic Exercise for Patients with Anxiety Disorders

The body of literature on the psychological benefits of exercise is voluminous. However, most of this research has been limited to healthy populations. Relatively few studies have been conducted with psychiatric patient groups (Tkachuk & Martin, 1999). The bulk of these studies have been conducted with patients with major depressive disorder (MDD). Findings from this work have consistently pointed to decreased depressive symptoms in patients who engaged in regular exercise compared to those who did not (aan het Rot, Collins, & Fitterling, 2009; Barbour & Blumenthal, 2005; Barbour, Edenfield, & Blumenthal, 2007; Brosse, Sheets, Lett, & Blumenthal, 2002; Carek, Laibstain, & Carek, 2011; A. Daley, 2008; Daley, Macarthur, & Winter, 2007; Dinas, Koutedakis, & Flouris, 2011; Kirby, 2005; Larun, Nordheim, Ekeland, Hagen, & Heian, 2006; Lawlor & Hopker, 2001; Mead et al., 2009; Palmer, 2005; Salmon, 2001; Strohle, 2009), with exercise being shown to be as effective as cognitive therapy and pharmacotherapy for treating depression (Mead, et al., 2009).

However, relative to the work done in patients with depressive disorders, only a few controlled studies have examined the effect of exercise on patients diagnosed with an anxiety disorder. In an early study, Broocks and colleagues (1998) compared a 10-week aerobic exercise (running) intervention, 112.5mg/day of clomipramine, and pill placebo in panic disorder. There were significant reductions in anxiety symptoms in both the exercise and clomipramine groups compared to placebo. A direct comparison of exercise and clomipramine revealed that the drug treatment improved anxiety symptoms earlier and more effectively. Another study (Merom et al., 2008) examined the effect of a home-based walking program as an adjunct to group cognitive behavioral therapy in patients diagnosed with panic disorder, generalized anxiety disorder (GAD) or social phobia. Patients randomized to the walking program, relative to a contact control education condition, demonstrated greater reductions in depression, anxiety, and stress at the end of the 6-week intervention. More recently, Herring and colleagues (2012) conducted a randomized controlled trial with 30 patients diagnosed with generalized anxiety disorder who were assigned to either 6 weeks of resistance training, aerobic exercise training, or a wait list. At the end of treatment, 60% of patients in the resistance training group and 40% of patients in the aerobic exercise training group had shown GAD remission. In addition to the promising rates of remission, Herring and colleagues (2012) concluded exercise training is feasible and low-risk and associated with significant decreases in worry symptoms in patients with GAD.

More recently, two preliminary, uncontrolled studies examined the effect of exercise on OCD symptoms (Brown et al., 2007; Lancer, Motta, & Lancer, 2007). Lancer and colleagues (2007) found that a 6-week aerobic exercise intervention was associated with reductions in YBOCS symptoms from the severe to the moderate range in 11 treated OCD patients. We (Brown, et al., 2007) enrolled 15 patients who still had significant OCD symptoms (i.e., Y-BOCS scores above 16) despite receiving behavior therapy and/or medications for OCD. They underwent a 12-week moderate-intensity exercise intervention. We found a substantial reduction in Y-BOCS OCD severity (Cohen's $d=1.69$) and a decrease in negative mood, as well as improvements in quality of life and cardiorespiratory fitness. In addition, reductions in OCD symptom severity persisted when assessed 6 months after the intervention ended. The degree of OCD severity reduction with exercise was comparable in these two preliminary studies.

In summary, there is evidence for an anxiety reducing effect of aerobic exercise in healthy volunteers, and promising preliminary findings in patients with anxiety pathology, including

specifically in OCD. Exercise is also associated with improvement in affective symptoms, which are commonly comorbid with OCD. It is important to determine if exercise has therapeutic promise in OCD in a controlled study.

1.4. How Exercise may Improve OCD severity: Potential Mechanisms

It has long been recognized that OCD entails both pathological anxiety and abnormal reward-related behavior (Marks et al., 1988). The net result is a distortion of behavioral priorities so that approach behaviors are weak compared to avoidance. Although this tells us little about how the avoidance central to OCD begins in the first place, it suggests a mechanism to maintain the disorder once it is established. Indeed, addressing this process is the goal of exposure and response prevention CBT: repeated nontraumatic exposures to anxiety cues activate habituation processing that down-regulates OCD-related fears. Even though the end result in this case is a reduction in OCD severity, the path to this change relies on changes in approach and avoidance behaviors that are nonspecific to OCD and would be expected to play similar roles across anxiety and mood disorders.

This hypothesis is congruent with an influential conception of how independent processes of behavioral activation (approach) and behavioral inhibition (avoidance), relate to an individual's affective state (Carver & White, 1994). There is convincing evidence that aerobic exercise increases positive and decreases negative affect (see below). Exercise thus represents a potentially useful tool for normalizing the balance between approach and avoidant behaviors in OCD. A key consequence of that change would be a self-reinforcing series of naturalistic exposures to OCD triggers, which would in turn act to reduce OCD-related avoidance and distress over the longer term. Therefore, we hypothesize that decreases in negative affect and avoidance behaviors and increases in positive affect and approach behaviors will be related to improvement in OCD severity (see Figure 1).

1.4.1. Mediation through Negative Affective States—Individuals in treatment for OCD frequently report difficulty managing concomitant negative affect and may be characterized by a lack of positive affect (Spinella, 2005). Evidence also suggests that additional vulnerabilities place them at increased risk for mood disturbances (Hasler et al., 2005; Rector, Richter, & Bagby, 2005). Comorbid anxiety disorders, high levels of trait anxiety, including anxiety sensitivity, are also commonly present in patients with OCD (Carter, Pollock, Suvak, & Pauls, 2004; Fullana et al., 2004; Regier, Rae, Narrow, Kaelber, & Schatzberg, 1998; Robins & Regier, 1991). Risk for mood or anxiety pathology in OCD is believed to be linked to a common vulnerability to negative affect as indexed by global traits such as negative emotionality/neuroticism (Bienvenu et al., 2004; Fullana, et al., 2004). Interestingly, even among individuals with subclinical OCD, severity of obsessions and compulsions was related to reported intensity of negative moods (i.e., anger, depression, confusion, fatigue, and tension) (Spinella, 2005).

A number of negative affective states improve after exercise (e.g., Edwards, Gardiner, Ritchie, Baldwin, & Sands, 2008; Hunt-Shanks, Blanchard, & Reid, 2009). In a review of the literature, Biddle (2000) reported that when quantified trends were identified, aerobic exercise had a small-to-moderate effect on reducing tension, depression, fatigue, and confusion, and a small effect on reducing anger. These effects were strongest for moderate-intensity exercise. These results have been demonstrated in cross-sectional (Edwards, et al., 2008; Hunt-Shanks, et al., 2009) and intervention studies (Elavsky & McAuley, 2007; Knapen et al., 2009; Watt & Spinks, 1997), with both acute and chronic exercise, and for clinical and nonclinical populations.

1.4.2. Mediation through Positive Affective States—A lot less attention has been given to examining positive affect in OCD. In one study, among patients with prominent hoarding symptoms, lower levels of positive affect were associated with difficulty discarding (Frost, Steketee, & Grisham, 2004). Similarly, while healthy controls are normally biased toward unrealistic optimism (i.e., predicting they will experience positive events), this positive bias is absent in OCD (Moritz & Jelinek, 2009). Consistent with these results, recent research has focused on abnormalities in reward-related behaviors among patients with OCD such that the pursuit of reward has been found to be impaired in patients with OCD resulting in accompanying anhedonia (Endrass, Kloft, Kaufmann, & Kathmann, 2011).

The relationship between positive affect and exercise has been demonstrated both cross-sectionally and through controlled studies. For example, Stephens (1988) conducted a secondary data analysis of four North American surveys including over 55,000 people. More recently, Kelsey and colleagues (2006) using a survey of 1093 women participating in a health promotion intervention, found that positive affect related directly to their self-reported exercise. In a meta-analysis conducted by Reed & Ones (2006), the overall mean effect size for the effect of acute aerobic exercise in improving positive affect was moderate (.47). Moreover, more recent exercise intervention studies (Brown, Liu-Ambrose, Tate, & Lord, 2009; Hoffman & Hoffman, 2008; Mutrie et al., 2007; Stroth, Hille, Spitzer, & Reinhardt, 2009) have shown that, while decreases in negative affect are not always found, significant increases in positive affect are consistently demonstrated.

1.5. Aims of the Proposed Trial

Interventions to increase aerobic exercise in patients with obsessive-compulsive disorder (OCD) represent a potentially useful yet unexplored strategy for ameliorating OCD symptomatology. We propose to conduct a randomized, controlled trial (RCT) in patients with clinically significant OCD symptoms despite engaging in recommended treatments (pharmacotherapy and/or CBT) of recommended dose and duration by comparing an aerobic exercise intervention (AE) to a health education control (HEC) comparison intervention. We hypothesize that patients receiving AE as compared to HEC will have greater reductions in OCD symptom severity, greater reductions in psychopathology (i.e., anxiety and depressive symptoms), and greater increases in quality of life and cardiorespiratory fitness at post-treatment, 3-, 6- and 12-month follow-ups. In addition, we propose to examine potential mechanisms that may mediate the effect of AE on reduced OCD symptom severity. We hypothesize that normalization of self-regulatory systems (i.e., behavioral activation and behavioral inhibition), as evidenced by increases in positive affect and approach behaviors and decreases in negative affect and avoidance behaviors will mediate the relationship between AE and YBOCS OCD severity.

1.6 Sample Size

Our primary decision in deciding on the number of participants to enroll was based on a desire to maintain sufficient power to detect the treatment differences between AE vs. HEC. We estimated power for the current preliminary trial using effect size (ES) estimates from our pilot data (Brown et al., 2007; $d = 1.69$) and available ES estimates from a recent meta-analysis of 20 OCD trials that reported pre- and post-treatment YBOCS ES for a placebo-arm of $d = .32$ (Eddy, et al., 2004). We decided to maintain an alpha of 0.05 and set our desired power of .80. To be conservative, when compared to placebo estimates over time (Eddy, et al., 2004), we set the treatment ES using the minimum value that fell within our 95% CI in power calculations of 1.30, 1.01, 0.41, and 0.32 for the end-of-treatment, 3-, 6- and 12-month assessments and the specification of the correlation of YBOCS ($r = .20-.60$) across time. Using these effects, the planned design ($N=102$) provides greater than 0.86

power for detecting the treatment differences between AE vs. HEC (Pinheiro & Bates, 2000). Effects of attrition were also examined and revealed that random drop-out of less than 20% does not result in power < .80.

2. Study Procedure

2.1. Study Design

This is a RCT to examine the efficacy of a 12-week aerobic exercise intervention versus a health education comparison intervention that is controlled for contact time in a sample of patients with clinically significant OCD symptoms despite adequately dosed treatment. All participants will complete a comprehensive assessment battery and undergo a submaximal graded exercise treadmill test under the supervision of the study internal medicine specialist. All participants will be assessed at the end of treatment, 3-, 6- and 12-month follow-ups on measures of OCD symptom severity, negative mood (e.g. depression and anxiety), psychosocial functioning, quality of life, executive functioning, and cardiorespiratory fitness.

2.2. Recruitment

We will recruit a total of 102 participants to participate in the proposed project. Participants will be recruited from a large OCD clinic in a psychiatric hospital in the United States. All patients currently in treatment in this clinic will be informed of the study by their clinician and invited to participate in a brief screening.

2.3. Participants

2.3.1 Eligible participants—(a) are between 18 and 65 years of age, (b) meet DSM-IV criteria for OCD as assessed by the Structured Clinical Interview for DSM-IV Axis I Disorders – Patient version (SCID-P; First, Spitzer, Gibbon, & Williams, 1995), (c) have Y-BOCS scores >16, (d) are currently engaged in at least a 12-week trial of pharmacotherapy for OCD, with adequate and stable dosage over the last month and/or are currently engaged in cognitive behavior therapy (CBT) for OCD, and have been receiving this treatment for at least the past 13 weeks (March, Frances, Carpenter, & Kahn, 1997), and (e) are physically inactive; i.e., have not participated regularly in aerobic physical exercise (for at least 20 minutes per day, three days per week) for the past six months.

2.3.2. Exclusion criteria include—(a) DSM-IV diagnosis of substance abuse/dependence (except nicotine dependence) within the past 6 months, (b) current DSM-IV diagnosis of anorexia or bulimia nervosa, (c) DSM-IV diagnosis of bipolar disorder, (d) a history of psychotic disorder or current psychotic symptoms, (e) current suicidality or homicidality, (f) marked organic impairment according to either the medical record or responses to the diagnostic assessments, (g) physical or medical problems that would not allow safe participation in a program of moderate intensity aerobic exercise, and (h) current pregnancy or intent to become pregnant during the next 12 weeks. Given the high rates of mood disorders in patients with OCD, participants who meet diagnostic criteria for other anxiety disorders, major depression, and/or dysthymia will not be excluded.

2.4. Screening process and informed consent

The brief screening process will include assessment of participants' current OCD treatment status and extent of physical activity. Participants appearing to meet study criteria will be scheduled for a more comprehensive baseline assessment. Research staff will carefully explain all aspects of the study, including the experimental nature of the research, the potential risks and benefits, and the expected duration and time commitment of their

participation. After informed consent is obtained, participants will then be evaluated using the diagnostic and screening measures detailed below to confirm eligibility.

2.5. Measures

See Table 1 for a list of all the measures and the timepoints they are administered.

2.5.1. Psychiatric and Physical Health Screening and Assessment Measures

2.5.1.1. Physical Activity Screen: To ensure that potential participants are blind to the nature of the screening procedure, the physical activity screen will be embedded in a brief interview that assesses a variety of health behaviors such as sun safety, seatbelt use, and nutritional practices. The exercise portion of this interview will serve as the screen to determine whether patients meet criteria to be considered physically inactive. Participants will be asked whether they regularly engage in moderate intensity activity for at least 20 uninterrupted minutes. Follow-up probes assess the frequency (less than three times per week) and length of time (less than 6 months) that patients have been participating in exercise of this type.

2.5.1.2. Health Questionnaire: This measure inquires about participants' health history and general health status, including medical conditions that might prevent or make difficult participation in a moderate intensity exercise program. This measure will be administered during recruitment and reviewed prior to clearance for participation in the study. It will also provide a record of participants' medical status and will be reviewed to assess changes in health status prior to each follow-up graded exercise test.

2.5.1.3. Medical Clearance to Participate in Exercise Program and Cardiorespiratory Fitness: The study physician will review the patient's medical history. A resting electrocardiogram (ECG) will then be obtained. Unless contraindicated by the resting ECG, the physician then will have the patient complete a submaximal graded exercise test on a treadmill, with continuous ECG monitoring using a modified, Balke-Ware protocol (ACSM, 2009). Prior to testing, participants will not eat or smoke for a minimum of one hour. The speed of the treadmill will be constant at 3.5 mph with the initial grade set at 0% and will progress by 1% at 1-minute intervals. During testing, heart rate will be measured every minute and at the point of test termination using a 12-lead ECG. Blood pressure and rating of perceived exertion (Borg 6-20 scale) will be measured during the final minute of each stage and at the point of test termination. This submaximal graded exercise test will be terminated at 85% of the participant's age-predicted maximal heart rate. In addition, test termination guidelines outlined by the American College of Sports Medicine (ACSM, 2009) will be followed. Following test termination, each participant will undergo a 3-minute active cool-down and 5-7 minute seated cool-down, during which time heart rate will be assessed at each minute with blood pressure measured at 2-minute intervals. Based on this test, if moderate intensity exercise is contraindicated for a participant, he/she will be excluded from participation in the study and will be referred to his/her primary care physician for a follow-up evaluation. If deemed eligible and once in the study, this protocol will also be conducted at each follow-up timepoint to obtain a measure of cardiorespiratory fitness.

2.5.1.4. The Structured Clinical Interview for DSM-IV Axis I Disorders – Patient version: [SCID-P: (First, Spitzer, Gibbon, & Williams, 1995)]. Psychiatric disorders, both current and lifetime, for establishing inclusion/exclusion criteria will be determined by the relevant sections of the SCID-P (First, et al., 1995). Adequate reliability of the Axis I SCID has been demonstrated (First, et al., 1995; Spitzer, Williams, Gibbon, & First, 1989). The SCID will be administered by research staff who have received extensive training in its

administration and will have no involvement with participants in the intervention aspects of the study. SCID interviews will be audiotaped and reviewed in weekly meetings.

2.5.1.5. The Butler Hospital OCD Database Interview: is a semi-structured rater administered interview that will be used to collect detailed information on demographic and clinical features of OCD (Rasmussen, 1993). Participants are asked to recall information such as age of onset of OCD symptoms, age first received treatment, and pharmacologic treatments received.

2.5.2. OCD Symptom Severity

2.5.2.1. Yale-Brown Obsessive Compulsive Scale (Y-BOCS): The Y-BOCS is a clinician-administered 10-item scale with specific probes and anchors that assess severity of 5 domains for obsessions and compulsions. These domains include time, distress, interference, resistance, and control. This scale, developed in part by our research team, has established reliability and validity and is widely accepted as the major outcome measure for OCD studies (Goodman, Price, Rasmussen, Mazure, Delgado, et al., 1989; Goodman, Price, Rasmussen, Mazure, Fleischmann, et al., 1989). The Y-BOCS has been found to have excellent inter-rater reliability (IRR) with lowest IRR for the obsession and compulsion subtotals of 0.95 and 0.96, respectively (Goodman, Price, Rasmussen, Mazure, Fleischmann, et al., 1989). The Y-BOCS has been shown to be highly homogeneous with regard to internal consistency, with mean of all raters at 0.89 (Goodman, Price, Rasmussen, Mazure, Delgado, et al., 1989). In addition, good convergent validity has been demonstrated for the Y-BOCS as it significantly correlates with such measures as the Obsessive Compulsive Inventory-Revised ($r=.45$), Beck Depression Inventory ($r=.46$), Brown Assessment of Beliefs Scale ($r=.34$), and the Self-Rating Anxiety Scale ($r=.38$) (Deacon & Abramowitz, 2005). We will use the self-report version of the Y-BOCS checklist to identify types of obsessions and compulsions. Y-BOCS raters will not be blind to treatment allocation.

2.5.3. Mediator Variables

2.5.3.1. The 20-item Positive and Negative Affect Schedule: (PANAS; Watson, L. A. Clark, & A. Tellegen, 1988) a self-report scale, will be used to assess changes in positive and negative affect. The PANAS Positive Affect (PA) and Negative Affect (NA) scales have been shown to have high internal consistency with Cronbach alphas of .88 for the PA scale, and .87 for the NA scale high test-retest reliabilities (.79 for PA and .81 for NA) as well as excellent factorial validity with convergent correlations above .9 (Watson, L.A. Clark, & A. Tellegen, 1988). In addition, we will include items from the longer version of the PANAS (i.e., PANAS-X; Watson & Clark, 1994) to obtain scores on the fear and self-assurance subscales.

2.5.3.2. Behavioral Activation for Depression Scale: (BADS; Kanter, Mulick, Busch, Berlin, & Martell, 2006). The BADS consists of 25 items grouped into four subscales (Activation, Avoidance/Rumination, Work/School Impairment, and Social Impairment). Respondents are provided with a seven-point scale ranging from 0 (not at all) to 6 (completely) to which they rate how true each item was for them over the past week. Results with depressed individuals have shown the BADS to have good internal consistency for the total scale ($\alpha=.92$), and subscales: Activation ($\alpha=.84$), Avoidance/Rumination ($\alpha=.82$), Work/School Impairment ($\alpha=.75$), and Social Impairment ($\alpha=.85$) (Kanter, Rusch, Busch, & Sedivy, 2009). Construct validity was also demonstrated with significantly high correlations between the BADS total score and the Cognitive Behavioral Avoidance Scale (CBAS; $r=-.59$), Social Support Questionnaire (SSQ; $r=.34$), and the Center for Epidemiological Studies Depression Scale (CES-D; $r=-.72$) (Kanter, Rusch, Busch, & Sedivy, 2009).

2.5.4. Anxiety, Depression, and Mood

2.5.4.1. The 21-item Beck Depression Inventory-II: (BDI-II; Beck, Steer, & Brown, 1996)) will be used to assess depressive symptoms. The BDI has been found to have excellent internal consistency with an alpha coefficient of .94 and good convergent validity with the Mental Health subscale of the Short-Form General Health Survey (SF-20; $r = -.65$) (Arnau, Meagher, Norris, & Bramson, 2001).

2.5.4.2. The Spielberger State-Trait Anxiety Inventory: (STAI; Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1988) will be used to evaluate anxiety symptoms. Only the trait subscale of the STAI will be examined when determining the treatment effect of AE on anxiety symptoms. Test-retest reliability of the STAI-trait has been high (.86; Spielberg et al. 1970). Concurrent validity for the trait subscale has also been demonstrated with positive correlations with the Anxiety Scale Questionnaire (ASQ, $r = .73$) and the Manifest Anxiety Scales (MAS; $r = .85$) (Spielberger, Reheise, Ritterband, Sydeman, & Unger, 1995).

2.5.4.3. Four items from the NIMH Self-Rating Scale: (Greenberg et al., 1998) will be used as global ratings of mood, anxiety, obsessions and compulsions just prior to exercising and immediately afterwards. These rating scales were sensitive to acute change pre- to post-exercise among patients with OCD (Abrantes et al., 2009).

2.5.5. Potential Predictors of Exercise Adherence

2.5.5.1. Social Support for Exercise: (SSE) will be evaluated using a scale designed by Sallis et al. (Sallis, Grossman, Pinski, Patterson, & Nader, 1987) to measure the extent to which an individual has family or friends who are sources of support specific to physical activity. Examination of the psychometric properties of the SSE revealed a 4-factor structure, each with adequate internal consistency (alphas ranging from .55 to .86) and test-retest reliability (ranging from .55 to .86) (Sallis, et al., 1987).

2.5.5.2. Physical Activity Enjoyment Scale: (PACES; (Kendzierski & DeCarlo, 1991) will be used to assess exercise enjoyment. The PACES instrument has excellent internal consistency ($\alpha = .96$) and good test-retest reliability (ranging from .60 to .93) (Kendzierski & DeCarlo, 1991).

2.5.6. Physical Activity and Cardiorespiratory Fitness Outcomes

2.5.6.1. Objective Measurement of Physical Activity—Participants will be given an Actigraph (GT3X model) at the end of their baseline assessment with instruction to wear it every day for 7 days. The Actigraph has been widely accepted in the field as a valid approach to assessing physical activity (Abel et al., 2008). The accelerometer collects data 30 times per second and sums it up across a period of time (epoch). Data outputs are in counts per minute, from which the intensity and duration of physical activity can be determined. In addition, step count data can be collected with the Actigraph. Participants will also be mailed (via Federal Express) Actigraphs one-week prior to each follow-up assessment timepoint (i.e., baseline, 3-, 6-, and 12-month) and instructed to return them at their follow-up appointment.

2.5.6.2. Self-reported Physical Activity—The short 7-day recall version of the International Physical Activity Questionnaire (IPAQ; (Craig et al., 2003) will be administered to collect a self-report of physical activity at each timepoint. In an examination of the IPAQ's psychometric properties, data collected from 12 different countries revealed acceptable test-retest reliability (Spearman's rho clustered around 0.8) and criterion validity of approximately .3, which is comparable to other self-report measures (Craig et al., 2003).

2.5.6.3. Body Composition—will also be evaluated across multiple domains, including body mass index, body fat percentage, and waist-to-hip ratio. Body fat will be assessed with a handheld bioelectrical impedance device.

2.5.6.4. Cardiorespiratory Fitness—will be evaluated at follow-ups using a submaximal graded exercise test as described in above (see 2.5.1.3.).

2.5.7. Quality of Life and Psychosocial Functioning Outcomes

2.5.7.1. Quality of Life—The Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) is a self-report instrument that consists of 8 sub-scales that examine quality of life in a variety of areas. Internal consistency of the Q-LES-Q has been shown to be high, at 0.89 (Pitkanen et al., 2012). Test-retest coefficients were 0.9 and 0.93 (Stevanovic, 2011)

2.5.7.2. Global Assessment of Functioning (GAF) and Social and Occupational Functioning Assessment Scale (SOFAS)—As an index of DSM-IV axis V, the GAF is used to rate overall psychological, social, and occupational functioning, excluding physical and environmental impairment. Inter-rater reliability of the GAF has been shown to be high, at 0.92. Convergent validity with the SCL-90-R was -0.46 (Hilsenroth et al., 2000). The SOFAS provides a complementary assessment of social and occupational functioning on a continuum of 0 to 100. Inter-rater reliability for the SOFAS has been shown to be high, at 0.89. Convergent validity with the SCL-90-R was -0.37 (Hilsenroth, et al., 2000). Unlike the GAF, the individual's psychological and psychiatric symptoms do not influence SOFAS rating (APA, 1994).

2.5.8. Concurrent Treatment

2.5.8.1. Treatment History Interview—(Linehan, 1996). Non-study related treatments will be tracked throughout the course of the intervention using the Treatment History Interview (THI). This semi-structured interview assesses patient's psychiatric and medical treatment during a specified time frame (i.e., since the participant's last assessment).

2.6. Randomization

Following determination of eligibility and medical clearance to exercise, participants will be randomly assigned to the AE or HEC condition using the urn randomization procedure (Wei, 1978), with gender (male/female), OCD symptom severity [low Y-BOCS (17-24) vs. high Y-BOCS (>25)], current pharmacotherapy for OCD (yes/no) and current cognitive behavioral therapy for OCD (yes/no) as blocking variables.

2.7. Intervention Conditions

2.7.1. Moderate Intensity Aerobic Exercise (AE)

There are three components to the AE condition: 1) aerobic exercise, 2) cognitive-behavioral sessions to promote exercise participation, and 3) incentive system. The AE intervention is conducted individually with participants.

2.7.1.1. Aerobic Exercise Component of the Exercise Intervention—Participants in the AE condition will be required to attend aerobic exercise sessions supervised by an exercise physiologist, once a week at the Butler Hospital Fitness Facility. Participants will be given exercise prescriptions to engage in exercise a minimum of 2 to 4 (depending on the week of the intervention) additional times a week in the context of their own environment (e.g., in their home or through community resources) with the goal of achieving 150 minutes of moderate-intensity aerobic exercise per week by the last several weeks of the 12-week

intervention. In addition, participants will be required to self-monitor their exercise by filling out a weekly exercise log with the various exercise activities they engaged in during the week, the duration of each activity, and their self-reported ratings of perceived exertion (RPE) for each activity. Exercise sessions at the Butler Hospital Fitness Facility will begin at 20 minutes per session with weekly gradual increases with heart rate monitoring by the exercise physiologist to ensure training in the moderate-intensity range of 64-76% of age-predicted maximal heart rate (Garber et al., 2011). Each workout session will also include a 5-minute warm-up and a 5-minute cool-down to ensure safe exercise procedures. Several types of exercise equipment will be available to participants, including treadmills, recumbent bicycles, and elliptical machines.

2.7.1.2. Cognitive-Behavioral Component of the Exercise Intervention—Given the demonstrated efficacy of behavioral modification strategies in increasing physical activity (see meta-analysis by Dishman & Buckworth, 1996) behavioral techniques will be incorporated into the exercise intervention condition through 20-minute weekly didactic sessions. Through these weekly sessions, participants are guided as to how to increase overall fitness through behavioral changes in their daily lives. Each session will be focused on a certain topic designed to increase overall motivation to improve exercise adoption and maintenance (see Table 2).

2.7.1.3. Incentive Component of the Exercise Intervention—In order to maximize adherence to the exercise program and self-monitoring of daily exercise activities, participants will be entitled to incentives for various levels of compliance to exercise program. The incentive plan will provide participants with \$5 for attending each combined exercise session and for returning their completed exercise self-monitoring form from the prior week. In addition, participants will have the opportunity to draw prizes from a fish bowl (value ranging from \$10-\$50) for consecutive attendance at the weekly exercise sessions.

2.7.2. Health Education Contact Control

In order to equate for contact time received by participants in the AE intervention, the HEC condition will include: 1) 12 weekly hour-long psychoeducational sessions on 12 health and wellness topics and 2) an incentive component comparable to the AE (see 3.1.3). Similar to AE, this intervention is also conducted individually. The only modification to the incentive system utilized in the AE will consist of an automatic \$5 for attendance because they will not be keeping self-monitoring logs. Otherwise, participants will also be eligible to draw prizes for consecutive attendance to HEC sessions. Thus, both conditions will be equated for monetary incentives. While the last HEC session will include information about the general physical benefits of physical activity, no information will be provided regarding making behavioral changes toward increasing physical activity. See Table 3 for a list of topics covered.

2.8. Intervention fidelity

Treatment fidelity will be monitored on an ongoing basis for both intervention protocols through weekly group supervision of therapists, audiotaping of treatment sessions and independent ratings of therapist adherence (from audiotapes). If therapist drift from the protocol is detected, therapists will be given feedback and the problem will be corrected through supervision. All AE and HEC sessions will be audiotaped and 20% of these sessions will be randomly selected and rated shortly thereafter by independent raters (e.g., raters not otherwise associated with the treatment delivery) to assess therapist competence with and adherence to the treatment protocol, using a checklist system. To determine the level of adherence for intervention fidelity, raters will indicate whether a specific treatment

component was discussed in the session for each of the AE and HEC protocols. Initially, rating procedures will be modified and further rater training provided until adequate inter-rater reliability is obtained. Random reliability checks will be conducted to insure accurate ratings.

2.9. Participant safety

All participants must be medically cleared prior to intervention enrollment. Patients will undergo a comprehensive medical screening process conducted by the study physician, including a resting electrocardiogram (ECG), prior to completing the submaximal graded exercise test. In potentially medically complicated cases, the study physician will contact the participant's own primary care physician to discuss readiness for exercise. Patients who are deemed to be medically appropriate for study inclusion will complete moderate exercise sessions under the direct supervision of a masters-level exercise physiologist, who will be trained in Basic Cardiac Life Support procedures. An automated defibrillator will be available in the Fitness Facility for use in the unlikely event of cardiac arrest. To minimize the risk of injury during exercise sessions, participants will be trained in the proper use of the exercise equipment, and the exercise physiologist will supervise exercise sessions, including obtaining measures of heart rate and blood pressure before, during and post-exercise. In addition, participants will be instructed in appropriate warm-up and cool-down exercises.

All research staff who have direct involvement with participants will be fully trained by the principal investigator in procedures for assessment and intervention in cases where suicidal ideation is expressed. In such cases, research staff will also immediately contact the principal investigator, who is a licensed clinical psychologist and will be on-call at all times. Appropriate clinical action will be taken in such circumstances, including hospitalization and/or referral to another level of clinical care. Records of treating clinicians for participants in ongoing treatment will be maintained, and we will contact these treatment providers when clinically indicated.

2.10. Data Analytic Plan

As a first step, the equivalence of the random assignment of groups with regard to key baseline characteristics will be assessed. This will involve comparison of treatment groups on sociodemographic characteristics, OCD symptom severity, history of CBT or ER/P treatment, fitness, and affective measures. Should groups differ on any characteristics, these variables will be used as covariates in the primary outcomes analyses. We will also examine the degree to which participants report changes in their OCD treatment during the 12-week intervention phase to provide assurance that changes in outcomes of interest are related to the AE intervention over and above possible effects of any concurrent OCD treatment(s) received.

Data analysis will follow a sequence that is designed to examine the primary outcome question, "Does a moderate-intensity aerobic exercise intervention (AE) result in greater OCD symptom reductions than health education (HEC)?" These analyses will be followed by examination of the effect of AE (relative to HEC) on changes in symptoms of psychopathology (i.e., non-specific anxiety and depressive symptoms), quality of life, and cardiorespiratory fitness outcomes as well as positive affect and approach behavior and decreases in negative affect and avoidance behavior. Additionally, we will evaluate mediators that change in response to AE with Y-BOCS outcomes using single mediation and/or multiple mediation models. In further exploratory analyses, we will examine predictors of treatment compliance and exercise adoption among subjects assigned to the AE intervention and in the sample as a whole. All analyses assume $\alpha = .05$.

Analyses of repeated measures will be conducted using generalized linear mixed models (GLMM). Although less familiar than classical methods of data analyses, techniques based on generalized linear mixed models (GLMM; such as hierarchical linear modeling) and generalized estimating equations (GEE), offer distinct advantages in the analysis of OCD symptom outcomes including greater flexibility for handling missing data, for modeling the effects of time and the variance/covariance structures of repeated measures, and for analyzing dependent variables that are not normally distributed (Carbonari, Wirtz, Muenz, & Stout, 1994; Hall et al., 2001). They also allow for inclusion of time-varying covariates.

3. Summary

Relative to other mental health disorders, there have been few advances in the treatment of OCD over the last twenty years. Given refusal and drop out rates with conventional therapies, as well as significant residual symptoms with treatment, there exists an important unmet need for new approaches. Augmenting OCD treatment with exercise offers a potential solution to this problem. As discussed above, preliminary, uncontrolled pilot studies of aerobic exercise for patients with OCD were promising (Brown, et al., 2007; Lancer, et al., 2007). If benefit is observed, we expect the mechanism of action will involve an exercise-related normalization of self-regulatory systems (i.e., behavioral activation and behavioral inhibition). This would be evidenced by increases in positive affect and approach behaviors and (possibly) decreases in negative affect and avoidance. A key consequence of that change would be a self-reinforcing series of naturalistic exposures to OCD triggers, which would in turn act to reduce OCD-related avoidance and distress over the longer term and decrease OCD symptom severity. Other psychological benefits of exercise, such as improved depressive and anxiety symptoms, which are commonly comorbid with OCD, should add to the impact of this intervention on quality of life.

An intervention to increase physical activity should be cost-effective, flexible, and accessible. Many forms of physical activity (e.g., walking, doing housework and gardening, exercise videos) may be conducted independently, either at home or outdoors, with minimal associated costs. Further, engaging in physical activity has minimal side effects (e.g., Brooks, et al., 1998). With the use of proper precautions for prevention of injuries (ACSM, 2009), physical activity carries a relatively low risk of adverse events. Increased physical activity could meaningfully benefit OCD patients in other important ways, as its physiological health effects have been well documented (Bovens et al., 1993; King, Frey-Hewitt, Dreon, & Wood, 1989; Kohl, LaPorte, & Blair, 1988; Oberman, 1985; Pinto & Marcus, 1994; USDHHS, 1996).

Thus, the key, next step in this line of research is to conduct a well-designed and rigorously controlled trial to determine whether exercise represents a viable option for patients with OCD. If efficacious, an exercise intervention may provide a valuable treatment augmentation option for patients with OCD who are experiencing clinically significant residual symptoms after an adequate dose and duration of pharmacological and/or cognitive behavioral treatment. In addition, once efficacy can be demonstrated, future work can then begin dismantling the individual components of the intervention to determine its more active ingredients (e.g., exercise-focused CBT groups, improved fitness, increase activity minutes, self-monitoring, financial incentives).

Acknowledgments

This research was supported by an NIMH-funded grant (R01MH086513) awarded to Dr. Abrantes.

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Highlights

- Patients with OCD continue to experience clinically significant symptoms even with available treatments
- Aerobic exercise is helpful for symptom reduction in other psychiatric populations
- Aerobic exercise interventions for patients with OCD represent a potentially useful yet relatively unexplored strategy

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Figure 1.
Proposed Mediating Mechanisms

Table 1

Schedule of Assessments

Measures	Pre-Baseline	Baseline	At Weekly Exercise Sessions	Post-intervention	3-, 6- and 12-month Follow-up
Demographic	X				
Psychiatric & Physical Health Screening					
Physical Activity Screen	X				
Health Questionnaire		X		X	X
Cardiorespiratory Fitness (i.e., MET level and duration of exercise test)		X		X	X
SCID-P*		X			
Butler Hospital OCD Database Interview		X			
OCD Symptoms					
Yale-Brown Obsessive Compulsive Scale (Y-BOCS)		X	X*	X	X
Mediator Variables					
Positive and Negative Affect Schedule (PANAS)		X	X*	X	X
Behavioral Activation for Depression Scale (BADS)		X	X*		
Anxiety/Depressive Symptoms and Mood					
Beck Depression Inventory (BDI)		X		X	X
State-Trait Anxiety Inventory (STAI)		X		X	X
NIMH Self-Rating Scale Items		X	X	X	X
Potential Predictors of Exercise Adherence					
Social Support for Exercise		X		X	X
Physical Activity Enjoyment Scale		X		X	X
Physical Activity/Fitness Outcomes					
7-day accelerometer counts		X		X	X

Measures	Pre-Baseline	Baseline	At Weekly Exercise Sessions	Post-intervention	3-, 6- and 12-month Follow-up
International Physical Activity Questionnaire (IPAQ)		X		X	X
Body Composition (BMI, Skinfold, Weight)		X		X	X
Cardiorespiratory Fitness (i.e., MET level and duration of exercise test)		X		X	X
Quality of Life and Psychosocial Functioning Outcomes					
Global Assessment of Functioning (GAF) and Social and Occupational Functioning Scale (SOFAS)		X		X	X
Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q)		X		X	X
Concurrent Treatment					
Treatment History Interview		X		X	X

* To be administered at 3rd, 6th, 9th, and 12th weeks of the intervention

Table 2**Cognitive Behavioral Component of the Aerobic Exercise Intervention**

Week	Topic	Description
1	The Basics – Exercising Wisely	Discussion of ACSM's guidelines for physical activity, how to determine whether one is engaging in moderate exercise, and the 3 components of a good workout (i.e., warm-up, moderate intensity aerobic activity, and cool-down)
2	Physical Health Benefits of Exercise	A general discussion of the overall physical/health benefits of exercise.
3	Goal Setting	A discussion of goal setting as a skill that is acquired through practice, and specific steps toward developing effective goals (i.e., generating personal, attainable, realistic, and measurable goals), and generating exercise-specific goals.
4	Getting Motivated	A discussion of various techniques to get and stay motivated for exercise such as selecting activities that are enjoyable, generating positive self-statements, visualization of success, and generating rewards for accomplished exercise goals.
5	Getting Back on Track	A discussion of how to identify situations considered high-risk for deviating from an exercise program and developing strategies on how to plan for and handle these situations.
6	Exercise and Mental Health	A discussion of the benefits of exercise for coping with depressive and anxious moods.
7	Identifying and Overcoming Barriers to Exercise	A discussion of how to identify both planned and unplanned barriers to engaging in exercise along with various cognitive and behavioral strategies to deal with them.
8	Time Management	A discussion of the key principles of time management such as prioritizing and planning activities with a special emphasis on exercise.
9	The Benefits of Exercise for OCD	A discussion of the potential benefits of exercise for OCD symptom reduction such as decreased depression, increased confidence, decreased stress, improved coping, providing a distraction, and increasing serotonin levels.
10	Making Plans for Action	A discussion on the stages of change along with techniques to move from various stages into the action stage of exercise.
11	Getting Social Support	A discussion of how to seek different types of support from others including general encouragement, exercise advice from knowledgeable individuals, and exercising with others.
12	Maintenance	A discussion on various techniques to increase the likelihood that the exercise program will be maintained long-term such as: trying new activities, setting new goals, thinking positively, reflecting on previous exercise accomplishments, and utilizing problem solving skills to address barriers to exercise.

Table 3**Health and Wellness Education Contact Control**

Week	Topic	Description
1	Nutrition	A discussion of the general facts about good nutrition, how to use the CDC's My Plate food model, and the relationship between OCD and poor nutrition.
2	Sleep Hygiene	A discussion focused on the relationship between OCD and sleep hygiene, and healthy behaviors that can promote good sleeping patterns.
3	Assertiveness Skills	A discussion of how assertiveness is defined and ways to improve assertiveness skills when working with others so that both side's needs are met without being aggressive or passive.
4	The Science of OCD Part 1	A discussion of how OCD is defined and characterized, along with various co-morbid conditions and a genetic component that can be associated with the disorder.
5	Relaxation Training	A discussion of the types of relaxation training strategies available and how these can help to reduce the stress and anxiety that is often associated with OCD.
6	Caffeine, Alcohol, and Cigarette Smoking	A discussion of how overuse of caffeine and alcohol can negatively affect the human body and OCD symptoms, and the detrimental effects that cigarette smoking can have on physical and mental health.
7	Complementary and Alternative Medicine	A discussion of the types of complementary and alternative medicines/methods available, the benefits of such use, and the need to research CAM methods to determine safety.
8	The Science of OCD Part 2	A discussion of how OCD affects brain circuitry functioning, and subsequently executive, verbal, and visuospatial functioning.
9	Time Management and Goal Setting	A discussion of the key principles of time management such as prioritizing and planning activities, along with the need to practice good goal setting skills while managing OCD symptoms.
10	Coordinating Your Medical Treatment	A discussion of the importance of coordinating medical treatment for OCD, with emphasis on practicing self-management skills and effectively communicating with treatment providers.
11	The Science of OCD Part 3	A discussion of the different treatment options available for individuals diagnosed with OCD, including pharmacotherapy, cognitive behavioral therapy, and neurosurgery.
12	Physical Activity and Exercise	A discussion of the ACSM's guidelines for physical activity, how to determine whether one is engaging in moderate-intensity exercise, the 4 components of a good workout (i.e., warm-up, moderate intensity aerobic activity, cool-down, and stretching)