EFFECT OF EXERCISE INTENSITY DURING AEROBIC TRAINING ON DEPRESSIVE SYMPTOMS IN INITIALLY SEDENTARY DEPRESSED WOMEN

DISSERTATION

Presented in Partial Fulfillment of the Requirements for
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By

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Depression is a serious mental disorder in the U.S. Each year, approximately 13.7 million American adults suffer from depression. Research has shown that exercise can decrease depressive symptoms, yet an optimal exercise program for treating depression has not been established. The mechanisms that mediate the antidepressant effect of exercise also require investigation. The purpose of this study was to examine the effect of different exercise intensities prescribed for aerobic training on depressive symptoms in initially sedentary depressed women. A secondary purpose was to examine the mediation effect of self-efficacy on depression.

Sedentary women scoring ≥ 14 on the Beck Depression Inventory-II (BDI-II) were randomized to one of two aerobic exercise treatment groups that differed on exercise intensity [high (65-75% MaxVO₂ reserve) or low (40-55% MaxVO₂ reserve)], or to a stretching exercise control group. All three groups had one supervised exercise session per week. The aerobic groups also exercised 3-4 times per week on their own and exercised to expend 1000 Kcal per week. The total training period was 10 weeks. Participants’ depressive symptoms (BDI-II) and self-efficacy (Exercise Self-Efficacy
Questionnaire & Depression Coping Self-Efficacy Scale) were measured at study entry, week 5, and week 10.

Results showed that participants in all groups (high, $n = 15$; low, $n = 11$; stretching, $n = 12$) had significant reductions in depressive symptoms after 10 weeks, $p < .001$. The BDI-II change scores were not significantly different among the groups. After 10-weeks of exercise training, participants in both aerobic exercise groups had significantly increased depression coping self-efficacy, $p < .01$, but their exercise self-efficacy did not change. Neither exercise self-efficacy nor depression coping self-efficacy had significant correlation with BDI-II changes. There was no mediation effect for either type of self-efficacy.

It was concluded that when controlling total energy expenditure (1000 Kcal per week), both high and low intensity aerobic exercise training programs were equally effective in reducing mild to moderate depressive symptoms in initially sedentary women. While depression coping self-efficacy improved for the two aerobic groups, there was no evidence that self-efficacy mediated the effect of exercise training on depressive symptoms.
Dedicated to my parents and my husband
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CHAPTER 1

INTRODUCTION

Background Information

Depression is a serious mental disorder throughout the world. According to data from the 2000 Global Burden of Disease Study, depression is the fourth leading cause of disease burden, accounting for 4.4% of total disability adjusted life years in the world (Ustun, Ayuso-Mateos, Chatterji, Mathers, & Murray, 2004). Moreover, depression is projected to become the world’s second leading cause of disability and mortality by 2020 (Murray & Lopez, 1996). In the United States, the estimated lifetime prevalence of major depressive disorder (MDD) is 16.2% (Kessler et al., 2003). In any given year, approximately 13.7 million American adults (about 6.6 % of the U.S. population age 18 and older) suffer from a depressive disorder (Kessler et al., 2003). The prevalence of depression is different between genders. Research shows that women are twice as likely as men to suffer from depression (Buckworth & Dishman, 2002; Preskorn, 1999). Results from a national survey indicated that the lifetime prevalence for MDD is 12.6% among women and 6.3% among men (Riolo, Nguyen, Greden, & King, 2005). Reasons for this
difference are unknown, but are likely related to genetics, endocrine effects, and social learning (Buckworth & Dishman, 2002).

Despite the availability of effective pharmacological and psychotherapeutic treatments for depression, only 51.6% of adults suffering from this disease seek treatment, and only 21.7% is adequately treated (Kessler et al., 2003). Unlike the traditional treatments (i.e., pharmacological and psychotherapeutic treatments), which usually carry social stigma, exercise does not carry stigma and hence may be a more acceptable treatment for the general population (Dunn, Trivedi, Kampert, Clark, & Chambliss, 2002). Research has shown that involvement in structured exercise can decrease symptoms of depression (Craft & Perna, 2004; Paluska & Schwenk, 2000). Meta-analytic studies also indicate that exercise training is as effective as antidepressant medication and psychotherapy in alleviating depressive symptoms (Craft & Landers, 1998; North, McCullagh, & Tran, 1990). Recently, Dunn and her colleagues (2005) reported that aerobic exercise at a dose consistent with public health recommendations (i.e., at least 30 minutes of moderate intensity physical activity on most, preferably all, days of the week; termed public health dose) is an effective monotherapy for MDD of mild to moderate severity. In addition, when controlling for total energy expenditure, exercise frequency (i.e., either 3 or 5 days per week) did not moderate the effect of exercise on depression. The authors suggested that the determining factor for reduction of depressive symptoms was total energy expenditure rather than exercise frequency. However, in this study, the exercise intensity was not controlled. The participants were instructed to exercise at their
preferred intensity. Therefore, it was not clear whether exercise intensity played a role in the antidepressant effect of exercise.

Purpose of the Study

Exercise intensity is an essential component in exercise prescriptions. Results from previous research regarding exercise intensity and depression have been equivocal. While some studies suggested that both vigorous and moderate intensity exercise are equally effective in alleviating symptoms of depression (Craft & Landers, 1998; Craft & Perna, 2004), others reported an inverse relationship between exercise intensity and depressive symptoms (Lampinen, Heikkinen, & Ruoppila, 2000). It is still unclear whether a certain exercise intensity, when controlling for total energy expenditure, is required for reduction of depressive symptoms. Therefore, the purpose of this study was to examine the effect of two different exercise intensities (high vs. low) during aerobic training on depressive symptoms in initially sedentary depressed women. A secondary research objective was to examine the relationship between changes in self-efficacy and depressive symptoms. Self-efficacy is the psychosocial variable with the most support as a mediator of exercise adoption and adherence, but little has been done to examine the relationship between self-efficacy and depression, nor the role of self-efficacy in respect to training intensity.

Research Hypotheses

There are eight research hypotheses. First, it was hypothesized that after 10 weeks of aerobic exercise training, both high and low intensity exercise groups would have improved depressive symptoms. Second, the level of improvement would be the same for
both groups. In other words, when exercising at the public health dose, exercise intensity would not moderate the effect of exercise on depressive symptoms. Third, it was hypothesized that both high and low intensity exercise groups would have increased exercise self-efficacy after 10 weeks of exercise training. Fourth, it was hypothesized that both high and low intensity exercise groups would have increased depression coping self-efficacy after 10 weeks of exercise training. Fifth, there would be a negative relationship between changes in exercise self-efficacy and depressive symptoms. Sixth, there would be a negative relationship between changes in depression coping self-efficacy and depressive symptoms. Seventh, changes in exercise self-efficacy would mediate the effect of exercise on depressive symptoms. Eighth, changes in depression coping self-efficacy would mediate the effect of exercise on depressive symptoms. The results of this study contribute to establishing an optimal exercise program for treating depression.

Limitations and Assumptions

The generalization of the findings in this study is limited to women between 18-45 years of age and either studying or working on a mid-western university campus. The type of exercise training in this study was limited to aerobic exercise. The main reason is that depressed individuals are found to have higher morbidity and mortality rates from cardiovascular disease (Rozanski, Blumenthal, & Kaplan, 1999). By engaging in aerobic exercise, participants will not only improve their depressive symptoms but also decrease their risk of cardiovascular disease. In the current study, participants were asked to keep an exercise diary. We assumed that a participant’s exercise diary accurately reflected the intensity, duration, and frequency of exercise the participant performed during
unsupervised exercise sessions. The total energy expenditure from exercise was controlled at 1000 kcal per week. Instead of direct measurement, the energy expenditure was calculated from exercise intensity and duration from the self-report using the formula provided in the American College of Sports Medicine (ACSM)’s *Guidelines for Exercise Testing and Prescription* (2000). We assumed that the calculated energy expenditure approximates the actually energy expenditure from exercise.

**Operational Definitions**

**Aerobic Exercise**

According to the ACSM, aerobic exercise is defined as any activity that uses large muscle groups, can be maintained continuously, and is rhythmic in nature (Roitman et al., 2001). It is a type of exercise that overloads the heart and lungs and causes them to work harder than at rest. When appropriately performed on a regular basis, aerobic exercise helps to increase maximal oxygen uptake (Roitman et al., 2001).

**Operational definition:** In the current study, the aerobic exercise during supervised exercise sessions was treadmill walking or jogging. During unsupervised sessions, the aerobic exercise could have included aerobic dance, bicycling, brisk walking, jogging, and stair climbing.

**Depressive symptoms**

A depressive disorder is an illness that involves the body, mood, and thoughts (National Institute of Mental Health, 2006). Depressive symptoms are used to classify or diagnose someone as being depressed. The criteria for a diagnosis for major depression are that at least five of the following symptoms are present during the same 2-week period, and one
of which must be either depressed mood or loss of interest or pleasure (American Psychiatric Association, 2000).

1. Depressed mood most of the day, nearly every day
2. Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly everyday
3. Significant weight loss when not dieting or weight gain, or decrease or increase in appetite
4. Insomnia or hypersomnia
5. Psychomotor agitation or retardation
6. Fatigue or loss of energy
7. Feelings of worthlessness or excessive or inappropriate guilt
8. Diminished ability to think or concentrate, or indecisiveness
9. Recurrent thoughts of death or suicide

**Operational definition:** In the current study, depressive symptoms were assessed based on responses to the Beck Depression Inventory II (BDI-II) (Beck, Steer, & Brown, 1996). The BDI-II is a self-report inventory with 21 items assessing the behavioral and cognitive symptoms of depression. Symptoms assessed in the BDI-II include sad mood, feelings of pessimism and guilt, loss of pleasure and interest, suicidal thoughts, irritability, changes in appetite and sleeping pattern, concentration difficulty, fatigue, and loss of interest in sex. Total score on BDI-II can range from 0 to 63. Scores of 0-13 indicate minimal depression, 14-19 indicate mild depression, 20-28 indicate moderate depression, and 29-63 indicate severe depression.
Energy Expenditure

Energy expenditure refers to the amount of calories utilized to perform an activity.

**Operational definition:** In the current study, energy expenditure was defined as the amount of calories expended to perform exercise. Participants in both high- and low-intensity exercise groups were instructed to exercise to expend 1000 kcal per week. We calculated participants’ weekly energy expenditure based on the exercise intensity, duration, and frequency recorded in their activity diary. The following formula from the ACSM’s guidelines for exercise testing and prescription (2000) was used to calculate the caloric cost of exercise:

\[
\text{\text{(Net oxygen consumption (VO2) in ml/kg/min x body weight in kg)/200 = kcal/min}}
\]

If a participant with a body weight of 65 kg exercised at a VO2 of 21 ml/kg/min for 40 minutes/session, four sessions per week (frequency), her weekly energy expenditure from exercise is calculated as follows:

\[
\frac{(21 \text{ ml/kg/min x 65kg})}{200} = 6.8 \text{ kcal/min}
\]

\[
6.8 \text{ kcal/min x 40 min/session x 4 sessions/week} = 1088 \text{ kcal/week}
\]

This participant’s weekly energy expenditure from exercise is 1088 kcal.

Exercise Intensity

Exercise intensity refers to the level of workload during exercise.

**Operational definition:** For the purpose of this study, the exercise intensity is defined by the rate of oxygen uptake (VO2) during exercise. The oxygen uptake reserve (VO2R) method was used to calculate the target VO2 (i.e., exercise intensity). The following equation was used to calculate the target VO2 based on VO2R (Franklin et al., 2000):
Target VO₂ = ([VO₂max – VO₂rest] x %) + VO₂rest

VO₂max: maximal oxygen uptake
VO₂rest: resting oxygen uptake

In the current study, high intensity was defined as 65% to 75% of VO₂R, and low intensity was defined as 40% to 55% of VO₂R. For example, for a participant with a VO₂max of 35 ml/kg/min and VO₂rest of 3.5 ml/kg/min, her target training VO₂ range is calculated as follows (Assuming she is randomized to high intensity exercise group):

Target VO₂ = ([35 – 3.5] x 65%) + 3.5 = 23.98 ml/kg/min
Target VO₂ = ([35 – 3.5] x 75%) + 3.5 = 27.13 ml/kg/min

This participant’s target training VO₂ range is between 23.98 and 27.13 ml/kg/min.

**Maximal Oxygen Uptake**

Maximal oxygen uptake (VO₂max) refers to the highest rate of oxygen consumption.

**Operational definition:** In the current study, the maximal oxygen uptake refers to the highest rate of oxygen consumption recorded during a maximal exercise test on a treadmill using Balke’s protocol (Pollock et al., 1982).

**Sedentary**

Sedentary is defined as participating in a lifestyle with minimal bodily movement (Dietz, 1996).

**Operational definition:** In the current study, sedentary was defined as exercising less than 3 times per week and less than 20 minutes per session, and weekly energy expenditure from exercise is less than 500 kcal.
Self-efficacy

Self-efficacy is the degree to which an individual believes he or she can successfully engage in a specific behavior in a particular situation with known outcomes (Bandura, 1986).

**Operational definition:** In the current study two types of self-efficacy were measured, including exercise self-efficacy and depression coping self-efficacy.

Exercise self-efficacy is defined by one’s confidence to exercise under different conditions, such as being tired or during bad weather. The Exercise Self-efficacy questionnaire (Garcia & King, 1991) was used to measure exercise self-efficacy. In this questionnaire, participants were asked to rate their confidence from 0% (I cannot do it at all) to 100% (certain that I can do it) in their ability to exercise under 15 different conditions over the next three months. The ratings for all items were summed and then divided by 15 to obtain a mean score. The higher the mean score the higher one’s exercise self-efficacy, and vice versa.

Depression coping self-efficacy is defined by one’s confidence to engage in different activities to cope with the depressive symptoms. Depression coping self-efficacy was measured by the Depression Coping Self-Efficacy Scale (Perraud, 2000). Participants were asked to rate their confidence from 0% (not at all confident) to 100% (confident) in their ability to engage in 24 different coping activities. The ratings for all items were summed and then divided by 24 to obtain a mean score. The higher the mean score the higher one’s depression coping self-efficacy, and vice versa.
CHAPTER 2

LITERATURE REVIEW

The following review provides a rationale and foundation for this research study. The chapter begins with information about depression as a public health problem and important area of research, particularly in respect to adult women. This is followed by evidence on the effect of exercise on depression with a focus on the effect of aerobic exercise training. We continue with a discussion on the impacts of exercise mode, energy expenditure, and intensity on depressive symptoms. This chapter ends with a summary of potential mechanisms by which exercise may alleviate symptoms of depression with a focus on the mediation effect of self-efficacy. Databases searched were Medline and PsycINFO from the years 1970 through 2007 using combinations of the following keywords: exercise, physical activity, training, intensity, depression, and depressive symptoms. Additional searches were conducted using reference lists from review articles and meta-analyses.

Depression

Depression is categorized as one type of mood disorders (American Psychiatric Association, 2000). According to Diagnostic and Statistical Manual of Mental Disorders
(DSM-IV), mood disorders are placed into four categories: (1) depressive disorder, (2) bipolar disorder, (3) mood disorders due to a medical condition, and (4) substance-induced mood disorders. The first category includes major depressive disorder and the milder form, dysthymic disorder (American Psychiatric Association, 2000). Symptoms of major depressive disorder include (1) depressed mood most of the day, nearly every day; (2) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly everyday; (3) significant weight loss when not dieting or weight gain, or decrease or increase in appetite; (4) insomnia or hypersomnia; (5) psychomotor agitation or retardation; (6) fatigue or loss of energy; (7) feelings of worthlessness or excessive or inappropriate guilt; (8) diminished ability to think or concentrate, or indecisiveness; and (9) recurrent thoughts of death or suicide. To be diagnosed as major depression, at least five of the above symptoms are present during the same 2-week period, and at least one of the symptoms is either depressed mood or loss of interest or pleasure.

Depression is a serious mental disorder in the United States. The estimated lifetime prevalence of major depressive disorder (MDD) is 16.2% (Kessler et al., 2003). One year prevalence is 6.6%, which suggests that each year about 13.7 million American adults suffer from a depressive disorder (Kessler et al., 2003). Although for a formal diagnosis, the symptoms of MDD need to persist for only 2 weeks, most episodes last longer, with a mean episode duration of 16 weeks (Kessler, et al., 2003). Furthermore, a majority of people who recover from an episode of MDD will have a recurrence of the disorder (Brosse, Sheet, Lett, & Blumenthal, 2002).
The debilitating effects and enormous cost of MDD have been well documented (Brosse et al., 2002). Each year, over 40 billion dollars is spent on lost work productivity and medical treatment related to depression (Craft & Perna, 2004). Both MDD and dysthymia were associated with increased use of general medical services, increased use of emergency departments, lost time at work, and increased rates of attempted suicide (Brosse et al., 2002). Reports from the Global Burden of Disease study indicated that depression is the fourth leading cause of disease burden, which accounted for 4.4% of total disability adjusted life years in the year 2000 (Ustun, Ayuso-Mateos, Chatterji, Mathers, & Murray, 2004). Thus, MDD is a prevalent and recurrent disorder and is associated with significant economic costs.

Women are twice likely as men to suffer from a depressive disorder (Preskorn, 1999). Results from a national survey indicated that the lifetime prevalence of MDD is 12.6% among women and 6.3% among men (Riolo, Nguyen, Greden, & King, 2005). Global Burden of Disease study also showed that depression is the fourth leading cause of disease burden in women but ranks seventh for men (Ustun et al., 2004). Reasons for this difference are unknown, but are likely related to genetics, endocrine effects, and social learning (Buckworth & Dishman, 2002).

The highest rates of depression are seen among women of reproductive age (Stewart, Gucciardi, & Grace, 2004). The scientific literature suggests that the first episode of MDD usually happens when individuals are 19 to 44 years of age (Kessler et al., 2005). Furthermore, individuals in their 20s to 40s have the highest visit rates to
psychiatrists, and the reason for their visits is mainly for anxiety or mood disorders (Wang et al., 2005).

Although there have been major advances in effective pharmacological and psychotherapeutic treatments for depression, it is estimated that only 51.6% of people with MDD seek treatment, and only 21.7% is adequately treated (Kessler et al., 2003). Social stigma and distrust of the medical regimens used to treat depression are two main reasons why individuals with depression do not seek treatment (Goldman et al., 1999). Moreover, pharmacological treatments have many detrimental side effects, including fatigue, cardiovascular complications, and possible addiction (Buckworth & Dishman, 2002). Weight gain caused by antidepressant medications is another major reason for patient noncompliance with treatment (Deshmukh & Franco, 2003). Recently, researchers also found that taking selective serotonin reuptake inhibitor (SSRIs), a widely used class of antidepressants, is associated with low bone mineral density (Haney et al., 2007).

Exercise has been proposed as a plausible adjunct or alternative treatment for depression (Callaghan, 2004; Craft, 2005). Unlike the traditional pharmacological and psychotherapeutic treatments, exercise does not carry social stigma, is relatively less expensive than antidepressant medication and psychotherapy, has fewer side effects, and has additional health benefits. Hence, exercise can serve as a more acceptable treatment for individuals with depression. Moreover, individuals engaging in regular exercise can also improve their physical health and reduce the risk of other diseases, such as coronary heart disease, diabetes, and colon cancer (Pate et al., 1995).
The Effects of Exercise on Depression

Since ancient times, physical activity has been recommended by physicians to combat depression. For example, about 2500 years ago, Hippocrates had prescribed exercise for his patients who experienced depression (Buckworth & Dishman, 2002). Since the early 1900s, researchers have been interested in the association between exercise and depression (Craft & Landers, 1998). The results of early studies suggested that moderate-intensity exercise should be beneficial for depression (Craft & Perna, 2004). In 1970, Morgan et al. conducted the first experimental study examining the relationship between exercise training and depressive symptoms in men. The results showed that self-rated depressive symptoms could be reduced after an exercise training program. In the 1980’s, a number of randomized control trials were conducted to examine the effect of exercise training (mainly aerobic exercise) on depression (Dustman et al., 1984; Klein et al., 1984; Martinsen, Hoffart, & Solberg, 1989; McCann & Holmes, 1984; Roth & Holmes, 1987). Results from these studies suggested that participation in an exercise program was effective for reducing depression. From the 1990s to the present, a number of correlational, quasi-experimental, and experimental studies have been conducted to examine the relationship between exercise and depression. In these studies, two types of exercise were examined, aerobic exercise (e.g., walking, jogging) and resistance exercise (e.g., weightlifting). Most exercise intervention studies have examined the effects of aerobic exercise training, which usually involved brisk walking or jogging, while significantly fewer studies have focused on resistance training. In general, participants in
the intervention studies exercised under supervision for 30 to 60 minutes, three times per week.

Cross-sectional Studies

Cross-sectional studies of clinical and nonclinical samples have consistently found that regular physical activity is associated with lower depression scores. Ruuskanen and Ruoppila (1995) conducted a cross-sectional study investigating the association between physical activity and psychological well-being among the elderly (age 65-84 yr). They found that in this population, no regular physical exercise was significantly associated with a higher prevalence of depression. Another cross-sectional study by Hassmen, Koivula, and Uutela (2000) showed a similar inverse relation. A total of 3403 participants in Finland (age 25-64 yr) were randomly sampled and depressive symptoms were measured using Beck Depression Inventory. The results showed that individuals reporting less frequent exercise experienced more depressive symptoms.

More recently, de Moor and his colleagues (2006) examined whether regular exercise is associated with anxiety, depression and personality in a large population-based sample (N = 19,288) in the Netherlands. The authors found that exercisers were on average less anxious, depressed, and neurotic than non-exercisers. Galper, Trivedi, Barlow, Dunn, and Kampert (2006) examined 5451 men and 1277 women who participated in the Aerobics Center Longitudinal Study. They found that in this sample, higher maximal cardiorespiratory fitness and habitual physical activity were associated with lower depressive symptomatology and greater emotional well-being. Findings from
these cross-sectional studies suggest a consistent association between regular physical exercise and reduced depressive symptoms.

**Prospective Studies**

A number of prospective studies also indicated an inverse relationship between physical activity and depressive symptoms. Camacho, Roberts, Lazarus, Kaplan, and Cohen (1991) examined the relationship between level of physical activity and risk of subsequent depression by comparing data from the Alameda County Study. Depressive symptoms and level of physical activity were measured in 1965, 1974, and 1983. The results showed that participants who reported low physical activity levels at baseline were at significantly higher risk for depression at follow-up than those who reported high physical activity levels at baseline. In addition, those who were inactive at baseline, but increased their physical activity levels during follow-up had a risk for depression as low as did those who had been highly active from baseline. This finding suggests that the risk of depression can be altered by changes in level of physical activity. The authors concluded that there is a positive mental health benefit associated with increased levels of physical exercise.

Another prospective study by Paffenbarger, Lee, and Leung (1994) examined data from a cohort of 21,596 Harvard college male alumni. The study found that those who expended 1000-2499 Kcal per week in walking, stair climbing, and sportsplay were 17% less likely to develop clinical depression than those who were less active (i.e., expended less than 1000 Kcal per week). Moreover, those who expended 2500 or more Kcal per
week had a 28% lower risk of developing clinical depression. The authors concluded that risk of depression was lower among the physically active and sports players.

Two recent prospective studies also reported an inverse relationship between exercise and depression. Harris, Cronkite, & Moos (2006) conducted a 10-year cohort study of clinically depressed patients. Physical activity, exercise coping, depression, and other psychosocial constructs were measured at baseline, 1-year, 4-years, and 10-years. The study reported that more physical activity was associated with less concurrent depression. This inverse relationship was not changed after controlling for gender, age, medical problems, and negative life events. The study also found that physical activity helped counteract the negative effects of medical conditions and negative life events on depression. The authors suggested that encouraging clinically depressed patients to participate in physical activity is likely to have benefits with few obvious risks. Another study by Lindwall, Rennemark, Halling, Berglund, and Hassmen (2007) investigated the relationship between light and strenuous exercise and depression in a sample of 860 elderly Swedish men and women. The authors found that the inactive elderly had higher depression scores than more active individuals. In addition, both continuously inactive individuals and individuals reporting a shift from activity to inactivity during the preceding year had higher depression scores than the continuously active individuals.

Meta-analyses and Literature Reviews

Results from review articles and meta-analyses also indicate an inverse relationship between physical activity and depressive symptoms. In a meta-analysis by North, McCullagh, and Tran (1990), the authors indicated that both acute and chronic
exercise significantly decreased depressive symptoms and this antidepressant effect continued through follow-up measures. The authors concluded that exercise was a better antidepressant than relaxation activities and was as effective as psychotherapy. In Craft and Landers’ meta-analysis (1998), the effect of exercise was examined in individuals with clinical depression or depression resulting from mental illness. The results showed that exercise programs were effective in decreasing depressive symptoms among clinically depressed individuals and individuals with depression resulting from mental illness.

In Dunn, Trivedi, and O’Neal’s review (2001), the researchers compared eighteen cross-sectional and prospective epidemiologic studies examining physical activity and depression. They concluded that correlational studies consistently demonstrate an association between physical activity and reduced symptoms of depression. They also suggested that randomized control trials are needed to explore the possible underlying biological and psychological mechanisms of the effects of exercise. In a review by Brosse, Sheets, Lett, and Blumenthal (2002), the authors concluded that the available evidence supports the value of exercise in reducing depressive symptoms in both healthy and clinical populations. The authors also suggested that carefully conducted clinical trials are needed before exercise can be recommended as an alternative to antidepressant medication or psychotherapy. In a more recent review by Callaghan (2004), the author concluded that exercise is effective in reducing anxiety and depression, and in improving self-esteem and cognitive functioning.
Exercise Training Studies

Exercise training has been consistently shown to reduce symptoms of depression (Craft & Perna, 2004; Paluska & Schwenk, 2000). Several intervention studies have investigated the effect of aerobic exercise training on depression. Pappas, Golin, and Meyer (1990) conducted a 10-week training study on 32 women with symptoms of depression who enrolled in aerobic-dancing or racquetball classes. Another 19 depressed women served as nonexercising controls. The authors found that after 10-weeks of training, decline in depressive symptoms was significantly greater in the two exercise groups than the control group. Stein and Motta (1992) studied 89 undergraduates who engaged in aerobic exercise of swimming or nonaerobic exercise of weight training, and compared them to a non-exercise control group. The exercise training program was two sessions per week for seven weeks and about 90 minutes per session. The results indicated that the aerobic training group significantly reduced self-reported depression as compared to the controls.

Blumenthal et al. (1999) examined the effects of aerobic exercise training on older patients (age $\geq 50$ yr) with major depressive disorder. One hundred fifty-six participants were randomized to 1 of 3 treatment groups (i.e., aerobic exercise, antidepressant medication, combined exercise and medication). Depressive symptoms were evaluated using Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, Hamilton Rating Scale for Depression and Beck Depression Inventory. The training program was three times per week at 70 – 85% maximal heart rate. After 16 weeks of treatment, all treatment groups had statistically and clinically significant
reductions in depressive symptoms and there was no significant group difference. The authors concluded that aerobic exercise training is equally effective in reducing depression as antidepressants and may be an alternative for treatment of depression in older adults. Depressive symptoms of these participants were assessed again 6 months after the treatment conclusion (Babyak et al., 2000). These results showed that participants in the exercise group had significantly lower rates of depression (30%) than participants in the medication (52%) and combined groups (55%) ($p = .028$). In addition, the relapse rates were significantly lower in the exercise group (8%) than in the medication (38%) and combined groups (31%) ($p = .01$). The authors concluded that a modest exercise program (e.g., three times per week with 30 minutes at 70% of maximum heart rate reserve) is an effective, robust treatment for older patients with major depression. Also, exercise benefits are likely to endure among patients who adopt exercise as a regular, ongoing life activity.

Similarly, in Dunn et al.’s review (2001), the authors found that eight of the 18 exercise training studies indicated a 50% reduction in depressive symptoms. In addition, in the seven studies that also included a follow-up, the reduction of depressive symptoms was maintained for 3-21 months. The authors concluded that aerobic exercise training consistently demonstrates a reduction in symptoms of depression.

Exercise training of a short period can also be beneficial. Dimeo, Bauer, Varahram, Proest, and Halter (2001) evaluated the effects of a short-term aerobic training program on patients with moderate to severe major depression. These patients were trained by walking on a treadmill for 30 minutes per day for 10 consecutive days with breaks on
Sundays. The results showed that the training program significantly reduced the depression scores, measured by Hamilton Rating Scale for Depression. The authors concluded that aerobic exercise can produce substantial improvements in depressive symptoms in a short training period.

The benefit of exercise training on depression was also shown in older populations. Mather and her colleagues (2002) examined the effectiveness of exercise as an adjunct to antidepressant therapy in reducing depressive symptoms. Patients aged 53-78 years were randomly assigned to either exercise classes or health education talks for 10 weeks. Results showed that at 10 weeks, significantly more patients in the exercise group (55% vs. 33%) experienced a greater than 30% reduction in depression based on their scores on the Hamilton Rating Scale for Depression. The authors suggested that older adults with poorly responsive depressive disorder should be encouraged to participate in exercise activities. Motl et al. (2005) examined the effects of two physical activity modes on depressive symptoms among older adults. Participants were randomly assigned to 6-month walking group or low-intensity resistance/flexibility training group. Depressive symptoms were assessed before and after the 6-month intervention, and 12 and 60 months after intervention initiation. Results showed that depressive symptoms were decreased after the intervention and remained decreased for 12 and 60 months. The changes in depressive symptoms were not different between the physical activity modes.

Another randomized control trial (Antunes, Stella, Santos, Bueno, and de Mello, 2005) tested the effectiveness of an endurance exercise program on depression, anxiety, and quality of life in 46 sedentary seniors (60-75 years). Participants were randomized to
aerobic exercise group (ergometer cycle sessions 3 times/week at a heart rate corresponding to ventilatory threshold intensity) or non-exercise control group. After six months of training, the authors found a significant decrease in depression and anxiety scores and an improvement in the quality of life in the exercise group, but not in the control group. Results from these exercise intervention studies support the effectiveness of exercise training for alleviating depressive symptoms among sedentary older adults.

Dunn, Trivedi, Kampert, Clark, and Chambliss (2005) examined the dose-response relationship between exercise and reduction in depressive symptoms. In this study, participants with mild to moderate major depressive disorder were randomly assigned to one of four aerobic exercise groups that varied total energy expenditure (7.0 kcal/kg/week, low dose [LD] or 17.5 kcal/kg/week, public health dose [PHD]) and frequency (3 days/week or 5 days/week) or to exercise placebo control (3 days/week flexibility exercise). After 12 weeks of training, the mean scores on the Hamilton Rating Scale for Depression (HRSD) were reduced 47% from baseline for PHD, compared with 30% for LD and 29% for control. Exercise frequency, however, did not affect the changes in HRSD scores at 12 weeks. These results indicated that aerobic exercise at a dose consistent with public health recommendations (i.e., 17.5 kcal/kg/week) is an effective treatment for mild to moderate major depressive disorder, and that exercise frequency does not moderate the beneficial effect of exercise on depression.

More recently, Blumenthal et al. (2007) compared the effect of aerobic exercise training performed either at home or in a supervised group setting to standard antidepressant medication and placebo control. A total of 202 adults diagnosed with
major depression were randomly assigned to one of four conditions: supervised group exercise, home-based exercise, antidepressant medication (sertraline), or placebo pill. After 16 weeks of treatment, all groups had decreased HRSD scores, and scores for the active treatment groups (i.e., exercise groups and medication group) were not significantly different from the placebo group. The authors concluded that the effect of exercise (either supervised or home-based) in patients seems comparable with antidepressant medication. Also, the high placebo response rates suggest that a considerable portion of the therapeutic response may be determined by patient expectations, ongoing symptom monitoring, attention, and other nonspecific factors.

Another recent study by Craft, Freund, Culpepper, and Perna (2007) compared two exercise programs on improvements in physical activity, depressive symptoms, body composition, and fitness. Thirty-two sedentary women with a diagnosis of depression were randomized to either clinic-based or home-based exercise program for three months. The results showed that both exercise programs were associated with reductions in depressive symptoms and increased physical activity participation. Neither exercise program impacted body composition or fitness. The authors concluded that both clinic-based and home-based exercise program can benefit women with depressive symptoms.

Summary

Researchers have been interested in the association between exercise and depression for decades. Both cross-sectional and prospective studies have consistently showed an association between physical activity and reduced symptoms of depression.
This relationship was reported in both healthy and clinical populations. Exercise intervention studies have consistently indicated that exercise training is effective in reducing depressive symptoms. Both supervised and home-based exercise programs can benefit individuals with depression. Based on one study, aerobic exercise at a dose of 17.5 kcal/kg/week is recommended to obtain the beneficial effects of exercise training on depression.

Characteristics of Exercise

Aerobic versus Resistance Training

Only a few studies have investigated the effect of resistance training on depression. In Stein and Motta’s study (1992), the effects of aerobic and resistance training on depression were investigated. This study found that both aerobic and resistance training were equally effective in reducing the symptoms of depression as compared to the controls. Another study by Singh et al. (1997) examined the effect of progressive resistance training in depressed elders. The results showed that resistance training was effective in reducing depressive symptoms. The authors concluded that resistance training is an effective antidepressant in depressed elders. A more recent study by Timonen, Rantanen, Timonen, and Sulkava (2002) examined the effects of a group-based strength training program on the mood state of frail older women. After 10 weeks of training, participants had significantly reduced depressive symptoms and this reduction was still apparent three months after the intervention ceased.

Several review articles and meta-analyses have includes information on the antidepressant effect of resistance training (Craft & Landers, 1998; Dunn et al., 2001;
North et al., 1990; Paluska & Schwenk, 2000). The authors of these articles concluded that resistance training is an effective antidepressant and that resistance training is as effective in reducing depression as aerobic exercise.

*Exercise Intensity and Treatment Response*

There are only four studies that have compared the effects of different exercise intensities on depression, and the results from these studies were equivocal. Sexton and his colleagues (1989) compared the psychological benefits of walking versus jogging in 52 symptomatic neurotics. Participants in both groups exercised 30 minutes 3-4 times per week for 8 weeks. Psychological variables (i.e., anxiety, depression, and global symptoms) were measured at study entry, at completion, and again at 6-month follow-up. Results showed that at 8 weeks, both groups showed marked reductions in anxiety, depression, and global symptoms. Joggers had significantly greater aerobic gains than walkers. There was no significant difference in psychological benefit between joggers and walkers. At 6-month follow-up, both walkers and joggers had significant increases in their aerobic capacity. Walkers increased their exercise frequency from baseline, while the joggers did not. The psychological benefits were similar for both groups at follow-up. There were limitations in this study. First, the exercise training was not supervised and no exercise log was kept. Participants might not have completed the exercise they were prescribed. Second, the total energy expenditure was not controlled. When exercising at the same duration and frequency, joggers expend more calories than the walkers. However, walkers had increased exercise frequency from baseline at follow-up, while joggers did not change their exercise frequency. With more frequent exercise sessions, walkers might
have the same total energy expenditure as the joggers. Since there is a dose-response relation between the amounts of aerobic exercise (energy expenditure) and the reduction of depressive symptoms (Dunn et al., 2005), without controlling for total energy expenditure it is difficult to differentiate the effects of exercise intensity from that of energy expenditure.

King, Taylor, and Haskell (1993) also found no difference in treatment effect between high- (73-88% peak heart rate) and low-intensity (60-73% peak heart rate) exercise on depressive symptoms. The authors randomly assigned 357 non-depressed adults aged 50-65 years to one of four conditions: assessment-only control, higher intensity group exercise, higher intensity home exercise, or lower intensity home exercise for 12 months. Results showed no significant reduction in BDI scores in all four conditions and no significant differences in BDI scores among the four conditions. These results suggested that exercise training was not effective in reducing depressive symptoms. Also, high- and low-intensity exercise had similar effect on depressive symptoms. The finding of no change in BDI scores might be due to a floor effect since most participants (92%) in this study scored less than 12 (minimal depressive symptoms) on BDI. It was unknown whether high- and low-intensity exercise would affect depressive symptoms differently in depressed population.

In Swoap, Norvell, Graves, and Pollock’s study (1994), 49 sedentary older men and women were randomly assigned to high intensity aerobic exercise (80-85% heart rate reserve), moderate intensity aerobic exercise (65-70% heart rate reserve), or no-exercise control group. After 26 weeks of treatment, all three groups had significant reductions in
depressive symptoms and there was no significant group difference. Similar to King et al.’s study (1993), this study might suffer from a floor effect since all participants had low depression scores at study entry. It is hard to make psychologically normal individuals “more normal.” Therefore, findings in this study may not reflect the actual effects of exercise intensity in a depressed population.

In 2000, Lampinen, Heikkinen, & Ruoppila examined the predictive value of physical exercise in relation to depressive symptoms among older adults (aged 65+) during an 8-year follow-up. The current intensity of physical exercise and depressive symptoms were assessed during interviews at baseline and follow-up. Results showed that those who reported reduced intensity of physical exercise during the eight-year follow-up period had more depressive symptoms than those who remained active or increased their intensity of physical exercise. The authors concluded that decrease in the intensity of physical exercise increases the risk of depressive symptoms among older adults. Since this is a prospective study, we can’t tell whether the lower intensity of exercise caused the increase of depressive symptoms, or vice versa. It may be that those who reported more depressive symptoms became less active due to their advanced symptoms. Therefore, it is still unclear whether high- and low-intensity exercises affect depressive symptoms differently.

The sparseness of randomized control trials and the methodological limitations in these studies have made it difficult to draw any adequate conclusions about the effect of exercise intensity on depression. These equivocal findings led to the present research
study, in which different exercise intensities (high vs. low) were compared and total energy expenditure was controlled.

Summary

Results from exercise intervention studies indicated that both aerobic exercise and resistance training are effective in alleviating symptoms of depression and that exercise is as effective as antidepressant medication and psychotherapy. While there is a dose-response relationship between the amounts of aerobic exercise and the reduction of depressive symptoms, the effect of exercise intensity on depression requires further investigation.

Mechanisms for the Antidepressant Effects of Exercise

A variety of physiological and psychological mechanisms have been hypothesized to mediate the antidepressant effects of exercise. Yet, research to date has not extensively examined these mechanisms (Craft, 2005). A better understanding of these mechanisms is essential for us to gain insight into the possible causal relationship between exercise and depression. Findings from mechanism studies will also help us develop effective training programs for depressed individuals. Hence, more randomized control trials are needed to examine the possible underlying physiological and psychological mechanisms of the effects of exercise (Dunn et al., 2001). One of the frequently proposed psychological mechanisms that is based on existing theories of depression is the self-efficacy hypothesis, which warrants further examination in respect to exercise.
Self-efficacy Hypothesis

Self-efficacy is the degree to which an individual believes he or she can successfully engage in a specific behavior in a particular situation with known outcomes (Bandura, 1986). In a review by deVries, Wiswell, Bulbulian, and Moritani (1981), the authors indicated that depressed individuals have low self-efficacy to cope with their depressive symptoms. The low sense of efficacy often leads to negative self-evaluations, negative ruminations, and faulty styles of thinking (Bandura, 1997), which can worsen and prolong the symptoms of depression (Peterson & Seligman, 1984). According to Bandura’s self-efficacy theory, the mastery experience of a difficult skill can help increase a person’s self-confidence, self-efficacy, and ability to cope with personal problems. Thus, it is speculated that for depressed individuals, engaging in regular exercise, which is usually perceived as a difficult task, is likely to result in increased self-efficacy and enhanced ability to cope with the symptoms of depression.

Research examining the relationship between exercise and self-efficacy in the depressed population is scarce and findings have been equivocal. Bodin and Martinsen (2004) tested the changes in mood and self-efficacy during an acute exercise. Twelve clinically depressed participants completed two 45 minutes exercise sessions consisting of stationary bike exercise and martial arts. Stationary bike exercise represents a familiar, continuous skill activity with initial high self-efficacy. Martial arts, on the other hand, is a new serial skill activity with low initial self-efficacy. The authors hypothesized that participants would have high and stable self-efficacy during the stationary bike session and initially low but increasing self-efficacy during martial arts session. A 30-min waiting
control condition was conducted before each exercise session. Participants’ mood and self-efficacy were measured at multiple time points during the exercise sessions. Results showed that during martial arts, participants had significant increases in positive affect, reductions in negative affect and state anxiety, and increases in self-efficacy. On the contrary, no significant changes were found during the stationary bike exercise. The authors concluded that an increase in self-efficacy may be important for mood benefits to occur during exercise. Although findings from this study suggest that self-efficacy may mediate the effect of acute exercise on mood, it is unknown whether self-efficacy mediates the effect of exercise training on depression.

Craft (2005) examined the relationship between exercise and depression coping self-efficacy in clinically depressed individuals. Nineteen women with clinical depression self-selected to either a control or an aerobic exercise group. Results showed that after 9 weeks of treatment, the exercise group had lower depression scores than the control group, and the depression coping self-efficacy was higher in the exercise group than in the control group. There was a significant negative relationship between depression coping self-efficacy and depression ($r = -.77, p < .05$). The author concluded that aerobic exercise was effective in reducing symptoms of depression and that depression coping self-efficacy was a potential mechanism mediating the antidepressant effect of exercise. Although this study provides evidence that supports self-efficacy as a plausible mechanism, it has several methodological weaknesses, including self-selected group assignment and small sample size.
A randomized controlled trial by Singh et al. (2005) examined the dose-response relationship between weight training and depression in older adults with clinical depression. This study also tested whether self-efficacy predicted the antidepressant response. Sixty participants (> 60 years) with major or minor depression were randomized to supervised high intensity progressive resistance training (PRT) (80% maximum load), low intensity PRT (20% maximum load), or general practitioner (GP) care for 8 weeks. Self-efficacy was measured using the Self-Efficacy Scale of Sherer at baseline and 8 weeks. Results showed that after 8 weeks of training, significantly more participants in the high intensity group (61%) achieved a 50% reduction in the HRSD scores as compared to 29% in the low intensity group and 21% in the GP care group. All three groups had significant improvements in self-efficacy, but there was no group difference. The authors found that change in self-efficacy did not predict antidepressant response. At present, this is the only randomized control trial that examined the relationship between exercise training and self-efficacy in depressed populations and its finding was different from the previous two studies. This suggests that more randomized control trials involving exercise training and measurements of self-efficacy are needed in depressed population to elucidate the mediation effect of self-efficacy.

Conclusions

Depression is a common mental disorder in the United States and in the developed world. While there are effective pharmacological and psychotherapeutic treatments for depression, only about half of adults suffering from depression seek treatment. Research has shown that engaging in regular exercise can alleviate symptoms of depression.
Exercise may be an effective and acceptable adjunct or alternative treatment for depressed population. Cross-sectional and prospective studies have consistently shown an inverse relationship between physical activity and symptoms of depression. Intervention studies also indicated that exercise can reduce depressive symptoms and is as effective as antidepressant medication and psychotherapy. From the literature review, we know that both aerobic and resistance training are effective exercise modes for reducing depressive symptoms. In addition, individuals with depression can benefit from both supervised and home-based exercise programs. Research has shown a dose-response relation between the amounts of exercise and the reduction of depressive symptoms, suggesting that individuals will experience more improvements in depressive symptoms with higher energy expenditure from exercise. Based on one study, aerobic exercise at a dose of 17.5 kcal/kg/week is recommended to obtain the beneficial effects of exercise training on depression. Exercise frequency, on the other hand, has not been shown to moderate the effect of exercise on depression. Individuals can decrease their depressive symptoms by exercising three times per week or five times per week as long as they reach the recommended amount of exercise (i.e., 17.5 kcal/kg/week). Research on the effect of exercise intensity on depression had mixed results. It is still unclear whether a certain exercise intensity is required to obtain the antidepressant effects of exercise. More research is needed to clarify whether exercise intensity plays a role in the beneficial effects of exercise on depression.

A number of biological and psychological mechanisms have been proposed to mediate the antidepressant effects of exercise. Among these mechanisms, increased
self-efficacy after exercise training appears to be a plausible mechanism. However, very few studies have examined the relationship between exercise and self-efficacy in depressed population and the findings were equivocal. More randomized control trials involving exercise training and measurements of self-efficacy are needed in depressed population to elucidate the mediation effect of self-efficacy.
CHAPTER 3

METHODS

The purpose of this study was to test hypotheses related to the effect of different exercise training intensities after 10-weeks of aerobic training on depressive symptoms in initially sedentary depressed women. The following sections will describe the subject characteristics and recruitment processes, the study design, measures, intervention protocol, and data analysis.

Participants

All participants were volunteers recruited from the university and surrounding community through area physician referrals, posted flyers, and word of mouth. Participants were also recruited from academic classes upon instructor’s approval. To enroll in this study, participating had to be women 18 to 45 years old. Since women are twice as likely as men to suffer from depression (Buckworth & Dishman, 2002; Preskorn, 1999; Riolo, Nguyen, Greden, and King, 2005), in the current study we focused on examining the antidepressant effect of exercise in women. The sample was limited to volunteers 18-45 years old for two reasons. Firstly, the scientific literature suggests that the first episode of Major Depressive Disorder (MDD) usually happens when individuals...
are 19 to 44 years of age (Kessler et al., 2005). Secondly, individuals in their 20s to 40s have the highest visit rates to psychiatrists, and the reason for their visits is mainly for anxiety or mood disorders (Wang et al., 2005). Thus, this age criterion was set to ensure the selection of a sample from the population most affected by depressive symptoms.

Participants were required to have mild to moderate depressive symptoms (a score of 14 to 28 on Beck Depression Inventory-II [BDI-II]). If a volunteer’s score indicated she had severe depressive symptoms (a score above 28 on BDI-II), she could participate with written permission from a physician or other health care professional. The scientific literature suggests that exercise can decrease symptoms of depression (Craft & Perna, 2004; Paluska & Schwenk, 2000). However, most studies that examined the effect of exercise on depression have investigated either healthy individuals or individuals with mild to moderate depression (Dunn, Trivedi, & O’Neal, 2001). It is unclear whether exercise is also an effective treatment for severe depression. Therefore, for ethical reason, individuals with severe depression were excluded from this study unless they have written permission to take part in this study from their physician or other health care professional.

Eligible participants had to have had a regular menstrual cycle during the previous 6 months (not menopausal or perimenopausal) because perimenopausal women were shown to have increased depressive symptoms as compared to premenopausal women (Bromberger et al., 2001; Bromberger et al., 2003). A longitudinal study also reported greater risk for episodes of clinical depression around menopause (Schmidt, Haq, & Rubinow, 2004). Thus, to prevent the influence of menopause from confounding the study results, only women with regular menstrual cycle were enrolled in this study.
Participants also had to have a body mass index (BMI) between 18.5 and 35. There are two reasons for setting the criterion for BMI. First of all, the current study involved 10-weeks of exercise training. Individuals who are underweight (BMI < 18.5) or obese (BMI >= 35) may have had physical limitations to participating in the training program, especially in the high intensity exercise group. Secondly, underweight or obesity may be indicative of some underlying medical problems, such as anorexia nervosa, heart disease, or diabetes. These medical problems may affect depressive symptoms. For instance, individuals with heart disease have been shown to have four times higher prevalence rate of depression than individuals without heart disease (Forrester, Lipsey, Teitelbaum, DePaulo, & Andrzejewski, 1992). In addition, individuals suffering depressive symptoms as a result of a medical condition may be inherently different from those who suffer from clinical depression (Craft & Landers, 1998). Therefore, individuals who were underweight or obese, according to their BMI values, were excluded from the current study.

To participate in the study, women also had to be sedentary (exercising less than three times per week for less than 20 minutes per session, assessed by interviewing the participants using Godin Leisure-Time Exercise Questionnaire) and report an energy expenditure from exercise less than 500 kcal per week (estimated using the information from the Godin Leisure-Time Exercise Questionnaire). Participants also could not take medication for depression or have psychotherapy or other therapies for treating depression since these therapies would have confounded the effect of exercise on depressive symptoms. However, if participants had been taking medication for depression
for more than three weeks, they could enroll in this study because the effect of medication on depressive symptoms had stabilized. To make sure that participants could safely engage in the 10-weeks exercise program, they could not have been pregnant or nursing at study entry, had no plan for pregnancy during the following 6 months, and had no physical contraindications to exercise (e.g., orthopedic problems, heart disease, assessed through the Physical Activity Readiness Questionnaire [PAR-Q], a standard screening form used in exercise setting [Franklin et al., 2000]).

Participants were instructed to maintain normal contact with their physician and report to the primary investigator any change in antidepressant medication or medication dosage during the course of the study.

The sample size needed for this study was calculated in consultation with the OSU Statistics Department, and was based on the results of previous meta-analyses on exercise and depression in clinical populations (Craft & Landers, 1998; Lawlor & Hopker, 2001). The calculated total sample size to detect a significant difference between intensity groups on changes in BDI-II scores was 42 (i.e., 14 participants in each group) with an alpha level of 0.05, a power of 0.8, and an effect size of 0.5. The sample size was calculated using a computer software – GPOWER (Erdfelder, Faul, & Buchner, 1996). The formula used to calculate sample size is as follows:

\[ n = \Phi^2 \left(1 - \omega^2 / \omega^2\right) \]

n is the number of participants in each group; \( \Phi^2 \) is the noncentrality parameter, estimated from the power functions chart; \( \omega^2 \) is the effect size (Keppel & Wickens, 2004). Based on previous exercise training studies with depressed participants, attrition was expected to be
approximately 30%. Therefore, the recruitment goal was 54 participants (i.e., 18 participants in each group).

Research Design

The research design is an experimental design. The participants were randomly assigned to one of two aerobic exercise groups (i.e., high intensity exercise or low intensity exercise), or to a stretching exercise control group. All participants met with the investigator once a week for a supervised exercise session. Participants in the two aerobic exercise groups were also instructed to do three to four exercise sessions on their own during the rest of the week. The weekly energy expenditure was controlled at 1000 kcal/week for both the high and low intensity exercise groups. All participants were asked to keep an activity diary. The investigator reviewed the diary weekly to monitor participants’ exercise intensity and weekly energy expenditure. The total period for the exercise training program was 10 weeks.

The independent variable was exercise intensity, and the dependent variables were depressive symptoms and self-efficacy (Exercise Self-efficacy and Depression Coping Self-efficacy). Other neutral variables included maximal oxygen consumption (VO₂ max), level of physical activity, energy expenditure, and rating of perceived exertion (RPE). Depressive symptoms and self-efficacy were measured and compared at study entry (pre-test), week 5 (mid point), and week 10 (post-test). A two-way ANOVA mixed design with one between-subject factor (exercise intensity: high, low, stretching control) and one within-subject factor (time: pre-test, mid point, post-test) was employed (see Table 3.1).
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Table 3.1
Two-way ANOVA Mixed Design
Measures

Exercise Intensity

Exercise intensity was controlled using exercise workload (e.g., speed and grade of the treadmill, watts of the stationary bicycle). The level of exercise workload is determined by the rate of oxygen consumed during exercise. The higher the rate of oxygen uptake (VO2) during exercise, the higher the workload (i.e., higher exercise intensity). At study entry, all participants performed a maximal exercise test to determine their maximal oxygen uptake (VO2max). The VO2max was used to calculate the target VO2 (workload) using the VO2 reserve (VO2R) method. The VO2R method is suggested by ACSM as an approach to determining exercise intensity for exercise prescription (Franklin et al., 2000). The following equation was used to calculate the target VO2 based on VO2R (Franklin et al., 2000):

\[
\text{Target VO2} = ([\text{VO2max} - \text{VO2rest}] \times \% ) + \text{VO2rest}
\]

(VO2rest: resting oxygen uptake)

Participants in the high intensity exercise group exercised at 65% to 75% of VO2R, and participants in the low intensity exercise group exercised at 40% to 55% of VO2R.

After determining the target VO2 for the participants, the following equations (Franklin et al., 2000) were used to calculate the speed and grade of the treadmill necessary for the participants to achieve their target VO2 (i.e., exercise intensity) during supervised exercise sessions:

Walking: \( \text{VO2} = (0.1 \times \text{Speed}) + (1.8 \times \text{Speed} \times \text{Grade}) + 3.5 \)

Treadmill Running: \( \text{VO2} = (0.2 \times \text{Speed}) + (0.9 \times \text{Speed} \times \text{Grade}) + 3.5 \)
An exercise prescription was provided to the participant based on her preferred type of exercise (e.g., jogging, walking, aerobic dance, or bicycling) and her assigned exercise intensity to use during unsupervised exercise sessions. The Compendium of Physical Activities (Ainsworth et al., 2000) was referenced for exercise prescription to determine the intensity of each type of exercise. The Compendium of Physical Activities uses the metabolic equivalents (METs) for the intensity of physical activity. One MET equals an oxygen consumption (VO₂) of 3.5 ml/kg/min. If a participant’s target training VO₂ was 21 ml/kg/min, she could choose to do physical activities with a MET level of 6 (21/3.5 = 6) in the compendium.

**Depressive Symptoms**

Depressive symptoms were measured using Beck Depression Inventory-II (BDI-II). The BDI-II is a self-report inventory with 21 items assessing the behavioral and cognitive symptoms of depression (Beck, Steer, & Brown, 1996). Each item consists of four statements numbered from “0” to “3,” with higher number indicating more severe depressive symptoms. Participants were asked to circle the statement that best describes their symptoms in each item. The circled number from each item was summed to obtain a total score. The total score can range from 0 to 63. According to Beck et al. (1996), scores of 0-13 indicate minimal depression, 14-19 indicate mild depression, 20-28 indicate moderate depression, and 29-63 indicate severe depression. This inventory has demonstrated acceptable internal consistency with Cronbach’s alphas ranging from .92 to .93 (Beck et al., 1996). In addition, psychometric analyses for both normal and
psychiatric populations have consistently indicated that the BDI is a reliable and valid measure of self-reported depression (Steer & Beck, 1996).

**Exercise Self-efficacy**

Exercise Self-efficacy questionnaire (Garcia & King, 1991) was used to measure exercise self-efficacy. In this self-report questionnaire, participants were asked to rate their confidence from 0% (I cannot do it at all) to 100% (certain that I can do it) in their ability to exercise under 15 different conditions over the next three months. The ratings for all items were summed and then divided by 15 to obtain a mean score. The higher the mean score the higher one’s exercise self-efficacy, and vice versa. This scale has demonstrated acceptable internal consistency with Cronbach’s alpha ranging from .90 to .94 (Wilcox, Sharpe, Hutto, & Granner, 2005). Psychometric analyses in a diverse sample of men and women indicated that the ESE questionnaire is a valid and reliable measure for use with diverse populations (Wilcox et al., 2005).

**Depression Coping Self-Efficacy**

Depression Coping Self-efficacy was measured by the Depression Coping Self-Efficacy Scale (DCSES). The DCSES is a self-report scale with 24 items designed to assess the coping self-efficacy of depressed patients (Perraud, 2000). Each item describes a coping response and participants were asked to rate their confidence from 0% (not at all confident) to 100% (confident) in their ability to engage in each coping response. The ratings for all items were summed and then divided by 24 to obtain a mean score. The higher the mean score the higher one’s depression coping self-efficacy, and vice versa. This scale has a test-retest reliability of .84 and has demonstrated acceptable internal
consistency reliability with a Cronbach’s alpha of .93 (Perraud, 2000). The BDI was chosen as a test of concurrent validity of the DCSES, and the validity analysis showed a significant inverse correlation between DCSES and the BDI ($r = - .73$, $p < .001$).

Maximal Oxygen Uptake

Maximal oxygen uptake (VO$_2$ max) is determined during a maximal exercise test. The participant was instructed to wear a heart rate monitor and a mouth piece which was connected to a Cardio O$_2$ Metabolic Cart used to calculate oxygen consumption. The Balke treadmill protocol (Pollock et al., 1982) was used to estimate VO$_2$ max. The treadmill was started at a speed of 3.0 mph and 0% grade and the participant would begin to walk on the treadmill. The speed stayed the same at 3.0 mph throughout the test. The inclination of the treadmill was increased by 2.5% after the first 3 minutes and every 3 minutes thereafter. Heart rate and blood pressure were measured prior to the test, during each stage of the exercise testing protocol (i.e., every 3 minutes), at the termination of the test, and at 2-minute intervals during the recovery period. The rating of perceived exertion (RPE) was recorded during each stage of the exercise testing protocol. The participant was instructed to perform to the best of her ability. The test was terminated when the participant reached volitional fatigue and signaled the investigator by placing both hands on the rails of the treadmill. The 5-minute recovery period then began with the participant walking at 2 mph and at 0% grade and continued until heart rate and blood pressure stabilized. The VO$_2$max was determined when the participant has reached volitional fatigue.
**Level of Physical Activity**

Level of physical activity was measured using Godin Leisure-Time Exercise Questionnaire (Godin & Shephard, 1985). This self-administered four-item questionnaire measures weekly frequencies of strenuous (e.g., running, vigorous bicycling, soccer, basketball), moderate (e.g., fast walking, easy bicycling, baseball, folk dancing), and light (e.g., easy walking, yoga, bowling, golf) physical activities. A total leisure activity score was calculated by the following formula: Weekly leisure activity = (9 x Strenuous) + (5 x Moderate) + (3 x Light). For example, if a participant does one strenuous, three moderate, and five light activities per week, the total leisure activity score for this participant will be: (9 x 1) + (5 x 3) + (3 x 5) = 39. The test-retest reliability of the Godin Leisure-Time Exercise Questionnaire ranges from .62 to .74 (p < .05). The validity coefficients between total Godin score and other activity measures range from .45 to .61 (p < .05). Participants were asked to fill out this questionnaire at study entry and at the end of the training program. At study entry, after the participant filled out this questionnaire, the investigator asked what type of strenuous, moderate, and light physical activities she did, if any, and the duration of each activity. If the combined weekly frequency of strenuous and moderate physical activities was less than three times per week, the participant was considered sedentary and could be enrolled in this study. If the participant exercised three or more than three times per week in the strenuous and moderate physical activity categories, but each time the exercise lasted for less than 20 minutes, the participant was still considered sedentary and could be enrolled in this study.
Rating of Perceived Exertion

Rating of perceived exertion (RPE) was measured using Borg’s RPE scale (Borg, 1982). This scale rates exercise intensity on a scale of 6 (very, very light) to 20 (very, very hard). The validity coefficients between RPE on the Borg RPE scale and physiological criterion variables range from .80-.90 (Borg, 1982). Participants were asked to select the number that best describes the exercise intensity they felt they were working at during supervised exercise sessions. Also, participants were instructed to record their RPE during unsupervised exercise sessions to self-monitor their exercise intensity. The high intensity exercise group was instructed to exercise at an RPE range of 14-16, while the low intensity exercise group was instructed to exercise at an RPE range of 11-13. The control group learned to use RPE during the maximal exercise test, but did not monitor RPE during exercise sessions.

Energy Expenditure

Weekly energy expenditure was calculated from the recorded exercise intensity, duration, and frequency. According to the ACSM’s guidelines for exercise testing and prescription (2000), the following formula was used to approximate the caloric cost of exercise:

\[
\text{[Net oxygen consumption (VO}_2\text{) in ml/kg/min x body weight in kg]/200 = kcal/min}
\]

If a participant is walking on a treadmill, her VO\textsubscript{2} can be calculated from the walking speed and percent elevation of the treadmill [i.e., \(\text{VO}_2 = (0.1 \times \text{Speed in m/min}) + (1.8 \times \text{Speed x percent elevation}) + 3.5\)]. The net VO\textsubscript{2} can then be calculated by subtracting 3.5 from the calculated walking VO\textsubscript{2}. We can then obtain this participant’s minute energy...
expenditure by putting the net VO$_2$ and this participant’s body weight into the aforementioned formula. If we know the total minutes this participant exercised during a week (assume that this participant always exercised at the same intensity), we will know how many kilocalories she expended exercising during a week. The treadmill speed and inclination were recorded by the investigator during the supervised exercise sessions for energy expenditure calculation. During unsupervised sessions, participants were asked to record the speed and inclination of the treadmill on an exercise log. If the participants did not exercise on a treadmill during unsupervised sessions, a metabolic equivalent (MET) level was assigned to the activity (e.g., walking, jogging) according to the compendium of physical activities by Ainsworth et al. (2000). The energy expenditure formula based on the MET level of the activity is as follows: (METs x 3.5 x body weight in kg)/200 = kcal/min. The estimation of participants’ weekly energy expenditure helped the investigator make sure that participants in the two aerobic exercise groups achieved the energy expenditure goal (i.e., 1000 kcal/week).

Procedures

Visit 1

During this visit, the investigator met with the volunteer at PAES Building room A20. Study goals and procedures were explained to the volunteer. The volunteer had the opportunity to ask the investigator questions about the study and her participation and about the information in the Consent form. If the volunteer agreed to participate, she filled out and signed the Consent form. After signing the Consent form, the participant filled out a health information form recording demographic and personal health
information, including age, menstrual cycle pattern, pregnancy status, current medication use, and current health problems. Participant had to be between age 18 to 45, not currently pregnant or nursing, and had no treatment for depression or had been taking medication for more than three weeks to be eligible to enroll in this study. Participant also filled out Godin Leisure-Time Exercise Questionnaire, which assesses level of physical activity, the BDI-II, which assesses depressive symptoms, and the Physical Activity Readiness Questionnaire (PAR-Q), which assesses physical contraindications to exercise. Participant had to have mild to moderate depressive symptoms and a sedentary lifestyle to be eligible to participate in this study. If participant’s responses on the BDI-II showed that she might have a severe form of depression, she would be referred to a mental health professional that day. She would not be eligible to participate in this study unless she had written permission to take part in this study from her physician or other health care professional (e.g., psychologist). If the participant responded to item #9 on the BDI-II with a score of 2 or 3 (2 - I would like to kill myself; 3 - I would kill myself if I had a chance), the participant would be immediately referred to their current therapist or another mental health profession. If the participant answered yes to one or more questions in PAR-Q, which indicates that she might have contraindications to begin exercise, she would be referred to her doctor for medical clearance before she could enroll in this study.

After completing the questionnaires, the participant’s weight and height were measured to calculate her BMI. The participant was asked to remove her shoes and her height was measured using a medical height measuring scale to the nearest quarter inch. Her weight was measured on a medical weighing scale to the nearest half pound. The
units of the participant’s height and weight were then be converted to meter and kilogram, respectively. The BMI was calculated by dividing body weight in kilograms by height in meters squared (kg/m²). Participant’s BMI had to be between 18.5 and 35 to be eligible to participate in this study. If the participant was eligible for the study, the investigator would schedule her second visit for additional tests within the next two weeks. Before the second visit, the investigator randomly assigned the participant to one of the three groups (i.e., high intensity exercise, low intensity exercise, stretching exercise control group). The participant was informed of her group assignment after she completed all the tests during visit 2.

Visit 2

During the second visit, participant first filled out the Exercise Self-Efficacy questionnaire and the Depression Coping Self-Efficacy Scale (DCSES). Next, the procedures of the maximal exercise test were explained to the subject. The participant was instructed to wear a heart rate monitor and a mouth piece that was connected to a Cardio O₂ Metabolic Cart used to calculate oxygen consumption. The Balke treadmill protocol was used to estimate the maximal aerobic capacity (VO₂max). The treadmill was started at a speed of 3.0 mph and 0% grade and the participant would begin to walk on the treadmill. The speed stayed the same at 3.0 mph throughout the test. The inclination of the treadmill was increased by 2.5% after the first 3 minutes and every 3 minutes thereafter. Heart rate and blood pressure were measured prior to the test, during each stage of the exercise testing protocol (i.e., every 3 minutes), at the termination of the test, and at 2-minute intervals during the recovery period. The rating of perceived exertion (RPE) was
recorded during each stage of the exercise testing protocol. The participant was instructed to perform to the best of her ability. The test was terminated when the participant reached volitional fatigue and signaled the investigator by placing both hands on the rails of the treadmill. The 5-minute recovery period then began with the participant walking at 2 mph and at 0% grade and continued until HR and blood pressure stabilized. After the exercise test, the investigator informed the subject of her group assignment and discussed with the participant about her exercise training program. The investigator would answer any questions the participant might have and scheduled a date within the next two weeks to begin the training program.

Visit 3 (week 1)

The 10-weeks exercise training program began at visit 3. For the two aerobic exercise groups (i.e., high and low intensity exercise groups), participants met with the investigator once a week in a group of one to four for a 30 to 40 minutes supervised exercise session. Participants were also instructed to exercise by themselves three to four times during the rest of the week. Participants kept an activity diary recording the date of an exercise session, type, intensity, and duration of the exercise, and RPE during exercise. Participants were instructed to bring their activity diary to each supervised session. The investigator reviewed the diary weekly during the supervised exercise session to make sure that participants met the goal of energy expenditure (i.e., 1000 kcal/week) and exercised at the prescribed intensity.

For the aerobic exercise groups, during Visit 3, the investigator gave the participants an activity record booklet and instructed the participants to keep an activity
diary using the booklet. The investigator showed the participants how to adjust the speed and inclination of a treadmill. The participants were informed of their prescribed exercise workload (i.e., the speed and inclination of the treadmill) at each session. For both high and low intensity exercise groups, the exercise intensity began at 40-55% oxygen uptake reserve (VO₂R). The participants were informed that the energy expenditure goal of each session was 200 kcal. Before the treadmill exercise, the participants were instructed to do a 5-minute gentle stretching. Next, participants walked on the treadmill for a 5-minute warm-up at a speed of 2.5-3.0 mph with 0% grade. After warm-up, the investigator helped the participants adjust the treadmill speed and inclination to their prescribed workload. The investigator calculated the minute energy expenditure based on the prescribed workload to determine how long the participants should exercise on the treadmill to expend 200 kcal. After achieving the energy expenditure goal, the participants began to cool down for 5 minutes by walking at 2.5-3.0 mph with 0% grade. At the conclusion of the exercise session, the participants recorded the type, intensity (i.e., speed and inclination of the treadmill), and duration of exercise, and their RPE during exercise on the activity diary. The investigator then worked with the participants to plan their unsupervised exercise sessions. The investigator considered the participants’ daily schedule and accessibility to exercise facilities to help them find the type of exercise they could do and the time and location to do the exercise. The investigator prescribed an exercise workload (e.g., speed and inclination of the treadmill, watts of the stationary bike) to the participants for their unsupervised exercise sessions. At the end of the supervised exercise session, the investigator confirmed the date for the next supervised session and
reminded the participants to exercise three to four times on their own during the week and keep an activity diary.

The stretching exercise control group also met with the investigator once a week in a group of one to four for a 30-minute stretching session. During the stretching session, the investigator instructed the participants to perform a series of stretching exercise to relax muscles from head to toe, including neck muscles, shoulder girdle, triceps, back muscles, quadriceps, hamstrings, and calf muscles. The participants in the control group were not instructed to exercise on their own during the rest of the week and were advised to maintain their usual physical activity. The investigator gave the participants an activity record booklet and instructed the participants to keep an activity diary using the booklet. The participants were instructed to bring their activity diary to each supervised session so the investigator could monitor their level of physical activity. At the conclusion of the stretching session, the investigator confirmed the date for the next stretching session.

Visit 4 & 5 (week 2 & 3)

For the aerobic exercise groups, at the beginning of each visit, the investigator reviewed the activity diary and calculated weekly energy expenditure to check whether the participants expended 1000 kcal per week. Next, the participants began to exercise with 5-minute stretching, followed by 5-minute warm-up, 30-40 minutes training period (depending on individual minute energy expenditure), and 5-minute cool-down. For both high and low intensity exercise groups, the exercise intensity was set at 40-55% oxygen uptake reserve (VO₂R). All participants exercised to expend about 200 kcal during the supervised session. At the conclusion of the training session, the participants recorded the
type, intensity, and duration of exercise, and RPE during exercise on the activity diary. The investigator checked with the participants on their unsupervised exercise sessions and helped them adjust their exercise plan to fit into their schedule. At the end of the session, the investigator confirmed the date for the next supervised session and reminded the participants to exercise three to four times on their own during the week and keep an activity diary.

For the stretching exercise control group, participants were instructed to do a 30 minutes stretching exercise. At the conclusion of the stretching session, the investigator confirmed the date for the next session and reminded the participants to keep an activity diary.

Visit 6-12 (week 4-10)

For the aerobic exercise groups, at the beginning of each visit, the investigator reviewed the activity diary and calculated weekly energy expenditure to check whether the participants expended 1000 kcal per week. The exercise intensity for the high intensity group was increased to 65-75% oxygen uptake reserve (VO2R) beginning Visit 6. The intensity for the low intensity group remained the same (i.e., 40-55% oxygen uptake reserve (VO2R)). The participants began to exercise with 5-minute stretching, followed by 5-minute warm-up, 30-40 minutes training period (depending on individual minute energy expenditure), and 5-minute cool-down. All participants exercised to expend about 200 kcal during the supervised session. At the conclusion of the training session, the participants recorded the type, intensity, and duration of exercise, and RPE during exercise on the activity diary. The investigator checked with the participants on their
unsupervised exercise sessions and helped them adjust their exercise plan to fit into their schedule. At the end of the session, the investigator confirmed the date for the next supervised session and reminded the participants to exercise three to four times on their own during the week and keep an activity diary.

For the stretching exercise control group, participants were instructed to do a 30 minutes stretching exercise. At the conclusion of the stretching session, the investigator confirmed the date for the next session and reminded the participants to keep an activity diary.

Visit 7 (week 5)

During visit 7, the investigator performed a mid-point measurement. All participants were instructed to come to the supervised session 30 minutes earlier to fill out the questionnaires, including the BDI-II, exercise self-efficacy questionnaire, and DCSES. If the participants responded to item #9 on the BDI-II with a score of 2 or 3 (2 - I would like to kill myself; 3 - I would kill my self if I had a chance), the participant would be immediately referred to her current therapist or another mental health profession. After completing the questionnaires, the participants would begin their usual training session.

Visit 12 (week 10)

Visit 12 was the last supervised training session of the 10-weeks exercise training program. At the end of this session, the investigator scheduled an appointment with the participants within the next week for post-test questionnaires and maximal exercise testing. The investigator reminded the participants to bring their activity diary to the scheduled appointment.
Visit 13 (week 11 post-test)

During Visit 13, the investigator collected the activity diary from the participant. The participant was instructed to fill out several questionnaires, including BDI-II, exercise self-efficacy questionnaire, DCSES, and Godin Leitute-Time Exercise Questionnaire. If the participant responded to item #9 on the BDI-II with a score of 2 or 3 (2 - I would like to kill myself; 3 - I would kill my self if I had a chance), the participant would be immediately referred to her current therapist or another mental health profession. After completing the questionnaires, the participant performed a maximal exercise test. At the conclusion of the exercise test, the investigator congratulated the participant for successfully completing the training program. The investigator provided a personalized exercise prescription to the participant and encouraged the participant to continue to exercise regularly. Participants in the stretching exercise control group were given a chance to participate in an aerobic exercise training program provided by the investigator after the conclusion of the study.

Data Analyses

Descriptive statistics was performed for baseline characteristics of the participants. Three separate repeated measures ANOVAs were performed to examine the effect of the intervention on depressive symptoms, exercise self-efficacy, and depression coping self-efficacy (Hypotheses 1-4). Simple main effect was tested to check whether these variables changed over time within each group. A planned comparison was performed to compare BDI-II change scores between high and low intensity groups. The change scores were computed by subtracting the baseline score from the score at 10 weeks.
For the fifth and sixth hypotheses, two Pearson Correlation were calculated to examine 1) the relationship between ESE change score and BDI-II change score and 2) the relationship between DCSE change score and BDI-II change score. The change scores were computed by subtracting the baseline score from the score at 10 weeks.

For the seventh and eighth hypotheses, two mediation analyses were performed to test 1) the mediation effect of ESE and 2) the mediation effect of DCSE. To test for mediation, three regression equations were examined: first, ESE (or DCSE) change score was regressed on group assignment; second, BDI-II change score was regressed on group assignment; and third, BDI-II change score was regressed on group assignment and ESE (or DCSE) change score. To establish mediation, group assignment must affect ESE (or DCSE) change score in the first equation; group assignment must affect BDI-II change score in the second equation; and ESE (or DCSE) change score must affect BDI-II change score in the third equation (Baron & Kenny, 1986). If all these conditions hold, another criterion must be met. For mediation to be found, the effect of group assignment on BDI-II change score must be less in the third equation than in the second equation (Baron & Kenny, 1986).

The significance level ($\alpha$ level) was set at .05. The effect size ($\eta^2$) was calculated for each repeated measures ANOVA. An $\eta^2 = .01$ indicates a small effect size; an $\eta^2 = .06$ indicates a medium effect size; and an $\eta^2 = .15$ indicates a large effect size (Keppel & Wickens, 2004). All data analyses were performed with the Statistical Package for the Social Sciences (SPSS) (version 14.0, 2004).
CHAPTER 4

RESULTS

One hundred and four volunteers contacted the investigator through e-mails and phone calls. Eligibility was assessed by e-mail or telephone prescreening and one screening visit. After the screening visit, 64 volunteers were eligible to participate in this study and signed the consent form. The reasons for exclusion included over 45 years of age, BMI over 35, no depressive symptoms (BDI-II score < 14), irregular menstrual cycle, and not being sedentary (exercised three or more times per week). Ten eligible participants did not show up for visit 2 for pre-test questionnaires and maximal exercise testing and refused to continue to be in this study. The main reason for discontinued participation was lack of time. When comparisons on baseline data were made between those who stayed in the study and those who dropped out, there were no significant differences on age, BMI, BDI-II scores, and medication use. A total of 54 participants were randomized to the two treatment conditions – high intensity aerobic exercise (HI) or low intensity aerobic exercise (LO) – or the stretching exercise control (SC) group. There were 18 participants in each group at study entry. Of the 54 participants, 14 (26%) did not finish the 10-weeks training program. The LO group had the highest drop out rate (39%;
final sample \( n = 11 \) and the HI group had the lowest drop out rate (17%; final sample \( n = 15 \)). Four participants (22%) in the SC group did not complete the study, and two additional participants in the SC group were excluded from data analysis (final sample \( n = 12 \)). One of the two participants reported that she began to take medication to treat her depressive symptoms around the 5th week of the training program. Since the medication could have affected her depressive symptoms and thus confounded the results of this study, this participant was excluded from data analysis. The other SC participant was excluded because her average weekly energy expenditure (EE) from exercise was 891.2 kcal, and exercise frequency (EF) was 3.8 sessions/week. Compared to the average weekly EE and EF in HI (1007.3 kcal/week, 3.7 sessions/week) and LO (905.2 kcal/week, 4.9 sessions/week) this participant was considered too active to be included in SC, for which the average was 215.8 kcal/week, 2.1 sessions/week (this participant not included). The remaining 38 participants were included for the following data analyses.

**Baseline Characteristics**

Baseline characteristics of the participants (mean and standard deviation) are shown in Table 4.1. The average age of all participants was 26.4 years with the youngest at 18 and the oldest at 43 years. There was no age difference between groups \( (p = .73) \). Participants’ body mass index (BMI) ranged from 18.73 to 34.89 and there was no group difference \( (p = .41) \). More than half of the participants \( (n = 25) \) had a normal BMI (18.5-24.9) according to ACSM’s guidelines (Franklin et al., 2000). The scores from Godin leisure-time exercise questionnaire (GODIN) showed that participants in HI were slightly more active than LO and SC, but this difference was not significant \( (p = .09) \).
Similar levels of self-reported leisure-time exercise were reflected in similar baseline maximal oxygen consumption (VO₂max) (HI = 32.3 ml/kg/min; LO = 33.0 ml/kg/min; SC = 34.6 ml/kg/min; \( p = .60 \)).

Of the 38 participants, 11 (28.9%) were taking medication for their depressive symptoms and had been taking medication for more than three weeks before entering this study. The medications they were taking included Effexor, Lexapro, Paxil, Wellbutrin, and Zoloft. Among these 11 participants, four were in HI (26.7%), five in LO (45.5%), and two in SC (16.7%). Since these participants had been taking medication for their depression for more than three weeks before they entered this study, and they did not change the type and amount of their medication during the course of this study, the effects of the medication should not have affected the following results.

The average BDI-II scores at baseline were not different among the groups (\( p = .80 \)), and were above 20 (total sample BDI-II baseline range 15 – 37), suggesting that on average the participants in each group were experiencing moderate depressive symptoms (BDI-II scores 20-28). There were also no significant differences among the groups at baseline for exercise self-efficacy (ESE), \( p = .45 \), or depression coping self-efficacy (DCSE), \( p = .53 \).
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>HI (n = 15)</th>
<th>LO (n = 11)</th>
<th>SC (n = 12)</th>
<th>Group Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
<td>M</td>
<td>SD</td>
</tr>
<tr>
<td>Age, years</td>
<td>27.2</td>
<td>7.8</td>
<td>26.6</td>
<td>6.6</td>
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<tr>
<td>BMI, kg/m²</td>
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<td>4.5</td>
<td>23.8</td>
<td>4.2</td>
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<td>8.1</td>
<td>7.9</td>
<td>6.2</td>
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<tr>
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<td>5.5</td>
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<td>BDI-II</td>
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<td>6.5</td>
<td>23.3</td>
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<tr>
<td>ESE, %</td>
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<td>13.3</td>
<td>62.4</td>
<td>22.1</td>
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<tr>
<td>DCSE, %</td>
<td>71.0</td>
<td>8.4</td>
<td>71.5</td>
<td>12.3</td>
</tr>
</tbody>
</table>

Table 4.1

*Baseline Characteristics*

*Note.* BDI-II = Beck Depression Inventory II; BMI = Body Mass Index; ESE = Exercise Self-efficacy; DCSE = Depression Coping Self-efficacy.

**Exercise Training**

All participants met with the investigator for a supervised exercise session once per week for 10 weeks. The average attendance rate for these weekly meetings was 98.4% for the whole sample, with no difference among the groups (HI = 97.3%; LO = 99.1%; SC = 99.2%, p = .475) (See Table 4.2). Even those with the lowest attendance rate (80%) still attended eight of the ten supervised training sessions.

The average weekly EE from exercise was 1007.3 kcal for HI, 905.2 kcal for LO, and 215.8 kcal for SC. The weekly EE did not differ significantly between HI and LO (p = .420) and both groups had significantly higher EE than SC (p < .001). The energy expenditure goal for the two aerobic groups was 1000 kcal per week. Participants in HI reached the goal, while participants in LO expended about 100 kcal less than desired.
The average weekly exercise frequency (EF) was 3.7 sessions for HI, 4.9 sessions for LO, and 2.1 sessions for SC. Both aerobic exercise groups had significantly higher EF than SC \((p < .001)\). LO also had significantly higher EF than HI \((p = .005)\). The average duration for a supervised exercise session was significantly longer for LO (39.3 minutes) than for HI (34.9 minutes, \(p < .001\)) and SC (30 minutes, \(p < .001\)). The HI also had significantly longer supervised sessions than SC \((p < .001)\). Participants in HI and LO spent significantly more time exercising during unsupervised sessions each week (137.6 minutes for HI, 186.6 minutes for LO) as compared to SC (55.8 minutes, \(p < .01\)). The time spent during unsupervised sessions did not differ significantly between the two aerobic groups \((p = .151)\).

After the conclusion of the study, six participants (50%) in the stretching exercise control group continued to participate in a 10-weeks aerobic exercise program provided by the investigator.

<table>
<thead>
<tr>
<th>Variables</th>
<th>HI ((n = 15))</th>
<th>LO ((n = 11))</th>
<th>SC ((n = 12))</th>
<th>Group Difference</th>
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</thead>
<tbody>
<tr>
<td>Attendance, %</td>
<td>97.3 5.9</td>
<td>99.1 3.0</td>
<td>99.2 2.9</td>
<td>.475</td>
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<td>EE, kcal/wk (^a)</td>
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<td>905.2 236.5</td>
<td>215.8 132.8</td>
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<td>4.9 1.1</td>
<td>2.1 0.7</td>
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<td>34.9 2.5</td>
<td>39.3 1.9</td>
<td>30.0 0.0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Unsupervised, min/wk (^a)</td>
<td>137.6 62.3</td>
<td>186.6 71.4</td>
<td>55.8 46.5</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Table 4.2  
Exercise Training Variables
After 10 weeks of exercise training, participants in HI had a significant increase in VO$_{2\text{max}}$ (See Table 4.3). The average VO$_{2\text{max}}$ increased from 32.3 ml/kg/min to 34.6 ml/kg/min, $F(1,14) = 11.692, p = .004, \eta^2 = .455$. The average VO$_{2\text{max}}$ did not change significantly for LO, although the weekly EE did not differ significantly between HI and LO. As expected, there was no change in VO$_{2\text{max}}$ for SC.

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>10 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>VO$_{2\text{max}}$</td>
<td>M</td>
<td>SD</td>
</tr>
<tr>
<td>HI</td>
<td>32.3</td>
<td>5.5</td>
</tr>
<tr>
<td>LO</td>
<td>33.0</td>
<td>4.5</td>
</tr>
<tr>
<td>SC</td>
<td>34.6</td>
<td>7.1</td>
</tr>
</tbody>
</table>

Table 4.3
VO$_{2\text{max}}$ Change by Group

Depressive Symptoms

During the course of the study, none of the participants responded to item #9 on the BDI-II with a score of 2 or 3 (2 - I would like to kill myself; 3 - I would kill myself if I had a chance). The first research hypothesis proposed that after 10 weeks of aerobic exercise training, both HI and LO groups would have improved depressive symptoms.
The repeated measures ANOVA for BDI-II scores revealed a significant main effect of time, \( F(1, 35) = 187.828, p < .001, \eta^2 = .843 \), and there was no significant time and group interaction (See Table 4.4). The analysis also showed no significant group effect for BDI-II score (See Table 4.5). The average BDI-II score decreased from 22.45 (moderate depressive symptoms) at baseline to 8.05 (minimal depressive symptoms) at 10 weeks. This result indicated that overall the depressive symptoms improved after the 10-weeks training program.

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
<th>( \eta^2 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>3803.547</td>
<td>1</td>
<td>3803.547</td>
<td>187.828</td>
<td>&lt;.001</td>
<td>.843</td>
</tr>
<tr>
<td>Time*Group</td>
<td>61.785</td>
<td>2</td>
<td>30.892</td>
<td>1.526</td>
<td>.232</td>
<td>.080</td>
</tr>
<tr>
<td>Error (Time)</td>
<td>708.755</td>
<td>35</td>
<td>20.250</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4.4
*Tests of Time Effects for Beck Depression Inventory-II Score*

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
<th>( \eta^2 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>17682.706</td>
<td>1</td>
<td>17682.706</td>
<td>555.591</td>
<td>&lt;.001</td>
<td>.941</td>
</tr>
<tr>
<td>Group</td>
<td>104.811</td>
<td>2</td>
<td>52.405</td>
<td>1.647</td>
<td>.207</td>
<td>.086</td>
</tr>
<tr>
<td>Error</td>
<td>1113.939</td>
<td>35</td>
<td>31.827</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4.5
*Tests of Group Effects for Beck Depression Inventory-II Score*

I further tested the simple effect of time at each level of group. The results showed that both HI and LO had significant reductions in BDI-II scores at 10 weeks (See Table
The average BDI-II score for HI decreased from 21.87 to 5.80, $F(1, 14) = 70.868, p < .001, \eta^2 = .835$, and the average BDI-II score for LO decreased from 23.27 to 8.36, $F(1, 10) = 74.339, p < .001, \eta^2 = .881$. Participants in both groups had changed from reporting moderate depressive symptoms (BDI-II score 20-28) to reporting few depressive symptoms (BDI-II score 0-13) after 10 weeks of aerobic exercise training. These results supported the first hypothesis that both HI and LO would have improved depressive symptoms after the exercise training program.

The SC also had a significant reduction in BDI-II scores, $F(1, 11) = 57.107, p < .001, \eta^2 = .838$, at 10 weeks. The average score decreased from 22.42 to 10.58.

<table>
<thead>
<tr>
<th></th>
<th>BDI-II</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>10 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
<td>M</td>
<td>SD</td>
<td>F</td>
<td>p</td>
<td>\eta^2</td>
<td></td>
</tr>
<tr>
<td>HI</td>
<td>21.87</td>
<td>6.48</td>
<td>5.80</td>
<td>3.38</td>
<td>70.868</td>
<td>&lt;.001</td>
<td>.835</td>
<td></td>
</tr>
<tr>
<td>LO</td>
<td>23.27</td>
<td>4.94</td>
<td>8.36</td>
<td>5.66</td>
<td>74.339</td>
<td>&lt;.001</td>
<td>.881</td>
<td></td>
</tr>
<tr>
<td>SC</td>
<td>22.42</td>
<td>3.78</td>
<td>10.58</td>
<td>5.66</td>
<td>57.107</td>
<td>&lt;.001</td>
<td>.838</td>
<td></td>
</tr>
</tbody>
</table>

Table 4.6
Beck Depression Inventory-II Change by Group

My second research hypothesis proposed that the level of improvement in depressive symptoms would be the same for both HI and LO. To test this hypothesis, an interaction comparison was performed. After 10 weeks of exercise training, HI had 16.07 points reduction in average BDI-II score and LO had 14.91 points reduction in average BDI-II score (See Figure 4.1). The interaction comparison showed that the BDI-II change
scores were not significantly different between HI and LO, $F(1, 35) = .210, p = .650, \eta^2 = .006$, suggesting that participants in both HI and LO had similar improvement in depressive symptoms after 10 weeks of exercise training. This result supported my second hypothesis. Since the energy expenditure from exercise was kept the same for both aerobic groups (i.e., 1000 kcal/week), the finding from the above comparison suggested that when controlling for total energy expenditure, both high and low intensity aerobic exercise were equally effective in reducing mild to moderate depressive symptoms.

The BDI-II change scores were also compared between HI and SC. The results showed no significant difference between the two groups, $F(1, 35) = 2.950, p = .095, \eta^2 = .078$. This finding suggested that the improvements in depressive symptoms were similar in HI and SC after 10-weeks of training. The BDI-II change scores also were not significantly different between LO and SC, $F(1, 35) = 1.341, p = .255, \eta^2 = .037$, suggesting that both groups had similar improvements in depressive symptoms after the training program. These results suggested that neither high nor low intensity aerobic exercise was more effective than stretching exercise in reducing mild to moderate depressive symptoms.
Figure 4.1. Mean Beck Depression Inventory-II change scores for HI ($n = 15$), LO ($n = 11$), and SC ($n = 12$) groups.

Although at 10 weeks, the mean BDI-II scores in all three groups indicated minimal depressive symptoms, when looking at individual scores, five participants scored greater than 13, indicating mild to moderate depressive symptoms at 10 weeks. Two of them were in LO (2 out of 11, 18.2%), and the other three participants were in SC (3 out of 12, 25.0%). None of the 15 participants in HI could be placed in the BDI-II mild to moderate depression category (score 14-28) at 10 weeks.

**Exercise Self-efficacy**

My third research hypothesis proposed that both HI and LO groups would have increased exercise self-efficacy (ESE) after 10 weeks of exercise training. The repeated
measures ANOVA for ESE revealed a significant main effect of time, $F(1, 35) = 5.530, p = .024, \eta^2 = .136$. There was no significant time and group interaction (See Table 4.7). The analysis also showed no significant group effect for ESE score (See Table 4.8). The average ESE score increased from 64.92% at baseline to 71.97% at 10 weeks. This result indicated that overall ESE increased after the 10-weeks training program.

![Table 4.7](image)

Table 4.7
Tests of Time Effects for Exercise Self-efficacy Score

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
<th>$\eta^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>1005.774</td>
<td>1</td>
<td>1005.774</td>
<td>5.530</td>
<td>.024</td>
<td>.136</td>
</tr>
<tr>
<td>Time*Group</td>
<td>334.750</td>
<td>2</td>
<td>167.375</td>
<td>0.920</td>
<td>.408</td>
<td>.050</td>
</tr>
<tr>
<td>Error (Time)</td>
<td>6366.198</td>
<td>35</td>
<td>181.891</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

![Table 4.8](image)

Table 4.8
Tests of Group Effects for Exercise Self-efficacy Score

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
<th>$\eta^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>346860.372</td>
<td>1</td>
<td>346860.372</td>
<td>953.728</td>
<td>&lt;.001</td>
<td>.965</td>
</tr>
<tr>
<td>Group</td>
<td>1199.677</td>
<td>2</td>
<td>599.838</td>
<td>1.649</td>
<td>.207</td>
<td>.086</td>
</tr>
<tr>
<td>Error</td>
<td>12729.113</td>
<td>35</td>
<td>363.689</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

However, when I further tested the simple effect of time at each level of group, none of the three groups had a significant increase in ESE at 10 weeks (See Table 4.9). The average ESE score for HI increased from 69.53% to 75.27%, $F(1, 14) = 2.638, p = .127, \eta^2 = .159$. The ESE score for LO increased from 62.36% to 75.73%, $F(1, 10) =$
The SC also had a non-significant increase in ESE score, from 61.50% to 64.42%, \( F(1, 11) = 0.347, p = .568, \eta^2 = .031 \). These results suggested that group membership was not a factor in the increase in ESE.

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>10 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>HI</td>
<td>69.53</td>
<td>75.27</td>
</tr>
<tr>
<td></td>
<td>13.34</td>
<td>14.24</td>
</tr>
<tr>
<td>LO</td>
<td>62.36</td>
<td>75.73</td>
</tr>
<tr>
<td></td>
<td>22.13</td>
<td>15.46</td>
</tr>
<tr>
<td>SC</td>
<td>61.50</td>
<td>64.42</td>
</tr>
<tr>
<td></td>
<td>19.12</td>
<td>14.95</td>
</tr>
</tbody>
</table>

Table 4.9

*Exercise Self-efficacy Change by Group*

Depression Coping Self-efficacy

My fourth research hypothesis proposed that both HI and LO groups would have increased depression coping self-efficacy (DCSE) after 10 weeks of exercise training. The repeated measures ANOVA for DCSE revealed a significant main effect of time, \( F(1, 35) = 28.212, p < .001, \eta^2 = .446 \), and there was no significant time and group interaction (See Table 4.10). There also was no significant group effect for DCSE score (See Table 4.11). The average DCSE score increased from 69.71% at baseline to 78.61% at 10 weeks. This result indicated that overall DCSE increased after the 10-weeks training program.
Table 4.10
Tests of Time Effects for Depression Coping Self-efficacy Score

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
<th>$\eta^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>1437.403</td>
<td>1</td>
<td>1437.403</td>
<td>28.212</td>
<td>&lt;.001</td>
<td>.446</td>
</tr>
<tr>
<td>Time*Group</td>
<td>40.531</td>
<td>2</td>
<td>20.266</td>
<td>0.398</td>
<td>.675</td>
<td>.022</td>
</tr>
<tr>
<td>Error (Time)</td>
<td>1783.258</td>
<td>35</td>
<td>50.950</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Table 4.11
Tests of Group Effects for Depression Coping Self-efficacy Score

<table>
<thead>
<tr>
<th>Source</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>p</th>
<th>$\eta^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>409594.309</td>
<td>1</td>
<td>409594.309</td>
<td>1806.113</td>
<td>&lt;.001</td>
<td>.981</td>
</tr>
<tr>
<td>Group</td>
<td>643.726</td>
<td>2</td>
<td>321.863</td>
<td>1.419</td>
<td>.255</td>
<td>.075</td>
</tr>
<tr>
<td>Error</td>
<td>7937.380</td>
<td>35</td>
<td>226.782</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I further tested the simple effect of time at each level of group (See Table 4.12).

The average DCSE score for HI increased significantly from 71.00% to 81.40%, $F(1, 14) = 27.445, p < .001, \eta^2 = .662$. The average DCSE score for LO also increased significantly from 71.55% to 80.55%, $F(1, 10) = 10.735, p = .008, \eta^2 = .518$. On the contrary, the SC had a non-significant increase in DCSE score, from 66.42% to 73.33%, $F(1, 11) = 3.308, p = .096, \eta^2 = .231$. These results suggest that participants in both HI and LO had increased depression coping self-efficacy after 10 weeks of exercise training, while participants in SC did not.
Correlation Analysis

The fifth research hypothesis was that there would be a negative relationship between changes in exercise self-efficacy and depressive symptoms. Pearson Correlation was performed to test the relationship between ESE change score and BDI-II change score. Change scores were computed by subtracting the baseline score from the score at 10 weeks. The Pearson Correlation revealed a non-significant negative correlation between ESE change score and BDI-II change score, $r = -.301$, $p = .066$. I further performed Pearson Correlation for each group. For all three groups, the Pearson Correlations revealed a non-significant negative correlation between ESE change score and BDI-II change score (See Table 4.13). These results indicated that for all three groups there was no relationship between ESE change score and BDI-II change score, suggesting that changes in participants’ exercise self-efficacy during the training program were not related to changes in their depressive symptoms.

Table 4.12
Depression Coping Self-efficacy Change by Group

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>10 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$M$</td>
<td>$SD$</td>
</tr>
<tr>
<td>HI</td>
<td>71.00</td>
<td>8.40</td>
</tr>
<tr>
<td>LO</td>
<td>71.55</td>
<td>12.33</td>
</tr>
<tr>
<td>SC</td>
<td>66.42</td>
<td>15.85</td>
</tr>
</tbody>
</table>


The sixth research hypothesis was that there would be a negative relationship between changes in depression coping self-efficacy and depressive symptoms. Pearson Correlation was performed to test the relationship between DCSE change score and BDI-II change score. Change scores were computed by subtracting the baseline score from the score at 10 weeks. The Pearson Correlation revealed a non-significant negative correlation between DCSE change score and BDI-II change score, \( r = -.105, p = .529 \). I further performed Pearson Correlation for each group. For HI and LO groups, the Pearson Correlations revealed a non-significant negative correlation between DCSE change score and BDI-II change score (See Table 4.14). For SC, the Pearson Correlation showed a non-significant positive correlation between DCSE change score and BDI-II change score, \( r = .218, p = .497 \). These results indicated that for all three groups there was no relationship between DCSE change score and BDI-II change score, suggesting that changes in participants’ depression coping self-efficacy during the training program were not related to changes in their depressive symptoms.

<table>
<thead>
<tr>
<th>Group</th>
<th>( r )</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>HI</td>
<td>-.302</td>
<td>.274</td>
</tr>
<tr>
<td>LO</td>
<td>-.425</td>
<td>.192</td>
</tr>
<tr>
<td>SC</td>
<td>-.167</td>
<td>.604</td>
</tr>
<tr>
<td>All</td>
<td>-.301</td>
<td>.066</td>
</tr>
</tbody>
</table>

Table 4.13
*Pearson Correlations for Exercise Self-efficacy Change Score and Beck Depression Inventory-II Change Score*
<table>
<thead>
<tr>
<th></th>
<th>$r$</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>HI</td>
<td>-.208</td>
<td>.457</td>
</tr>
<tr>
<td>LO</td>
<td>-.299</td>
<td>.372</td>
</tr>
<tr>
<td>SC</td>
<td>.218</td>
<td>.497</td>
</tr>
<tr>
<td>All</td>
<td>-.105</td>
<td>.529</td>
</tr>
</tbody>
</table>

Table 4.14
*Pearson Correlations for Depression Coping Self-efficacy Change Score and Beck Depression Inventory-II Change Score*

Mediation Effect of Self-efficacy

The seventh research hypothesis proposed that changes in exercise self-efficacy would mediate the effect of exercise on depressive symptoms. To test the mediation effect of ESE, a series of regression analyses was performed: first, ESE change score was regressed on group assignment; second, BDI-II change score was regressed on group assignment; and third, BDI-II change score was regressed on group assignment and ESE change score. Change scores were computed by subtracting the baseline score from the score at 10 weeks. Since group assignment is a categorical variable, two dummy variables (H and L) were created for the three groups:

Both H and L variables can have a value of 0 or 1
If $H = 1$ the participant was in HI group
If $H = 0$ the participant was not in HI group
If $L = 1$ the participant was in LO group
If $L = 0$ the participant was not in LO group
If $H$ and $L$ were both 0 the participant was in SC group
The results showed no mediation effect for ESE (See Table 4.15). The regression equations for ESE were as follows: 1) ESE change score was regressed on group assignment (H: standardized $\beta = 0.073$, $p = .705$; L: standardized $\beta = 0.252$, $p = .198$), 2) BDI-II change score was regressed on group assignment (H: standardized $\beta = -0.325$, $p = .095$; L: standardized $\beta = -0.219$, $p = .255$), and 3) BDI-II change score was regressed on group assignment and ESE change score (group assignment [H: standardized $\beta = -0.304$, $p = .108$; L: standardized $\beta = -0.147$, $p = .441$]; ESE change score [standardized $\beta = -0.287$, $p = .085$]). These results indicated that group assignment did not affect ESE change score, group assignment did not affect BDI-II change score, and ESE change score did not affect BDI-II change score. Since the first equation did not show that the independent variable affected the mediator, the second equation did not show that the independent variable affected the dependent variable, and the third equation did not show that the mediator affected the dependent variable, the conditions for mediation did not hold. In other words, exercise self-efficacy did not mediate the effect of exercise on depressive symptoms.

<table>
<thead>
<tr>
<th></th>
<th>$B$</th>
<th>$SE$</th>
<th>$\beta$</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1st</strong>: Regress ESE on group assignment</td>
<td>H</td>
<td>2.817</td>
<td>.073</td>
<td>.705</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>10.447</td>
<td>.252</td>
<td>.198</td>
</tr>
<tr>
<td><strong>2nd</strong>: Regress BDI-II on group assignment</td>
<td>H</td>
<td>-4.233</td>
<td>-.325</td>
<td>.095</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>-3.076</td>
<td>-.219</td>
<td>.255</td>
</tr>
<tr>
<td><strong>3rd</strong>: Regress BDI-II on group assignment and ESE</td>
<td>ESE</td>
<td>-0.097</td>
<td>-.287</td>
<td>.085</td>
</tr>
<tr>
<td></td>
<td>H</td>
<td>-3.960</td>
<td>-.304</td>
<td>.108</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>-2.060</td>
<td>-.147</td>
<td>.441</td>
</tr>
</tbody>
</table>

Table 4.15

Regression Equations for Exercise Self-efficacy Mediation Analysis
The eighth research hypothesis proposed that changes in depression coping self-efficacy would mediate the effect of exercise on depressive symptoms. To test the mediation effect of DCSE, a series of regression analyses was performed. The method is the same as described for ESE mediation analysis. The results showed no mediation effect for DCSE (See Table 4.16). The regression equations for DCSE were as follows: 1) DCSE change score was regressed on group assignment (H: standardized $\beta = 0.174, p = .379$; L: standardized $\beta = 0.096, p = .624$), 2) BDI-II change score was regressed on group assignment (H: standardized $\beta = -0.325, p = .095$; L: standardized $\beta = -0.219, p = .255$), and 3) BDI-II change score was regressed on group assignment and DCSE change score (group assignment [H: standardized $\beta = -0.314, p = .115$; L: standardized $\beta = -0.213, p = .276$]; DCSE change score [standardized $\beta = -0.065, p = .698$]). These results indicated that group assignment did not affect DCSE change score, group assignment did not affect BDI-II change score, and DCSE change score did not affect BDI-II change score. The first equation did not show that the independent variable affected the mediator, the second equation did not show that the independent variable affected the dependent variable, and the third equation did not show that the mediator affected the dependent variable. The conditions for mediation did not hold, suggesting that depression coping self-efficacy did not mediate the effect of exercise on depressive symptoms.
Table 4.16

*Regression Equations for Depression Coping Self-efficacy Mediation Analysis*

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>B</th>
<th>SE B</th>
<th>β</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st: Regress DCSE on group assignment</td>
<td>H</td>
<td>3.483</td>
<td>3.910</td>
<td>.174</td>
<td>.379</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>2.083</td>
<td>4.214</td>
<td>.096</td>
<td>.624</td>
</tr>
<tr>
<td>2nd: Regress BDI-II on group assignment</td>
<td>H</td>
<td>-4.233</td>
<td>2.465</td>
<td>-.325</td>
<td>.095</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>-3.076</td>
<td>2.656</td>
<td>-.219</td>
<td>.255</td>
</tr>
<tr>
<td>3rd: Regress BDI-II on group assignment and DCSE</td>
<td>H</td>
<td>-4.086</td>
<td>2.523</td>
<td>-.314</td>
<td>.115</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>-2.988</td>
<td>2.699</td>
<td>-.213</td>
<td>.276</td>
</tr>
</tbody>
</table>
Depression is a serious mental disorder, but we know little about the optimal exercise prescription to alleviate depressive symptoms. The purpose of this study was to compare the effects of a high intensity aerobic training program to a low intensity aerobic training program on depressive symptoms in initially sedentary women. The secondary purpose was to examine potential mediating effects of changes in self-efficacy on depressive symptoms.

The first hypothesis proposed that both high and low intensity aerobic exercise groups would have improved depressive symptoms after 10 weeks of exercise training. This hypothesis was supported by the data. Participants in both aerobic groups began the study with moderate depressive symptoms as indicated by their scores on the BDI-II. At the end of the training program, participants in both groups had only minimal depressive symptoms. Therefore, aerobic exercise at a dose of about 1000 kcal per week was effective in reducing mild to moderate depressive symptoms. This finding was comparable to results of a number of other exercise intervention studies, which demonstrated a reduction in depressive symptoms following an exercise program.
The second hypothesis proposed that both high and low intensity groups would have similar improvement in depressive symptoms. This hypothesis was supported by the data. The results suggested that both high and low intensity aerobic training were equally effective in reducing mild to moderate depressive symptoms. The finding of no difference between the high and low intensity conditions suggests that in this study, exercise intensity did not moderate the effect of exercise on depressive symptoms. Accordingly, individuals can obtain the antidepressant effect of exercise through either high intensity exercise (e.g., running) or low intensity exercise (e.g., fast walking). This finding is similar to results of another exercise intervention study by Dunn et al. (2005). In their study, the authors suggested that the determining factor for reduction and remission of depressive symptoms is total energy expenditure, and that exercise frequency (i.e., 3 days per week or 5 days per week) does not moderate the effect of exercise on depressive symptoms. The current study adds information about the effects of training intensity on depressive symptoms.

The lower drop out rate (17%) in HI, however, suggests that high intensity aerobic exercise may be a more practical and acceptable treatment for reducing depressive symptoms. Participants in HI on average exercised 2.9 hours per week. On the other hand, participants in LO had to exercise 3.8 hours per week to obtain the same amount of exercise (i.e., 1000 kcal per week). The more time-consuming exercise regime for LO made it more difficult for participants to reach their exercise goal each week, and may
explain the higher dropout rate (39%) in this group. Therefore, compare to low intensity, high intensity aerobic exercise may be a more practical and acceptable treatment for sedentary women with mild to moderate depressive symptoms. Furthermore, while two participants in LO still scored greater than 13 on BDI-II at 10 weeks, none of the 15 participants in HI could be placed in the BDI-II mild to moderate depression category (score 14-28) at 10 weeks. This finding suggests that high intensity aerobic exercise may be more promising in reducing mild to moderate depressive symptoms.

Participants in SC also had significant reductions in their depressive symptoms. This finding suggests that the social contact and personal attention participants received from the investigator may partially contribute to the improved depressive symptoms seen in this study. In addition, stretching exercise, although used as a placebo control, may actually be an effective treatment for depressive symptoms. In our study, we included many yoga poses from Hatha Yoga for the stretching exercise. Recently, research conducted on yoga and depression has suggested that yoga practice can be an effective treatment for depressive symptoms. In Elavsky and McAuley’s study (2007), the authors randomized 164 menopausal women to either walking, yoga, or wait-list control group. The results indicated that after 4 months of training, both walking and yoga were effective in reducing depressive symptoms, assessed by BDI. Another randomized controlled trial by John, Sharma, Sharma, and Kankane (2007) examined the effectiveness of yoga practice for patients with migraine. After 3 months of training, anxiety and depression scores (assessed by the Hospital Anxiety Depression Scale) were significantly lower in the yoga group compared to the self-care control group. Research conducted on
psychiatric inpatients also reported that yoga was associated with significant improvements on all five of the negative emotion factors on the Profile of Mood States (POMS), including improvement on depression-dejection (Lavey et al., 2005). Yoga programs in Elavsky and McAuley’s study (2007) and Lavey et al.’s study (2005) were both based on Hatha Yoga. These findings suggest the beneficial effect of yoga on depression and may explain the significant improvement in depressive symptoms seen in our stretching control group. Therefore, our stretching group should be considered a comparison group and did not meet the criteria of a control group. This may be the reason why we did not see difference in BDI-II change scores between the aerobic groups and SC. For future randomized control trials, we would recommend a different type of activity (e.g., lecture meetings) or a wait-list control rather than stretching exercise for the control condition.

In the current study, we examined two proposed psychological mechanisms, exercise self-efficacy and depression coping self-efficacy. It was hypothesized that participants in the aerobic exercise groups would report increased levels of exercise self-efficacy and depression coping self-efficacy. This hypothesis was supported for depression coping self-efficacy, but not for exercise self-efficacy. Participants in the aerobic groups had significantly increased depression coping self-efficacy at 10 weeks, while their exercise self-efficacy did not change significantly during the training program. These findings suggest that the aerobic exercise program helped enhance participants’ confidence to cope with their depressive symptoms, but not their confidence to exercise.
The finding about depression coping self-efficacy mirrors the results of a previous study by Craft (2005). In Craft’s study, the author found an increase in depression coping self-efficacy following involvement in a 9-weeks aerobic exercise program. Several different factors can influence the development of self-efficacy (Bandura, 1997); however, mastery experiences appear to provide the most potent influence on efficacy expectations (Buckworth & Dishman, 2002). In our exercise program, the investigator helped participants set long-term and short-term exercise goals. Short-term goals were set based on participants’ performance each week and were more achievable goals. With each short-term goal achieved, participants were more confident they could achieve desired outcome. This provided a mastery experience and might encourage participants to use this self-regulatory strategy (i.e., goal setting) to manage their depressive symptoms. Furthermore, according to Bandura (1997), an intervention that teaches the individual how to self-monitor behaviors and utilize social support to maintain the desired behaviors can lead to enhanced coping self-efficacy. In our exercise program, participants learned how to keep an activity diary to self-monitor their exercise behaviors. During each supervised session, the investigator provided positive support by reinforcing participants’ success behaviors (e.g., achieving 1000 kcal per week), and by providing strategies for participants to overcome barriers to exercise. These components could all contribute to feelings of mastery and could lead to enhanced self-efficacy to cope with one’s depressive symptoms.

The exercise program, however, did not affect exercise self-efficacy. Exercise self-efficacy in both aerobic groups increased at 10 weeks (5.8% increase for HI and
13.3% increase for LO), but the increase did not reach statistic significance. The relationship between exercise and exercise self-efficacy has not been previously tested in women suffering from mild to moderate depressive symptoms. Research conducted on older adults did not support our finding. Two exercise intervention studies (Gary, 2006; Lee, Arthur, & Avis, 2007) utilized a walking program for adults 50 years and older reported that participants in the walking groups had significant increase in exercise self-efficacy. Results from a meta-analysis of intervention studies in older adults without clinical disorders also suggested that physical activity improves exercise self-efficacy (Netz, Wu, Becker, & Tenenbaum, 2005). Our data showed that both HI and LO had large effect size of exercise self-efficacy score ($\eta^2 = 0.159$ for HI, $\eta^2 = 0.222$ for LO) but low power ($1-\beta = 0.328$ for HI, $1-\beta = 0.333$ for LO). These results suggest that exercise self-efficacy might indeed have increased in both aerobic groups after 10-weeks of exercise training, yet the data did not have enough power to detect the difference. Also, the exercise self-efficacy questionnaire used in this study measures barriers efficacy (i.e., perceived ability to overcome barriers to exercising), which might not have captured the aspect of self-efficacy targeted. If we had measured a different type of exercise self-efficacy, such as the efficacy to engage in incremental bouts of exercise or the efficacy for making time to exercise, we might have found significant changes in exercise self-efficacy in this study. Therefore, base on current findings it is difficult to draw any conclusion on the relationship between exercise and exercise self-efficacy in our study population. More research with proper power and measures of a precise type of exercise self-efficacy is needed to elucidate this relationship in women with depressive symptoms.
We performed mediation analysis for both types of self-efficacy. The results showed that neither exercise self-efficacy nor depression coping self-efficacy mediated the beneficial effect of exercise on depressive symptoms. In the mediation analysis, we found that group assignment did not affect either exercise self-efficacy or depression coping self-efficacy; group assignment did not affect depressive symptoms; and neither exercise self-efficacy nor depression coping self-efficacy affected depressive symptoms. According to Baron and Kenny’s rules for mediation effect (1986), no mediation effect was found for both types of self-efficacy. Since exercise self-efficacy did not change significantly in this study, it was not surprising to us to find no mediation effect for exercise self-efficacy. It was interesting that there was no mediation effect for depression coping self-efficacy. In other words, even though participants in the aerobic groups had higher depression coping self-efficacy after exercise training, this change did not affect changes in their depressive symptoms. These results suggest that the antidepressant effect of exercise might be mediated by other mechanisms, including biological mechanism (e.g., serotonin, norepinephrine), psychological mechanism (time out/distraction, social interaction), or a combination of these mechanisms. These mechanisms were not measured in our study and thus can not be tested for a mediation effect. More randomized control trials are needed to examine whether these mechanisms mediate the antidepressant effect of exercise.

There were limitations in the study. First, participants in the aerobic groups had one supervised exercise session and two to four unsupervised sessions. The only way for the investigator to monitor participants’ exercise behaviors and estimate the weekly
energy expenditure was through checking their activity diary. It was possible for participants to overestimate the intensity and duration of exercise, or record more exercise sessions than they actually did. However, the significant increase in VO$_2$max in HI suggests that participants in HI indeed exercised at their recorded exercise intensity, duration, and frequency. Therefore, it is highly likely that participants in all groups kept a genuine activity diary. In addition, when learning how to keep the activity diary, participants were instructed to record their exercise sessions in detail. For instance, if they played tennis they need to indicate whether they played single or doubles, if they went walking they need to record their speed if they walked on a treadmill, or distance and time if they walked outdoors. Participants were also instructed not to count the time when they took breaks during their exercise sessions. These instructions have reduced the likelihood of overestimation of exercise intensity and duration, and helped the investigator obtain a better estimation of participants’ weekly energy expenditure.

Second, participants were not required to have a diagnosis of depression to enroll in this study. Therefore, findings in this study may not reflect actual responses in women with clinical depression, although the 11 women on medication for depression had similar responses compared to those who were not on medication. Research conducted on clinically depressed populations has reported similar reductions in BDI-II scores following involvement in an exercise program (Blumenthal et al., 1999; Craft, 2005). Our findings may still provide meaningful information for the development of an effective exercise program for treating clinical depression.
Finally, the sample is relatively small compared to many exercise intervention studies. While the study power was adequate for detecting differences in BDI-II score and DCSE score, it was too small to provide meaningful information for exercise self-efficacy.

In summary, aerobic exercise at a dose of about 1000 kcal per week was effective in reducing mild to moderate depressive symptoms in initially sedentary women. Stretching exercise was also effective in reducing depressive symptoms. The amount of reduction in BDI-II score is comparable to the amount reported in other exercise intervention studies. This antidepressant effect of exercise can be obtained through both high and low intensity aerobic exercise, including regular stretching exercise. Exercise self-efficacy and depression coping self-efficacy did not mediate the beneficial effect of exercise on depression, and other mechanisms should be explored.
REFERENCES


reuptake inhibitor use by older men. *Archives of Internal Medicine, 167*(12), 1246-1251.


APPENDIX A

FLYER
A New Beginning for a New Year!!
Depressive Symptoms & Depression Research Study

Did you know that ..........

➢ Physical activity can alleviate symptoms of depression
➢ Exercise is as effective as antidepressant medications and psychotherapy in decreasing depressive symptoms

Volunteer Participants Needed!!!

Volunteers should be:

• Female
• Age 18-45
• Not pregnant or nursing
• Not obese
• Not currently enrolled in an exercise program
• Have a current diagnosis of depression or feel that you are coping with mild to moderate depressive symptoms

If you meet the above criteria, you can participate in this OSU study on the benefits of exercise in alleviating depressive symptoms. For further information, please contact:

Li Lin Chiu
(614) 329-2447 or chiu151@osu.edu
302 Cottrell Hall, 1841 Millikin Road
Columbus, OH, 43210

This research study will take place on the campus of
THE OHIO STATE UNIVERSITY
APPENDIX B

ORAL SCRIPT FOR RECRUITMENT
Oral script for academic class recruitment:

Hello everyone! My name is I-Hua Chu. I am a third year Ph.D. student in the program of Sport and Exercise Science. I’m currently recruiting volunteers to participate in my dissertation research. The purpose of this study is to examine the benefits of exercise for helping reduce the symptoms of depression. Exercise has been shown to reduce depressive symptoms and can be as effective as antidepressant medications and psychotherapy. So for this study, I would like to recruit females who have a current diagnosis of depression or feel that they are coping with mild to moderate depressive symptoms, such as feeling sad, hopeless, or helpless, loss of interest or pleasure in hobbies and activities that were once enjoyed, insomnia or oversleeping. This study will involve a 12-week exercise program. Here is my phone number and email address (written on the blackboard). If you or you know someone who may be interested in participating in this study, please feel free to contact me for further information. I’d really appreciate it. Thank you very much for your time.
APPENDIX C

BECK DEPRESSION INVENTORY-II
1. Sadness
   0  I do not feel sad.
   1  I feel sad much of the time.
   2  I am sad all the time.
   3  I am so sad or unhappy that I can't stand it.

2. Pessimism
   0  I am not discouraged about my future.
   1  I feel more discouraged about my future than I used to be.
   2  I do not expect things to work out for me.
   3  I feel my future is hopeless and will only get worse.

3. Past Failure
   0  I do not feel like a failure.
   1  I have failed more than I should have.
   2  As I look back, I see a lot of failures.
   3  I feel I am a total failure as a person.

4. Loss of Pleasure
   0  I get as much pleasure as I ever did from the things I enjoy.
   1  I don't enjoy things as much as I used to.
   2  I get very little pleasure from the things I used to enjoy.
   3  I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings
   0  I don't feel particularly guilty.
   1  I feel guilty over many things I have done or should have done.
   2  I feel quite guilty most of the time.
   3  I feel guilty all of the time.

6. Punishment Feelings
   0  I don't feel I am being punished.
   1  I feel I may be punished.
   2  I expect to be punished.
   3  I feel I am being punished.

7. Self-Dislike
   0  I feel the same about myself as ever.
   1  I have lost confidence in myself.
   2  I am disappointed in myself.
   3  I dislike myself.

8. Self-Criticalness
   0  I don't criticize or blame myself more than usual.
   1  I am more critical of myself than I used to be.
   2  I criticize myself for all of my faults.
   3  I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes
   0  I don't have any thoughts of killing myself.
   1  I have thoughts of killing myself, but I would not carry them out.
   2  I would like to kill myself.
   3  I would kill myself if I had the chance.

10. Crying
    0  I don't cry anymore than I used to.
    1  I cry more than I used to.
    2  I cry over every little thing.
    3  I feel like crying, but I can't.
<table>
<thead>
<tr>
<th>11. Agitation</th>
<th>17. Irritability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: I am no more restless or wound up than usual.</td>
<td>0: I am no more irritable than usual.</td>
</tr>
<tr>
<td>1: I feel more restless or wound up than usual.</td>
<td>1: I am more irritable than usual.</td>
</tr>
<tr>
<td>2: I am so restless or agitated that it's hard to stay still.</td>
<td>2: I am much more irritable than usual.</td>
</tr>
<tr>
<td>3: I am so restless or agitated that I have to keep moving or doing something.</td>
<td>3: I am irritable all the time.</td>
</tr>
<tr>
<td><strong>12. Loss of Interest</strong></td>
<td><strong>18. Changes in Appetite</strong></td>
</tr>
<tr>
<td>0: I have not lost interest in other people or activities.</td>
<td>0: I have not experienced any change in my appetite.</td>
</tr>
<tr>
<td>1: I am less interested in other people or things than before.</td>
<td>1a: My appetite is somewhat less than usual.</td>
</tr>
<tr>
<td>2: I have lost most of my interest in other people or things.</td>
<td>1b: My appetite is somewhat greater than usual.</td>
</tr>
<tr>
<td>3: It's hard to get interested in anything.</td>
<td>2a: My appetite is much less than before.</td>
</tr>
<tr>
<td><strong>13. Indecisiveness</strong></td>
<td><strong>19. Concentration Difficulty</strong></td>
</tr>
<tr>
<td>0: I make decisions about as well as ever.</td>
<td>0: I can concentrate as well as usual.</td>
</tr>
<tr>
<td>1: I find it more difficult to make decisions than usual.</td>
<td>1: I can't concentrate as well as usual.</td>
</tr>
<tr>
<td>2: I have much greater difficulty in making decisions than I used to.</td>
<td>2: It's hard to keep my mind on anything for very long.</td>
</tr>
<tr>
<td>3: I have trouble making any decisions.</td>
<td>3: I find I can't concentrate on anything.</td>
</tr>
<tr>
<td><strong>14. Worthlessness</strong></td>
<td><strong>20. Tiredness or Fatigue</strong></td>
</tr>
<tr>
<td>0: I do not feel I am worthless.</td>
<td>0: I am no more tired or fatigued than usual.</td>
</tr>
<tr>
<td>1: I don't consider myself as worthwhile and useful as I used to.</td>
<td>1: I get more tired or fatigued more easily than usual.</td>
</tr>
<tr>
<td>2: I feel more worthless as compared to other people.</td>
<td>2: I am too tired or fatigued to do a lot of the things I used to do.</td>
</tr>
<tr>
<td>3: I feel utterly worthless.</td>
<td>3: I am too tired or fatigued to do most of the things I used to do.</td>
</tr>
<tr>
<td>0: I have as much energy as ever.</td>
<td>0: I have not noticed any recent change in my interest in sex.</td>
</tr>
<tr>
<td>1: I have less energy than I used to have.</td>
<td>1: I am less interested in sex than I used to be.</td>
</tr>
<tr>
<td>2: I don't have enough energy to do very much.</td>
<td>2: I am much less interested in sex now.</td>
</tr>
<tr>
<td>3: I don't have enough energy to do anything.</td>
<td>3: I have lost interest in sex completely.</td>
</tr>
<tr>
<td><strong>16. Changes in Sleeping Pattern</strong></td>
<td></td>
</tr>
<tr>
<td>0: I have not experienced any change in my sleeping pattern.</td>
<td></td>
</tr>
<tr>
<td>1a: I sleep somewhat more than usual.</td>
<td></td>
</tr>
<tr>
<td>1b: I sleep somewhat less than usual.</td>
<td></td>
</tr>
<tr>
<td>2a: I sleep a lot more than usual.</td>
<td></td>
</tr>
<tr>
<td>2b: I sleep a lot less than usual.</td>
<td></td>
</tr>
<tr>
<td>3a: I sleep most of the day.</td>
<td></td>
</tr>
<tr>
<td>3b: I wake up 1–2 hours early and can't get back to sleep.</td>
<td></td>
</tr>
</tbody>
</table>

**NOTICE:** This form is printed with both blue and black ink. If your copy does not appear this way, it has been photocopied in violation of copyright laws.
APPENDIX D

GODIN LEISURE-TIME EXERCISE QUESTIONNAIRE
**Godin Leisure-Time Exercise Questionnaire**

1. Considering a 7-Day period (a week), how many times on the average do you do the following kinds of exercise for more than 15 minutes during your free time (write on each line the appropriate number).

   **Times Per Week**

   **a) STRENUOUS EXERCISE**
   **(HEART BEATS RAPIDLY)**
   (i.e. running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)

   **b) MODERATE EXERCISE**
   **(NOT EXHAUSTING)**
   (i.e. fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folding dancing)

   **c) MILD EXERCISE**
   **(MINIMAL EFFORT)**
   (i.e. yoga, archery, fishing from river bank, bowling, horseshoes, golf, snowmobiling, easy walking)

2. Considering a 7-Day period (a week), during your leisure-time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)?

<table>
<thead>
<tr>
<th>OFTEN</th>
<th>SOMETIMES</th>
<th>NEVER/RARELY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ☐</td>
<td>2. ☐</td>
<td>3. ☐</td>
</tr>
</tbody>
</table>
APPENDIX E

HEALTH INFORMATION FORM
Health Information Form

Today’s Date: ________

Name: __________________________
  Last                   First                   Middle

Age: __________________________

Address: __________________________

Phone: __________________________ e-mail: __________________________

Signature ______________________ Date ______________________

Page 1 of 3
Health Information Form

ID ______________________

Height: _______  Weight: _______  (height & weight will be measured by the investigator)

Primary Care Physician:  Name: _____________________________________________
                        Location: _____________________________________________
                        Phone: _____________________________________________

Are you currently receiving any treatment for your depressive symptoms?  □ YES  □ NO
If YES, please list the treatment(s) you are currently receiving:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Are you currently taking any medications?  □ YES  □ NO
If YES, please list the medications you are now taking:
________________________________________________________________________
How long have you been taking this medication?
________________________________________________________________________
How long have you been taking this medication?
________________________________________________________________________
How long have you been taking this medication?

Are you currently under medical care for reasons other than your depressive symptoms?
□ YES  □ NO
If YES, please explain:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Please continue on next page.....

Page 2 of 3
ID ____________________

Age when menstural periods began
Are your periods regular? □ YES □ NO How Often? ____________________

How long have your periods been regular? □ < 6 months □ > 6 months □ Never

Are you currently pregnant? □ YES □ NO

Are you currently nursing? □ YES □ NO

Do you plan to be pregnant during the next 6 months? □ YES □ NO

Are you using any birth control method? □ YES □ NO If YES, which kind? ____________________

Please check if any relative (parents, siblings, grandparents, children) have had any of the conditions listed below:

High blood pressure: ______ Heart Disease: ______ Stroke: ______
Elevated cholesterol: ______ Diabetes: ______ Obesity: ______
Mental Illness: ______

Thank you! You are finished

Page 3 of 3
APPENDIX F

PHYSICAL ACTIVITY READINESS QUESTIONNAIRE – PAR-Q
**PAR-Q & YOU**

(A Questionnaire for People Aged 15 to 69)

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start if you are over 69 years of age and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: check YES or NO.

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ 1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?</td>
<td>☐</td>
</tr>
<tr>
<td>☐ 2. Do you feel pain in your chest when you do physical activity?</td>
<td>☐</td>
</tr>
<tr>
<td>☐ 3. In the past month, have you had chest pain when you were not doing physical activity?</td>
<td>☐</td>
</tr>
<tr>
<td>☐ 4. Do you lose your balance because of dizziness or do you ever lose consciousness?</td>
<td>☐</td>
</tr>
<tr>
<td>☐ 5. Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?</td>
<td>☐</td>
</tr>
<tr>
<td>☐ 6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?</td>
<td>☐</td>
</tr>
<tr>
<td>☐ 7. Do you know of any other reason why you should not do physical activity?</td>
<td>☐</td>
</tr>
</tbody>
</table>

**YES to one or more questions**

Talk to your doctor about polling or if you feel that you are becoming much more physically active than you are now, start by answering the seven questions in the box below. If you start becoming much more physically active, you should consult with your doctor.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. You may need to limit your activities to those which are safe for you. Talk with your doctor about the kinds of activities you want to participate in and follow his or her advice.
- Find out which community programs are safe and helpful for you.

**NO to all questions**

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you:
- are taking care of your whole body.
- are taking care of your whole body.
- Take part in a fitness appraisal — this is an excellent way to determine your fitness level. If you are over 15 years of age and you find the activity difficult, consult with your doctor before you start becoming much more physically active.

**PLEASE NOTE:**

- If you have any problem with your health or you are feeling better, please talk to your doctor before starting to become more active.

Information about the PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and its agents assume no liability for persons who undertake physical activity and its advice after completing this questionnaire, consult your doctor prior to physical activity.

**No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.**

**Note:** If the PAR-Q is being used in a remote location, the participant is a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood, and completed this questionnaire. Any questions I had were answered to my full satisfaction."
Physical Activity Readiness Questionnaire (PAR-Q+)

Choices a moderate of activities from above three groups:

- Exercise
- Physical activity
- Leisure

Physical activity improves health:
- How much is too much? How little is too little? How much is too much?

Time needed depends on effort:
- Light: Light effect, no matériel for training
- Moderate: Moderate effect, no matériel for training
- Vigorous: Vigorous effect, matériel for training

Get Active Your Way, Every Day—For Life!

The following questions are available for doctors’ use by contacting the Canadian Society for Exercise Physiology (address below):

- The Physical Activity Readiness Medical Examination (PARmed-A) — to be used by doctors with people who answer YES to one or more questions on the PARQ.
- The Physical Activity Readiness Medical Examination for Pregnancy (PARmed-Q for Pregnancy) — to be used by doctors with pregnant patients who wish to become more active.

References:

For more information, please contact:
- Canadian Society for Exercise Physiology
202-185 Somerset Street West
Ottawa, ON K2P 0C2
Tel: 1-877-652-1255 • Fax: 613-234-0563
Online: www.cscep.ca

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Health Canada
Canada's Physical Activity Guide to Healthy Active Living

FITT and Health Professionals May Be Interested in the Information Below:

The following questionnaires are available for doctors’ use by contacting the Canadian Society for Exercise Physiology (address below):

- The Physical Activity Readiness Medical Examination (PARmed-A) — to be used by doctors with people who answer YES to one or more questions on the PARQ.
- The Physical Activity Readiness Medical Examination for Pregnancy (PARmed-Q for Pregnancy) — to be used by doctors with pregnant patients who wish to become more active.

References:

For more information, please contact:
- Canadian Society for Exercise Physiology
202-185 Somerset Street West
Ottawa, ON K2P 0C2
Tel: 1-877-652-1255 • Fax: 613-234-0563
Online: www.cscep.ca

© Canadian Society for Exercise Physiology 2002.

The original PARQ was developed by the British Columbia Ministry of Health. It has been revised by an Expert Advisory Committee of the Canadian Society for Exercise Physiology chaired by Dr. J. M. Girard (2000).

Disponible en français sous le même questionnaire our Equivalente à l’activité physique - QAPP (rev. 2002).

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APPENDIX G

EXERCISE SELF-EFFICACY QUESTIONNAIRE
Exercise Self-Efficacy

Using the scale below as a yardstick, please answer the following: How confident are you that you could exercise under each of the following conditions over the next 3 months?

<table>
<thead>
<tr>
<th>0%</th>
<th>10%</th>
<th>20%</th>
<th>30%</th>
<th>40%</th>
<th>50%</th>
<th>60%</th>
<th>70%</th>
<th>80%</th>
<th>90%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>cannot do it at all</td>
<td>moderately certain</td>
<td>certain that I can do it</td>
<td>can do it</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Confidence rating 0-100%

I could exercise

a. when tired. __________

b. during or following a personal crisis. __________

c. when feeling depressed. __________

d. when feeling anxious. __________

e. during bad weather. __________

f. when slightly sore from the last time I exercised. __________

g. when on vacation. __________

h. when there are competing interests (like my favorite TV show). __________

i. when I have a lot of work to do. __________

j. when I haven’t reached my exercise goals. __________

k. when I don’t receive support from my family/friends. __________

l. when I have not exercised for a prolonged period of time. __________

m. when I have no one to exercise with. __________

n. when my schedule is hectic. __________

o. when my exercise workout is not enjoyable. __________
APPENDIX H

DEPRESSION COPING SELF-EFFICACY SCALE
**Depression Coping Self-Efficacy Scale**

Instructions:
The following measure describes coping activities that may be helpful in treating the symptoms of depression. Using a pen or pencil, under the column headed CONFIDENCE, mark how confident you are that you could do each activity using a number from 0 to 100. These numbers mean that you are not at all confident or sure (0%) to completely confident or sure (100%) that you can do each of these things listed. You may use any number from 0-100.

<table>
<thead>
<tr>
<th>0%</th>
<th>10%</th>
<th>20%</th>
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<tbody>
<tr>
<td>Not confident</td>
<td>Moderately confident</td>
<td>Confident</td>
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</table>

*Confidence rating 0-100%

I am ______% confident that I will be able to do the following things that may relieve or prevent the symptoms of depression:

1. tell others how I feel in a socially acceptable manner.  
2. be aware of my behavior and how it affects others.  
3. refuse requests of others when I do not wish to do something that someone else wants me to do, including authority figures and strangers.  
4. go to bed and get up at the same time every day.  
5. plan pleasant things to do for my free time.  
6. limit naps to 20-30 minutes during the day.  
7. ask for help when I am having trouble understanding something because I am not concentrating well (like income tax, legal documents, etc.).  
8. eat five servings of fruits and vegetables daily.  
9. drink 6 to 8 glasses of water daily.  
10. recognize when I am blaming myself for my symptoms and try to stop.  
11. engage in some sort of creative activity like writing, reading, drawing, playing music, or working on projects.  
12. get together with at least one very close person when I am feeling lonely.

Please continue on next page......
ID

PICK ONE OF THESE NUMBERS AND WRITE ON THE LINE NEXT TO EACH ITEM BELOW

<table>
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<tr>
<th>0%</th>
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<tr>
<td>Not confident</td>
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</table>

I am __________% confident that I will be able to do the following things that may relieve or prevent the symptoms of depression:

13. get up and do something relaxing if I cannot sleep, before trying again.
14. question whether it is reasonable to think this way each time I think about myself in a negative way or assume that I am no good.
15. take a bath or do some other soothing activity before bedtime.
16. take medication the way my doctor recommends.
17. exercise or do some active thing every day.
18. be aware of when I am thinking about myself in a negative way or assuming that I am no good.
19. laugh and try to find humor in my situation, in spite of my problems.
20. challenge the thought that suicide is the only way I can deal with my problems.
21. attempt to understand why I am anxious when I have anxiety.
22. keep a journal describing my mood or how I feel emotionally each day.
23. meditate or do relaxation exercises at least once a day.
24. become aware of those feelings that bother me so I can work on not letting them bother me.

Confidence rating: __________%
APPENDIX I

MAXIMAL EXERCISE TESTING SHEET
Maximal Exercise Testing Sheet

ID: __________

Date: __________
Time: __________

Testing Person: __________
Testing Protocol: __________

<table>
<thead>
<tr>
<th>Testing Time</th>
<th>Blood Pressure</th>
<th>RPE</th>
<th>Commomrs</th>
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APPENDIX J

SUPERVISED EXERCISE PROGRAM SHEET
<table>
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<tbody>
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<td>Treadmill</td>
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<tr>
<td>Speed</td>
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<tr>
<td>wk1</td>
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APPENDIX K

ACTIVITY DIARY
Activity Diary

Name:

Sport and Exercise Science
The School of Physical Activity & Educational Services
The Ohio State University
### Activity Diary Week:

<table>
<thead>
<tr>
<th>Date</th>
<th>Type of activity (walking, cycling, stretching, etc.)</th>
<th>Workload</th>
<th>Minutes of activity</th>
<th>Ratings of perceived exertion (RPE)</th>
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**Problems/Barriers:**

**Successes:**

---

### Activity Diary Week:

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<tr>
<th>Date</th>
<th>Type of activity (walking, cycling, stretching, etc.)</th>
<th>Workload</th>
<th>Minutes of activity</th>
<th>Ratings of perceived exertion (RPE)</th>
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<td>Sunday</td>
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**Problems/Barriers:**

**Successes:**
APPENDIX L

APPLICATION FOR INITIAL REVIEW OF HUMAN SUBJECTS RESEARCH
APPLICATION FOR INITIAL REVIEW OF HUMAN SUBJECTS RESEARCH

The Ohio State University Institutional Review Board

Office of Responsible Research Practices (ORRP)
390 Research Foundation Building, 1940 Kenny Road, Columbus, OH 43210
Phone: (614) 688-0457 Fax: (614) 688-0309 www.orrp.osu.edu

<table>
<thead>
<tr>
<th>ISCH</th>
<th>DATE RECEIVED</th>
<th>DATE VERIFIED COMPLETE</th>
<th>OSU PROTOCOL NUMBER</th>
</tr>
</thead>
</table>

1. PROJECT TITLE

Effect of exercise intensity during aerobic training on depressive symptoms in initially sedentary women with self-reported depressive symptoms.

2. INSTITUTIONAL REVIEW BOARD

Select the Board to review this research:
- Behavioral and Social Sciences
- Biomedical Sciences
- Cancer

Final Board assignment is determined by ORRP.

3. PRINCIPAL INVESTIGATOR (or Advisor) - see Qualifications for service as a PI

Name (Last, First, MD): Bukuczewska, Janet

University Academic Title: Associate Professor

Degree(s): Ph.D.

Department Name: PAES

Department #: 1270

Campus Mailing Address: PAES Building, Exercise Science A44

OSU ID Number (if applicable): 90876024

Email: bukuczewska@osu.edu

Phone: 614-292-0757

Fax: 614-688-3422

4. CO-INVESTIGATOR(S)

Are there any OSU Co-Investigators on this protocol? Yes □  No □

Are the original signatures of Co-Investigator(s) required? Yes □  No □

5. OTHER KEY PERSONNEL

Are there any OSU key personnel on this protocol? Yes □  No □

Key personnel are defined as individuals who contribute in a substantive way to the scientific development or execution of the project. At a minimum, include individuals who recruit or consent participants or who collect study data.

6. ADDITIONAL CONTACT

If further information about this application is needed, specify the contact person of other than the PI (e.g., study coordinator).

Name (Last, First, MD): Chu, Hsuan

Phone: 614-326-2467

Email: chu.151@osu.edu

Fax: 614-608-3432

7. EDUCATION

Have all OSU investigators and key personnel completed the required web-based course (CTE) in the protection of human research subjects? Yes □  No □
5. CONFLICT OF INTEREST

Does any OSU investigator (including principal or co-investigator), key personnel, or their immediate family members have a significant financial interest (e.g., speaking and consultation fees, travel expenses, proprietary interest in the initial product, stock ownership or other equity or membership in the sponsor over $50,000 per year or representing greater than 5% ownership in the sponsor) with the entity supporting the research or any company that may benefit from the research?  

☐ Yes  ☐ No

Each OSU investigator must have a current COI disclosure form filed before IRB review. See [www.osu.edu/ethics/conflict/](http://www.osu.edu/ethics/conflict/) for more information.

---

6. EXPEDITED REVIEW

Are you requesting Expedited Review?  

☐ Yes  ☐ Complete Appendix B  

☐ No

---

7. FUNDING

Is the research funded or has funding been requested?  

☐ Yes  ☐ No

If Yes, specify sponsor (e.g., Grants and Research, Graduate School, etc.) and provide OSU RFP project number and/or P200 number if applicable.

If the research is federally funded and involves a subcontract to or from another entity, an IRB Authorization Agreement may be required. Contact ORRP for more information.

---

11. OTHER INSTITUTIONAL APPROVALS

Check all that apply and provide applicable documentation.

☐ None

☐ General Clinical Research Center Advisory Committee (GCAC) – for research conducted in the General Clinical Research Center (GCRC) or with any services provided by the GCRC. Contact 203-4876 or see [www.gcrc.osu.edu](http://www.gcrc.osu.edu)

☐ Institutional Biosafety Committee (IBC) – for research involving biohazards (recombinant DNA, infectious agents, select agents, toxins), gene transfer, or xenotransplantation. Contact 688-6485 or see [www.cchmc.org/biosafety](http://www.cchmc.org/biosafety)

☐ James Cancer Center Clinical Scientific Review Committee (CSCRC) – for cancer-related research. Contact 203-4670 or see [www.cancer.osu.edu](http://www.cancer.osu.edu)

☐ Maternal-Infant Committee – for research involving pregnant women and fetuses. Contact 203-9756.

☐ Radiation Safety Committee – for research involving radioactive material or use of ionizing radiation for research purposes (e.g., X-rays, PET scans, DECA scans, and CT scans). Contact 282-1284 or see [www.osu.edu/radiation-safety](http://www.osu.edu/radiation-safety)

*IRB and GCAC review may be performed concurrently; GCAC approval must be provided to the IRB before you begin the research.

---

12. LOCATION OF THE RESEARCH

a. List the specific site(s) at which the OSU research will be conducted (include both domestic and international locations).

<table>
<thead>
<tr>
<th>Location</th>
<th>Name</th>
<th>Street Address</th>
<th>Suite</th>
<th>City, State or Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAES Building</td>
<td>360 West 17th Avenue</td>
<td>209, 207</td>
<td>Columbus, OH</td>
<td></td>
</tr>
<tr>
<td>Recreation &amp; Physical Activity Center (RPAC)</td>
<td>337 W. 17th Avenue</td>
<td>1st Floor Balcony</td>
<td>Columbus, OH</td>
<td></td>
</tr>
<tr>
<td>Recreation &amp; Physical Activity Center (RPAC)</td>
<td>227 W. 17th Avenue</td>
<td>Cardio Loft, Cardio Canyon</td>
<td>Columbus, OH</td>
<td></td>
</tr>
</tbody>
</table>

Page 2 of 16

From Date: 07/01/08
Version 1.2
3. SUMMARY OF THE RESEARCH

Summarize the proposed research using non-technical language that can be readily understood by someone outside the discipline. Explain briefly the research design, procedures to be used, risks and mitigated benefits, and the importance of the knowledge that may reasonably be expected to result. Use complete sentences (limit 350 words).

Depression is a prevalent mental disorder in U.S. Each year, approximately 10 million American adults suffer from depression. In addition to traditional pharmacological and psychosocial treatments, research has shown that exercise can decrease depressive symptoms. Unlike traditional treatments, exercise does not carry social stigma and has fewer side effects and additional health benefits. Therefore, exercise can be a more acceptable treatment for depressed individuals.

However, an optimal exercise program for treating depression has not been well established. The mechanisms that mediate the antidepressant effect of exercise also require investigation. Thus, the purpose of this study is to examine the effect of different exercise intensities during aerobic training on depressive symptoms in initially sedentary depressed women. The study will also examine the mediating effect of self-efficacy on depression. Self-efficacy refers to the belief that one possesses the necessary skills to complete a task and the confidence that the task can actually be completed with the desired outcome obtained.

Subjects will be randomized to high intensity, low intensity, or stretching exercise control group. The total training period is 16 weeks. Subjects’ depressive symptoms and self-efficacy will be measured and compared at study entry, week 3, and week 10.

The exercise training program requires an amount of weekly exercise that is recommended for healthy adults. The risks to the subjects beyond those incurred by this recommendation would come from the higher intensity program. However, the exercise training is progressive and personalized to reduce any adverse effects. Importantly, the anticipated benefits, such as decreased symptoms of depression, and physical benefits associated with regular exercise outweigh the risks. The results of this study will help to establish an optimal exercise program for treating depression, and may encourage clinical practitioners to prescribe an exercise program as an adjunct or monotherapy for depressed individuals.

4. SCIENTIFIC BACKGROUND & LITERATURE REVIEW

Summarize existing knowledge and previous work that support the expectation of obtaining useful results without undue risk to human subjects. Use complete sentences (limit 350 words).

Research has shown that involvement in structured exercise can decrease symptoms of depression (Craft & Perrin, 2004; Palszak & Schwenk, 2001). Meta-analytic studies also indicate that exercise training is as effective as antidepressant medication and psychotherapy in alleviating depressive symptoms (Craft & Landers, 1999, North, McCullagh, & Tian, 1995). Recently, Dunn et al. (2005) reported that aerobic exercise at a dose consistent with the CDC and ACHF public health recommendations (i.e., at least 30 minutes of moderate intensity physical activity on most, preferably all, days of the week) is an effective monotherapy for major depressive disorder of mild to moderate severity. In addition, when controlling for total energy expenditure, exercise frequency (i.e., either 3 or 5 times per week) did not moderate the effect of exercise on depression. These findings suggest that the determining factor for reduction of depressive symptoms is total energy expenditure rather than exercise frequency (Dunn et al. 2005).
In addition to frequency, exercise intensity is also an essential component in exercise prescriptions. Results from previous research regarding exercise intensity have been equivocal. While some studies suggested that both vigorous and moderate intensity exercise are equally effective in alleviating symptoms of depression (Craft & Landers, 1998; Craft & Perera, 2004), others reported an inverse relationship between exercise intensity and depressive symptoms (Bueno-Nadal et al., 1998; Lamminen, Halkkainen, & Ruppala, 2009). It is still unclear whether a certain exercise intensity, when controlling for total energy expenditure, is required for reduction of depressive symptoms. Additional research is needed to determine the effect of exercise intensity on depressive symptoms. The results of this study will help to establish an optimal exercise prescription for depressed population.

15. RESEARCH OBJECTIVES

List the specific scientific or scholarly aims of the research study.

Primary Aim:
To examine the effect of two different exercise intensities (high vs. low) during aerobic training on depressive symptoms in initially sedentary depressed women.

Secondary Aim:
To examine the relationship between changes in self-efficacy after exercise training and depressive symptoms.

16. RESEARCH METHODS & PROCEDURES

Identify all procedures that are to be performed solely for the research study.

Visit 1:
During this visit, the investigator will meet with the volunteer at PAES Building room A10. Study goals and procedures will be explained to the volunteer. The volunteer will not know the specific information about the study hypotheses because this information could bias the subjects' responses to the interventions. The volunteer will then fill out and sign the Consent form. After signing the Consent, the subject will fill out a health information form recording demographics and personal health information, including age, menstrual cycle pattern, pregnancy status, current medication use, current health problems, etc. The subject has to be between age 18 to 45, not currently pregnant or nursing, and have no treatment for depression or have been taking medications for more than three weeks to be eligible to enroll in this study. Subject will also fill out the 20-Item-Two Exercise Questionnaire, which assesses level of physical activity, the Beck Depression Inventory-II (BDI-II), which assesses depressive symptoms, and the Physical Activity Readiness Questionnaire (PAR-Q), which assesses physical contraindications to exercise. Subject has to have mild to moderate depressive symptoms and a sedentary lifestyle to be eligible to participate in this study. If volunteer’s responses on the BDI-II show that she might have a severe form of depression, she will be referred to a mental health professional that day. She will not be eligible to participate in this study unless she has written permission to take part in this study from her physician or other health care professional (e.g., psychologist). If volunteer’s responses on item #9 on the BDI-II with a score of 2 or 3 (2-1 would like to kill myself: 3-1 would kill myself if I had a chance), the volunteer will be immediately referred to their current therapist or another mental health profession and the volunteer will not be eligible to participate in this study. If the volunteer is a student at The Ohio State University (OSU), she will be referred to the Student Health Services at the Office Student Health Center (Phone number 614-292-4311 and e-mail shs@osu.edu) or the OSU Counseling and Consultation Service (CCS) at the Otis Towers Center (Phone number 614-292-5700). Otherwise, the volunteer will be referred to the OSU Harding Hospital (Phone number 614-292-9600). If the volunteer answers yes to one or more questions in PAR-Q, which indicates that she may have contraindications to begin exercise, she will be referred to her doctor for medical clearance before she can enroll in this study.

After completing the questionnaires, the subject’s weight and height will be measured to calculate her Body Mass Index (BMI). The subject will be asked to remove her shoes and her height will be measured using a medical height measuring scale to the nearest quarter inch. Her weight will be measured on a medical weighing scale in the nearest half pound. The sum of the subject’s height and weight will then be converted to meter and kilogram, respectively. The BMI will be calculated by dividing body weight in kilograms by height in meters squared (kg/m^2). Subject’s BMI has to be between 18.5 and 35 to be eligible to participate in this study. If the subject is eligible for the study, the investigator will schedule her second visit for additional tests within the next two weeks. Before the second visit, the investigator will randomly assign the subject to one of the three groups (i.e., high intensity exercise, low intensity exercise, stretching exercise control group). The subject will be informed of her group assignment after she completes all the tests during visit 1.

Visit 2:
During the second visit, subject will fill out the Exercise Self-Efficacy Questionnaire and the the Depression Coping Self-Efficacy Scale (DCSES). Next, the procedures of the maximal exercise test will be explained to the subject. Subject will be instructed to wear a heart rate
monitor and a mouth piece which will be connected to a Cardio Q 2 Minivacuole Cart used to calculate oxygen consumption. The Balance tread mill protocol will be used to estimate the maximal aerobic capacity (VO2 max). The treadmill will be started at a speed of 3.0 mph and 0% grade and subject will begin to walk on the treadmill. The speed will stay the same at 3.0 mph throughout the test. The inclination of the treadmill will be increased by 2.5% after the first 3 minutes and every 3 minutes thereafter. Heart rate and blood pressure will be measured prior to the test, during each stage of the exercise testing protocol (i.e., every 3 minutes), at the termination of the test, and at 5-minute intervals during the recovery period. The rating of perceived exertion (RPE) will be recorded during each stage of the exercise testing protocol. Subject will be instructed to perform to her best of her ability. The test will be terminated when subject reaches additional fatigue and signals the investigator by placing both hands on the rails of the treadmill. The 5-minute recovery period will then begin with subject walking at 2 mph and 0% grade and will continue until heart rate and blood pressure stabilizes. After the exercise test, the investigator will inform the subject of her group assignment and discuss with the subject about her exercise training program. The investigator will answer any questions the subject might have and schedule a date within the next two weeks to begin the training program.

Visit 3 (week 3):

The exercise training program will begin at visit 3. For the two aerobic exercise groups (i.e., high and low intensity exercise), subjects will meet with the investigator once a week in a group of three to five for a 30 to 60 minutes supervised exercise session. Subjects will also be instructed to exercise by themselves three to four times during the rest of the week. Subjects will keep an activity diary recording the date, time, intensity, and duration of the exercise, and RPE during exercise. Subjects will be instructed to bring their activity diary to each supervised session. The investigator will review the diary weekly during the supervised exercise session to make sure that subjects meet the goal of energy expenditure (i.e., 1000 kcal/week) and exercise at the prescribed intensity.

For the aerobic exercise groups, during Visit 3, the investigator will give the subjects an activity record booklet and instruct the subjects to keep an activity diary using the booklet. The investigator will show the subject how to adjust the speed and inclination of a treadmill. The subjects will be informed of their prescribed exercise workload (i.e., the speed and the inclination of the treadmill) at each session. For both high and low intensity exercise groups, the exercise intensity will begin at 40-55% oxygen uptake reserve (VO2r). The subjects will be informed that the energy expenditure goal of each session is 300 kcal. Before the treadmill exercise, subjects will be instructed to do a 5-minute gentle stretching. Next, subjects will walk on the treadmill for a 5-minute warm-up at a speed of 2.0 mph with 0% grade. After warm-up, the investigator will help the subjects to adjust the treadmill speed and inclination to their prescribed workload.

The investigator will calculate the minute energy expenditure based on the prescribed workload to determine how long the subjects should exercise on the treadmill to expend 200 kcal. After achieving the energy expenditure goal, the subject will begin to cool down for 5 minutes by walking at 1.5-2 mph with 0% grade. At the conclusion of the exercise session, the subjects will record the type, intensity (i.e., speed and inclination of the treadmill), and duration of exercise, and their RPE during exercise on the activity diary. The investigator will then work with the subjects to plan their unsupervised exercise sessions. The investigator will consider the subjects’ daily schedule and accessibility to exercise facilities to help them find the type of exercise they can do and the time and location to do the exercise. The investigator will prescribe a specific exercise workload (i.e., speed and inclination of the treadmill, walk of the stationary bike) to the subjects for their unsupervised exercise sessions. At the end of the supervised exercise session, the investigator will confirm the date for the next supervised exercise session and remind the subjects to exercise three to four times on their own during the week and keep an activity diary.

The stretching exercise control group will also meet with the investigator once a week in a group of three to five for a 30-minute supervised exercise session. The investigator will give the subjects an activity record booklet and instruct the subjects to keep an activity diary using the booklet. Before starting the exercise session, the investigator will inform the subject of the specific exercise workload (i.e., speed and inclination of the treadmill, walk of the stationary bike) to the subjects for their unsupervised exercise sessions. At the end of the supervised exercise session, the investigator will confirm the date for the next supervised exercise session and remind the subjects to keep an activity diary.

Visit 4 (week 4 & 5):

For the aerobic exercise groups, at the beginning of each visit, the investigator will review the activity diary and calculate weekly energy expenditure to confirm whether the subjects expend 1600 kcal per week. The subjects will begin to exercise with 5-minute stretching, followed by 5-minute warm-up, 30-40 minutes training period (depending on individual minute energy expenditure), and 5-minute cool-down. For both high and low intensity exercise groups, the energy intensity is set at 40-55% oxygen uptake reserve (VO2r). All subjects will exercise to expend 300 kcal during the supervised session. At the conclusion of the training session, the subjects will record the type, intensity, and duration of exercise, and RPE during exercise on the activity diary. The investigator will check with the subjects on their unsupervised exercise sessions and help them adjust their exercise plan to fit into their schedule. At the end of the session, the investigator will confirm the date for the next supervised session and remind the subjects to exercise three to four times on their own during the week and keep an activity diary.

For the stretching exercise control group, subjects will be instructed to do a 30-minute stretching exercise. The investigator will review the activity diary to monitor subjects’ level of physical activity. At the conclusion of the exercise session, the investigator will...
confirms the date for the next supervised session and reminds the subjects to keep an activity diary.

Visit 6 (week 4-10):
For the aerobic exercise groups, at the beginning of each visit, the investigator will review the activity diary and calculate weekly energy expenditure to confirm whether the subject expended 1000 kcal per week. The exercise intensity for the high intensity group will be increased to 60-70% oxygen uptake reserve (VO2R) beginning Visit 6. The intensity for the low intensity group will remain the same (i.e., 45-59% oxygen uptake reserve (VO2R)). The subjects will begin to exercise with 5-minute stretching, followed by 5-minute warm-up, 30-40 minute training period (depending on individual minute energy expenditure), and 5-minute cool-down. All subjects will exercise to expend 300 kcal during the supervised session. At the conclusion of the training session, the subjects will record their type, intensity, and duration of exercise, and RPE during exercise on the activity diary. The investigator will check with the subjects on their unsupervised exercise sessions and help them adjust their exercise plan to fit into their schedule. At the end of the session, the investigator will confirm the data for the next supervised session and remind the subjects to exercise three to four times on their own during the week and keep an activity diary.

For the stretching exercise control group, subjects will be instructed to do a 30-minute stretching exercise. The investigator will review the activity diary to monitor subjects’ level of physical activity. At the conclusion of the exercise session, the investigator will confirm the date for the next supervised session and remind the subjects to keep an activity diary.

Visit 7 (week 5):
During visit 7, the investigator will perform a mid-point measurement. All subjects will be instructed to come to the supervised session 30 minutes earlier to fill out the questionnaire, including the BDI-II, exercise self-efficacy questionnaire, and OCQES. If subject’s responses to item #1 on the BDI-II with a score of 2 or 3 (I would like to kill myself), and #1 on the OCQES will be immediately referred to her current therapist or another mental health profession. After completing the questionnaires, the subjects will receive tax dollars and begin their usual training session.

Visit 8 (week 10):
Visit 8 is the last supervised training session of the 16-week exercise training program. At the end of this session, the investigator will schedule an appointment with the subjects within the next week for post-test questionnaires and maximal exercise testing. The investigator will remind the subjects to bring their activity diary to the scheduled appointment.

Visit 9 (week 15 post-test):
During visit 9, the investigator will collect the activity diary from the subject. The subject will be instructed to fill out several questionnaires, including BDI-II, exercise self-efficacy questionnaire, OCQES, and Godin-Learner Time Exercise Questionnaire. If subject’s responses to item #1 on the BDI-II with a score of 2 or 3 (I would like to kill myself), and #1 on the OCQES will be immediately referred to her current therapist or another mental health profession. After completing the questionnaires, the subject will do a maximal exercise test. At the conclusion of the exercise test, the investigator will congratulate the subject for successfully completing the training program and the subject will receive twenty dollars. The investigator will provide a personalized exercise prescription to the subject and encourage the subject to continue to exercise regularly. Subjects in the stretching exercise control group will be given a chance to participate in an exercise training program provided by the investigator after the conclusion of the study.

b. Check all research procedures that apply:
- Anesthesia (general or local) or sedation
- Audio, video, digital, or image recordings
- Blood samples
- Biological samples (other than blood)
- Blood drawing
- Coordination center
- Data, not publicly available
- Data, publicly available
- Materials that may be considered sensitive, offensive, threatening, or degrading
- Medical examination
- Non-invasive medical procedures (e.g., EKG, Doppler)
- Oral history (does not include medical history)
- Placebo
- Observation of participants (including field notes)
- Pregnancy testing
- Questionnaire protocol (Umbrella Protocol)
- Radiotopes or other sources of ionizing radiation

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The Ohio State University Institutional Review Board - APPLICATION FOR INITIAL REVIEW OF HUMAN SUBJECTS RESEARCH

- Data repositories - Complete Appendix C
- Deception - Complete Appendix D - Appendix M
- Devices - Complete Appendix F
- Dorsal, axillary, or sleep modifications
- Emergency research
- Focus groups
- Food supplements
- Gait transfer
- Genetic testing - Complete Appendix G
- Internet or e-mail data collection
- Magnetic resonance imaging (MRI)
- Radioactive materials (requires approval from Radiation Safety Committee)
- Randomization
- Record review (which may include PHI)
- Stem cell research
- Storage of biological materials - Complete Appendix H
- Surgical procedures (including biopsies)
- Surveys, questionnaires, or interviews (one-on-one)
- Surveys, questionnaires, or interviews (group)
- X-rays or mammograms
- Other

Specify: Self-monitoring (exercise)

17. DURATION

Estimate the time required from each participant, including long-term follow-up, if any. Describe the time commitment in detail.

Visit 1:
- It will take about 60 minutes for the subject to go through the orientation of the study and complete the questionnaires. If the subject is eligible for the study, the investigator will schedule the second visit within the next two weeks.

Visit 2:
- Subject will fill out two other questionnaires and then participate in an exercise test on a treadmill. These processes will take about 40 to 50 minutes.

Visit 3 to 12:
- Subject will participate in a 10-week exercise training program. Each week, subject will have a 30 to 40 minutes supervised exercise session. Subjects in the high and low intensity exercise groups will also exercise three to four times by themselves during the rest of the week. The total time spent exercising each week will be between two and three hours.

Visit 7:
- Subject will be instructed to come in the supervised session 30 minutes earlier to fill out several questionnaires (mid-point measurements of depressive symptoms and self-efficacy). After completing the questionnaires, subject will begin the usual training session (30 to 40 minutes).

Visit 13:
- Subject will be instructed to fill out several questionnaires for post-test measurements. After completing the questionnaires, subject will participate in an exercise test on a treadmill. These processes will take about 70 minutes.

The total time commitment for the subjects in exercise will be 5-7 hours in supervised exercise and 15-27 hours in unsupervised exercise over a 16-week training period. Including the time spent in assessment (2 hours 20-30 minutes), the total time commitment for the subjects will be 23 hours 20 minutes to 37 hours 30 minutes.

18. NUMBER OF PARTICIPANTS

a. Provide the maximum number of participants (or number of participant records, specimens, etc.) for whom you are seeking OHSR approval.

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not complete the study.

b. Explain how this number was derived.

The sample size needed for this study was calculated in consultation with the OSU Statistics Department, and is based on the results of the previous meta-analysis. The calculated total sample size is 42 (i.e., 14 subjects in each group) with an effect size of 0.5, an alpha level of 0.05, and a power of 0.80. Based on previous exercise training studies with depressed subjects, attrition is expected to be...
10. PARTICIPANT POPULATION

a. Specify the age(s) of the individuals who may participate in the research:
   Age(s): 18-65

b. Specify the population(s) to be included (check all that apply):
   - Adults
   - Pregnant Women/Furthers/Nurses
   - Complete Appendix L
   - Parolees
   - Complete Appendix L
   - Psychology Research Education Program (REP)
   - Specify participant pool (other than REP)
   - Students
   - Complete Appendix L
   - Specify
   - Unrestrained (e.g., research using secondary data/specimens, non-targeted surveys, program protocols)

c. Describe the characteristics of the population(s) and explain how the nature of the research requires/justifies inclusion of the proposed population(s):

   All subjects will be volunteers and have the following characteristics:
   - Female
   - Aged 18-65 years old
   - Will to moderate depressive symptoms defined as a score of 14-24 on Beck Depression Inventory-II (BDI-II)
   - Severe depressive symptoms (a score above 28 on BDI-I) with a physician or health care professional’s permission to participate in the study
   - Regular menstrual cycle during the previous 8 months
   - Body mass index (BMI) between 18.5 and 25
   - Sedentariness (exercise < 3 times per week, < 20 minutes per session)
   - Energy expenditure from exercise that is less than 300 kcal per week
   - Not taking medications for depression or has been taking medication for more than 3 weeks
   - No psychotherapy or other therapies, except for medication, for treating depression (if the subject is on medication for depression, she has to have been taking the medication for more than 3 weeks to be eligible for the study)
   - Not currently pregnant or nursing and no plan for pregnancy during the following 6 months
   - No physical contraindications to exercise (e.g., orthopedic problems, heart disease). Subjects have to pass the PAR-Q criteria before they can participate in an exercise training program.

   These conditions are set to ensure the selection of a sample from the population most affected by depressive symptoms. These conditions also ensure that subjects can participate in a 10-week exercise training program.

d. If pregnant women are to be included, explain how the nature of the research requires/justifies their inclusion. Address means of pregnancy screening.

   Pregnant women are excluded because the study involves exercising at high intensity which is not recommended during pregnancy. Also, hormonal changes during pregnancy may be a confounding factor.

   Pregnancy screening for all potential subjects will be addressed in the medical history form. If unsure of the pregnancy status, the subject will be asked to complete a commercial urine pregnancy test provided by the investigator.

20. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

a. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.).

   Explain how the method(s) for identifying potential participants respects their privacy.
All subjects will be volunteers recruited through area physicians’ referrals, posted flyers, and word of mouth. Subjects will also be recruited from academic classes upon instructor’s approval. Interested individuals will e-mail or call the co-investigator. All information and communication with potential subjects will be held confidential.

b. State (who/what key personnel will recruit participants and what process will be used to determine participant eligibility).

Hua Chu (co-investigator) will be responsible for the recruitment of subjects. Recruitment materials will state the inclusion and exclusion criteria, which will be repeated by Ms. Chu during initial phone or verbal inquiries. Participant eligibility will be determined after completion of the informed consent process. Eligibility will be assessed through responses of all potential subjects to questions in the medical history form and through responses to the “Godin Leisure-Time Exercise Questionnaire.”

The severity of depression will be measured using The Beck Depression Inventory-II (BDI-II). Only subjects with BDI-II scores between 14 and 29 will be included in the study. The score guidelines are as follows: 0-13 minimal; 14-19 mild; 20-28 moderate; 29-63 severe depression (BDI Manual, 1996). If volunteer’s responses on the BDI-II show that she has a severe form of depression, she will not be eligible to participate in this study unless she has written permission to take part in this study from her physician or other health care professional (e.g., psychologist). It is agreed that potential subjects who respond to item 9 on the BDI-II with a score of 2 or 3 (I would like to kill myself; I would kill my self if I had a chance) would be immediately referred to their current therapist or another mental health professional.

Potential subjects will have a body mass index (BMI) between 18.5 and 35. BMI will be calculated by dividing weight in kilograms by height in meters squared (McNeele et al., 2001). All subjects should have a sedentary lifestyle. This will be determined by responses to “Godin Leisure-Time Exercise Questionnaire.” Subjects should exercise less than 3 times per week, for less than 20 minutes per session. Subjects weekly energy expenditure from exercise should be less than 500 kcal. This will be estimated from the responses to “Godin Leisure-Time Exercise Questionnaire” using reports of typical weekly exercise intensity and duration. Exercise intensity will be used to calculate minute energy expenditure using the following formula: (METs (exercise intensity) x 3.5 x body weight in kg x 200 = kcal). The result of this calculation will be multiplied by the duration (in minutes) of exercise per week to calculate the weekly energy expenditure from exercise.

All subjects should report that they are not currently pregnant or nursing, or planning to become pregnant during the next six months, are not receiving treatment or have been taking more than 3 weeks of medication for their depression, and do not have physical contraindications to exercise (e.g., orthopedic problems, heart disease, assessed through the PAR-Q, a standard screening form used in exercise setting).

c. Describe the recruitment process, including how and where recruitment will take place. (Attach copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, and written scripts).)

The recruitment will be done through area physician referrals, posted flyers, and word of mouth. We will also recruit subjects from academic classes upon instructor’s approval. The physician in the Wise Student Health Center will be informed of the current study and be encouraged to refer potential subjects to participate in this study. Flyers will be posted in various locations on the OSU campus, including Wise Student Health Center and Counseling and Consultation Service located in the Yankin Student Center of OSU. The posting of the flyers will have to be approved by each department.

Please refer to the Appendix C and D for the proposed recruitment flyer and oral script.

d. Explain how you will assure that recruitment and selection of participants is equitable.

Subjects are volunteers with the following characteristics:

1. Female
2. Age 18-40
3. Mild to moderate depressive symptoms
4. Severe depressive symptoms with a physician or health care professional’s permission to participate in the study
5. Sedentary
6. 18.5 < BMI < 35
7. If using medications for depression, subjects should have been taking the medications for more than three weeks
8. No physical contraindications to exercise (e.g., orthopedic problems, heart disease)

The above criteria describe the population most affected by depressive symptoms. We restricted the study to these characteristics for homogeneity.
21. INCENTIVES TO PARTICIPATE
Will participants receive compensation or other inducements (e.g., free services, cash payments, gift certificates, parking, classroom credit, novel remuneration) to participate in the research study?
Yes ☐ No ☐

If Yes ☐ Describe the inducement. Compensation should be presented e.g., per visit and not contingent upon study completion. The subject will receive ten dollars when she completes the mid-point measurements at week five and twenty dollars when she completes the post-test measurements.

22. INFORMED CONSENT PROCESS
a. Indicate the consent process(es) to be used in the study. Check all that apply. Provide copies of documents (using OSU templates) and/or complete relevant appendices, as needed. See http://www.orhp.hhs.gov/humansubjects/consent.htm or contact ORHP for more information.

☐ Informed Consent Document☐ Parental Permission Form
☐ Informed Consent – Addendum☐ Waiver or Alteration of Consent Process Complete Appendix M1
☐ Assent Form☐ Waiver of Documentation of Consent Complete Appendix M1
☐ Verbal Consent/Assent (script)☐ Translated Consent/Assent Document(s)

b. Describe the consent process. Explain when and where consent will be obtained and how participants and/or their legally authorized representatives will be provided sufficient opportunity to consider participation.

Participation in this study will be on a voluntary basis. An informed consent detailing both the risks and benefits of this study will be administered to all potential subjects prior to any testing or data collection. Subjects will be administered the consent form during the first visit and then the second visit will be scheduled within 1 week. Subjects will be given the consent form in a private room in FHES Building, where the subject will read and sign the consent form, and have opportunities to ask the investigator questions.

☐ N/A
c. List the investigator(s) and/or key personnel who will obtain consent from participants or their legally authorized representatives.

Hua Chu (co-investigator)

☐ N/A
d. Explain how the possibility of coercion or undue influence will be minimized in the consent process.

Volunteer subjects will be individually administered the same consent process, by the same person. All questions and concerns raised by the subjects will be answered prior to the subjects administering their consent. There will be no attempt to persuade subjects who do not wish to participate in the study.

☐ N/A

23. CAPACITY TO CONSENT
Will adult participants with limited decision-making capacity or who lack the ability to consent be recruited in this research study?
Yes ☐ No ☐

If Yes ☐ Describe the likely range of participant impairment and explain how, and by whom, the capacity to consent/assent will be determined. For adults unable to provide legally effective informed consent, indicate whether assent will be obtained. If not, explain why not.
24. PRIVACY & CONFIDENTIALITY

a. Does the research require access to personally identifiable private information?  
☐ Yes  ☐ No

If Yes → Describe the steps you will take to ensure protection of the participants' privacy.

b. Will personal or sensitive information (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) be acquired or collected from participants?  
☐ Yes  ☐ No

If Yes → Describe information.

Information related to mental health - depressive symptoms

c. Could disclosure of information be potentially damaging to participants' financial standing, employability or reputation, or place the participants at risk of criminal or civil liability?  
☐ Yes  ☐ No

If Yes → Explain:

Disclosure of depressive symptoms could damage the participants' employability or reputation because unfortunately, prejudice against mental health problems still exists in our society.

d. Explain how you will protect the confidentiality of identifiable data, including where data will be stored, what security measures will be applied, and who will have access to the data.

Procedures to ensure confidentiality:
- All collected data will be safely secured in a locked filing cabinet, accessible only to individuals involved in the study with a key to the filing drawer.
- To further ensure confidentiality and to provide identity safeguards, all subjects will be assigned an identification number. Any and all the data collected will be filed and analyzed according to this number. Only the primary investigator and the co-investigator will have access to the subject’s name and corresponding number assignment, which will be kept separate for study data.
- The identity records will be destroyed following data analysis.
- Publications from this study will not include the name or reveal identity in any other way.

e. Will you be obtaining a NIH Certificate of Confidentiality?  
☐ Yes → Provide a copy before you begin the research.  
See http://grants2.nih.gov/grants/guide/accredit.html  ☐ No

f. Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality.  
☐ NA

g. Indicate what will happen to the identifiable data at the end of the study. Check all that apply:
- Identifiers secured or permanently removed from the data
- Identifiable/confidential data is retained
- Other, specify:
- NA

h. Indicate how study results might be disseminated. Check all that apply:
- Conference/Presentation
- Dissertation/Thesis
28. HIPAA RESEARCH AUTHORIZATION

Will individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements (HHS, 45 CFR Parts 160 and 164) be accessed, used, or disclosed in the research study?  
☐ Yes  ☐ No  Go to Question #26

If Yes  ☑️ Will a written authorization be used?

☐ Yes  ☑️ Provide a copy of the authorization form.

a. Describe the PHI involved in the research (e.g., demographic information, health history, diagnosis, test results). Be as specific as possible. Provide a copy of the data collection forms to be used.

b. List the source(s) of the PHI (e.g., OSUMC Information Warehouse, physician’s own records, etc.), including whether any information will be obtained from sources external to OSU.

☐ No  ☑️ Indicate the type of waiver or alteration requested (check all that apply) and complete Appendix N.

☐ Partial Waiver (recruitment purposes only)
☐ Full Waiver (entire research study)
☐ Alteration (written documentation)

29. RISKS, HAZARDS, & DISCOMFORTS

a. Indicate all risks/benefits/discomforts that may apply to the research study:

☐ Breach of confidentiality  ☑️ Psychological stress
☐ Discovery of previously unknown condition  ☑️ Risk to reputation
☐ Economic risk  ☑️ Social or legal risk
☐ Invasion of privacy (participants or other individuals)  ☑️ Other:
☐ Physical injury or discomfort  ☑️ Specify:

b. For each category of risk checked above, describe the specific risk. For physical injury or discomfort include the following:

- Fragility/Likelihood of occurrence
- Potential severity of the harm/discomfort
- Possible consequences (including long-term effects)

Reference the section of this application (e.g., Appendix F for drugs) if the risks are described elsewhere.

Risk: Breach of confidentiality

Likelihood of occurrence: Very unlikely

Potential severity of harm/discomfort: Psychological distress from breach of confidentiality could be mild to moderate depending on the subject and the information revealed.

Possible long-term consequences are minimal considering the general nature of the information being gathered in this study.

Risk: Psychological stress

Likelihood of occurrence: Very unlikely

Potential severity of harm/discomfort: Psychological stress from answering the questionnaires could be mild to moderate depending on the subject and information asked.
Possible long-term consequences are minimal considering the general nature of the information being gathered in this study.

Risk: Physical injury or discomfort.
Frequency of occurrence: Several times during the first few weeks of exercise training.
Potential severity of harm/discomfort: Muscle soreness from unaccustomed physical activity may occur during the first 2 to 3 weeks of the training period. This discomfort usually goes away as our body adapts to the training regime. There are no long-term consequences.

c. Describe the specific protections that will be used to minimize the identified risks and harms.

Protection for breach of confidentiality. All collected data will be safely secured in a locked filing cabinet, accessible only to individuals involved in the study with a key to the filing drawer. To further prevent breach of confidentiality and to provide identity safeguards, all subjects will be assigned a number. Any and all data collected will be filed and analyzed according to this number. Only the primary investigator and the co-investigator will have access to the subject's name and corresponding number assignment, which prevents individuals not associated with the study from being able to associate data with a subject. In addition, all identity records will be destroyed following data analysis and publications from this study will not include names or reveal identity in any other way.

Protection for risk of psychological stress from completing the questionnaires. All subjects will complete questionnaires on a voluntary basis. The investigator will emphasize instructions that the subject will not have to answer questions she is not comfortable answering, and can discontinue participation at any time.

Protection for physical injury or discomfort: Proper warm-up and cool-down exercise will be instructed. Also, the training program will begin with low intensity walking exercise to help subjects slowly build up their physical conditions and reduce the occurrence and severity of muscle soreness.

27. MONITORING

Does the research involve greater than minimal risk (i.e., are the harms or discomforts described in Question 26 beyond what is ordinarily encountered in daily life or during the performance of routine physical or psychological tests)?

☐ Yes
☐ No

If Yes: Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. Include the following:

- The information that will be evaluated (e.g., incidence and severity of adverse events compared to those expected);
- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee);
- Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled, etc.),
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early if unanticipated problems).
The potential benefits of this study significantly outweigh the risks associated with this investigation. The risk of the maximal oxygen consumption test and aerobic exercise training is considered minimal. The investigator’s experience, the subject’s age, and the non-invasive nature of each procedure reduce the chance that adverse effects and incidents will occur. Exercise has been shown to be as effective as antidepressant medications and psychotherapy in treating depression. However, an optimal exercise prescription for depressed populations has not been well established. Determining the intensity that provides most psychological benefits (lower depressive symptoms) could lead to a better understanding of how to prescribe exercise for this population.

30. ALTERNATIVES TO STUDY PARTICIPATION

Other than choosing not to participate, list any specific alternative procedures or treatments available that may be advantageous to the participant.

NA

31. PARTICIPANT COSTS/REIMBURSEMENTS

a. List any potential costs participants (or their insurers) will incur as a result of study participation (e.g., parking, study drugs, diagnostic tests, etc.).

There will be no additional cost to subjects for participating in the study.

b. List any costs to participants that will be covered by the research study.

There will be no costs to participants covered by the research study itself.
32. APPLICATION CONTENTS

Indicate what documents are being submitted for this research project. Check all appropriate boxes and provide the version number and date, if available.

☒ Application for Initial Review of Human Subjects Research
☒ Appendix A1: Co-Investigators (question 4)
☐ Appendix A2: Key Personnel (question 5)
☒ Appendix B: Expedited Review - Initial Review (question 9)
☐ Appendix C: Data Repositories (question 16b)
☐ Appendix D: Deception (question 16b)
☐ Appendix E: Devices (question 16b)
☐ Appendix F: Drugs or Biologics (question 16b)
☐ Appendix G: Genetic Testing (question 16b)
☐ Appendix H: Storage of Biological Materials (question 16b)
☐ Appendix I: Children (question 16b)
☐ Appendix J: Non-English Speaking Participants (question 16b)
☐ Appendix K: Pregnant Women/Fetuses/Neonates (question 16b)
☐ Appendix L: Prisoners (question 16b)
☐ Appendix M1: Waiver or Alteration of Consent Process (questions 16b & 22a)
☐ Appendix M2: Waiver of Documentation of Consent (question 22a)
☐ Appendix N: Waiver of HIPAA Research Authorization (question 25)
☐ Research Protocol (required)
☐ Grant Application (required for all sponsored projects not part of a cooperative group)
☐ NIH-funded Protocol (required for NIH-funded multicenter clinical trials)
☐ NIH-funded Consent Form (required for NIH-funded multicenter clinical trials)
☐ Consent Form(s), Assent Form(s), Parental Permission Form(s), Translated Consent/Assent Form(s), Verbal Consent/Assent Script(s) (question 22a)
☐ Supplemental Consent Form(s), Consent Tool(s) (question 22a, I)
☐ HIPAA Research Authorization Form (question 25)
☐ Recruitment Materials (e.g., ads, flyers, TV/video scripts, internet solicitations) (question 26c)
☐ Script(s) or Information Sheet(s), including Delivering Materials (question 10b)
☐ Test Instruments (e.g., questionnaires to be completed by participants) (question 10b)
☐ Data Collection Form(s) involving PHI (question 25)
☐ Device Manufacturer’s Approved Labeling (Appendix E)
☐ Drug Manufacturer’s Approved Labeling/Investigator’s Drug Brochure (Appendix F)
☐ Other Committee Approvals/Letters of Support (questions 11 & 12)
☒ Other

Specify: Activity diary
AX. ASSURANCE

PRINCIPAL INVESTIGATOR (or Advisor):

I agree to follow all applicable policies and procedures of The Ohio State University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as with professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to, the following:

- The research will be performed as approved by the IRB under the direction of the Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources;
- The research will not be initiated until written notification of IRB approval has been received;
- Informed consent and HIPAA research authorization (from human subjects or their legally authorized representatives) will be obtained and documented (unless waived) prior to their involvement in the research using the currently IRB-approved consent form(s) and process;
- Serious, unexpected and related adverse events, unanticipated adverse device effects, and unanticipated problems involving risks to participants or others will be promptly reported to the IRB, as well as any other information necessary for appropriate oversight of the research;
- Significant new findings that develop during the course of the study that may affect the risks or benefits of participation will be reported;
- The IRB will be informed of any proposed changes in the research or informed consent process before changes are implemented, and no changes will be made until approved by the OSG IRB (except where necessary to eliminate apparent immediate risk to participants);
- An Application for Continuing Review of Human Subjects Research will be completed and submitted before the deadline for review at intervals determined by the IRB to be appropriate to the degree of risk (but not less than once per year) to avoid expiration of IRB approval and cessation of all research activities;
- Research-related records (and source documents) will be maintained in a manner that documents the validity of the research and integrity of the data collected while protecting the confidentiality of the data and privacy of participants;
- Research-related records will be retained and available for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the University;
- The Office of Responsible Research Practices will be contacted for assistance in amending (to request a change in Principal Investigator) or terminating the research if I leave the University or am unworkable to conduct or supervise the research personally (e.g., sabbatical or extended leave);
- A Final Study Report will be provided to the IRB when all research activities have ended (including data analysis with individually identifiable or coded private information); and
- All Co-investigators, research staff, employees, and students assisting in the conduct of the research will be informed of their obligations in carrying out the above commitments.

I verify that the information provided in this Application for Initial Review of Human Subjects Research is accurate and complete.

[Signature of Principal Investigator (or Advisor)]

[Date]

[Name]

[Title]

[Department]

DEPARTMENT CHAIR

As Department Chair (or Signatory Officer) for the Principal Investigator, I acknowledge that this research is in keeping with the standards set by our unit and that it has met all Department/College/University requirements for review.

If the PI is not a Co-Investigator and is also the Department Chair, the signature of the Dean or other appropriate Signatory Officer, such as the Associate Dean for Research, must be obtained.

[Signature of Department Chair]

[Date]

[Name]

[Title]
APPENDIX M

THE OHIO STATE UNIVERSITY CONSENT TO PARTICIPATE IN RESEARCH
The Ohio State University Consent to Participate in Research

Study Title: Effect of exercise intensity during aerobic training on depressive symptoms in initially sedentary women with self-reported depressive symptoms.

Principal Investigator: Janet Backworth

Sponsor: Alumni Grants for Graduate Research and Scholarship

1. This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

2. Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

3. You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

4. You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

The purpose of this study is to better understand the psychological responses to exercise in women with self-reported depressive symptoms. You will not know specifically any differences we expect between the groups until the study is over to keep from influencing the results.

2. How many people will take part in this study?

The approximate number of people who will take part in this study is 54.
3. What will happen if I take part in this study?

Visit 1:
During this visit, the goals and procedures involved in participating in this study will be explained. Your height and weight will be measured to calculate your body mass index (BMI). You will fill out questionnaires about your personal characteristics, age and education, your normal level of physical activity (Godin Leisure-Time Exercise Questionnaire) and level of symptoms of depression (Beck Depression Inventory-II). You have to have mild to moderate depressive symptoms and a sedentary lifestyle to be eligible for this study, and receive no treatment for depression except for medication that you have been taking for more than three weeks. You will also fill out the Physical Activity Readiness Questionnaire (PAR-Q), which assesses some physical reasons that exercise would not be recommended. If you have physical reasons that mean you should be cautious about starting regular exercise, you will be referred to your doctor for medical clearance before you can participate in this study. If you are currently pregnant or nursing you will not be eligible to participate in the study. If your responses to the questions about level of depressive symptoms show that you might have a severe form of depression, we will let you know and refer you to a mental health professional that day. You will not be eligible to participate in this study unless you have written permission to take part in this study from your physician or other health care professional (e.g. psychologist). If you are a student at the Ohio State University (OSU), you will be referred to the Student Health Services at the Wilke Student Health Center (Phone number 614-292-4321 and e-mail shs@osu.edu) or the OSU Counseling and Consultation Service (CCS) at the Yountin Success Center (Phone number 614-292-5766). Otherwise, you will be referred to the OSU Harding Hospital (Phone number 614-292-5600). If you are eligible for the study, we will schedule your second visit for additional tests.

Visit 2:
During this visit, you will fill out another two questionnaires, which assess your exercise self-efficacy and depression coping self-efficacy. Exercise self-efficacy refers to your confidence to exercise in different conditions, such as when you are tired, or when the weather is bad. Depression coping self-efficacy refers to your confidence to do something to help you cope with your depressive symptoms, for example, creative activities like writing. After you fill out the questionnaires your aerobic capacity will be estimated from an exercise test on a treadmill. The treadmill will be started at a speed of 3.0 mph and 0% grade and you will begin to walk on the treadmill. The speed will stay the same at 3.0 mph throughout the test. The inclination of the treadmill will be increased by 2.5% after the first 3 minutes and every 3 minutes thereafter. At the end of each stage, your heart rate and blood pressure will be recorded and you will be asked to say how hard you feel that you are working. You will be instructed to perform to the best of your ability. If you feel that you are exercising as much as you can or need to stop, you can signal the investigator to stop the test. If you can maintain your exercise, you will be assigned to one of the three exercise groups by chance: high intensity aerobic exercise group, low intensity aerobic exercise group, or stretching exercise group. The
investigator will discuss with you about your exercise training program and schedule a
date within the next two weeks to begin the training program.

Visit 3-12:
From visit 3 to 12, you will participate in an exercise training program. You will meet
with the investigator once a week for a supervised training session. During the supervised
session, you will learn how to properly warm up and cool down. After you warm up, you
will begin to exercise on a treadmill at an intensity and duration prescribed by the
investigator. If you are assigned to the stretching exercise group, you will be instructed to
do a 30 minutes stretching exercise with the investigator. During the rest of the week, you
will be instructed to exercise three to four times by yourself if you are in one of the two
aerobic exercise groups. An exercise prescription will be provided for you. Regardless of
your assigned group, you will keep a record of all your exercise sessions and bring your
activity diary to the supervised training session for weekly review.
During visit 7, a mid-polar measurement will be performed. You will be instructed to
come to the supervised session 30 minutes earlier to fill out the questionnaires, which
assess your level of symptoms of depression and self-efficacy. After completing the
questionnaires, you will begin your usual training regime.

Visit 13:
During this visit, you will turn in your activity diary and similar tests as visit 1 and 2 will
be performed. You will be instructed to fill our several questionnaires, which assess your
level of physical activity, level of symptoms of depression, and self-efficacy. After
completing the questionnaires, your aerobic capacity will be estimated from an exercise
test on a treadmill. If you are in the stretching exercise group, you will be given a chance
to participate in an aerobic exercise program provided by the investigator after the
conclusion of the study.

You will not be audio or videotaped during the study, and your educational or medical
records will not be accessed.

4. How long will I be in the study?

During your first visit, it will take you about 60 minutes to go through the orientation of
the study and complete the questionnaires. If you are eligible for the study, we will
schedule your second visit within the next two weeks.
During your second visit, you will fill out two other questionnaires and then you will
participate in an exercise test on a treadmill. These processes will take about 40 to 50
minutes.
From visits 3 to 12, you will participate in a 10-week exercise training program. Each
week, you will have a 30 to 40 minutes supervised exercise session. You will also exercise
three to four times by yourself during the rest of the week if you are in one of the two
aerobic exercise groups.
During visit 7 at week 5, you will be instructed to come to the supervised session 30 minutes earlier to fill out several questionnaires assessing depressive symptoms and self-efficacy. After completing the questionnaires, you will begin the usual training session (30 to 40 minutes). The total time spent during visit 7 will be between 60 and 70 minutes. During visit 13 at week 11, you will be instructed to fill out several questionnaires for post-test measurements. After completing the questionnaires, you will participate in an exercise test on a treadmill. These processes will take about 70 minutes.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

The risks associated with the study are minimal. The most frequent risk is related to muscle soreness from unaccustomed physical activity. This is most likely to happen during the first 2 to 3 weeks of the training program and there are no long-term effects. To prevent muscle soreness, you will be instructed proper warm-up and cool-down exercise. Also, the exercise training will begin with low intensity to allow time for your body to adapt to the training regime and reduce the occurrence and severity of muscle soreness. It is possible but very unlikely that you will experience some temporary psychological stress from answering the questionnaires. Please remember that your participation is voluntary, and you can choose not to answer any questions.

7. What benefits can I expect from being in the study?

Exercise has been shown to alleviate symptoms of depression. Following the study, you will be given your individual research results, an explanation of the study’s findings and exercise guidelines that may improve your general health. You will be provided an individualized exercise prescription following the study.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.
9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):
- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If the study involves the use of your protected health information, you may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form.

10. What are the costs of taking part in this study?

There will be no additional costs to participate in the study.

11. Will I be paid for taking part in this study?

You will be paid $10 when you complete 5 weeks of the training program after the mid-point measurements, and $20 when you complete 10 weeks of the training program, the post-test measurements, and return the activity diaries for a total of $30.

By law, payments to subjects are considered taxable income. If you are an OSU employee, any compensation you receive as a result of participating in the study will be made through the payroll system and applicable taxes will be deducted.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health-care expenses for this study.
13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Jian-Hua Chu, at phone number (614) 392-2447 or e-mail chu.151@osu.edu, or the Principal Investigator, Janet Backworth, at phone number (614) 292-6767 or e-mail backworth.1@osu.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6231.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact OSU Sports Medicine at (614) 293-3600.
CONSENT
Biomedical/Cancer

IRB Protocol Number: 2006H0122
IRB Approval Date: 08.27.2007
Version: 07.15.2007

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject
Signature of subject
Date and time

Printed name of person authorized to consent for subject (when applicable)
Signature of person authorized to consent for subject (when applicable)

Relationship to the subject
Date and time

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent
Signature of person obtaining consent
Date and time

Witness(es) - May be left blank if not required by the IRB

Printed name of witness
Signature of witness
Date and time

Printed name of witness
Signature of witness
Date and time
APPENDIX N

BIOMEDICAL IRB APPROVAL LETTER FOR INITIAL REVIEW
January 30, 2007

Protocol Number: 2006EO262
Protocol Title: EFFECT OF EXERCISE INTENSITY DURING AEROBIC TRAINING ON DEPRESSIVE SYMPTOMS IN INITIALLY SEDENTARY DEPRESSED WOMEN. Janet Backworth, B. Hns Clin. PAUS • Student Services

Type of Review: Initial Review
IRB Staff Contact: Sarah Marie Smith
614-292-8569
smith.5111@osu.edu

Dear Dr. Backworth,

The Biomedical IRB APPROVED the above referenced protocol.

Date of IRB Approval: January 30, 2007
Date of IRB Expiration: January 16, 2008

If applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-approved consent form and process must be used. Changes in the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects).

This approval is valid for one year from the date of IRB review when approval is granted or modifications are required. The approval will no longer be in effect on the date listed above as the IRB expiration date. A Continuing Review application must be approved within this interval to avoid expiration of IRB approval and cessation of all research activities. A final report must be provided to the IRB and all records relating to the research (including signed consent forms) must be retained and available for audit for at least 3 years after the research has ended.

It is the responsibility of the investigator to promptly report to the IRB any serious, unexpected and related adverse events or potential unanticipated problems involving risks to subjects or others.

This approval is issued under The Ohio State University’s OHRRP Federalwide Assurance 500006578.

All forms and procedures can be found on the ORSP website – www.osa.osu.edu. Please feel free to contact the IRB staff contact listed above with any questions or concerns.

Karla Zedik, DO, PhD, Chair
Biomedical Institutional Review Board
APPENDIX O

BIOMEDICAL IRB APPROVAL LETTER FOR AMENDMENT 1
April 26, 2007

Protocol Number: 2006HR214
Protocol Title: EFFECT OF EXERCISE INTENSITY DURING AEROBIC TRAINING ON DEPRESSIVE SYMPTOMS IN INITIALLY SEDENTARY DEPRESSED WOMEN, Janet Backworth, Bc, Hsc Cnt, PANS - Student Services

Request for change(s) to the protocol dated April 16, 2007 (change locations, shorten length of training program, change intensity for low intensity group and revise protocol, consent form, and oral script to reflect the changes).

Approval Date: April 24, 2007
Type of Review: Amendment
IRB Staff Contact: Sarah Marie Smith 614-292-6559

Dear Dr. Backworth,

The Biomedical IRB APPROVED the above referenced protocol.

Note that if applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-approved consent form and process must be used. Changes in the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects).

It is the responsibility of the investigator to promptly report to the IRB any serious, unexpected and related adverse events or potential unanticipated problems involving risks to subjects or others.

This approval is issued under The Ohio State University’s OHRP Federative Assurance 4000009378.

All forms and procedures can be found on the OHRP website – www.cerp.osu.edu. Please feel free to contact the IRB staff contact listed above with any questions or concerns.

Kara Zachals, OD, PhD, Chair
Biomedical Institutional Review Board

Amended Approval
Version 05/08/16
APPENDIX P

BIOMEDICAL IRB APPROVAL LETTER FOR AMENDMENT 2
September 4, 2007

Protocol Number: 2004HR242
Protocol Title: EFFECT OF EXERCISE INTENSITY DURING AEROBIC TRAINING ON DEPRESSIVE SYMPTOMS IN INITIALLY SEVERELY DEPRESSED WOMEN, Janet Buckworth, PI: Hsu Cht. Physical Activity & Educational Services

Request for change(s) to the protocol dated July 25, 2007 (Revise inclusion criteria to include subjects with BMI between 18.5 and 25 and with HDS-R score above 28 with physician’s permission; revise consent form and protocol accordingly).

Approval Date: August 27, 2007
Type of Review: Amendment
IRB Staff Contact: Jennifer Hart
614-292-9804
Hart.151@osu.edu

Dear Dr. Buckworth,

The Biomedical IRB APPROVED the above referenced protocol.

Note that if applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-approved consent form and process must be used. Changes in the research (e.g., research procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects).

It is the responsibility of the investigator to promptly report to the IRB any serious, unexpected and related adverse events or potential unanticipated problems involving risks to subjects or others.

This approval is issued under The Ohio State University’s OHHRP Federally Assurance #000095378.

All forms and procedures can be found on the ORRP website - www.ohrpp.osu.edu. Please feel free to contact the IRB staff contact listed above with any questions or concerns.

[Signature]

Kars Zadnik, CO, IRB, Chair
Biomedical Institutional Review Board
APPENDIX Q

BIOMEDICAL IRB APPROVAL LETTER FOR CONTINUING REVIEW
Dear Dr. Backworth,

The Biomedical IRB APPROVED BY EXPEDITED REVIEW the above referenced protocol. The Board was able to provide expedited approval under 45 CFR 46.110(b)(3) because the research presents minimal risk to subjects and qualifies under the expedited review category(s) listed below.

Date of IRB Approval: November 27, 2007
Date of IRB Expiration: November 27, 2008
Expeditied Review Category: 4

If applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-approved consent form and process must be used. Changes in the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects).

This approval is valid for one year from the date of IRB review when approval is granted or modifications are required. The approval will no longer be in effect on the date listed above as the IRB expiration date. A Continuing Review application must be approved within this interval to avoid expiration of IRB approval and cessation of all research activities. A final report must be provided to the IRB and all records relating to the research (including signed consent forms) must be retained and available for audit for at least 3 years after the research has ended.

It is the responsibility of the investigator to promptly report to the IRB any serious, unexpected and related adverse events or potential unanticipated problems involving risks to subjects or others.

This approval is issued under The Ohio State University’s OHRP Federally-Assisted #0000567B.

All forms and procedures can be found on the ORRP website - www.orrp.osu.edu. Please feel free to contact the IRB staff contact listed above with any questions or concerns.

Kada Zadnik, OD, PhD, Chair
Biomedical Institutional Review Board