COMPARISON OF SUPERVISED AND UNSUPERVISED PHYSICAL ACTIVITY PROGRAMS DURING A STANDARD BEHAVIORAL WEIGHT LOSS INTERVENTION FOR ADULTS WHO ARE OVERWEIGHT OR OBESE

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Submitted to the Graduate Faculty of

The School of Education in partial fulfillment

of the requirements for the degree of

Doctor of Philosophy

University of Pittsburgh

2016

UNIVERSITY OF PITTSBURGH

SCHOOL OF EDUCATION

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Both supervised and unsupervised physical activity programs have successfully increased physical activity and reduced body weight when combined with a standard behavioral weight management program. However, it remains unclear if supervised and unsupervised physical activity programs with similar activity prescriptions change physical activity behavior and physiological responses comparably. **Purpose:** The primary aim of this study was to examine changes in moderate-to-vigorous physical activity (MVPA) in response to a supervised physical activity program prescribed in minutes/week (SUP-PA), an unsupervised physical activity program prescribed in minutes/week (UNSUP-PA), and an unsupervised physical activity program prescribed in steps/day (STEP) during a standard behavioral weight loss intervention. **Methods:** Fifty-two overweight and obese adults (age: 43.5 ± 10.1 years, BMI: 31.5 ± 3.5 kg/m^2) were randomized to STEP (n=18), UNSUP-PA (n=17), and SUP-PA (n=17). Subjects were prescribed a calorie-restricted diet (1200-1800 kcals/day) and increased physical activity (150 min/week or 10,000 steps/day with 2,500 brisk steps/day). All three groups attended weekly in-person group intervention sessions for 12 weeks. **Results:** All three groups significantly increased MVPA in bouts of ≥10 minutes over the 12-week intervention (STEP: 11.5 ± 31.2 min/day, UNSUP-PA:

16.1 ± 25.8 min/day, and SUP-PA: 21.6 ± 24.9 min/day, $p<0.001$) with no differences between groups ($p=0.94$) or group by time interaction ($p=0.81$). In addition, there were no significant differences in weight loss between the groups ($p=0.81$). **Conclusions:** This study provides evidence that unsupervised physical activity prescribed in minutes/week and an unsupervised physical activity program prescribed in steps/day can increase physical activity equally compared to a supervised physical activity program during a standard behavioral weight loss program eliciting similar physiological responses in adults who are overweight or obese.

TABLE OF CONTENTS

PREFACE XIV

1.0 INTRODUCTION 1

- **1.1 BACKGROUND 1**
- **1.2 SIGNIFICANCE AND THEORETIC RATIONALE 4**
- **1.3 SPECIFIC AIMS 8**
- **1.4 HYPOTHESES 9**

2.0 REVIEW OF LITERATURE 14

- **2.1 INTRODUCTION 14**
- **2.2 OVERWEIGHT AND OBESITY 15**
  - **2.2.1 Prevalence 15**
  - **2.2.2 Consequences of Obesity 16**
  - **2.2.3 Factors Affecting the Etiology of Obesity 17**
  - **2.2.4 Energy Balance 19**
- **2.3 EFFECTS OF BEHAVIORAL WEIGHT LOSS INTERVENTIONS 20**
  - **2.3.1 Dietary Modification 21**
  - **2.3.2 Physical Activity 22**
- **2.4 PHYSIOLOGICAL RESPONSES TO PHYSICAL ACTIVITY 23**
- **2.5 THE PHYSICAL ACTIVITY SPECTRUM AND HEALTH 29**

2.5.1 Health Impact of Sedentary Behavior 29
2.5.2 Health Impact of Light Intensity Physical Activity 30
2.5.3 Health Impact of Moderate-to-Vigorous Physical Activity 31
2.6 COMPENSATORY CHANGES IN PHYSICAL ACTIVITY 33
2.7 TYPES OF PHYSICAL ACTIVITY PROGRAMS 34
2.7.1 Supervised and Unsupervised Physical Activity Programs 34
2.7.2 Steps per Day Programs 38
2.8 SUMMARY 40
3.0 METHODS AND EXPERIMENTAL DESIGN 42
3.1 SUBJECTS 42
3.2 RECRUITMENT AND SCREENING PROCEDURES 44
3.3 EXPERIMENTAL DESIGN 46
3.4 STANDARD BEHAVIORAL WEIGHT LOSS PROGRAM 47
3.4.1 Engagement and Retention 49
3.4.2 Dietary Component 49
3.4.3 Physical Activity Component 50
3.4.3.1 Supervised Physical Activity Program 50
3.4.3.2 Unsupervised Physical Activity Program 51
3.4.3.3 Steps/day Physical Activity Program 52
3.5 SELF-MONITORING 53
3.5.1 Self-Monitoring Dietary Intake 53
3.5.2 Self-Monitoring Physical Activity 53
3.6 SUMMARY 54

3.7 ASSESSMENT PROCEDURES 55
3.7.1 Height, Weight, Body Mass Index 55
3.7.2 Body Composition and Anthropometry 56
3.7.3 Resting Blood Pressure and Heart Rate 56
3.7.4 Physical Activity 58
3.7.5 Cardiorespiratory Fitness 58
3.7.6 Dietary Intake 59
3.7.7 Additional Survey Instruments 59
3.8 SAFETY PROCEDURES 61
3.9 RENUMERATION FOR VISITS 61
3.10 STATISTICAL ANALYSES 62
3.11 POWER ANALYSIS 63
4.0 RESULTS 64
4.1 STUDY PARTICIPANTS 64
4.2 STUDY RECRUITMENT AND RETENTION 65
4.3 CHANGE IN PHYSICAL ACTIVITY 68
4.3.1 Objectively Measured Physical Activity 68
4.3.2 Subjective Measures of Physical Activity 72
4.4 CHANGE IN WEIGHT 75
4.5 CHANGE IN BODY COMPOSITION 78
4.6 CHANGE IN CARDIORESPIRATORY FITNESS 79
4.7 CHANGE IN BLOOD PRESSURE AND RESTING HEART RATE 80
4.8 CHANGE IN ENERGY INTAKE AND EATING BEHAVIORS 81

4.9 CHANGE IN PHYSICAL ACTIVITY SELF-EFFICACY 84

4.10 CHANGE IN EXERCISE EXPECTATIONS AND BARRIERS 86

4.11 TREATMENT SATISFACTION 88

4.12 INTERVENTION PROCESS MEASURES 90

5.0 DISCUSSION 96

5.1 PARTICIPANT RETENTION 96

5.2 CHANGE IN PHYSICAL ACTIVITY 97

5.3 CHANGE IN WEIGHT, ANTHROPOMETRICS, AND BODY COMPOSITION 100

5.3.1 Change in Weight 100

5.3.2 Change in Body Composition and Anthropometrics 102

5.4 CHANGES IN PHYSIOLOGICAL VARIABLES 103

5.4.1 Changes in Cardiorespiratory Fitness 103

5.4.2 Changes in Resting Heart Rate and Blood Pressure 105

5.5 CHANGES IN DIETARY INTAKE AND EATING BEHAVIORS 105

5.6 PROCESS MEASURES 107

5.7 PHYSICAL ACTIVITY SELF-EFFICACY, EXPECTATIONS, AND BARRIERS 108

5.8 CLINICAL IMPLICATIONS 109

5.9 LIMITATIONS AND FUTURE DIRECTIONS 111

5.10 SUMMARY 115

APPENDIX A 116

APPENDIX B 118

APPENDIX C **125**

APPENDIX D **129**

APPENDIX E **130**

BIBLIOGRAPHY **132**

LIST OF TABLES

Table 1. Study Eligibility Requirements 43

Table 2. Recommended Caloric and Fat Intake by Body Weight 49

Table 3. Intervention Treatment Components 54

Table 4. Blood Pressure Cuff Sizes 57

Table 5. Baseline Characteristics 65

Table 6. Baseline Characteristics of Completers and Non-Completers 67

Table 7. Changes in Objectively Measured Physical Activity 70

Table 8. Physical Activity Comparisons across the 12-Week Intervention 71

Table 9. Changes in Self-Reported Physical Activity and Sedentary Time 74

Table 10. Change in Weight, Body Composition, and Anthropometrics 76

Table 11. Achievement of 5% Weight Loss by Group at Week 12 77

Table 12. Change in Cardiorespiratory Fitness, Resting Blood Pressure, and Heart Rate 80

Table 13. Change in Dietary Intake 82

Table 14. Change in Eating Behaviors 83

Table 15. Change in Physical Activity Self-Efficacy and Future Self-Efficacy 85

Table 16. Change in Expectations and Barriers to Exercise 87

Table 17. Treatment Satisfaction 89

Table 18. Objectively Measured Physical Activity 117

Table 19. Orientation Schedule... 129

LIST OF FIGURES

Figure 1. Theoretical Rationale 5

Figure 2. The Etiology of Overweight and Obesity 17

Figure 3. Energy Balance Diagram 20

Figure 4. Study Progression 46

Figure 5. Study Timeline 47

Figure 6. Consort Diagram 66

Figure 7. Change in Objective MVPA completed in bouts of ≥ 10 minutes 72

Figure 8. Individual Percent Weight Loss by Group at Week 12 (N=49) 77

Figure 9. Supervised Exercise Equipment Use 91

Figure 10. Objectively Measured Physical Activity via Observation for SUP-PA across the Intervention 92

Figure 11. Self-Reported Physical Activity via Diary for UNSUP-PA across the Intervention .. 92

Figure 12. Self-Reported Total Steps/Day via Diary for STEP across the Intervention 93

Figure 13. Self-Reported Brisk Steps/Day via Diary for STEP across the Intervention 93

Figure 14. Percent Weight Loss by Adherers and Non-Adherers 94

Figure 15. Change in Fitness by Adherers and Non-Adherers 95

Figure 16. Behavioral Intervention Meeting Schedule 131

PREFACE

"Lack of activity destroys the good condition of every human being, while movement and methodical physical exercise save it and preserve it." - Plato

1.0 INTRODUCTION

1.1 BACKGROUND

Approximately 69% of the U.S. adult population is overweight, defined by a body mass index (BMI) of ≥ 25.0 kg/m^2, and 35% are obese (BMI ≥ 30.0 kg/m^2), with the prevalence of overweight and obesity rising drastically over the past several decades.[1,2] Obesity increases the risk of several chronic diseases, including heart disease, metabolic syndrome, type II diabetes, and some forms of cancer.[3-5] In the United States, the burden of obesity related health problems is extremely costly with associated annual health care costs rising over 147 billion dollars.[6] Therefore, identifying and improving treatment strategies to prevent the negative health consequences associated with this disease are critically important.

One treatment strategy that is typically recommended to people who are overweight or obese is physical activity. Regular moderate-to-vigorous physical activity (MVPA) is associated with reduced health risk that may be present with obesity.[7-9] Public health recommendations for aerobic physical activity include 150 minutes of moderate intensity per week, 75 minutes of vigorous intensity per week, or an equivalent combination of both intensities for all adults.[10] This recommendation seeks to maximize health benefits with an attainable physical activity goal. Yet, nearly half of U.S. adults are not participating in the recommended amounts of aerobic physical activity according to self-report questionnaire.[11] Using objective measures, even fewer adults are participating in the recommended amounts of MVPA, with Troiano et al. reporting less than 5% of U.S. adults achieving 30 minutes of MVPA per day.[12] In addition to the health benefits associated with physical activity (e.g., fitness, glucose control, blood pressure, mood, etc.), physical activity is also important for weight management.[13,14] However, only 40.6% of U.S. adults trying to lose or maintain weight follow recommendations to engage in at least 150 minutes per week of physical activity according to self-report measures.[15] Identifying strategies to support sustained, health-enhancing physical activity participation continues to be a major public health priority, especially in adults who are overweight and obese.[8,9]

The manner in which physical activity is prescribed and monitored may influence physical activity engagement. Within the context of clinical research, physical activity has been prescribed in either a supervised or unsupervised manner. Supervised physical activity is typically done in a health-fitness facility under the direct supervision of trained staff. With this method, adherence to the physical activity prescription (e.g., duration, frequency, intensity, and type) can be closely monitored and verified. However, supervised physical activity requires qualified health-fitness staff and can be expensive and inconvenient for the participants.[16,17] This is of concern because, within the general population, commonly reported barriers to physical activity include lack of time, disruptions to routine, and lack of access to facilities, which limits the generalizability of supervised physical activity trials.[18] Thus, the use of supervised activity within clinical research may not reflect the participation that would be observed in a non-research setting, and therefore the physiological and health benefits may vary.

An alternative method is to prescribe physical activity in an unsupervised manner, which promotes physical activity participation in a setting that is convenient to the individual. This may be more advantageous for people reporting the aforementioned barriers. Unsupervised activity can be done in any environment or at any time that best suits the individual. This provides scheduling flexibility, which may enhance adherence to the physical activity prescription. Additionally, unsupervised physical activity programs require less staff and are less expensive compared to supervised physical activity programs.[19,20] This has resulted in many clinical research studies implementing unsupervised activity programs which may reflect a "real world" scenario, with these programs prescribing activity in minutes per day or with a daily step goal. Because these programs are unsupervised, they are often considered inferior to supervised physical activity programs when evaluating the physiological effects of physical activity. However, it remains unclear if an unsupervised physical activity program yields similar benefits compared to a supervised physical activity program of the same prescribed dose.

Comparisons of supervised physical activity programs versus unsupervised physical activity programs in an overweight and obese population have previously been studied with inconsistent results.[21-24] For example, Craighead and Blum concluded that, within a standard behavioral weight loss program (SBWP), the supervised physical activity group had greater weight loss and improvement in cardiorespiratory fitness compared to the unsupervised physical activity group.[23] In contrast, Perri et al. reported that unsupervised physical activity was superior to group-based physical activity in terms of physical activity participation, adherence, and weight loss outcomes after 1 year of weight loss treatment.[22] Andersen et al. reported that within a 16-week SBWP, both supervised and unsupervised physical activity produced similar effects of decreased body weight, decreased body fat, improved cardiorespiratory fitness, decreased blood pressure, decreased cholesterol, and decreased triglycerides.[21] After the 16 week intervention, participants were followed for one year, with participants in the supervised exercise group regaining 1.6 kg compared to a 0.08 kg in the unsupervised exercise group. Furthermore, the unsupervised group maintained cardiorespiratory fitness levels while the supervised group significantly decreased fitness.[21] Another trial, conducted by Leermakers et al. found that there was no difference in physical activity participation or weight loss outcomes between a home-based (unsupervised) and a clinic-based (supervised) weight loss program which included physical activity.[24]

A limitation of these previous studies is that the unsupervised conditions relied on self-report to confirm adherence to the prescribed dose of physical activity.[21-24] Moreover, these studies did not necessarily assess other components of physical activity that may contribute to energy expenditure (e.g., sedentary behavior, light intensity physical activity, other lifestyle forms of physical activity), and therefore may impact weight loss or other health-related outcomes. Thus, to properly compare the effects of supervised and unsupervised physical activity programs on physical activity and the resulting physiological changes, objective monitoring of physical activity may provide important insights that inform the observed results. While valuable information can be gained from these previous trials, no study to date has utilized objective monitoring of physical activity to compare the effects of supervised and unsupervised physical activity programs on physical activity engagement in adults who are overweight or obese participating in a SBWP.

1.2 SIGNIFICANCE AND THEORETIC RATIONALE

Few U.S. adults are meeting the recommended amount of physical activity.[11,12] Improving physical activity participation is an important health message for all U.S. adults. However, improving physical activity participation in an overweight and obese population could have even greater benefits because physical activity may offset some of the negative health consequences associated with excess body weight. Physical activity improves cardiorespiratory fitness,[19,21,22,25-29] blood pressure,[19,26,28,30] waist circumference measures,[25-28]body composition,[25-28,31] and weight loss.[14,27,32,33] Pertinent to this proposed study is that the addition of physical activity to an energy restricted diet within the context of a SBWP increases weight loss achieved by approximately 0.5 to 3.0 kg within the initial 6 months of the intervention.[33,34] Thus, the inclusion of physical activity within a SBWP can have numerous health-related benefits, one of which is improved weight loss, in adults who are overweight or obese. Improving weight loss and other health-related parameters could greatly reduce the burden associated with overweight and obesity. Thus, it is imperative to explore strategies to enhance physical activity participation in an overweight and obese population. Altering the physical activity prescription is one strategy that may influence participation. Figure 1 represents the theoretical framework of this study and how weight and health related outcomes are impacted by the physical activity prescription.

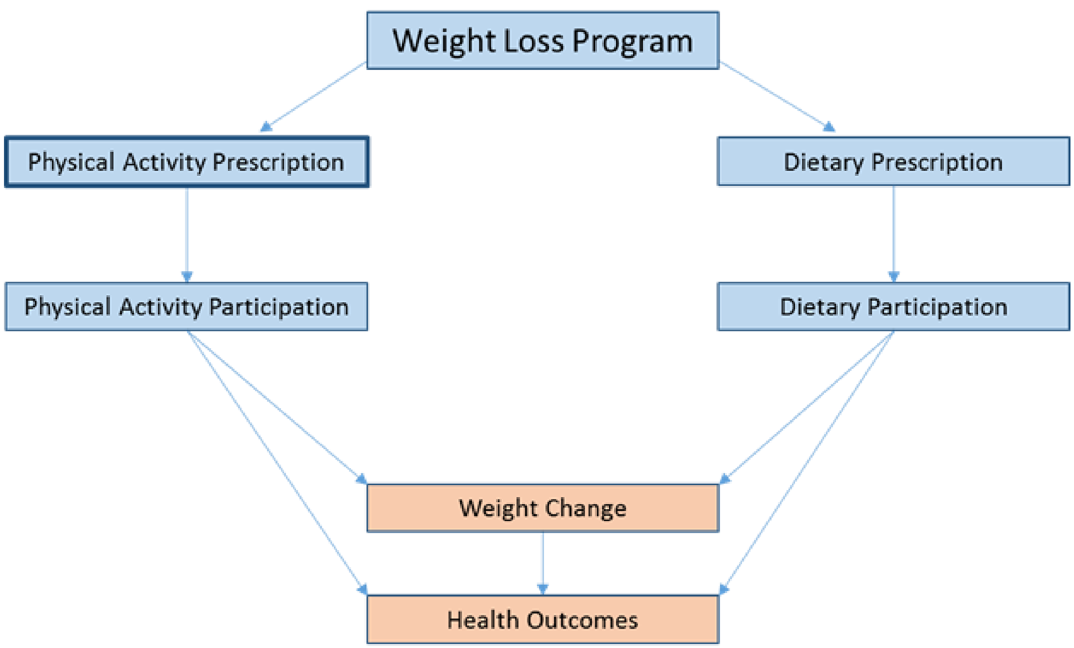


Figure 1. Theoretical Rationale

Two common intervention approaches to increase physical activity participation are prescribing supervised physical activity or unsupervised physical activity. Within a research setting, and in some clinical settings (e.g., cardiac rehabilitation), supervised physical activity programs have been preferred because of the ability to monitor compliance to prescribed amounts of physical activity, which allows for accurate quantification of dose of physical activity exposure.

Supervised physical activity interventions produce quantifiable study results because the physical activity is closely monitored and controlled for duration, intensity, frequency, type, or energy expenditure. The benefits of supervised physical activity programs have been well documented including improvements in MVPA, [19,21,22,25-29] cardiorespiratory fitness, [19,21,22,25-29] blood pressure, [19,26,28,30] abdominal adiposity, [25-28] and body composition.[25-28,31] Additionally, supervised physical activity programs offered in a health-fitness setting limit some barriers to activity (e.g., weather, walkability, safety, access to equipment, etc.) that are typically reported in unsupervised programs. While considered the "gold standard" to quantify physical activity exposure, supervised activity programs have many limitations. These limitations include: 1) the need for additional staff to supervise the activity sessions, 2) the need for facilities in which to conduct these supervised activity sessions, 3) the lack of generalizability outside of the research environment for participants who otherwise would not have access to a supervised program, 4) the additional barrier of traveling to a facility to complete physical activity 5) the lack of studies to quantify compensation or changes in physical activity occurring outside of the supervised sessions that could either enhance or blunt the observed responses.[35]

An alternative is to prescribe physical activity that allows participants to engage in the activity in an unsupervised manner, which is a typical clinical approach (i.e., a physician will simply instruct a patient to become more physically activity). Moreover, to allow for enhanced generalizability and to reduce the cost, unsupervised physical activity programs are also used within research studies. These have also been shown to be effective for improving health-related outcomes (e.g., fitness, body composition, etc.).[19,21,22,29,36,37] Because this type of programming allows for greater flexibility on the part of the participant (e.g., when and where they can be active, etc.), one could hypothesize that this may lead to greater physical activity participation when compared to supervised programs. In fact, there is some evidence that adherence to unsupervised physical activity programs may be better than supervised physical activity;[29,37] however, adherence has typically been measured using self-report measures, which are subject to several biases. Moreover, these comparisons have not assessed physical activity outside of the supervised sessions, which could affect health outcomes. Thus, additional research on unsupervised and supervised physical activity prescriptions is needed using objective measures of physical activity, particularly within the context of SBWP.

Unsupervised physical activity can be prescribed in several ways (e.g., minutes/week, steps/day, kcals/day, etc.) When directly comparing the effects of an unsupervised physical activity program versus a supervised physical activity program, the activity should be prescribed in a similar manner. Consistent with the national guidelines for physical activity, most programs use a minutes/week prescription. However, another method of prescribing unsupervised physical activity is based on steps taken per day, typically based on pedometer counts or other similar devices. This type of physical activity may provide even more flexibility than other activity prescriptions. The increased flexibility may further promote adherence and lead to a reduction in sedentary behavior since the physical activity does not need to be done in specific bouts with any opportunity to walk and increase steps counting towards the physical activity goal for the day.

Previously studies in which physical activity was prescribed as steps per day have shown limited impact on cardiorespiratory fitness, which is commonly reported as a benefit of increasing physical activity.[26,38,39] This may be a result of steps per day recommendations not including further guidance on the intensity at which those steps are to be taken. Thus, the effect of steps/day prescriptions that have been previously evaluated only focused on total steps per day and not on the intensity of the steps.[26,38-44] Moreover, prior studies evaluating the effect of steps per day have not directly compared this physical activity prescription to either supervised or other unsupervised physical activity prescriptions.

Knowing the effects of unsupervised physical activity is important because of the translation of this type of physical activity to non-research settings. Therefore, knowing the magnitude of the physiological effects of unsupervised physical activity compared to supervised physical activity at the same prescribed intensity and dose is of clinical and public health importance. This study is designed to provide insight on these important research questions that can inform future research and the application to clinical, public health, and health-fitness settings.

1.3 SPECIFIC AIMS

This study engaged subjects in a SBWP with a common diet intervention and subjects were randomized to the following physical activity conditions:

1. Supervised physical activity (SUP-PA)
2. Unsupervised physical activity with the dose matched to the prescription of SUP-PA (UNSUP-PA)
3. Unsupervised physical activity with the dose prescribed as steps per day (STEP)

These intervention conditions was used to test the following aims.

1. The primary aim of this study was to compare SUP-PA, UNSUP-PA, and STEP for changes in moderate-to-vigorous physical activity (MVPA) accumulated in bouts of ≥10 minutes.
2. Additional aims included comparing SUP-PA, UNSUP-PA, and STEP for changes in:
    a. Sedentary behavior, light-intensity physical activity, and steps per day.
    b. Cardiorespiratory fitness
    c. Body Weight
    d. Body Composition (Fat-Free Mass, Fat Mass, Percent body fat, waist circumference)
    e. Resting blood pressure
    f. Self-efficacy for physical activity and perceived self-efficacy to continue physical activity beyond the intervention period.
    g. Energy intake and eating behaviors

1.4 HYPOTHESES

1. It was hypothesized that MVPA (accumulated in bouts of ≥10 minutes) would differ by group across the intervention with SUP-PA > UNSUP-PA and SUP-PA > STEP.

Rationale: Supervised physical activity programs are considered the gold standard. Because an exercise physiologist was monitoring and verifying exercise intensity and duration for SUP-PA, we hypothesized that this group would engage in the highest amount of MVPA. It was hypothesized that the other groups (UNSUP-PA, STEP) may report engaging in similar amounts of MVPA compared the SUP-PA group, however, the intensity of this physical activity may not reach the moderate threshold reducing total MVPA time.

2. Hypotheses for additional aims included:
    a. Sedentary time would differ by group with STEP < SUP-PA and UNSUP-PA < SUP-PA across the intervention, and light-intensity physical activity would differ by group with STEP > SUP-PA and UNSUP-PA >SUP-PA across the intervention.

    Rationale: Because the STEP group had a total volume of activity goal (e.g., 10,000 steps/day) it was hypothesized that the STEP group would engage in less sedentary behavior and more light intensity physical activity compared to SUP-PA. Similarly, it was hypothesized that the UNSUP-PA group would reduce sedentary time because this unsupervised group may also increase lifestyle activities. This increase in lifestyle activity would also increase light intensity physical activity. Additionally, the SUP-PA group may have compensated for the increases in MVPA by increasing sedentary time according to the ActivityStat Hypothesis.[35] Thus, it was hypothesized that UNSUP-PA and STEP would engage in less sedentary behavior and more light-intensity physical activity compared to SUP-PA.

    b. Cardiorespiratory fitness would differ by group with SUP-PA > UNSUP-PA and SUP-PA > STEP across the intervention.

    Rationale: Supervised physical activity programs are considered the gold standard. Because an exercise physiologist was monitoring and verifying exercise intensity and duration for SUP-PA, we hypothesized that this group would engage in the highest amount of MVPA. It was hypothesized that the other groups (UNSUP-PA, STEP) may report engaging in similar amounts of MVPA compared the SUP-PA group, however, the intensity of this physical activity may not reach the moderate threshold reducing total MVPA time. Therefore, the SUP-PA group would have a greater increase in cardiorespiratory fitness compared to the STEP and UNSUP-PA groups.

c. Weight loss would differ by group with SUP-PA > UNSUP-PA and SUP-PA > STEP across the intervention.

Rationale: Supervised physical activity programs are considered the gold standard. Because an exercise physiologist was monitoring and verifying exercise intensity and duration for SUP-PA, we hypothesized that this group would engage in the highest amount of MVPA. It was hypothesized that the other groups (UNSUP-PA, STEP) may report engaging in similar amounts of MVPA compared the SUP-PA group, however, the intensity of this physical activity may not reach the moderate threshold reducing total MVPA time. Therefore, the SUP-PA group would have a greater energy expenditure and weight loss compared to the STEP and UNSUP-PA groups.

d. Resting blood pressure reductions would differ by group with SUP-PA > UNSUP-PA and SUP-PA > STEP.

Rationale: Supervised physical activity programs are considered the gold standard. Because an exercise physiologist was monitoring and verifying exercise intensity and duration for SUP-PA, we hypothesized that this group would engage in the highest amount of MVPA. It was hypothesized that the other groups (UNSUP-PA, STEP) may report engaging in similar amounts of MVPA compared the SUP-PA group, however, the intensity of this physical activity may not reach the moderate threshold reducing total MVPA time. MVPA participation reduces resting blood pressure in people who are normotensive or hypertensive.[45] Therefore, the SUP-PA group would have a greater reduction in resting blood pressure compared to the STEP and UNSUP-PA groups.

e. Retention of fat-free mass would differ by group with SUP-PA > UNSUP-PA and SUP-PA > STEP across the intervention, and reduction in fat mass, percent body fat, and waist circumference would differ by group with SUP-PA > UNSUP-PA and SUP-PA > STEP across the intervention.

Rationale: Supervised physical activity programs are considered the gold standard. Because an exercise physiologist was monitoring and verifying exercise intensity and duration for SUP-PA, we hypothesized that this group would engage in the highest amount of MVPA. It was hypothesized that the other groups (UNSUP-PA, STEP) may report engaging in similar amounts of MVPA compared the SUP-PA group, however, the intensity of this physical activity may not reach the moderate threshold reducing total MVPA time. Because retention of lean mass is associated with MVPA participation[46] and because increased MVPA would increase energy expenditure, we hypothesized that SUP-PA would have a greater retention of fat-free mass, reduction in fat mass, reduction in percent body fat, and reduction in waist circumference measures compared to the STEP and UNSUP-PA groups.

f. Physical activity self-efficacy across the intervention and perceived self-efficacy to continue physical activity following the intervention would differ by group with STEP > SUP-PA and UNSUP-PA > SUP-PA.

Rationale: UNSUP-PA and STEP would provide ample opportunities for increasing mastery experiences and self-confidence compared to SUP-PA. Thus, it was hypothesized that UNSUP-PA and STEP would have more physical activity self-efficacy and more perceived self-efficacy to continue physical activity compared to SUP-PA.

g. It was hypothesized that energy intake and eating behaviors would not differ between SUP-PA, UNSUP-PA, and STEP.

Rationale: Because the dietary intervention was identical across the intervention groups, it was hypothesized that energy intake and eating behaviors would not differ between SUP-PA, UNSUP-PA, and STEP.

2.0 REVIEW OF LITERATURE

2.1 INTRODUCTION

Overweight and obesity is a major public health concern in the United States.[47] Weight loss treatment is recommended for all individuals with a BMI over 30 kg/m^2 and for individuals with a BMI over 25 kg/m^2 and weight-related comorbidities.[34] Standard behavioral weight loss programs (SBWP) have been successful at reducing bodyweight by 8-10%.[48,49] However, many individuals will eventually regain the initial weight loss due to an inability to adhere to the diet and exercise prescription as well as physiological parameters that work against body weight reduction.[48,50-53] Modest weight losses of about 5% body weight have resulted in significantly improved health.[54] Moreover, independent of weight loss, regular MVPA can increase cardiorespiratory fitness,[19,21,22,25-29,36] reduce blood pressure,[19,26,28,30] improve body composition,[25,26,28,31,55] and reduce many other physiological parameters associated with poor health. Increased cardiorespiratory fitness is also associated with a reduced risk of heart disease and mortality,[56-58] which is independent of BMI status.[59] Thus, focusing on improving fitness and other cardiometabolic parameters through physical activity may be an efficacious strategy to reduce the health-risk associated with obesity.

Clinical research has typically prescribed physical activity in a supervised manner. The effects of supervised physical activity programs have been studied extensively. While these programs are considered the "gold standard," supervised physical activity may not translate to the general public because most individuals do not have access to a free health-fitness facility and personal training. An alternative strategy is prescribing physical activity in an unsupervised manner. Unsupervised physical activity programs may be more generalizable and representative of the "real world." However, the effects of unsupervised physical activity programs have rarely been compared to supervised physical activity programs. Because the effects of unsupervised physical activity may offer health benefits, the magnitude of these benefits compared to supervised physical activity should be investigated, particularly in an overweight and obese population.

2.2 OVERWEIGHT AND OBESITY

2.2.1 Prevalence

Overweight and obesity are characterized by an excess body weight determined by body mass index (BMI). BMI is calculated as weight in kilograms divided by height in meters squared (kg/m^2).[34] Overweight is classified as a BMI of 25.0-29.9 kg/m^2 and a BMI of $\geq$30.0 kg/m^2 is considered obese.[1] It is estimated that 33.9% of US adults are now overweight and 35.1% are classified as obese.[1] According to data from the National Health and Nutrition Examination Survey (NHANES) the prevalence of overweight and obese adults aged 20 years or older has increased markedly over the past 30 years.[1,2,60,61] It is now estimated that 69.0% of US adults are classified as overweight or obese.[1] This rapid increase in overweight and obesity has had several negative consequences.

2.2.2 Consequences of Obesity

Obesity is related to several chronic diseases and comorbidities including cardiovascular disease,[4,62-66] metabolic syndrome,[64-67] type II diabetes,[64-66,68] kidney disease,[64-66,69] gall bladder disease,[64-66,70] osteoarthritis,[66,71,72] sleep apnea,[66,73] and some forms of cancer.[64-67,74] The risk of developing these comorbid conditions is positively associated with an increase in BMI.[5] Subsequently, in 2005 Flegal et al. estimated that obesity was associated with 111,909 excess deaths compared to the normal weight category.[64] Furthermore, others have estimated that the number of annual deaths attributable to obesity is at least 325,000.[47] These extensive health complications associated with overweight and obesity have led to an economic burden as well.

The increased rates of overweight and obesity have consequently increased healthcare costs. For example, in 1998 the costs of overweight and obesity were approximately $78.5 billion with nearly half of this cost being covered by Medicare and Medicaid.[75] In 2008, the medical cost of obesity nearly doubled as it was estimated to cost $147 billion.[6] It was estimated that nearly 10% of medical spending was spent on obesity-related conditions. On average, overweight and obese individuals spent $1,429 more in healthcare costs compared to normal weight individuals.[6] Additionally, Medicare cost $600 more for obese individuals compared to normal weight beneficiaries.[6] These increased healthcare costs have affected both individuals, the government, as well as employers. Obesity-related conditions can affect disability, injuries, absenteeism, and healthcare claims.[76-78] The rising prevalence rates of overweight and obesity have created many unintended consequences, therefore, there is an increased need to identify strategies to help treat and limit these health-related conditions.

2.2.3 Factors Affecting the Etiology of Obesity

In order to properly treat overweight and obesity, it is important to understand the causes of the disease. The etiology of overweight and obesity is complex with multiple factors contributing to excess weight gain and fat accumulation. Hypotheses relating to the cause of obesity include increased energy intake, decreased energy expenditure, environmental factors, psychosocial factors, genetic factors, dysregulated endocrinology, as well as many other biological factors. These influences are outlined in Figure 2.

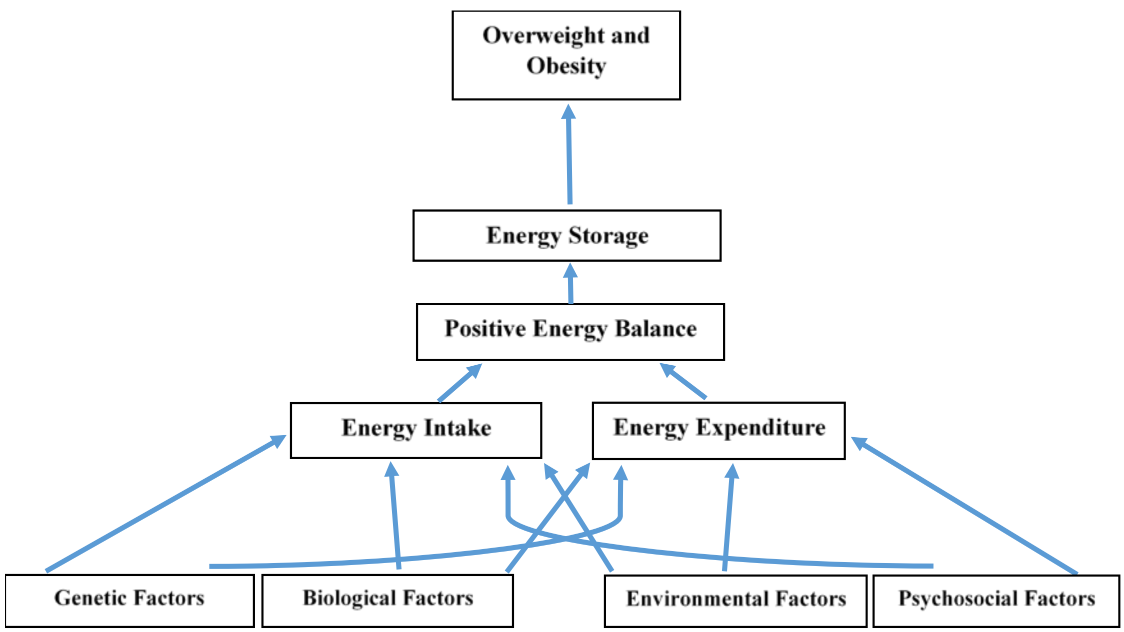


Figure 2. The Etiology of Overweight and Obesity

Genetic variables can be one of the predominant drivers in the pathogenesis of obesity; additionally, genetic determinants can increase susceptibility to the disease through other pathways (e.g. environment, psychosocial, biological, etc.). Genetic variables can influence both energy intake and energy expenditure components of the energy balance equation. James V. Neel first posed the "Thrifty Gene Hypothesis" to explain the rapid rise in type II diabetes; this hypothesis states that through natural selection humans have become very efficient at storing fat in times of food abundance to prepare for times of famine.[79] The U.S. is no longer a hunter-gatherer society, with a rich abundance of calorie-dense foods attributing to high levels of energy intake, fat storage, and ultimately obesity. Twin studies have also cited that there is a prominent genetic influence on BMI and childhood environment has very little influence.[80] Similarly, Ravussin et al. found that 40% of the variance in BMI is related to genetic influences on energy intake/ volitional activity.[53] Therefore, dysregulation of energy balance can be partially explained by genetic predisposition, and genetics should not be ignored when considering potential treatment methods for overweight and obesity. Behavioral changes such as increasing physical activity may be advantageous for individuals predisposed to having a higher BMI.

In addition to genetic factors, several biological factors may influence individuals towards a positive energy balance. These biological factors may be exacerbated by behavioral phenotypes promoting body weight gain. Low metabolic rates, leptin levels, low sympathetic nerve activity, and low levels of thyroid hormones may all promote weight gain.[81-84] These biological factors can be influenced by genetics, behavior, and the environment.

Environmental factors also play a pivotal role in the etiology of obesity. Over the past century, the human environment and human behavior have been altered to promote less physical activity while concurrently increasing sedentary behavior.[85,86] Sedentary behavior is a significant contributor to obesity,[87-89] type 2 diabetes,[87-89] metabolic syndrome,[88-90] and cardiovascular disease.[88,89] Additionally, calorie-dense foods are more available to the consumer. This concurrent increase in food availability and decrease in activity are actively contributing to the obesity epidemic.

Psychosocial factors such as consumerism, social norms, and cultural norms also have impacted and continue to impact the obesity prevalence trend. Eating is not only a form of energy intake that is essential for life, but it also has emotional and social influences.[91,92] Moreover, cultural norms may further promote increased body size.[93] African-American women have less strict criteria when it comes to perceived body fatness compared to white women.[94] Whereas, white women are more likely to practice eating restraint and have disordered eating.[94] Furthermore, males are less likely to be dissatisfied with their bodyweight and females are more likely to want to try to lose weight.[93] More cultural norms may exist, but further investigation is warranted.
All of these factors can contribute to the pathogenesis of obesity, making treatment difficult. Most treatments are foundationally rooted around the energy balance equation, focusing on strategies that ultimately alter either energy intake, energy expenditure, or both.

2.2.4 Energy Balance

While the ideology of energy balance is elementary and uncomplicated, energy intake equals energy expenditure, there are several dynamics that influence energy intake and energy expenditure making energy balance difficult to accomplish. More research is needed to know how all of these factors are interrelated and how to best treat obesity. Clearly, obesity treatment focusing on reducing body weight needs to be tailored to best treat the factors that are the predominantly driving the weight gain. These factors and treatment may vary by individual. Obesity and excess body weight has several health consequences that can be improved with weight loss, however, long-term weight loss has been difficult for some people to achieve.[48,50,51,53] Physical activity may be a potential treatment strategy for overweight and obese populations. Increasing physical activity is a common strategy to help promote a negative energy balance, and is commonly prescribed in weight loss programs.[48,49] However, physical activity is rarely the sole focus of these programs; most programs focus on weight loss instead. Physical activity helps reduce body weight, [14,32,33] promote weight loss maintenance,[14] and helps attenuate the complications associated with obesity independent of weight loss.[95] Moreover, physical activity can be achieved by most individuals regardless of the pathology of the individuals' obesity.

Energy balance is a result of energy intake being equivalent to energy expenditure. When these two conditions are in congruence, known as homeostasis, weight was maintained (Figure 3). Weight gain is a result of energy intake exceeding the amount of energy expenditure. Conversely, weight loss is a result of energy expenditure exceeding the amount of energy intake.

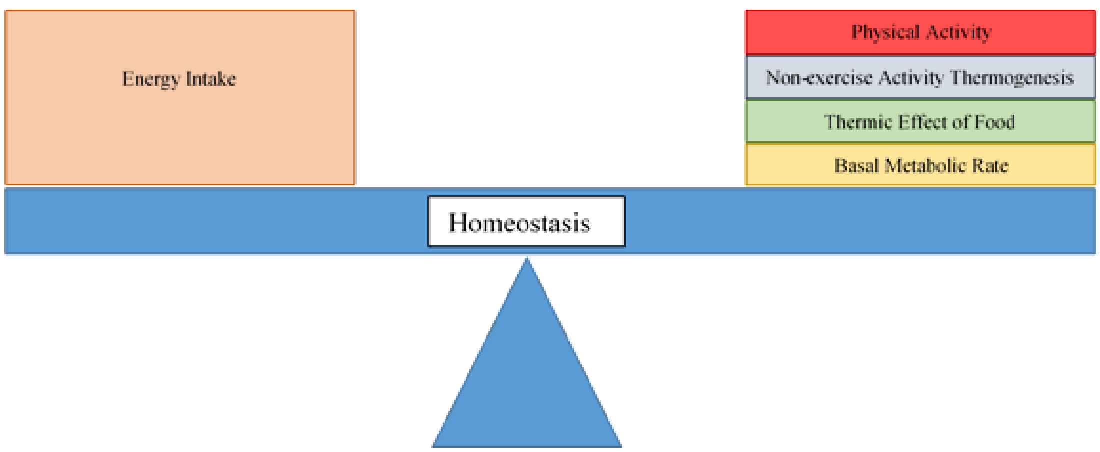


Figure 3. Energy Balance Diagram

2.3 EFFECTS OF BEHAVIORAL WEIGHT LOSS INTERVENTIONS

Standard behavioral weight loss programs (SBWP) are typically recommended as the first line of treatment against overweight and obesity. Organizations such as the National Heart Lung and Blood Institute, The American Heart Association, and The American College of Sports Medicine recommend behavioral treatment as a treatment strategy.[13,34,96] SBWP incorporate strategies to reduce dietary intake, increase physical activity and change other behaviors that may be contributing to weight gain. SBWP are typically based on behavior theories that include but are not limited to Social Cognitive Theory, Transtheoretical Model, Theory of Planned Behavior.[91] These theory-based SBWP approaches typically induce weight loss of 8-10% within 6 months,[48,49] with long-term weight loss being more variable.

SBWP are commonly delivered in a group-based format. A trained behavioral interventionist leads the group session, and each session has an educational and behavior change component. Integrated within these lessons are behavioral constructs that include, but are not limited to, goal setting, problem solving, cognitive restructuring, self monitoring, relapse prevention, and others.[91] These group intervention sessions also offer the participants an opportunity for social support.

2.3.1 Dietary Modification

Dietary modification and calorie restriction are key components of SBWP. General recommendations for weight loss include daily calorie goals of 1200-1800 calories depending on body weight. Additionally, fat intake is recommended at levels of 20-30% of total intake.[97] Most SBWP provide flexible dietary modifications to promote weight loss, self-efficacy, and long-term behavior change. However, other types of dietary modification have been successful for inducing weight loss.

Very Low Calorie Diets (VLCD) have been successful at inducing large weight losses.[91,98] VLCD’s offer very regimented diets, meal replacements, or other food provisions which minimize the individual's choice. Typical VLCD's prescribe up to 800 calories per day.[91,98] Studies utilizing VLCD's promote weight losses of approximately 20% of initial body weight in the first 12-16 weeks, however, these strategies may be difficult to sustain.[91,98] At one year of follow-up weight loss with VLCD's are similar to less stringent diets.[99]

The use of meal replacements is another dietary strategy used within weight loss interventions. Studies using this strategy have shown the efficacy of this strategy.[100,101] Clearly, dietary modification is an integral part of weight management regardless of the prescription.

2.3.2 Physical Activity

Physical activity is defined as any bodily movement produced by skeletal muscle that results in energy expenditure. The current public health recommendations suggest that all U.S. adults engage in 150 minutes of moderate intensity, 3.0-5.9 metabolic equivalents (METS), or 75 minutes of vigorous physical activity, ≥6.0 METS, or an equivalent combination of both per week done on most if not all days of the week and completed in bouts of ≥10 minutes. Moderate physical activity is equivalent to brisk walking at 3 to 4 mph.[102] Vigorous physical activity is equivalent to jogging at 4 to 5 mph or faster.[102] All U.S. adults are encouraged to participate in regular MVPA, however, only 5% of the population is meeting the recommended amounts.[12]

Increased body weight and obesity increases the risk of cardiovascular disease,[4,5,62-66] type II diabetes,[5,65,66,68] and mortality.[103,104] However, MVPA and cardiorespiratory fitness are associated with reduced risk of cardiovascular disease, type II diabetes, and mortality.[56-58,105-107] Therefore, overweight and obese individuals should be encouraged to engage in regular MVPA.

Because physical activity is the most variable and modifiable component of the energy balance equation, equating for 10-30% of total daily energy expenditure,[108] it may be efficacious to focus on this behavior in an overweight and obese population seeking weight loss. Physical activity alone has promoted minimal weight losses in men and women.[27,32,33] Wing reported that men and women lost about 1-2 kg. in weight loss interventions due to exercise alone,[33] and a meta-analysis done by Miller and colleagues reported that exercise alone contributed to a mean weight loss of 2.9 kg.[32] Given that physical activity alone only produces modest weight losses, most behavioral strategies for weight loss focus on increasing energy expenditure through physical activity in combination with decreasing energy intake. Studies have shown that adding physical activity to an energy reduced diet increases weight loss compared to what is achieved through diet alone.[14,32,33] Moreover, the American College of Sports Medicine (ACSM) recommends physical activity as an important lifestyle component to promote long-term weight loss and to prevention weight regain.[13,14]

2.4 PHYSIOLOGICAL RESPONSES TO PHYSICAL ACTIVITY

The body's physiological responses to aerobic physical activity primarily occur in the musculoskeletal, cardiovascular, respiratory, endocrine, and immune systems, but activity also impacts other systems in the body. The physiological stress of activity overloads the body's systems leading to adaptations which increase the body's efficiency at handling the activity stimulus. These adaptations lead to improved muscular strength, cardiorespiratory fitness, cardiometabolic health, body composition, and many other downstream effects.[109,110] Understanding the body's response to physical activity is important when evaluating the effects of physical activity on overall health.

Maximal oxygen consumption is commonly measured as an indicator of cardiorespiratory fitness.[109] Maximal graded exercise tests start at a relatively low workload which increases progressively during the test. The exercise test continued until participant exhaustion. These types of tests are excellent indicators of cardiorespiratory fitness.[109] Similarly, submaximal exercise tests can be used to predict maximal oxygen consumption while limiting the risk of the exercise. In a typical submaximal test, the workload will progress until a designated stopping point (e.g., 85% age-predicted maximal heart rate). The investigators can then predict maximal oxygen uptake or use the value at test termination as a relative marker of cardiorespiratory fitness.[109] When evaluating the effects of a physical activity intervention, cardiorespiratory fitness is one of the most common outcomes. Cardiorespiratory fitness is associated with a decreased risk of cardiovascular disease and mortality, [56-58,105] and it is used as a surrogate measure of the body's physiological changes due to physical activity. It is important to understand the physiological changes that are represented when evaluating changes in cardiorespiratory fitness due to physical activity participation.

The cardiovascular and the respiratory systems work together and their primary functions are to provide the body with oxygen and nutrients while also removing carbon dioxide, removing metabolic waste products, promoting body temperature regulation, promoting acid-base regulation, and transporting hormones.[111] Physical activity places a higher demand on these systems, making them work faster and more efficiently. When the activity is of a higher intensity or longer duration, a greater burden is placed on these systems leading to more prominent adaptions. However, even small increases in physical activity at relatively modest intensities can produce physiological adaptations.[25]

Many cardiovascular adaptations to physical activity are well understood. Cardiac output is a function of stroke volume and heart rate. Cardiac output acutely increases in response to physical activity to match the oxygen demand in the skeletal muscle.[109] Regular MVPA leads to physiological adaptations increasing the capacity of cardiac output. After aerobic training, stroke volume is increased at rest, during submaximal exercise, and during maximal exercise, thus, heart rate is decreased at rest and during submaximal exercise in order to match the change in stroke volume. The increase in stroke volume is due to increases in left ventricular size, myocardial contractility, plasma volume, increased end-diastolic volume, and decreased total peripheral resistance.[109,110] The increase in end-diastolic volume can largely be explained by the increased volume of blood, increased return of blood to the ventricle, and increased ventricular dilation or stretching.[109,110] Other structural changes in the heart, including hypertrophy of cardiac muscle, allow greater force to be exerted during each heartbeat, emptying more blood from the left ventricle. The carrying capacity of the blood is also increased due to increased hemoglobin. Regular MVPA also induces changes in the skeletal muscle to enhance the efficiency of oxygen delivery to the working muscle. Capillary density is increased resulting in a greater capacity for blood flow and more time to exchange gases, substrates, and metabolites; this also decreases total peripheral resistance allowing the left ventricle to disperse more blood because there is less resistance in the arteries.[109,110] Additionally increased mitochondrial size and density increases the working muscles' efficiency at removing and utilizing oxygen. Oxygen extraction or arteriovenous oxygen difference (a-vO2) is increased allowing the working muscle to work efficiently and longer until fatigue.[109] Furthermore, oxidative enzyme activity increases with aerobic training, and myoglobin content is decreased promoting oxygen storage in muscle fibers.[109] The sum of all these adaptations greatly enhances the oxidative capacity of the aerobically-trained muscle.

The respiratory system also responds acutely to physical activity leading to chronic adaptations. Pulmonary ventilation increases in response to physical activity through respiratory centers in the motor cortex and through proprioceptor feedback. During higher intensity activity increases in carbon dioxide production, hydrogen ions, and body temperature promote ventilation. Chronic respiratory adaptations to activity include increases in tidal volume, respiration rate, and pulmonary diffusion.[109,110] As the body becomes more efficient at utilizing oxygen, less ventilation is needed and the ventilatory rate decreases at rest and during submaximal exercise. In sum, these cardiovascular and respiratory physiological adaptations to aerobic exercise are the primary drivers when improving cardiorespiratory fitness, which is known to have lasting health benefits. Because obesity is related to poor cardiorespiratory fitness and cardiovascular disease it is important to note the potential benefits of physical activity on the cardiovascular and respiratory systems.

Another clinical measure that is evaluated during physical activity trials is blood pressure. Blood pressure is typically defined as the force exerted on the walls of blood vessels, specifically arteries, during cardiac systole and diastole. Blood pressure is related to both cardiovascular and metabolic health outcomes. Several studies have looked at the effect of physical activity on blood pressure in different populations.[25,45,112] In a review conducted by Whelton et al., the authors concluded that aerobic exercise caused a reductions in systolic blood pressure of 3.84 mmHg and reductions in diastolic blood pressure of 2.58 mmHg.[45] However, specific trials have found that aerobic exercise may not improve blood pressure in certain populations.[25,26] Understanding how physical activity impacts blood pressure has important clinical implications that may inform future activity prescriptions.

Physical activity acutely affects bloods pressure, and habitual physical activity can help to reduce blood pressure. During a session of MVPA systolic blood pressure rises linearly with work.

This increase in systolic blood pressure can largely be attributed to increases in cardiac output without an equivalent decrease in total peripheral resistance. This response is normal as the increased systolic blood pressure is needed to prevent hypotension during intense physical activity. Following a session of MVPA blood pressure drops below pre-exercise resting levels; this is known as post-exercise hypotension. Although the mechanisms of post-exercise hypotension are not completely understood several pathways may be involved. During exercise the baroreceptor reflex is "reset" to a higher point and sympathetic activity is increased.[109,110] Following exercise these arterial baroreflexes and cardiopulmonary receptor reflexes reset to a lower pressure, thus, sympathetic innervation is lower than pre-exercising levels.[113-115] There is evidence to suggest that the body is less reactive to catecholamines following a bout of exercise, but some of these mechanisms are unknown.[115] Additionally, it is hypothesized that vascular responses to α-adrenergic receptor stimulation is impaired reducing sympathetic nerve activity.[115] During exercise, increases in blood flow, cyclic wall stress, pulsatile blood flow, and catecholamines stimulate the release of nitric oxide, a vasodilator, reducing blood pressure.[115] Nitric oxide blunts α-adrenergic receptor stimulation reducing vasoconstriction.[115] Tanaka et al. also hypothesize that the increased pulse pressures and distension of the arteries during exercise may lead to the stretching of the collagen fibers, modifying cross-linking and ultimately increasing arterial compliance over time.[116] Some physiological mechanisms of blood pressure change remain unknown and should be investigated further.

Another physiological benefit of physical activity is weight loss. Aerobic physical activity alone produces a mean weight loss of about 2-3 kg.[27,32,33] however, physical activity can encourage positive body composition changes (e.g., increased skeletal muscle, decreased abdominal fat, etc.) independent of body weight change. This change in abdominal fat is important to recognize because abdominal obesity, specifically excess visceral fat has been linked to metabolic and cardiovascular health.[63,117-119] Using waist circumference (WC) measures and waist to hip ratios (WHR) as surrogate measure, studies have shown abdominal fat is related to metabolic risk,[120] cardiovascular risk,[121] and mortality.[120,121] Numerous cross-sectional studies have shown evidence that physical activity is inversely related to WC and WHR.[122,123] Additionally, randomized controlled trials have confirmed that increasing physical activity can help to reduce WC, WHR, and abdominal fat mass without a consequent change in body weight.[28,124] Because visceral fat is a predictor of dyslipidemia, glucose tolerance, insulin resistance, systemic inflammation, hypertension, cardiovascular disease, type II diabetes, and all-cause mortality,[117,125] it is reasonable to focus on reducing abdominal fat through physical activity rather than focusing specifically on weight loss. Understanding how physical activity influences abdominal fat is important.

Abdominal fat is comprised of both visceral fat and subcutaneous fat with most of the evidence suggesting that visceral fat is closely related to metabolic dysfunction leading to increased risk of diabetes and cardiovascular disease. Physical activity puts stress on the body to produce energy in order for the body to continue to move. During aerobic physical activity, glycogen is mobilized from the liver, working muscles absorb glucose from the blood, muscle glycogen is broken down and utilized via glycolysis, and intramuscular triglycerides are used for energy.[109,110] Additionally, lipolysis increases stimulating the release of free fatty acids from adipose tissue.[109,110] These free fatty acids go through beta oxidation converting them to acetyl coA which in turn produces ATP through the Krebs cycle, which is then utilized as an energy source.[109,110] It is hypothesized that free-fatty acid mobilization is one of the primary reasons abdominal fat is decreased with regular MVPA.

All of these physiological adaptations are important to understand when considering the effects of different physical activity prescriptions. These physiological responses may vary by exercise intensity, duration, and frequency. Being able to closely monitor the full spectrum of physical activity participation during a physical activity intervention may help explain some of the physiological changes that are occurring.

2.5 THE PHYSICAL ACTIVITY SPECTRUM AND HEALTH

2.5.1 Health Impact of Sedentary Behavior

Sedentary behavior is typically defined as any waking activity characterized by ≤1.5 metabolic equivalents (METs) done in a sitting or reclining posture.[126] Epidemiological studies using television viewing time as measurement of sedentary time have linked sedentary behavior to several negative health outcomes.[87,127-129] In 2003, Hu et al. found that sedentary behavior was associated with a higher risk of becoming obese and developing type II diabetes.[87] Furthermore, Warren et al. found that increased levels sedentary behavior were associated with a higher rate of cardiovascular mortality in men.[129] Therefore reducing sedentary behavior may be efficacious for overall health.

There have been relatively few studies focusing on strategies and the long-term effects of changing sedentary behavior. Reducing sedentary behavior by increasing energy expenditure through postural changes or increasing activity are potential strategies that need to be explored. Standing increases energy expenditure by about 9 kcal/hour compared to sitting.[130,131] Additionally, short bouts of walking have significantly increased energy expenditure compared to sitting alone.[132,133] However, the effects of increased participation in MVPA on sedentary behavior are not completely understood. Since sedentary behavior can adversely affect health independent of MVPA participation, further investigation is warranted.[127,134,135] Therefore activity interventions may want to focus on the total activity pattern (e.g. sedentary, light, MVPA) rather than simply focusing on MVPA. Strategies to increase MVPA while reducing sedentary behavior need to be investigated.

2.5.2 Health Impact of Light Intensity Physical Activity

Light intensity physical activity is defined as any activity producing energy expenditure at 1.5 to <3.0 METs. This includes slow walking, activities of daily living, and some forms of occupational-related activity. Light physical activity is not considered in the public health recommendations for physical activity, yet, light activity may be important for overall health.
Lee and Paffenbarger reported that light physical activity was not associated with a reduced risk of mortality but moderate and vigorous physical activity were.[136] However, these data were collected via self-report questionnaire and only the intensity of sport, fitness, and recreational activities were measured and used in the analysis. Light physical activity is commonly accumulated throughout the day and may not be as prominent in sport and fitness activities. Thus, these results should be interpreted carefully. Because light physical activity is accumulated throughout the day, it may be difficult to capture in a self-report questionnaire. Measuring light physical activity with objective physical activity monitors may be a more valid and reliable technique. Recent studies have shown that light physical activity is associated with health benefits when the activity is measured objectively.[137-141] Jakicic et al. reported individuals reducing the most body weight in a diet and exercise intervention also engaged in the highest levels of light

physical activity.[137] Healy and colleagues found that light physical activity is independently associated with 2 hour glucose.[138] Moreover, several studies have found that light physical activity is associated with lower BMI, reduced waist circumference, reduced inflammation, and increased insulin sensitivity.[139-141] Light physical activity may not stimulate the cardiovascular and respiratory systems enough to see significant changes in cardiorespiratory fitness, however, these other health benefits suggest that light physical activity is important for overall health.

2.5.3 Health Impact of Moderate-to-Vigorous Physical Activity

Moderate to vigorous physical activity (MVPA) is typically defined as any activity producing energy expenditure of ≥3.0 METs. MVPA is the most commonly studied form of physical activity and most public health recommendations focus on this threshold of activity because it is attainable and offers significant health benefits.

Most physical activity programs focus on increasing MVPA in the form of brisk walking.[142] Walking is the most common form of physical activity making it a reasonable target for increasing MVPA.[142,143] It is hypothesized that focusing on walking improves adherence to the MVPA prescriptions since opportunities to walk are plentiful. However, physical activity programs that have focused on other forms of activity (e.g., running, bicycling, swimming, sports, etc.) have been successful at increasing MVPA.[144,145] Individuals may have different preferences for physical activity and should be encouraged to engage in whichever activity is most enjoyable as long as the stimulus is enough to elicit health benefits. As stated previously, a proper stimulus should overload the systems of the body enough to encourage physiological adaptions increasing capacity and efficiency. Regular MVPA is associated with reduced risk of mortality, [56-58,146] cardiovascular disease, [56-58,146-148] type II diabetes,[107,149-151] hypertension,[152-154] psychological issues,[155,156] and some forms of cancer.[157,158] Similarly low levels of physical activity and low cardiorespiratory fitness have been linked to increased rates of all-cause mortality.[58,146] Low physical activity, low energy expenditure, and low fitness are also associated with excess body weight.[159,160] Thus, it is reasonable to prescribe overweight and obese individuals to increase MVPA for energy expenditure and cardiorespiratory benefits.

Randomized-controlled trials have demonstrated that increasing MVPA will acutely promote physiological adaptations. These adaptations have persisted in longer trials eliciting health benefits such as reduced waist circumference,[28,124,161] increased insulin sensitivity,[124] reduced blood pressure,[42,45,113] reduced prevalence of depression,[162] improved lipid profiles,[163,164] and increased cardiorespiratory fitness.[19,21,22,25,26,28,29,36,55] Randomized-controlled trials focusing on increasing MVPA have been successful at increasing MVPA levels whether the activity was supervised or unsupervised.[19,21,22,25,26,28,29,36,55] Participation rates in MVPA are still not as high as desired in these trials, however, participation is enough to elicit health benefits. In 2007, Church et al. found that relatively small increases in MVPA (72.2 ± 12.3 min/wk at 50% of peak maximal oxygen consumption) were sufficient to improve cardiorespiratory fitness by 4.2% over 6 months.[25] Participating in MVPA for a longer duration produced even more significant increases in cardiorespiratory fitness.[25] Moreover, Donnelly et al. found that participating in 2000 kcal/wk of supervised physical activity for 16 months improved cardiovascular fitness by 20% in males and 16% females.[27] In this trial, men also had significant reductions in body weight (5.2 ± 4.7 kg) total fat (73.9 ± 68.9 cm^2), visceral fat (22.5 ± 21.4 cm^2), and subcutaneous fat (51.4 ± 54.4 cm^2).[27] Similarly, Ross et al. found that 3 months of exercise training at 77% of maximal heart rate was sufficient to increase cardiorespiratory fitness by 16% and also decrease abdominal fat in obese men without a change in total body weight.[28]

Interventions focusing on increasing MVPA have been successful in the past. These changes in MVPA have elicited multiple health benefits. These trials have utilized either supervised or unsupervised physical activity, however, few studies have directly compared these two types of activity programs. Moreover, past studies have mostly focused on changes in MVPA and have not measured the simultaneous changes in sedentary behavior and light physical activity. Future studies should focus on the entire physical activity spectrum to better understand the physiological benefits associated with changes in physical activity.

2.6 COMPENSATORY CHANGES IN PHYSICAL ACTIVITY

Most public health initiatives have focused on increasing MVPA for health benefits, however, sedentary behavior and light physical activity are important contributors to health. Changing MVPA may positively or negatively influence sedentary behavior and light physical activity. The ActivityStat hypothesis states that increasing activity in one domain will lead to a compensatory change in activity in another domain in order to maintain overall energy expenditure levels over time.[35] This hypothesis is foundationally built upon total activity being homeostatic, thus increasing MVPA leads to an increase in sedentary behavior or a decrease in light physical activity. This is a relatively novel hypothesis and studies have recently begun to investigate total activity patterns. A systematic review of this hypotheses found that results are still mixed and methodological approaches are needed to test overall activity patterns and the compensation effect of activity interventions.[35] In the systematic review, 12 out of the 28 studies found clear evidence of physical activity compensation; another 3 studies had mixed results, while the remaining 13 studies found no compensation effect.[35] While there is conflicting evidence whether the

ActivityStat hypothesis is substantiated, further investigation into total activity patterns is needed, particularly in supervised exercise trials.

2.7 TYPES OF PHYSICAL ACTIVITY PROGRAMS

2.7.1 Supervised and Unsupervised Physical Activity Programs

Comparisons of supervised physical activity programs versus unsupervised physical activity programs in numerous populations have been previously studied.[19,21-24,26,29,36,37,165-167] In a systematic review, Dalal et al. reported that unsupervised and supervised cardiac rehabilitation programs have similar effects on improving clinical and health-related quality of life outcomes.[165] Similarly, Ashworth et al. compared supervised physical activity versus unsupervised physical activity programs in older adults finding that supervised physical activity programs were superior to unsupervised programs in the treatment of peripheral vascular disease (PVD), both physical activity programs were successful at improving outcomes in patients with chronic obstructive pulmonary disease (COPD), and unsupervised physical activity programs were superior in terms of long-term adherence to physical activity.[166] However, physical activity adherence was measured by self-report in all of these studies, which is a major limitation to the study results.[29,166] Dunn et al. compared the effects of supervised physical activity and lifestyle (unsupervised) physical activity finding that the supervised physical activity induced greater fitness benefits at 6 months despite physical activity increasing similarly.[36] At month 24, the supervised physical activity and lifestyle physical activity groups had equal improvements in physical activity, fitness, and blood pressure.[19] Again, physical activity was self-reported which is a major limitation. Furthermore, this trial was not done in an overweight and obese population, so it is unclear if these results are translatable to this population.

Previously, several studies have evaluated the effects of supervised and unsupervised programs in a population of overweight and obese adults. Craighead and Blum evaluated the effects supervised physical activity compared to physical activity contracting (i.e., signing a written contract to participate in physical activity) and minimal-contact physical activity contracting within the scope of standard behavioral weight loss program (SBWP) concluding that the supervised physical activity group had the most weight loss and greatest improvement in cardiorespiratory fitness.[23] In this study, the supervised exercise group met three times per week and participants were required to keep their heart rate up (75-80% of maximum) for about 20 minutes. Two days a week the participants participated in a walk-jog program and the other day participants were encouraged to do calisthenics. The physical activity contracting group and minimal contact group signed a contract to participate in about 90 minutes of exercise per week. No formal analyses were conducted to look at physical activity type, dose, or adherence, therefore, it is difficult to interpret the effects of the physical activity prescriptions.

Contrarily, Perri et al. found that unsupervised physical activity was superior to supervised, group-based physical activity in terms of physical activity participation, adherence, and weight loss outcomes after 1 year of weight loss treatment.[22] The supervised and unsupervised physical activity groups were prescribed 60-70% maximal heart rate, 30 min/day, 5 days/wk of walking. Both groups were also prescribed the same low-fat diet of 1,200 kcal/day. During the first 6 months, the group-based, supervised physical activity group was encouraged to get 3 days/week of supervised group exercise and supplement that with 2 days of walking on their own. During the second 6 months, the supervised physical activity group was encouraged to engage in 2 days of supervised group exercise and supplement that with 2 days of walking on their own. The unsupervised group was encouraged to get all of their activity in an unsupervised manner. After 6 months, the supervised and unsupervised groups were participating in the same amounts of physical activity (104.4 ± 39.5 and 104.0 ± 25.5 respectively). After 1 year the supervised physical activity group was engaging in less physical activity (45.4 ± 30.5) compared to the unsupervised group (66.2 ± 21.6). Both groups increased cardiorespiratory fitness similarly during the first 6 months, and these improvements were maintained through month 12. The unsupervised group self-reported better adherence to the physical activity protocol, but this could not be confirmed by the investigators. Also, the intensity of the physical activity was not evaluated.

Unsupervised lifestyle activity also had better weight maintenance outcomes after one year of follow-up in trial conducted by Andersen et al.[21] In this trial, participants in the supervised physical activity group were prescribed 16 weeks of supervised step aerobics for 45 min/day 3 days/wk. It was estimated participants expended 450-500 kcals per exercise session. After the initial 16 weeks of exercise training, the participants were given videotapes of the step classes for continued home use. The lifestyle activity group was encouraged to increase moderate-intensity physical activity by 30 minutes per day on most days of the week. During the initial 16 weeks, participants were given a 3-dimensional accelerometer to help self-monitor physical activity. Both groups received the same 1,200 kcal/day dietary prescription during the initial 16 weeks. After the first 16 weeks both groups lost weight, decreased body fat, improved cardiorespiratory fitness, decreased blood pressure, decreased cholesterol, and decreased triglycerides similarly.[21] After the 16 week intervention, participants were followed for one year. Participants in the supervised exercise group regained 1.6 kg compared to a 0.08 kg in the lifestyle group. Additionally the lifestyle group was able to maintain cardiorespiratory fitness levels, while the supervised group decreased fitness significantly.

In a trial to prevent weight gain in men, Leermakers et al. compared a clinic-based (supervised) and a home-based (unsupervised) behavioral weight management intervention that focused on increasing physical activity and decreasing fat intake.[24] The clinic-based group attended weekly meetings during the first 8 weeks, followed by 8 weeks of meeting every other week. These meetings included a 30 minute lesson on nutrition or exercise followed by a supervised exercise session. Participants were encouraged to supplement the supervised exercise session with at least three more days of exercise per week on their own. The home-based group had one group educational session on exercise safety followed by weekly newsletters to deliver intervention material. After the initial 8 weeks, newsletters were sent every other week to match the clinic-based group. Participants were encouraged to engage in at least 4 days of unsupervised physical activity on their own, and received telephone calls on a weekly or biweekly basis from study staff to provide feedback and assist with goal setting. The exercise program for both groups consisted of walking or jogging at least 4 days/week progressing up to 3 miles/day. Participants were encouraged to exercise at 60-70% of maximal heart rate reserve. All participants were given a pedometer to track total steps, and all participants were encouraged to self-monitor activity. Both groups were also instructed to reduce fat intake to 20% of total caloric intake; other dietary recommendations were similar for both groups. Following 4 months of treatment, there were no differences in weight change, body composition, change in fitness, or physical activity.[24] However, more participants self-monitored in the clinic-based group and the clinic-based group had more individuals achieving the physical activity goal of 120 miles completed (48% vs. 20.8%).

Based upon these studies, it is difficult to discern whether supervised or unsupervised physical activity programs promote better physical activity participation and health outcomes. These studies focused on the effects of different physical activity programs on weight loss, however, weight can be affected by much more than just the physical activity program. Moreover, the aforementioned studies lacked the measurement techniques and study design to properly compare the effects of supervised and unsupervised physical activity programs on physical activity participation. When studying the effects of varying physical activity programs in an overweight and obese population, physical activity should be prescribed in identical doses, and physical activity should be measured objectively to limit any potential reporting bias. Additionally, when studying the effects of physical activity, it is important to evaluate the participants' activity outside of the physical activity sessions. Sedentary behavior as well as all forms of physical activity spectrum (light, moderate, vigorous) can influence health outcomes.[137,141,168-171] Because of the possibility of compensation[35] (decreasing physical activity in one domain due to an increase in physical activity in another domain), measuring the total activity pattern is critically important when evaluating the effects of physical activity. No study to date has objectively measured physical activity or evaluated total activity patterns when comparing supervised and unsupervised physical activity programs.

2.7.2 Steps per Day Programs

Walking is the most common form of physical activity and many public health initiatives have focused on increasing physical activity through walking.[142,143] Many of these initiatives have utilized pedometers to help with self-monitoring and motivation. Most trials have focused on a total step goal of 10,000 steps/day. This recommendation was based off a study conducted by Yamanouchi et al., which recommended a 10,000 steps/day goal to promote glucose control in patients with type II diabetes.[40] By the end of the study, participants took an average of 19,200 ± 2,100 steps/day and improved their metabolic profile.[40] A recent review found that studies utilizing steps/day recommendations and pedometers have been successful at increasing step counts by 2,000-2,500 steps/day.[172] Because steps/day recommendations have been a successful intervention strategy, researchers have begun to focus on the clinical implications of these increases.

Steps/day is negatively associated with BMI.[173] Thus, increasing steps/day may be a positive strategy to increase activity and promote weight loss. Schneider et al. found that promoting 10,000 steps/day during a 36 week trial promoted a 4.5 kg. mean weight loss in individuals adherent to the prescription with no reported changes in dietary intake.[41] Other studies have noted that a 10,000 step/day recommendation has promoted positive changes in body composition, glucose control, lipid profiles, and blood pressure.[26,39,41,43,44,174] Steps/day recommendations do not focus on intensity of activity and no study has investigated the activity patterns of individuals adhering to this type of activity prescription. Because steps/day recommendations do not offer an intensity recommendation, the stimulus may not be enough to encourage changes in cardiorespiratory fitness. A few studies have found modest improvements in fitness in sedentary adults, however, most recently, Bell et al. found that the 10,000 steps/day recommendation did not change fitness.[26] Promoting brisk walking (equivalent to moderate intensity physical activity) for 25% of the total step count may be necessary to produce fitness benefits. However, this recommendation has not been investigated.

Utilizing pedometers and step counts has been a successful intervention strategy for previously sedentary adults. Using a recommendation of 10,000 steps/day has elicited health benefits. However, encouraging individuals to increase the intensity of some of their total steps may also be an efficacious strategy for increasing fitness. Additionally, little is known about the total activity pattern of individuals who are adhering to the 10,000 steps/day recommendation. Investigating the sedentary behavior, light activity, and MVPA of individuals who are adherent to the 10,000 steps/day prescription may help explain the health benefits of this recommendation.

2.8 SUMMARY

Overweight and obesity continues to be a significant public health concern. Behavioral treatment to alter physical activity and diet is one of the first intervention strategies to help reduce bodyweight and the consequences associated with excess weight. Physical activity alone has health benefits independent of weight change. Typically, physical activity is prescribed in a supervised or unsupervised manner. Supervised physical activity has been typically utilized in clinical research settings, but results from supervised physical activity programs may not be generalizable to "real world" settings. Unsupervised physical activity programs may be more generalizable, however, it is difficult to confirm adherence to the physical activity prescription. Using objective physical activity monitors may help investigators to confirm adherence to the prescription, while also allowing investigators to examine participants' participation in other forms of physical activity. To our knowledge, no study has examined physical activity adherence, physical activity compensation, and the physiological effects of a supervised and unsupervised physical activity program of the same prescribed dose. Furthermore, no study has investigated the efficacy of novel step/day program compared to a supervised physical activity program. Therefore, the primary aims of this study were to examine the effects an unsupervised physical activity program prescribed in minutes/week, an unsupervised physical activity program prescribed in steps/day, and a supervised physical activity program prescribed in minutes/week on MVPA participation, compensatory changes in physical activity, cardiorespiratory fitness, weight, and body composition.

3.0 METHODS AND EXPERIMENTAL DESIGN

3.1 SUBJECTS

Fifty-two apparently healthy overweight and obese (BMI 25.0 to <40.0 kg/m^2) adults between the ages of 18-55 years old were enrolled in this study at the University of Pittsburgh Physical Activity and Weight Management Research Center. Table 1 contains a complete list of all inclusion and exclusion criteria.

Table 1. Study Eligibility Requirements

Inclusion Criteria
• Male or Female
• Aged 18-55 years old
• BMI of 25.0 to <40.0 kg/m^2
• Ability to provide informed consent
• Ability to provide physician's clearance to participate in a weight loss intervention
Exclusion Criteria
• Engaging in ≥60 min/wk (accumulated in bouts of ≥10 minutes) of moderate-to-vigorous physical activity over the past month
• Presence of contraindications to physical activity as identified on a physical activity readiness questionnaire (PAR-Q)
• History of metabolic, cardiac, or pulmonary disease that classifies the individual as high risk by the American College of Sports Medicine (e.g., coronary heart disease, diabetes mellitus, uncontrolled hypertension, etc.)
• History of myocardial infarction, coronary bypass surgery, angioplasty, or other cardiovascular- related surgeries
• Taking medication that may affect heart rate or blood pressure responses to physical activity
• Resting systolic blood pressure ≥150mmHg or diastolic blood pressure ≥100mmHg
• Medication that may affect body weight/metabolism (e.g., synthroid)
• Current or previous participation in a physical activity or weight management research project in the past 6 months
• Weight loss of ≥5% or 15 pounds total of current body weight in the previous 6 months
• Currently being treated for an eating disorder (e.g., anorexia, bulimia, etc.)
• Previously undergone bariatric surgery (e.g., lap-band, gastric bypass, etc.)
• For women, those currently pregnant, pregnant during the previous 6 months, or plan on becoming pregnant in the next 6 months
• Currently being treated for any psychological issues or problems, taking any psychotropic medications, or receiving treatment with psychotropic medications within the previous 6 months
• Being out of town during for an extended amount of time during the weight loss intervention which may affect participation in the study
• Currently using a physical activity monitor to track activity (e.g., Jawbone UP, Fitbit, etc.)

3.2 RECRUITMENT AND SCREENING PROCEDURES

Subjects were recruited from the University of Pittsburgh Obesity and Nutrition Research Participant Registry, the University of Pittsburgh Clinical and Transitional Science Institute, and through an announcement from the University of Pittsburgh Read Green Email System. Potential subjects were instructed to call University of Pittsburgh Physical Activity and Weight Management Research Center (PAWMRC) where trained staff conducted a telephone screening to determine eligibility. The telephone screening included a detailed description of the study and its potential risks and benefits. Upon the potential subjects' verbal consent, trained staff began the initial telephone screen to determine eligibility. The telephone screen contained questions about medical history and other pertinent questions related to the inclusion/exclusion criteria. A copy of the telephone screening form can be seen in Appendix B. If the potential subject was ineligible based upon a telephone screening question, the telephone screen was stopped immediately and the study staff did not ask any more personal questions. Once the telephone screen was completed, study staff was instructed to obtain the potential subjects' contact information. The Principal Investigator reviewed all telephone screening forms before inviting anyone to the orientation session. The orientation invitation can be seen in Appendix C.

All eligible participants according to the initial telephone screen were invited to an in-person 60-minute orientation session at the PAWMRC where the principal investigator described the complete details of the study. Participants were encouraged to ask questions about the study at this time. After the orientation session, interested participants were asked to provide written informed consent, fill out the physical activity readiness questionnaire (PAR-Q), and provide a complete medical history as recommended by the American College of Sports Medicine. Potential subjects who attended the orientation session were allowed time to decide whether or not they wished to participate. Potential subjects were instructed to contact the principal investigator if they decided to participate at a later time. Participants were also required to obtain a medical doctor's clearance to participate in the behavioral weight loss intervention with physical activity. The cost of obtaining this clearance was the responsibility of the participant. Participants provided written informed consent, a completed PAR-Q, completed medical history, and physician's clearance prior to the baseline assessment.

Eligible participants who provided their consent and obtained medical clearance were scheduled to complete a baseline assessment. Assessment measures and procedures included height, weight, resting blood pressure, dietary intake, anthropometrics, body composition, submaximal graded exercise test, and physical activity. Participants were also asked to fill out questionnaires prior to the assessment. These questionnaires were collected at the baseline assessment visit. These questionnaires included demographics, Paffenbarger Exercise Habits, Eating Behavior Inventory, Three-Factor Eating, Block Food Frequency, Sedentary Behavior, Exercise Outcomes and Barriers, and Physical Activity Self-Efficacy. Eligible subjects were randomized to one of three groups (Figure 4) using a stratified, randomized block design. Participants were stratified by gender (e.g. male, female) and ethnicity (e.g. Non-Hispanic White, African-American, etc.). All of these procedures were approved by the University of Pittsburgh Institutional Review Board prior to the study beginning.

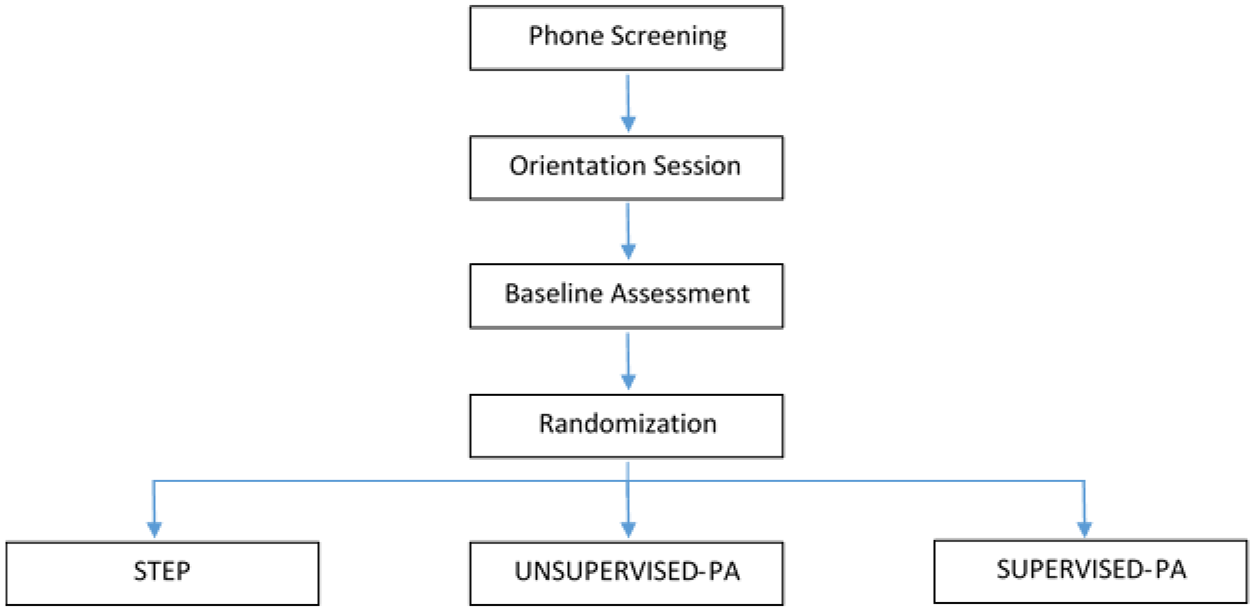


Figure 4. Study Progression

3.3 EXPERIMENTAL DESIGN

This study was a 12-week randomized trial designed to examine the effects of three different physical activity programs (SUP-PA, UNSUP-PA, and STEP) on physical activity participation, compensatory changes in physical activity, cardiorespiratory fitness, weight, and body composition during a SBWP. Secondary aims of this study included examining the effects of these programs on resting blood pressure, waist circumference measures, physical activity self-efficacy, and energy intake. Compliance to the prescribed physical activity program was assessed throughout the 12-week program using self-report methods, with additional objective monitoring of physical activity outcomes assessed at baseline, 4-weeks, 8-weeks, and at 12-weeks. The other outcome measures were assessed at pre-intervention (0-weeks) and post-intervention (12-weeks). The intervention was conducted at the University of Pittsburgh PAWMRC. Upon completion of the baseline assessments, subjects were randomized to one of three intervention conditions using a stratified randomized block design: 1) SUP-PA, 2) UNSUP-PA, 3) STEP. Participants were stratified by gender (e.g. male and female) and ethnicity (e.g. Non-Hispanic White and African American). The study timeline is illustrated in Figure 5.

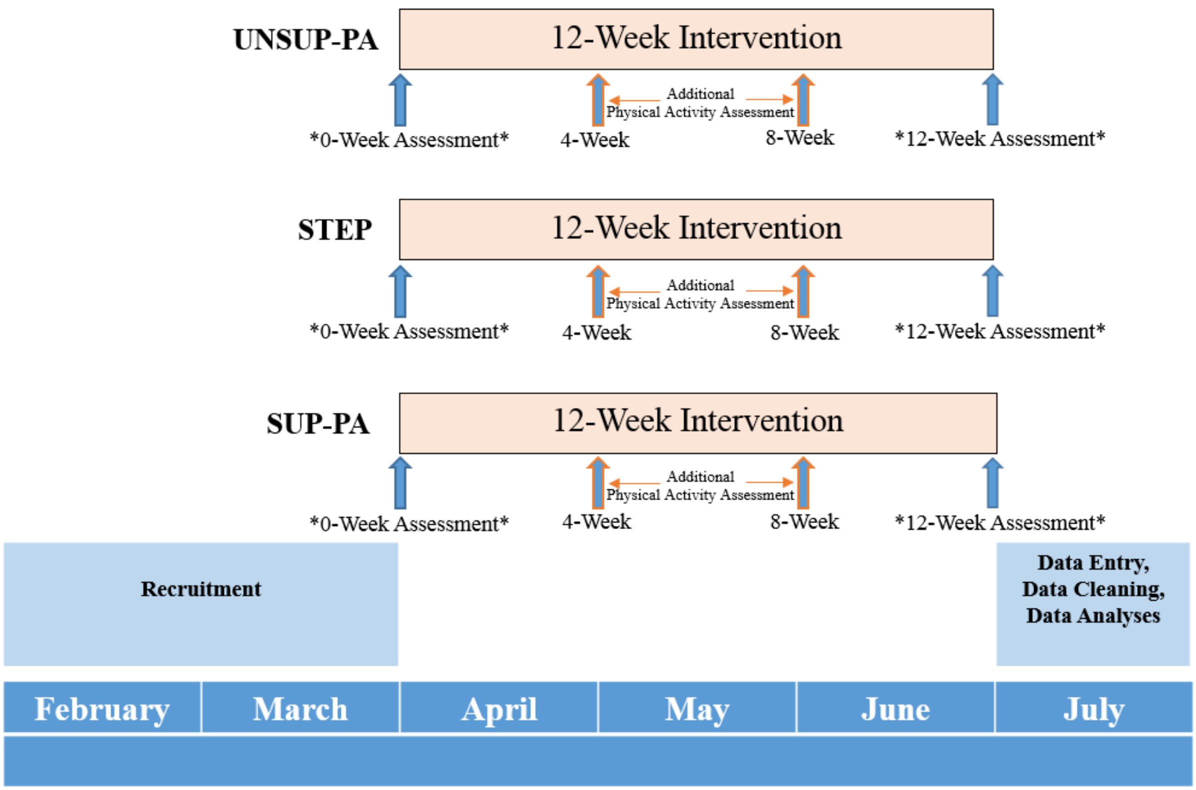


Figure 5. Study Timeline

3.4 STANDARD BEHAVIORAL WEIGHT LOSS PROGRAM

The 12-week SBWP was conducted at the University of Pittsburgh Physical Activity and Weight Management Research Center. Participants attended weekly group meetings for all 12 weeks of the study. SUP-PA, UNSUP-PA, and STEP each had separate group intervention sessions to avoid contamination of the physical activity prescriptions. Group meetings lasted approximately 30-45 minutes in duration and were led by trained behavioral interventionists with previous experience facilitating behavioral weight loss intervention meetings. These meetings focused on strategies to promote long-term behavior change and weight management including physical activity and caloric restriction. Non-exercise physical activity (e.g., slow walking, fidgeting, postural changes, etc.) are often recommended to increase energy expenditure and ultimately promote weight loss in most SBWP. However, because this study was evaluating how three different physical activity programs affect the total activity pattern of individuals, there were no comments made about non-exercise physical activity. (STEP was encouraged to increase total daily steps, but no other comments were made about non-exercise physical activity.) Strategies to promote behavior change included the Social Cognitive Theory, Problem Solving Theory, and Relapse Prevention. Self-efficacy was also a part of these lessons. Physical activity self-efficacy was an outcome measure of this study, thus, lessons focusing on self-efficacy were controlled across all groups. Participants were weighed weekly prior to group meetings to track changes in weight throughout the study and assist interventionists with weight counseling. Participants who did not attend the weekly group meeting were contacted via telephone call to reschedule for an individual weigh-in and make-up session with an interventionist prior to the next group meeting. If an individual make-up session was not scheduled, an interventionist would provide a brief counseling session by telephone and the written materials were mailed to the participant. The duration of group and individual sessions were recorded for fidelity purposes.

3.4.1 Engagement and Retention

Participants who did not attend the weekly group meeting were contacted via telephone call to reschedule for an individual weigh-in and make-up session with an interventionist prior to the next group meeting. If an individual make-up session could not be scheduled, an interventionist provided a brief counseling session by telephone and the written materials were mailed to the participant. If a participant missed a weekly meeting and study staff was unable to contact the participant via telephone, an email was sent to the participant. If the participant did not respond to the email, a formal letter was sent to the participant to determine their participation status. Study staff continued to attempt to contact the participant on a weekly basis until the participant was contacted or until the end of the 12-week intervention.

3.4.2 Dietary Component

Dietary recommendations were based on the participants' baseline body weight.[175] Caloric intake and fat intake goals are shown in Table 2. These calorie goals were based on intake recommendations that have been successful in other weight loss programs, and fat intake goals are consistent with the USDA Dietary Guidelines.[97,175]

Table 2. Recommended Caloric and Fat Intake by Body Weight

Initial Body Weight	Kcal/Day	Fat Grams/Day
<200 lbs.	1200	26-40
200 to <250 lbs.	1500	33-50
≥250 lbs.	1800	40-60

To promote adoption and adherence to these recommendations, participants were provided meal plans and sample recipes. Participants were provided paper diaries to self-monitor their eating behaviors, however, participants were allowed to use self-monitoring techniques such as MyFitnessPal, LoseIt, or other smartphone applications if they preferred. Participants were taught how to read nutrition labels and monitor food intake using The Calorie King Calorie, Fat, and Carbohydrate Counter.[176] Participants were instructed to self-monitor daily and were instructed to turn in self-monitoring food diaries to their interventionist prior to group intervention meetings. Printed intervention lessons also included information related to behavior strategies for achieving the recommended calorie and fat intake goals.

3.4.3 Physical Activity Component

3.4.3.1 Supervised Physical Activity Program

SUP-PA: Participants reported to a fitness facility (University of Pittsburgh Physical Activity and Weight Management Research Center) to engage in supervised physical activity sessions. Participants engaged in aerobic physical activity utilizing treadmills, elliptical trainers, adaptive motion trainers, and stationary cycles that were available at this facility. MVPA was prescribed at 100 min/wk for weeks 1-2, 125 min/wk for weeks 3-4, and 150 min/wk for weeks 5-12. This dose of physical activity was spread across 3-5 supervised sessions per week (allowed flexibility for the participant), with each supervised session being at least 10 minutes. Physical activity was completed at 60-75% of age-predicted maximal heart rate, which was monitored using a Polar heart rate monitor. These physical activity sessions were closely monitored by exercise physiologists under the supervision of the Principal Investigator. The exercise physiologists recorded attendance, duration of physical activity session, monitored the heart rate of the physical activity sessions, and provided instruction on safe use of exercise equipment. Additionally, the exercise physiologist recorded three heart rates for each participant during each physical activity session. The average of those three heart rates was recorded as the heart rate for that particular physical activity session. SUP-PA was not instructed on physical activity behaviors outside of the supervised physical activity session. A behavioral interventionist monitored each participant's supervised physical activity according to the log book kept by the exercise physiologist and provided appropriate feedback. The behavioral interventionist reinforced the importance of the supervised physical activity sessions.

3.4.3.2 Unsupervised Physical Activity Program

UNSUP-PA: Participants attended regular group sessions as part of the SBWP held at the University of Pittsburgh Physical Activity and Weight Management Research Center. During the first group session participants were anchored to the physical activity prescription, educated on appropriate monitoring of physical activity intensity, and educated on issues related to safety. Participants were anchored to MVPA using a validated Ratings of Perceived Exertion (RPE) Scale.[177] Participants were asked to participate in activity that was of at least a moderate intensity (RPE 12-14). Similar to SUP-PA, MVPA were prescribed at 100 min/wk for weeks 1-2, 125 min/wk for weeks 3-4, and 150 min/wk for weeks 5-12. This dose of activity was to be spread across at least 3 days each week in activity sessions of $\geq$10 minutes. Participants were provided a self-monitoring paper diary to record their MVPA. A member of the study staff collected self-monitored physical activity minutes weekly. These self-reported physical activity minutes were utilized by the behavioral interventionist for goal-setting and motivational purposes.

3.4.3.3 Steps/day Physical Activity Program

STEP: Participants attended regular group sessions as part of the SBWP held at the University of Pittsburgh Physical Activity and Weight Management Research Center. During the first group session participants were anchored to the physical activity prescription, educated on appropriate monitoring of physical activity intensity, and educated on issues related to safety. Participants were prescribed 6,000 steps/day for weeks 1-2, 8,000 steps/day for weeks 3-4, and 10,000 steps/day for weeks 5-12. To monitor steps, participants were provided a digital pedometer. Participants were instructed that 25% of these daily steps should be completed at a perceived "brisk" pace. Each participant was instructed to engage in 1,500 brisk steps/day during weeks 1-2, 2,000 brisk steps/day during weeks 3-4, and 2,500 brisk steps/day during weeks 5-12. This recommendation to increase the intensity of 25% of total steps per day was rationalized by an unpublished data analysis presented by Creasy et al. at the 2015 ACSM Annual Meeting.[178] Participants were anchored to "brisk walking" using a validated Ratings of Perceived Exertion (RPE) Scale similar to UNSUP-PA. Additionally, brisk walking is similar to walking at a pace of 100 steps/minute.[179] Thus, participants were also anchored to brisk walking by the message "Walk 1,500 steps in 15 minutes." Participants were provided a self-monitoring paper diary to record their daily steps. Similar to UNSUP-PA, study staff collected self-monitored daily steps on a weekly basis. These self-reported steps/day were utilized by the behavioral interventionist for goal-setting and motivational purposes.

3.5 SELF-MONITORING

3.5.1 Self-Monitoring Dietary Intake

UNSUP-PA, SUP-PA, and STEP self-monitored dietary intake every day. Participants were given a self-monitoring paper diary to keep track of total calories and fat grams. The paper diaries also had the daily calorie and fat goals for each day in the program. This served as a reminder for the study participants. The diaries allowed participants to keep track of the calorie and fat grams of all food items consumed throughout the day, including meals and snacks. These data were strictly used for intervention purposes. Interventionists reviewed the paper diaries weekly and provided constructive, personalized feedback to the participants with the overall goal of helping the participant to lose weight. If for any reason a participant demonstrated eating behaviors that were inconsistent with study recommendations, they were referred to a dietician. Furthermore, if a participant did not record dietary behaviors for seven consecutive days, an interventionist spoke with the participant about the importance of self-monitoring.

3.5.2 Self-Monitoring Physical Activity

Both UNSUP-PA and STEP self-monitored physical activity every day. Participants were given a self-monitoring paper diary to keep track of physical activity (minutes or steps). The paper diaries also had the weekly goals associated with each week in the program. This served as a reminder for the study participants. Participants in UNSUP-PA recorded structured physical activity minutes in bouts of $\geq$10 minutes at an RPE of 12-14. These data were self-monitored and a device was not used to keep track of physical activity minutes. Participants in STEP recorded steps/day according to the digital pedometer they were given by study staff. Steps/day were recorded daily covering all waking activity in a 24-hour period. The participant was instructed to record steps/day each night prior to going to sleep. Once the participant recorded the steps/day, he/she was instructed to clear the pedometer prior to using the device the next day.

3.6 SUMMARY

Table 3 outlines the treatment components for all three groups. SUP-PA, UNSUP-PA, and STEP received a behavioral intervention focusing on strategies for weight loss. SUP-PA was not instructed on physical activity outside of the supervised physical activity session.

Table 3. Intervention Treatment Components

Frequency and Type of Contact	**SUP-PA**	**UNSUP-PA**	**STEP**
• Weekly Group Intervention Meetings (Weeks 1-12)	X	X	X
• In-person Supervised Exercise (No behavior change strategies were employed)	X		
Physical Activity Prescription			
• Weekly Supervised Exercise Sessions (3-5 days/week for Weeks 1-12)	X		
• Monitoring of physical activity frequency, type, duration, and intensity by exercise physiologist	X		
• Pedometer			X
• Physical activity paper diaries for self-monitoring		X	X

3.7 ASSESSMENT PROCEDURES

Complete assessments were conducted at weeks 0 and 12 at the University of Pittsburgh Physical Activity and Weight Management Research Center. Each assessment took approximately 60 to 90 minutes to complete. During the assessment visit, measurements of height, weight, BMI, body composition and anthropometry, resting heart rate and blood pressure, cardiorespiratory fitness, physical activity, dietary intake and eating behaviors, and a variety of survey instruments were assessed. At the 12-week assessment, treatment satisfaction was also assessed. Participants were compensated for the 12-week assessment visit. Additionally, physical activity was assessed at weeks 4 and 8.

3.7.1 Height, Weight, Body Mass Index

Height was measured to the nearest 0.1 centimeter (cm) at week 0 and week 12 using a wall-mounted stadiometer (Perspective Enterprises; Portage, MI). Two measurements were taken. If the two measurements were not within 0.5 cm of each other, a third measurement was taken and an average of all three measurements was used as for data analyses. If the third measurement was not needed, an average of the first two measurements was used for data analyses.

Body weight was measured using a calibrated Tanita WB-110A digital scale (Tanita Corporation; Arlington Heights, IL) to the nearest 0.1 kilogram (kg) at week 0 and week 12. Participants were weighed two times in succession while wearing a lightweight hospital gown. If the two measurements were not within 0.2 kg, a third measurement was taken. The average of the measurements was used for data analyses. BMI was calculated as body weight in kilograms divided by height in meters squared (kg/m^2).

3.7.2 Body Composition and Anthropometry

Body composition was assessed via dual-energy x-ray absorptiometry (DXA) using the GE Lunar iDXA (GE Healthcare; Little Chalfont, UK) at weeks 0 and 12. Full-body DXA scans provide data for fat mass, fat-free mass, percent body fat, and bone mineral density. Non-pregnancy was confirmed in females prior to the DXA measure through a urine pregnancy test. The DXA scans were performed by trained staff who have been certified to perform these scans properly and safely.

Waist and hip circumferences were assessed using a Gulick measuring tape measured to the nearest 0.1 cm. Two different waist circumference measures were taken. One waist circumference was measured in the horizontal plane directly at the umbilicus and the other waist circumference was taken at the level of the iliac crest. Hip circumference was taken at the largest circumference in the horizontal plane at the largest part of the hips above the gluteal fold. Two measurements were taken at each site. A third measurement was taken if the first two measurements differed by more than 1.0 cm. The average of the measurements was recorded for data collection. In addition, the average waist measurement was divided by the average hip measurement to derive the waist-to-hip-ratio.

3.7.3 Resting Blood Pressure and Heart Rate

Resting blood pressure was assessed using a Dinamap automated blood pressure cuff (GE Healthcare; Little Chalfont, UK) at weeks 0 and 12. The participants were seated at rest (i.e., sitting upright with feet flat on floor) for 5 minutes prior to the assessment of the blood pressure. Two blood pressures were taken with one minute in between each measurement. If systolic blood pressure differed by >10 mmHg or if diastolic blood pressure differed by >6 mmHg between the two measurements, a third measurement was taken. To determine the proper cuff size, study staff assessed arm circumference using a Gulick measuring tape. The arm circumference was taken at the midpoint between the acromion process and the olecranon process. Cuff size was determined using Table 4.

Table 4. Blood Pressure Cuff Sizes

	Cuff Size
17.0 to < 4.0 cm	Adult small
24.0 to <33.0 cm	Adult
33.0 to <41.0 cm	Large Adult
≥41.0 cm	Thigh or Large Adult Long

The average of the blood pressure measurements was used for data analyses. If the mean systolic blood pressure at baseline was ≥150 mmHg or mean diastolic blood pressure was ≥100 mmHg the participant was excluded from the study and referred to his/her physician. Referral to the primary care physician also occurred if systolic blood pressure was ≥140 mmHg and <150 mmHg or mean diastolic blood pressure was ≥90 mmHg and <100 mmHg; however, they were not excluded from participation provided that they were granted secondary clearance from their physician.

3.7.4 Physical Activity

Physical activity was assessed using the SenseWear device (BodyMedia Inc.; Pittsburgh, PA) at weeks 0, 4, 8, and 12. The SenseWear device is a multi-sensor device that collects minute-by-minute physical activity data and has been previously validated.[180] Participants wore the device during assessment periods all waking hours for seven consecutive days. Participants were instructed to take off the device while sleeping, showering, swimming, and bathing. Participants completed a Physical Activity Device Tracking Form during the seven-day period, which monitors days worn, time the device was worn, and if the device was removed for any reason. Additionally, the SenseWear device is able to notify the investigators the dates and times the device was worn. Criteria for valid physical activity data were similar to what has been used in other studies evaluating physical activity (≥4 days with ≥10 hours/day of wear time). Compensatory changes in physical activity were also be assessed using the SenseWear device. Data from the device were used to identify changes in steps, sedentary activity, light-intensity activity, and MVPA performed in 1, 5, 10, and 20 minute bouts.

The Paffenbarger Exercise Habits Questionnaire[181] was also used to gather data on specific types of activities that participants report, and the questionnaire used in the EARLY trials[182] was used to collected data on self-reported sedentary behavior.

3.7.5 Cardiorespiratory Fitness

Cardiorespiratory fitness was measured using a submaximal graded exercise test at weeks 0 and 12. This graded exercise test started at 3.0 mph and 0% grade. The grade of the treadmill increased 1.0% each minute until the participant reached 85% of their age predicted maximal heart rate. The equation that was used to predict maximal heart rate was 220- age. This exercise test protocol has been shown to be sensitive to detecting change in fitness, without the participant burden or added cost of a maximal exercise test. Fitness was defined as the oxygen consumption, measured via a CareFusion Encore Metabolic Cart (CareFusion Corporation; San Diego, CA), at the point of test termination. Heart rate and blood pressure were assessed throughout the test. These tests were performed under the supervision of an ACSM certified clinical exercise physiologist to ensure participant safety. ACSM criteria for early test termination were followed to enhance participant safety.

3.7.6 Dietary Intake

Energy intake (kilocalories per day) and macronutrient composition, dietary intake were measured at week 0 and 12 using the Block Food Frequency Questionnaire (FFQ) (Dietary Data Systems; Berkeley, CA).[183] Participants were instructed to complete this questionnaire prior to the assessment visit and brought the questionnaire on the day of the assessment.

3.7.7 Additional Survey Instruments

Additional survey instruments were completed at 0 and 12 weeks. Physical activity barriers were assessed using the Exercise Outcomes and Barriers Questionnaire developed by Steinhardt and Dishman.[27] Self-efficacy for physical activity was assessed using the questionnaire developed by Marcus et al.[184] This questionnaire was also adapted to allow assessment of perceived self-efficacy for continuing physical activity after the study period. Eating behaviors associated with weight loss were assessed using the Eating Behavior Inventory[185] and the Three-Factor Eating Questionnaire.[186]

At week 12, participants in SUP-PA, UNSUP-PA, and STEP were asked to rate their satisfaction with the physical activity program. Participants were also asked questions regarding their effort, satisfaction, and overall progress for changing physical activity. Questions included the following:

1. What is your overall satisfaction with the weight management program received? (response options were “very dissatisfied”, “somewhat dissatisfied”, “somewhat satisfied”, “very satisfied”)
2. Would you recommend this weight management program to others? (response options were “Yes”, “No”)
3. What is your overall satisfaction with the physical activity program received? (response options were “very dissatisfied”, “somewhat dissatisfied”, “somewhat satisfied”, “very satisfied”)
4. Would you recommend the physical activity program to others? (response options were “Yes”, “No”)
5. Given the effort you put into the weight management program in this study, how satisfied are you with the progress you have made over the past 12 weeks? Would you recommend this weight management program to others? (response options were “very dissatisfied”, “somewhat dissatisfied”, “somewhat satisfied”, “very satisfied” and “Yes”, “No”)

3.8 SAFETY PROCEDURES

Participant safety was also monitored throughout the 12-week intervention. Investigators evaluated mood, eating behaviors, medications, and medical events to ensure participant safety. The Centers of Epidemiological Studies Depression Scale (CES-D) was asked at week 0 and week 12.[187] This questionnaire was used to determine if the subject was experiencing depressive symptoms that needed medical follow-up. The Eating Disorder Diagnostic Scale (EDDS) was completed at week 0 and week 12.[188] This questionnaire was used to determine if the subject was engaging in unhealthful eating behaviors during this study that required medical follow-up. Participant medications were also tracked at week 0 and week 12 to confirm eligibility and to have data on changes in medication that may influence study outcomes. Participants were also queried on medical events and serious adverse events at assessment visits. Serious adverse events were reported to the Institutional Review Board as per regulations.

3.9 RENUMERATION FOR VISITS

Participants were compensated $75 for completing the 12-week assessment. Participants were also compensated $10 for wearing the SenseWear device at week 4 and week 8 for a total of $20 if the device was worn for both time points. Thus, participants were compensated a total of $95 if they completed all assessment procedures.

3.10 STATISTICAL ANALYSES

Statistical analyses were performed using SPSS software (IBM-SPSS, version 24). Statistical significance was accepted at $p \leq 0.05$. Analyses were performed to examine if data were normally distributed. Normally distributed data are presented as mean ± standard deviation (SD). When data were not normally distributed, non-parametric tests were performed or proper transformations were conducted. Data that were not normally distributed are presented as median (25^{th}, 75^{th} percentiles). Intervention data were analyzed using a one-way ANOVA to compare data across the UNSUP-PA, SUP-PA, and STEP interventions. Chi-square was used for categorical data.

Descriptive statistics were used to describe the study sample at baseline, with one-way analysis of variance (ANOVA) used to compare baseline data across randomized groups (SUP-PA, UNSUP-PA, STEPS). Mean baseline values that were assessed include: age, weight, BMI, physical activity, fitness, blood pressure, dietary intake, waist circumference, and body composition. Data that were not normally distributed were analyzed using a Kruskal-Wallis Test. For significant effects, pairwise comparisons (SUP-PA vs. UNSUP-PA, SUP-PA vs. STEPS, UNSUP-PA vs. STEPS) were examined using a Bonferroni adjusted p-value for multiple comparisons.

Changes in MVPA, the primary outcome, other forms of physical activity, and sedentary behavior measured from the SenseWear device at 0, 4, 8, and 12 weeks. Primary outcomes were analyzed using a repeated measures ANOVA. Significance for the effects of treatment group, time, and group by time interaction were examined. Differences between SUP-PA, UNSUP-PA, and STEP groups were examined over time with the p-value adjusted for multiple comparisons using the Bonferroni procedure. Additional outcomes were assessed using a similar method with 2 time points (0 and 12 weeks).

3.11 POWER ANALYSIS

The primary aim of this study was to provide feasibility data to justify an appropriately powered long-term study. Given the pilot nature of this study, there were minimal data available to inform an effect size for between group comparisons. Based on a previous study conducted by Perri et al., the anticipated standard deviation for MVPA was 26.05 minutes.[22] It was hypothesized that a statistically meaningful difference in MVPA would be 20 minutes/week. With 80% power and a type one error rate of .05, adjusted to .025 for the multiple comparisons of STEP vs. SUP-PA and UNSUP-PA vs. SUP-PA, it was estimated that 17 participants per group would be needed. Therefore, a total of 51 participants were needed. Based on past studies at the Physical Activity and Weight Management Research Center we anticipated 90-95% retention across the study period. In order to allow for attrition, we proposed to enroll 60 subjects; this would allow for an attrition rate of 3 participants per group which was higher than the hypothesized attrition rate. Power calculations were conducted using G*Power, version 3.1.9.2.

4.0 RESULTS

The primary aim of this study was to compare the effectiveness of a supervised physical activity program prescribed in minutes per week (SUP-PA), unsupervised physical activity program prescribed in minutes per week (UNSUP-PA), and an unsupervised program prescribed in steps per day (STEP) during a behavioral weight loss intervention in adults who were overweight or obese. This was a 12-week randomized weight loss trial with assessments at baseline (0 weeks) and post-intervention (12 weeks). All study related procedures (physical assessments, behavioral intervention, and exercise sessions) were conducted at the University of Pittsburgh Physical Activity and Weight Management Research Center (PAWMRC). The results are presented below.

4.1 STUDY PARTICIPANTS

Fifty-two (N=52) inactive adults between the ages of 18-55 years old with a BMI of 25.0 to <40.0 were randomized in this trial. Mean age was 43.5 ± 10.1 years and mean BMI was 31.5 ± 3.5 kg/m^2, with 26.9% males and 32.7% non-white participants. Baseline characteristics are shown in Table 5. There was a significant difference in baseline cardiorespiratory fitness (peak oxygen consumption during the submaximal treadmill test) between groups (p=0.038). Post hoc analysis with Bonferroni adjustment revealed that STEP and UNSUP-PA were statistically different ($p<.05$). One-way analysis of variance (ANOVA) and Pearson Chi-Square revealed there were no other significant differences between the groups.

Table 5. Baseline Characteristics

CHARACTERISTICS	TOTAL N= 52 Mean ± SD	STEP N= 18 Mean ± SD	UNSUP-PA N= 17 Mean ± SD	SUP-PA N= 17 Mean ± SD
Age (years)	43.5 ± 10.1	39.3 ± 10.7	46.2 ± 10.1	45.2 ± 8.5
Height (cm)	165.5 ± 9.0	168.2 ± 8.9	165.9 ± 6.8	162.3 ± 10.4
Weight (kg)	86.4 ± 13.5	88.2 ± 14.5	86.5 ± 12.8	84.5 ± 13.6
BMI (kg/m^2)	31.5 ± 3.5	31.1 ± 3.8	31.3 ± 3.3	32.0 ± 3.5
Sex				
Male N,%	14, 26.9%	5, 27.8%	5, 29.4%	4, 23.5%
Female N,%	38, 73.1%	13, 72.2%	12, 70.6%	13, 76.5%
Race				
White N, %	35, 67.3%	12, 66.7%	11, 64.7%	12, 70.6%
Non-white N,%	17, 32.7%	6, 33.3%	6, 35.3%	5, 29.4%
Black or African American N, %	12, 23.1%	3, 16.7%	5, 29.4%	4, 23.5%
Asian N, %	5, 9.6%	3, 16.7%	1, 5.9%	1, 5.9%
Peak VO_2 (ml/kg/min)	25.2 ± 5.0	27.7 ± 5.4	23.7 ± 4.2	24.1 ± 4.4

4.2 STUDY RECRUITMENT AND RETENTION

Figure 6 illustrates recruitment, randomization, and retention. A total of 247 telephone calls were received by study staff from potential participants expressing interest in the study, and 174 (70.4%) consented for the telephone screening. Of the individuals screened, 83 (47.7%) were eligible for the study and invited to an orientation session at the PAWMRC. Sixty-nine individuals attended the orientation session with 63 consenting to participate in the study (Appendix D). Fifty-two individuals completed the baseline assessment and were randomized to STEP, SUP-PA, or UNSUP-PA. Reasons for ineligibility and reasons for not being randomized are provided in Figure 6.

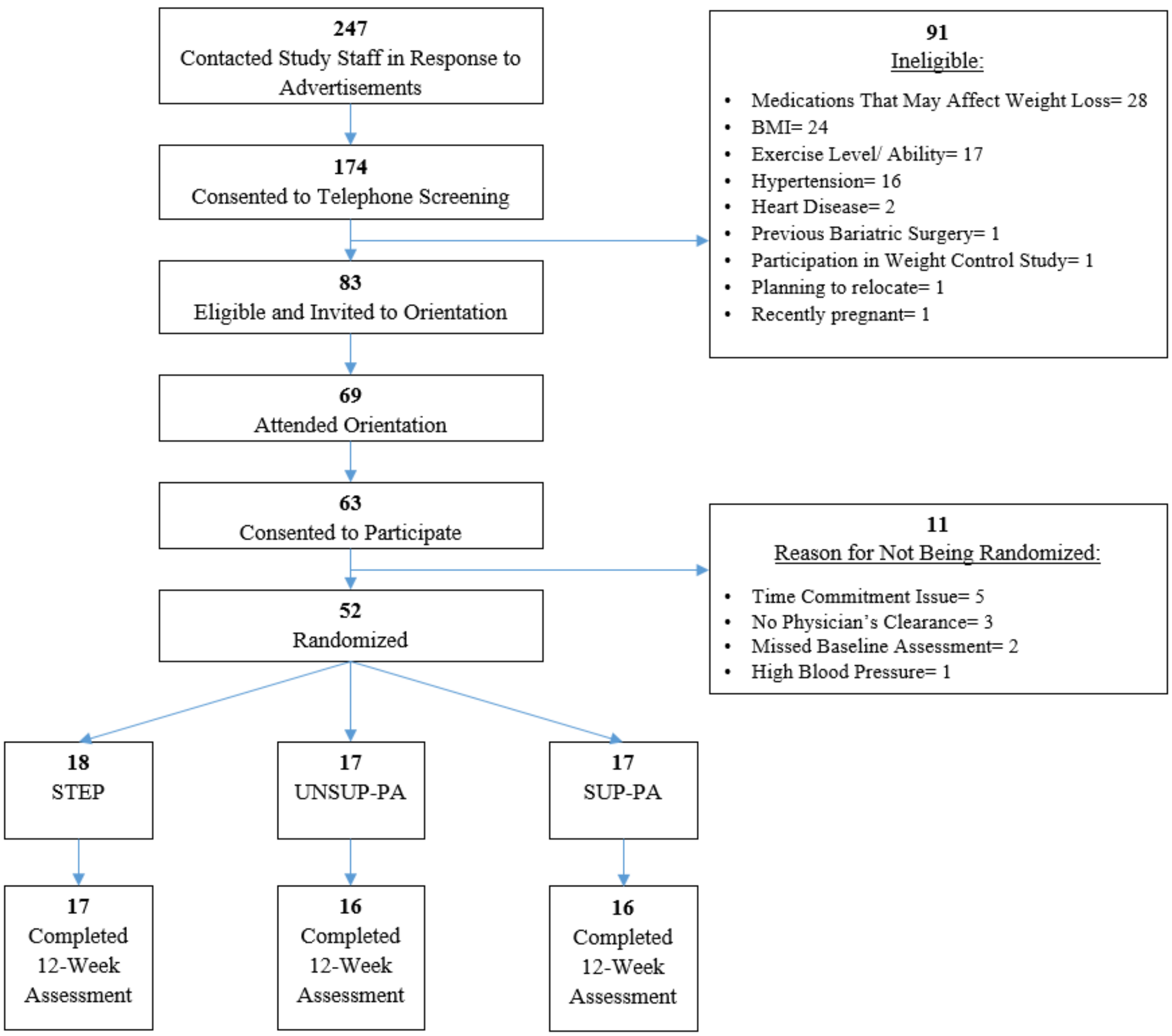


Figure 6. Consort Diagram

Forty-nine participants (94.2%) completed the baseline and 12-week physical assessment. Participants who did not complete the 12-week assessment will be referred to as "non-completers" while participants completing both assessments will be referred to as "completers." Baseline characteristics of completers and non-completers are shown in Table 6. All three non-completers were female and non-white. There was one non-completer in each treatment group (SUP-PA; N=1), (UNSUP-PA; N=1), (STEP; N=1). Because attrition was low and spread evenly across the treatment groups, only data from the completers' analyses are presented.

Table 6. Baseline Characteristics of Completers and Non-Completers

CHARACTERISTICS	Total Sample N=52 Mean ± SD	Completers N= 49 Mean ± SD
Age (years)	43.5 ± 10.1	43.2 ± 10.3
Height (cm)	165.5 ± 9.0	165.5 ± 9.3
Weight (kg)	86.4 ± 13.5	86.2 ± 13.7
BMI (kg/m^2)	31.5 ± 3.5	31.4 ± 3.5
Sex		
Male N,%	14, 26.9%	14, 28.6%
Female N,%	38, 73.1%	35, 71.4%
Race		
White N, %	35, 67.3%	35, 71.4%
Non-white N,%	17, 32.7%	14, 28.6%
Black or African American N, %	12, 23.1%	10, 20.4%
Asian N, %	5, 9.6%	4, 8.1%
Dietary Intake (kcal/day)	1797 ± 838	1819 ± 823
Self-Report Physical Activity (kcal/week)	863.7 ± 779.1	851.4 ± 735.9
Systolic Blood Pressure (mmHg)	118.2 ± 10.7	118.3 ± 10.9
Diastolic Blood Pressure (mmHg)	71.3 ± 8.7	71.4 ± 8.9
Resting Heart Rate (bpm)	68.6 ± 10.9	68.7 ± 10.9
VO_2 Peak (ml/kg/min)	25.2 ± 5.0	25.5 ± 4.9

4.3 CHANGE IN PHYSICAL ACTIVITY

4.3.1 Objectively Measured Physical Activity

Physical activity data were considered valid if the physical activity device was worn ≥ 4 days and ≥ 10 hours/day. Analyses were also conducted using all participants with ≥ 1 day and ≥ 10 hours/day. The pattern of the results were comparable, and therefore, the data for ≥ 1 day and ≥ 10 hours/day are presented below. The data for wear time of ≥ 4 days and ≥ 10 hours/day are presented in Appendix A (Table 18).

At baseline, there were no significant differences between groups for any measures of physical activity. Treatment groups reported similar amounts of wear time (days/week and hours/day) across the 12-week intervention. Objectively measured physical activity data are presented in Table 7 and Table 8.

A one-way ANOVA on the change in moderate-to-vigorous physical activity (MVPA, [≥3.0 METs in bouts of ≥10 minutes]) found no differences between the groups ($p=0.70$). All three groups significantly increased objectively measured MVPA completed in bouts of ≥10 minutes over the 12-week intervention (STEP: 11.5 ± 31.2 min/day, UNSUP-PA: 16.1 ± 25.8 min/day, and SUP-PA: 21.6 ± 24.9 min/day, $p<0.001$) with no differences between groups ($p=0.94$) or group by time interaction ($p=0.81$). Figure 7 illustrates the changes in MVPA minutes/week (≥3.0 METs in bouts of ≥10 minutes) during the 12-week intervention.

There was a significant increase in the number of bouts/day of MVPA (≥3.0 METs in bouts of ≥10 minutes) for all three treatment groups over the course of the intervention ($p<0.001$) with no group effect ($p=0.69$) or group X time interaction ($p=0.95$). Intensity of the physical activity bouts also increased over time ($p=0.01$) with no group effect ($p=0.43$) or group by time interaction (p=0.68). Following the 12-week intervention, all three groups were engaging in a significant amount of MVPA (STEP: 47.0 ± 28.2 min/day, UNSUP-PA: 41.7 ± 44.5 min/day, SUP-PA: 49.6 ± 38.7 min/day) A similar pattern was observed when analyzing MVPA in bouts of >1 minute. Data are presented in Table 7 and Table 8.

In addition, all treatment groups increased total steps/day (p<0.001) with no group differences (p=0.40) or interaction effect (p=0.79) (STEP: 2595 ± 2535, UNSUP-PA: 2133 ± 2909, SUP-PA: 1964 ± 1879). Following the 12-week intervention, STEP was taking 10323 ± 2538 steps/day, UNSUP-PA was taking 9108 ± 3589 steps/day, and SUP-PA was taking 9229 ± 2187 steps/day. MVPA steps/day completed in bouts of ≥10 minutes also increased in all three treatment groups (p<0.001) with no group differences (p=0.79) or interaction effect (p=0.94) (STEP: 1584 ± 2030, UNSUP-PA: 1420 ± 2418, SUP-PA: 1710 ± 1594).

STEP, UNSUP-PA, and SUP-PA significantly decreased objectively measured sedentary time (SED) over the 12-week intervention (STEP: -61.0 ± 91.9 min/day, UNSUP-PA: -56.2 ± 94.0 min/day, and SUP-PA: -62.8 ± 71.0 min/day, p<0.001) with no differences between groups (p=0.20) or group by time interaction (p=0.99). Because wear time may confound these results, analyses were also conducted with sedentary represented as a percentage of wear time. These analyses revealed the same pattern with all three groups significantly reducing SED over the 12-week intervention (STEP: -8.6 ± 10.7%, UNSUP-PA: -6.4 ± 8.2%, SUP-PA: -6.9 ± 7.0%).

All three treatment groups significantly increased Light-intensity physical activity (LPA) over the 12-week intervention (STEP: 69.7 ± 54.6 min/day, UNSUP-PA: 57.1 ± 88.7 min/day, and SUP-PA: 28.3 ± 49.5 min/day, p<0.001) with no differences between groups (p=0.27) or group by time interaction (p=0.30).

Table 7. Changes in Objectively Measured Physical Activity

Outcome	Groups	Assessment Periods				P-Values		
		Baseline	4 Weeks	8 Weeks	12 Weeks	Group	Time	Time X Group
Days of Wear Time	STEP (N=17)	6.8 ± 0.6	6.9 ± 0.3	6.5 ± 1.1	6.8 ± 0.4	0.40	0.02	0.23
	UNSUP-PA (N=16)	6.7 ± 0.9	6.8 ± 0.4	6.4 ± 0.8	6.8 ± 0.4			
	SUP-PA (N=16)	6.7 ± 0.6	6.9 ± 0.4	6.5 ± 1.1	5.8 ± 1.9			
Hours of Wear Time/Day	STEP (N=17)	14.3 ± 1.7	14.5 ± 1.4	14.4 ± 1.6	14.6 ± 1.6	0.68	0.41	0.79
	UNSUP-PA (N=16)	14.8 ± 1.0	14.9 ± 0.9	14.6 ± 1.2	14.8 ± 1.2			
	SUP-PA (N=16)	14.5 ± 1.4	14.7 ± 1.4	14.4 ± 1.1	14.3 ± 1.1			
SED (min/day)	STEP (N=17)	585.6 ± 113.6	579.2 ± 105.4	521.8 ± 126.3	524.7 ± 110.0	0.20	<0.001	0.99
	UNSUP-PA (N=16)	638.3 ± 106.4	621.3 ± 88.2	586.5 ± 103.0	582.1 ± 112.7			
	SUP-PA (N=16)	583.7 ± 109.1	571.8 ± 114.8	517.9 ± 110.6	520.9 ± 129.1			
LPA (min/day)	STEP (N=17)	189.3 ± 57.9	210.2 ± 62.2	252.7 ± 82.0	259.0 ± 65.3	0.27	<0.001	0.30
	UNSUP-PA (N=16)	174.0 ± 67.7	180.2 ± 66.7	199.8 ± 62.8	231.1 ± 81.2			
	SUP-PA (N=16)	209.1 ± 82.8	216.7 ± 73.9	249.4 ± 90.5	237.4 ± 76.6			
MVPA (min/day)	STEP (N=17)	60.9 ± 45.2	71.5 ± 33.3	76.9 ± 41.0	75.3 ± 40.2	0.74	<0.001	0.98
	UNSUP-PA (N=16)	49.2 ± 44.3	63.3 ± 49.8	67.6 ± 53.4	64.8 ± 50.2			
	SUP-PA (N=16)	55.3 ± 46.9	75.4 ± 43.4	80.3 ± 53.8	75.3 ± 55.4			
Bouted MVPA (min/day)	STEP (N=17)	35.4 ± 33.5	42.8 ± 23.6	51.2 ± 33.5	47.0 ± 28.2	0.94	<0.001	0.81
	UNSUP-PA (N=16)	25.6 ± 36.0	38.3 ± 42.6	46.1 ± 45.5	41.7 ± 44.5			
	SUP-PA (N=16)	28.0 ± 23.5	44.4 ± 24.0	54.3 ± 37.2	49.6 ± 38.7			
Bouts of MVPA/Day	STEP (N=17)	1.6 ± 1.4	2.0 ± 1.1	2.1 ± 1.2	2.2 ± 1.3	0.69	<0.001	0.95
	UNSUP-PA (N=16)	1.2 ± 1.3	1.5 ± 1.2	1.8 ± 1.4	1.9 ± 1.6			
	SUP-PA (N=16)	1.3 ± 1.2	1.8 ± 1.1	2.0 ± 1.6	2.0 ± 2.0			
Intensity of MVPA	STEP (N=16)	4.4 ± 0.8	4.8 ± 0.9	4.9 ± 0.9	5.0 ± 1.1	0.43	0.01	0.68
	UNSUP-PA (N=11)	4.2 ± 0.6	4.7 ± 0.6	4.5 ± 0.8	4.5 ± 0.6			
	SUP-PA (N=13	4.3 ± 0.4	4.5 ± 0.6	4.6 ± 0.7	4.7 ± 0.8			

SED: Sedentary Time (<1.5 METs)
LPA: Light-Intensity Physical Activity (≥1.5 METs to <3.0 METs)
MVPA: Moderate-to-Vigorous Physical Activity (≥3.0 METs in bouts of ≥1 minute)
Bouted MVPA: (≥3.0 METs in bouts of ≥10 minutes)
Intensity of MVPA: (average METs/ physical activity bout ≥10 minutes)

Table 8. Physical Activity Comparisons across the 12-Week Intervention

Outcome	Groups	Assessment Periods			
		Baseline	4 Weeks	8 Weeks	12 Weeks
MVPA	STEP (N=17)	248.1 ± 234.5	299.4 ± 165.1	358.4 ± 234.6	328.7 ± 197.7
(Minutes/week ≥3.0 METs in bouts of ≥10 minutes)	Change from Baseline		51.3 ± 222.8	110.3 ± 125.9	80.6 ± 218.5
	UNSUP-PA (N=16)	179.3 ± 252.2	268.0 ± 298.5	323.0 ± 318.8	292.1 ± 311.3
	Change from Baseline		88.7 ± 166.6	143.7 ± 220.8	112.9 ± 180.4
	SUP-PA (N=16)	196.2 ± 164.8	310.7 ± 168.2	379.9 ± 260.4	347.3 ± 270.7
	Change from Baseline		114.5 ± 106.7	183.7 ± 178.2	151.1 ± 174.0
Total Steps	STEP	7728 ± 1456	9883 ± 2142	10267 ± 2251	10323 ± 2538
(Steps/day)	Change from Baseline		2155 ± 2329	2539 ± 2095	2595 ± 2535
	UNSUP-PA	6975 ± 2716	8931 ± 4063	8701 ± 3622	9108 ± 3589
	Change from Baseline		1956 ± 3219	1725 ± 2587	2133 ± 2909
	SUP-PA	7265 ± 1875	9458 ± 2388	9980 ± 3114	9229 ± 2187
	Change from Baseline		2193 ± 1703	2715 ± 3189	1964 ± 1879
Bouted MVPA Steps	STEP	2178 ± 1391	3579 ± 1615	4067 ± 2149	3762 ± 1762
(Steps/day at ≥3.0 METs in bouts of ≥10 minutes)	Change from Baseline		1401 ± 1632	1888 ± 1677	1584 ± 2030
	UNSUP-PA	1943 ± 2724	3415 ± 4066	3480 ± 3738	3363 ± 3534
	Change from Baseline		1472 ± 2698	1537 ± 2284	1420 ± 2418
	SUP-PA	1385 ± 826	3148 ± 1601	3859 ± 2506	3096 ± 1451
	Change from Baseline		1763 ± 1419	2475 ± 2729	1710 ± 1594

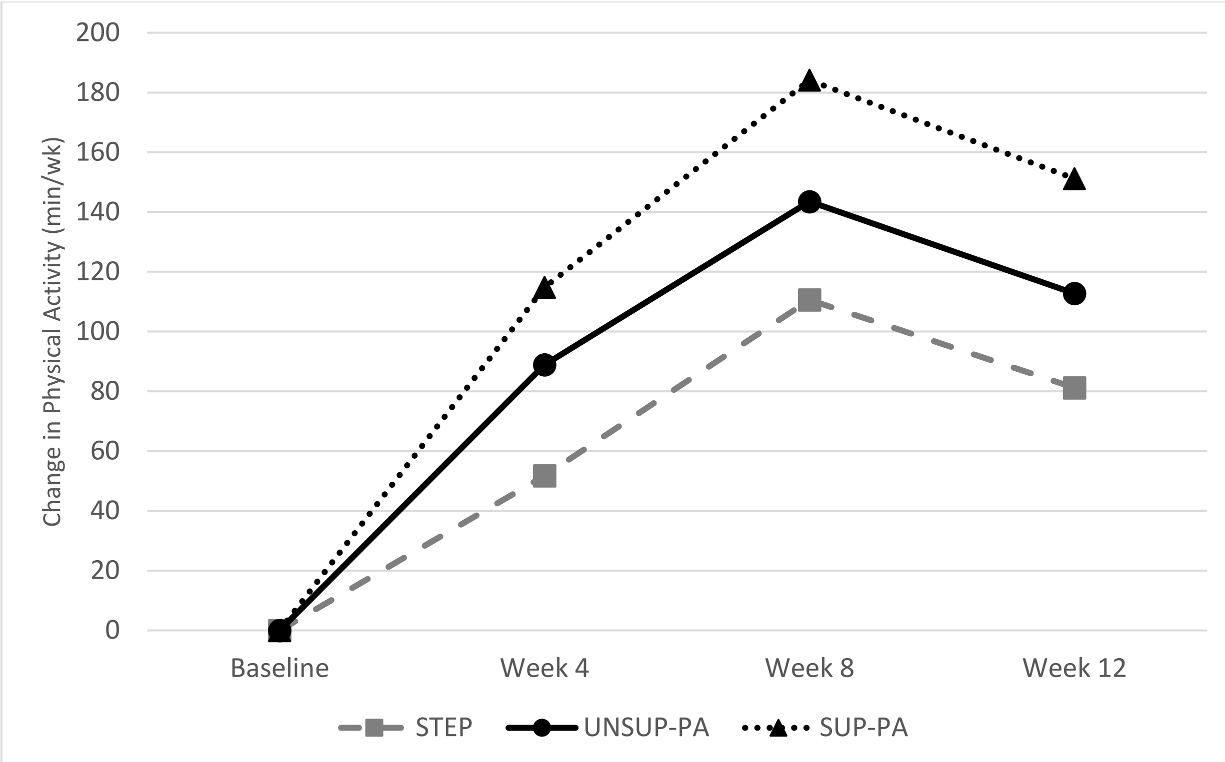


Figure 7. Change in Objective MVPA completed in bouts of ≥ 10 minutes

4.3.2 Subjective Measures of Physical Activity

Self-reported physical activity (kcal/week) was not normally distributed so data were log transformed. Results from the repeated measures ANOVA showed a significant time effect ($p<0.001$), with no group effect ($p=0.59$) or group by time interaction ($p=0.79$). Energy expenditure increased in STEP (949.5 ± 726.2 kcals/week at baseline, 1504.5 ± 576.1 kcal/week at week 12) UNSUP-PA (689.2 ± 620.6 kcals/week at baseline, 1468.4 ± 989.7 kcal/week at week 12) and SUP-PA (840.1 ± 845.3 kcals/week at baseline, 1821.6 ± 816.2 kcal/week at week 12). There was no group effect ($p=0.54$) or group X time interaction ($p=0.41$). Analyses were also performed removing the stairs from the physical activity energy expenditure with the pattern of results similar to those presented above. Self-reported physical activity data are reported in Table 9.

At baseline, all three groups were engaging in similar amounts of self-report sedentary behavior on weekdays (STEP, 10.8 ± 3.5 hr/day), (UNSUP-PA, 14.3 ± 5.9 hr/day), (SUP-PA, 12.0 ± 4.1 hr/day). There was no significant group X time interaction effect; however, STEP increased weekday sedentary time (1.9 ± 5.3 hr/day) while SUP-PA (-1.1 ± 2.8 hr/day) and UNSUP-PA (-0.1 ± 2.2 hr/day) decreased weekday sedentary time (p=0.08). There were no statistical differences between groups in self-reported sedentary time on weekend days (p=0.55), and there was no change in sedentary time on weekend days over the 12-week intervention (p=0.16). These data are reported in Table 9.

Table 9. Changes in Self-Reported Physical Activity and Sedentary Time

Outcome	Group	Baseline	12 Weeks	Change	P-Values Group	Time	Group X Time
Sedentary Time Weekday (hr/day)	STEP (N=17)	10.8 ± 3.5	12.7 ± 6.0	1.9 ± 5.3			
	UNSUP-PA (N=16)	14.3 ± 5.9	14.2 ± 6.4	-0.1 ± 2.2	0.20	0.67	0.08
	SUP-PA (N=16)	12.0 ± 4.1	11.0 ± 3.5	-1.1 ± 2.8			
Sedentary Time Weekend (hr/day)	STEP	9.0 ± 3.8	8.5 ± 4.7	-0.5 ± 4.1			
	UNSUP-PA	10.5 ± 4.7	10.1 ± 6.9	-0.4 ± 4.4	0.55	0.16	0.58
	SUP-PA	10.2 ± 4.9	8.3 ± 3.4	-1.9 ± 4.7			
**Leisure-time Physical Activity with Stairs (kcal/wk)	STEP	740 (460, 1712)	1388 (1118, 1785)	591 (213, 896)			
	UNSUP-PA	420 (280, 712)	1259 (716, 2224)	578 (84, 1507)			
	SUP-PA	560 (324, 1094)	1541 (1181, 2140)	889 (226, 1893)	0.59	<0.001	0.79
**Leisure-time Physical Activity without Stairs (kcal/wk)	STEP	456 (192, 1439)	1170 (992, 1364)	619 (213, 818)			
	UNSUP-PA	336 (24, 444)	1064 (450, 1736)	648 (126, 1453)			
	SUP-PA	216 (72, 842)	1413 (1125, 1842)	1001 (298, 1701)	0.56	<0.001	0.66

**Data presented as median (25^{th}, 75^{th} Percentiles)

4.4 CHANGE IN WEIGHT

There was a significant time effect for BMI across STEP, UNSUP-PA, and SUP-PA ($p<0.001$), but there was no significant group X time interaction ($p=0.55$). STEP, UNSUP-PA, and SUP-PA reduced BMI by 1.9 ± 1.3 kg/m^2, 1.8 ± 1.1 kg/m^2, and 1.5 ± 1.2 kg/m^2, respectively. Similarly, weight loss across the 12-week intervention was similar in all three groups STEP (-5.3 ± 3.6 kg), UNSUP-PA (-5.1 ± 3.3 kg), and (-3.8 ± 3.0 kg). There was a significant time effect ($p<0.001$), but there was no significant group X time interaction ($p=0.36$). Total weight loss for all the groups was 4.7 ± 3.3 kg. Percent weight loss for all the groups was $5.4 \pm 3.7\%$. There were no significant differences in percent weight loss between STEP, UNSUP-PA, and SUP-PA. Results are shown in Table 10.

Weight loss of 5% has been suggested as the minimal goal of behavioral weight loss interventions;[189] thus, STEP, UNSUP-PA, and SUP-PA were further examined based upon achievement of 5% weight loss. These data are presented in Table 11. Adjusted for multiple comparisons, Chi Square analyses demonstrated that STEP and UNSUP-PA had more individuals attain 5% weight loss compared to SUP-PA ($p<0.05$). Individual weight loss patterns by group are illustrated in Figure 8.

Table 10. Change in Weight, Body Composition, and Anthropometrics

Outcome	Group	Baseline	12 Weeks	Change	P-Values Group	Time	Group X Time
BMI (kg/m^2)	STEP (N=17)	30.9 ± 3.8	29.0 ± 3.5	-1.9 ± 1.3	0.59	<0.001	0.55
	UNSUP-PA (N=16)	31.3 ± 3.4	29.5 ± 3.3	-1.8 ± 1.1			
	SUP-PA (N=16)	32.0 ± 3.6	30.5 ± 3.4	-1.5 ± 1.2			
Weight (kg)	STEP (N=17)	87.7 ± 14.7	82.3 ± 14.1	-5.3 ± 3.6	0.81	<0.001	0.36
	UNSUP-PA (N=16)	86.8 ± 13.1	81.6 ± 11.8	-5.1 ± 3.3			
	SUP-PA (N=16)	84.0 ± 13.7	80.1 ± 13.2	-3.8 ± 3.0			
Percent Weight Change (%)	STEP (N=17)			-6.0 ± 4.0	0.43		
	UNSUP-PA (N=16)			-5.8 ± 3.6			
	SUP-PA (N=16)			-4.5 ± 3.5			
Fat mass (kg)	STEP (N=17)	33.7 ± 6.3	29.6 ± 6.2	-4.1 ± 2.4	0.77	<0.001	0.95
	UNSUP-PA (N=16)	35.4 ± 7.6	31.3 ± 8.2	-4.0 ± 2.8			
	SUP-PA (N=15)	34.6 ± 6.7	30.8 ± 6.4	-3.8 ± 2.8			
Fat Free Mass (kg)	STEP (N=17)	50.9 ± 10.5	49.7 ± 10.5	-1.2 ± 1.7	0.69	<0.001	0.06
	UNSUP-PA (N=16)	48.2 ± 9.9	47.2 ± 9.3	-1.0 ± 1.1			
	SUP-PA (N=15)	47.3 ± 11.1	47.3 ± 11.2	-0.1 ± 1.4			
Total Body Fat (%)	STEP (N=17)	38.7 ± 4.6	36.2 ± 5.6	-2.5 ± 2.1	0.49	<0.001	0.96
	UNSUP-PA (N=16)	41.1 ± 6.9	38.5 ± 8.4	-2.6 ± 2.3			
	SUP-PA (N=15)	41.2 ± 6.8	38.5 ± 7.2	-2.7 ± 2.2			
Tissue Body Fat (%)	STEP (N=17)	39.9 ± 4.7	37.5 ± 5.7	-2.5 ± 2.1	0.50	<0.001	0.96
	UNSUP-PA (N=16)	42.4 ± 7.0	39.8 ± 8.5	-2.6 ± 2.4			
	SUP-PA (N=15)	42.5 ± 6.9	39.7 ± 7.3	-2.7 ± 2.2			
Waist Circumference (umbilicus, cm)	STEP (N=17)	99.8 ± 11.1	94.1 ± 9.9	-5.7 ± 5.3	0.55	<0.001	0.89
	UNSUP-PA (N=16)	102.9 ± 9.1	97.1 ± 8.5	-5.8 ± 4.5			
	SUP-PA (N=15)	103.4 ± 9.9	96.9 ± 9.1	-6.5 ± 4.6			
Waist Circumference (iliac, cm)	STEP (N=17)	100.1 ± 9.6	94.6 ± 8.4	-5.5 ± 5.8	0.68	<0.001	0.32
	UNSUP-PA (N=16)	101.8 ± 6.8	97.9 ± 8.3	-3.9 ± 5.6			
	SUP-PA (N=15)	101.8 ± 9.2	94.7 ± 9.3	-7.0 ± 5.9			
Hip Circumference (cm)	STEP (N=17)	109.5 ± 8.8	105.3 ± 7.1	-4.2 ± 3.9	0.67	<0.001	0.65
	UNSUP-PA (N=16)	109.8 ± 6.5	105.7 ± 7.3	-4.0 ± 2.7			
	SUP-PA (N=15)	111.3 ± 9.2	108.1 ± 8.1	-3.2 ± 3.2			

Table 11. Achievement of 5% Weight Loss by Group at Week 12

Group	Did not Achieve 5% Weight Loss	Achieved 5% Weight Loss	Percent of Group Achieving 5% Weight Loss
STEP (N=17)	5	12	67% A
UNSUP-PA (N=16)	5	11	65% B
SUP-PA (N=16)	11	5	31% A,B
TOTAL (N=49)	21	28	57%

Groups with the same letters are significantly different at p<0.05

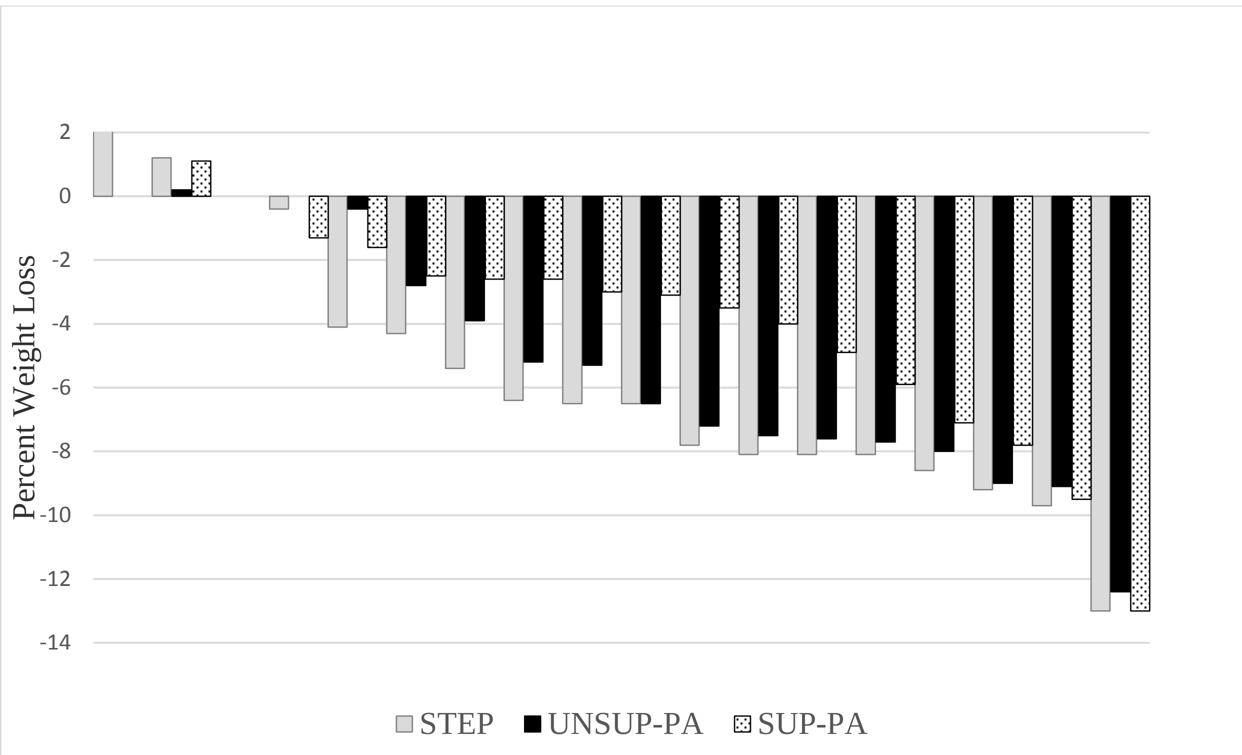


Figure 8. Individual Percent Weight Loss by Group at Week 12 (N=49)

4.5 CHANGE IN BODY COMPOSITION

There were significant reductions in waist circumference measured at the umbilicus ($p<0.001$) and the iliac crest ($p<0.001$) at 12 weeks for STEP (umbilicus: -5.7 ± 5.3 cm, iliac crest: -5.5 ± 5.8 cm), UNSUP-PA (umbilicus: -5.8 ± 4.5 cm, iliac crest: -3.9 ± 5.6 cm), and SUP-PA (umbilicus: -6.5 ± 4.6 cm, iliac crest: -7.0 ± 5.9 cm). There were no differences observed between groups for waist circumference at the umbilicus ($p=0.55$) or iliac crest ($p=0.68$) measurements and there were no significant group X time interactions (umbilicus: $p=0.89$, iliac crest: $p=0.32$). Similarly, there was a significant time effect for hip circumference ($p<0.001$) in STEP (-4.2 ± 3.9 cm), UNSUP-PA (-4.0 ± 2.7 cm), and SUP-PA (-3.2 ± 3.2 cm), but there was no significant group effect ($p=0.65$) or group by time interaction ($p=0.67$).

There were significant reductions in fat mass ($p<0.001$) at 12 weeks for STEP (-4.1 ± 2.4 kg), UNSUP-PA (-4.0 ± 2.8 kg), and SUP-PA (-3.8 ± 2.8 kg). There was no significant difference observed between groups for fat mass ($p=0.77$) and there was no significant group X time interaction ($p=0.95$). There were significant reductions in total percent body fat ($p<0.001$) and tissue percent body fat ($p<0.001$) at 12 weeks for STEP (total: -2.5 ± 2.1 kg, tissue: -2.5 ± 2.1 kg), UNSUP-PA (total: -2.6 ± 2.3 kg, tissue: -2.6 ± 2.4 kg), and SUP-PA (total: -2.7 ± 2.2 kg, tissue: -2.7 ± 2.2 kg). There were no significant differences observed between groups for total percent fat ($p=0.49$) or tissue percent fat ($p=0.50$) and there were no group X time interactions (total: $p=0.96$, tissue: $p=0.96$). In addition, there were was a significant time effect for lean mass ($p<0.001$) in STEP (-1.2 ± 1.7 kg), UNSUP-PA (-1.0 ± 1.1 kg), and SUP-PA (-0.1 ± 1.4 kg), but there was no significant group effect ($p=0.69$) or group by time interaction ($p=0.06$). Results are shown in Table 10.

4.6 CHANGE IN CARDIORESPIRATORY FITNESS

Cardiorespiratory fitness improved over the 12-week intervention ($p<0.001$). There was a significant group X time interaction effect for cardiorespiratory fitness ($p=0.01$). Bonferroni adjusted post hoc analysis revealed that SUP-PA (3.8 ± 1.6 ml/kg/min) and UNSUP-PA (3.8 ± 3.2 ml/kg/min) had a greater improvement in fitness compared to STEP (1.3 ± 2.4 ml/kg/min) ($p<0.05$). There was no statistical difference between SUP-PA and UNSUP-PA for change in cardiorespiratory fitness.

Because weight change could be a potential confounder when interpreting changes in relative VO_2 (ml/kg/min), analyses were also performed using absolute VO_2 (L/min) and treadmill time (minutes until test termination). When examining treadmill time, there were was a significant improvement across the intervention in all three groups ($p<0.001$). However, there was no significant group X time interaction ($p=0.41$). Measures of peak absolute VO_2 improved significantly over the 12-week intervention. There was a significant group X time interaction with UNSUP-PA (0.17 ± 0.24 L/min) and SUP-PA (0.22 ± 0.23 L/min) improving more than STEP (-0.04 ± 0.19 L/min) ($p<0.01$). Cardiorespiratory fitness data are presented in Table 12.

Table 12. Change in Cardiorespiratory Fitness, Resting Blood Pressure, and Heart Rate

Outcome	Group	Baseline	12 Weeks	Change	P-Values Group	P-Values Time	P-Values Group X Time
Resting Heart Rate (bpm)	STEP (N=17)	64.5 ± 10.2	61.0 ± 8.3	-3.5 ± 10.3	0.24	<0.001	0.07
	UNSUP-PA (N=16)	70.7 ± 11.2	64.5 ± 9.2	-6.2 ± 9.7			
	SUP-PA (N=16)	71.0 ± 10.7	59.8 ± 6.2	-11.3 ± 8.7			
Resting Systolic Blood Pressure (mmHg)	STEP	115.8 ± 10.5	113.0 ± 11.6	-2.8 ± 7.6	0.51	<0.01	0.93
	UNSUP-PA	120.5 ± 9.2	116.6 ± 10.6	-3.9 ± 7.3			
	SUP-PA	118.9 ± 13.0	115.3 ± 12.2	-3.6 ± 10.9			
Resting Diastolic Blood Pressure (mmHg)	STEP	69.8 ± 8.5	67.9 ± 9.2	-1.9 ± 4.1	0.66	<0.01	0.97
	UNSUP-PA	71.8 ± 10.0	69.5 ± 7.4	-2.3 ± 4.4			
	SUP-PA	72.7 ± 8.5	70.3 ± 9.5	-2.4 ± 6.1			
Treadmill Time (min)	STEP	11.1 ± 3.8	11.9 ± 3.7	0.8 ± 2.1	0.07	<0.001	0.41
	UNSUP-PA	8.4 ± 2.9	9.4 ± 3.7	1.0 ± 2.0			
	SUP-PA	8.2 ± 3.3	9.8 ± 4.1	1.7 ± 1.7			
Peak VO2 (ml/kg/min)	STEP	27.9 ± 5.5	29.2 ± 6.0	1.3 ± 2.4	0.26	<0.001	0.01
	UNSUP-PA	23.9 ± 4.5	27.7 ± 5.7	3.8 ± 3.2			
	SUP-PA	24.4 ± 4.2	28.2 ± 4.9	3.8 ± 1.6			
Peak VO2 (L/min)	STEP	2.43 ± 0.56	2.39 ± 0.60	-0.04 ± 0.19	0.44	<0.001	<0.01
	UNSUP-PA	2.08 ± 0.52	2.25 ± 0.54	0.17 ± 0.24			
	SUP-PA	2.09 ± 0.59	2.31 ± 0.71	0.22 ± 0.23			

4.7 CHANGE IN BLOOD PRESSURE AND RESTING HEART RATE

There were significant reductions in resting heart rate, resting systolic blood pressure, and diastolic blood pressure over time for STEP, UNSUP-PA, and SUP-PA ($p<0.001$). However, there was not a significant group effect or group X time interaction for any of these variables. Resting heart rate was reduced in STEP (-3.5 ± 10.3 beats/min), UNSUP-PA (-6.2 ± 9.7 beats/min) and SUP-PA (-11.3 ± 8.7 beats/min). Resting systolic blood pressure was reduced in STEP (-2.8 ± 7.6 mmHg), UNSUP-PA (-3.9 ± 7.3 mmHg) and SUP-PA (-3.6 ± 10.9 mmHg), and diastolic blood pressure was reduced in STEP (-1.9 ± 4.1 mmHg), UNSUP-PA (-2.3 ± 4.4 mmHg) and SUP-PA (-2.4 ± 6.1 mmHg). Data are presented in Table 12.

4.8 CHANGE IN ENERGY INTAKE AND EATING BEHAVIORS

There was a significant reduction in caloric intake for STEP (-388 ± 1056), UNSUP-PA (-431 ± 953), and SUP-PA (-561 ± 862) over the 12-week intervention ($p<0.001$). There were no significant differences between groups ($p=0.51$) and there was no significant group by time interaction ($p=0.88$). Consumption of fats, carbohydrates and proteins (grams) was significantly reduced over the 12-week intervention ($p=0.001$, $p<0.001$, $p=0.002$ respectively). There were no changes in percent of intake from fat ($p=0.34$) or percent of intake from carbohydrates ($p=0.75$), however, there was a significant increase in percent protein ($p<0.01$) for STEP (1.7 ± 3.8%), UNSUP-PA (1.0 ± 2.2%), and SUP-PA (1.2 ± 2.9). There were no group by time interactions for percent fat ($p=0.64$), percent carbohydrate ($p=0.47$), and percent protein ($p=0.74$). Data are presented in Table 13.

Table 13. Change in Dietary Intake

Outcome	Group	Baseline	12 Weeks	Change	P-Values Group	Time	Group X Time
Energy Intake (kcal/day)	STEP (N=17)	1885 ± 905	1497 ± 522	-388 ± 1056			
	UNSUP-PA (N=16)	1773 ± 922	1342 ± 438	-431 ± 953			
	SUP-PA (N=14)	1774 ± 679	1214 ± 370	-561 ± 862	0.51	<0.01	0.88
Dietary Fat (grams)	STEP	76.0 ± 39.4	54.4 ± 20.8	-21.5 ± 32.3			
	UNSUP-PA	74.3 ± 51.5	48.6 ± 17.8	-25.7 ± 54.7			
	SUP-PA	69.5 ± 30.7	53.5 ± 18.8	-15.9 ± 22.4	0.89	<0.01	0.79
Dietary Carbohydrates (grams)	STEP	216.6 ± 107.3	151.2 ± 66.8	-65.4 ± 80.6			
	UNSUP-PA	194.3 ± 84.6	153.7 ± 64.0	-40.7 ± 85.2			
	SUP-PA	215.8 ± 95.6	167.8 ± 47.0	-48.0 ± 72.9	0.79	<0.001	0.66
Dietary Protein (grams)	STEP	75.5 ± 36.6	60.3 ± 24.7	-15.2 ± 23.9			
	UNSUP-PA	69.5 ± 40.3	53.0 ± 19.2	-16.4 ± 40.5			
	SUP-PA	71.7± 28.2	61.3 ± 19.8	-10.4 ± 20.5	0.73	<0.01	0.85
% Intake From Fat	STEP	36.6 ± 5.0	36.9 ± 7.0	0.3 ± 5.8			
	UNSUP-PA	37.1 ± 8.1	35.1 ± 5.7	-2.0 ± 8.4	0.48	0.34	0.64
	SUP-PA	35.0 ± 6.6	33.9 ± 5.1	-1.1 ± 6.1			
% Intake From Carb	STEP	46.8 ± 7.4	44.7 ± 7.4	-2.1 ± 6.7			
	UNSUP-PA	47.0 ± 9.6	48.2 ± 6.3	1.2 ± 8.5	0.51	0.75	0.47
	SUP-PA	48.6 ± 8.8	48.5 ± 7.2	-0.1 ± 7.5			
% Intake From Protein	STEP	16.6 ± 3.7	18.3 ± 4.6	1.7 ± 3.8			
	UNSUP-PA	15.9 ± 2.3	16.9 ± 2.1	1.0 ± 2.2	0.58	<0.01	0.74
	SUP-PA	16.4 ± 2.9	17.6 ± 3.1	1.2 ± 2.9			

There was a significant improvement in Eating Behavior Inventory scores for STEP (5.8 ± 10.9), UNSUP-PA (13.1 ± 8.4), and SUP-PA (11.9 ± 10.3) over the 12-week intervention ($p<0.001$). There was no significant group effect ($p=0.48$) or group by time interaction effect ($p=0.09$). For the Three Factor Eating Questionnaire, there was a significant time effect on Restraint ($p<0.001$), Disinhibition ($p<0.001$), and Hunger ($p<0.001$). There was no group effect or group by time effect on Restraint (group: $p=0.30$, group x time: $p=0.94$), Disinhibition (group: $p=0.70$, group x time: $p=0.80$), and Hunger (group: $p=0.74$, group x time: $p=0.85$). Results are shown in Table 14.

Table 14. Change in Eating Behaviors

					P-Values		
Outcome	Group	Baseline	12 Weeks	Change	Group	Time	Group X Time
Eating Behavior Inventory	STEP (N=17)	62.6 ± 11.7	68.4 ± 12.8	5.8 ± 10.9	0.48	<0.001	0.09
	UNSUP-PA (N=16)	57.6 ± 5.2	70.7 ± 8.1	13.1 ± 8.4			
	SUP-PA (N=16)	61.5 ± 6.9	73.4 ± 7.4	11.9 ± 10.3			
Restraint	STEP (N=17)	12.8 ± 2.4	15.2 ± 4.5	2.4 ± 4.5	0.30	<0.001	0.94
	UNSUP-PA (N=16)	12.6 ± 1.9	15.4 ± 4.3	2.8 ± 3.8			
	SUP-PA (N=16)	13.8 ± 2.2	16.6 ± 2.3	2.8 ± 3.3			
Disinhibition	STEP (N=17)	10.9 ± 1.0	5.6 ± 3.3	-5.3 ± 2.7	0.70	<0.001	0.80
	UNSUP-PA (N=16)	10.6 ± 1.0	5.8 ± 4.4	-4.8 ± 4.3			
	SUP-PA (N=16)	11.1 ± 0.9	6.5 ± 3.2	-4.6 ± 2.6			
Hunger	STEP (N=17)	12.1 ± 1.1	3.5 ± 2.9	-8.6 ± 2.8	0.74	<0.001	0.85
	UNSUP-PA (N=16)	11.8 ± 1.0	2.9 ± 2.4	-8.9 ± 2.0			
	SUP-PA (N=16)	11.9 ± 1.0	3.3 ± 2.8	-8.4 ± 2.7			

4.9 CHANGE IN PHYSICAL ACTIVITY SELF-EFFICACY

There was no significant improvement in physical activity self-efficacy scores for STEP UNSUP-PA, and SUP-PA over the 12-week intervention (p=0.14). There was no group effect (p=0.69) or group X time interaction (p=0.43). There was no significant improvement for perceived physical activity self-efficacy over the next 3 months for STEP, UNSUP-PA, and SUP-PA over the 12-week intervention (p=0.95). There was also no group (p=0.66) or group by time interaction (p=0.15) for perceived physical activity self-efficacy over the next three months.

There were no significant changes in perceived self-efficacy to walk 1 mile over the next 3 months, or perceived self-efficacy to exercise in a gym setting over the next 3 months. There was a significant increase in perceived self-efficacy to walk 1 mile briskly over the next 3 months for STEP, UNSUP-PA, and SUP-PA over the 12-week intervention (p=0.02). There was no significant group effect (p=0.08) or group by time interaction effect (p=0.13) in perceived self-efficacy to walk 1 mile briskly over the next 3 months.

There was a group effect for perceived self-efficacy to achieve the prescribed physical activity goal over the next 3 months at baseline (p=0.04). Post hoc analyses with Bonferroni adjustment demonstrated that STEP was significantly different compared to UNSUP-PA (p=0.01) with no other differences between groups. (STEP vs. SUP-PA: p=0.125, UNSUP-PA vs. SUP-PA: p=1.00). There was no time effect (p=0.78) or group by time interaction (p=0.51) for perceived self-efficacy to achieve the exercise goal over the next 3 months. Data are presented in Table 15.

Table 15. Change in Physical Activity Self-Efficacy and Future Self-Efficacy

Outcome	Group	Baseline	12 Weeks	Change	P-Values Group	P-Values Time	P-Values Group X Time
Physical Activity Self-Efficacy-Total	STEP (N=17)	16.5 ± 3.3	16.4 ± 4.0	-0.1 ± 4.0	0.69	0.14	0.43
	UNSUP-PA (N=16)	15.3 ± 3.8	16.9 ± 5.0	1.6 ± 3.1			
	SUP-PA (N=16)	15.0 ± 3.8	16.0 ± 2.7	1.0 ± 4.2			
Perceived Physical Activity Self-Efficacy over the next 3 Months-Total	STEP (N=17)	18.1 ± 3.2	16.9 ± 3.6	-1.2 ± 4.5	0.66	0.95	0.15
	UNSUP-PA (N=16)	15.8 ± 4.0	17.4 ± 5.0	1.6 ± 3.1			
	SUP-PA (N=16)	17.8 ± 3.7	17.3 ± 3.6	-0.5 ± 4.5			
Perceived Self-Efficacy to Walk 1-mile over the next 3 Months	STEP (N=17)	4.88 ± 0.33	4.88 ± 0.33	0.00 ± 0.35	0.25	0.53	0.41
	UNSUP-PA (N=16)	4.75 ± 0.58	4.69 ± 0.87	-0.06 ± 0.93			
	SUP-PA (N=16)	4.50 ± 0.63	4.75 ± 0.45	0.25 ± 0.68			
Perceived Self-Efficacy to Walk 1-mile Briskly over the next 3 Months	STEP (N=17)	4.65 ± 0.61	4.82 ± 0.53	0.17 ± 0.53	0.08	0.02	0.13
	UNSUP-PA (N=16)	4.50 ± 0.82	4.56 ± 0.89	0.06 ± 0.93			
	SUP-PA (N=16)	3.87 ± 1.09	4.50 ± 0.73	0.63 ± 0.96			
Perceived Self-Efficacy to Exercise in the Gym over the next 3 Months	STEP (N=17)	4.53 ± 0.87	4.41 ± 1.06	-0.12 ± 0.70	0.80	0.45	0.24
	UNSUP-PA (N=16)	4.38 ± 1.03	4.38 ± 0.96	0.00 ± 1.15			
	SUP-PA (N=16)	4.06 ± 0.93	4.50 ± 0.82	0.44 ± 1.03			
Perceived Self-Efficacy to Achieve Physical Activity Goal over the next 3 Months	STEP (N=17)	4.65 ± 0.49	4.47 ± 0.72	-0.18 ± 0.81	0.04	0.78	0.51
	UNSUP-PA (N=16)	3.94 ± 1.00	4.12 ± 1.20	0.18 ± 0.98			
	SUP-PA (N=16)	4.06 ± 0.77	3.94 ± 0.68	-0.12 ± 1.09			

4.10 CHANGE IN EXERCISE EXPECTATIONS AND BARRIERS

There was no significant change in overall expectations of exercise for STEP, UNSUP-PA, SUP-PA ($p=0.08$), and there was no significant group effect ($p=0.35$) or group X time interaction ($p=0.07$). In addition there were no significant changes in psychological ($p=0.17$), health ($p=0.09$), and image ($p=0.17$) expectations for all three treatment groups across the 12-week intervention. There were no group (psychological: $p=0.77$, image: $p=0.19$, health: $p=0.12$) or group by time interaction effects (psychological: $p=0.19$, image: $p=0.08$, $p=0.12$) for psychological, image and health expectations.

There were significant reductions in the scores for effort barriers' ($p<0.001$) and overall barriers ($p<0.001$) for STEP, UNSUP-PA, and SUP-PA over the 12-week intervention. There were no significant group effects (effort: $p=0.60$; Overall: $p=0.51$) or group by time interactions for either of these variables (effort: $p=0.70$; Overall: $p=0.88$). There were no significant changes in time or obstacle barriers over the 12 week intervention for any of the treatment groups. Data are presented in Table 14.

Table 16. Change in Expectations and Barriers to Exercise

Outcome	Group	Baseline	12 Weeks	Change	P-Values Group	Time	Group X Time
Expectations (Benefits)							
Psychological	STEP (N=17)	3.80 ± .69	3.69 ± .74	-0.11 ± 0.66	0.77	0.17	0.19
	UNSUP-PA (N=16)	3.56 ± .81	3.76 ± .97	0.20 ± 0.50			
	SUP-PA (N=16)	3.43 ± .84	3.70 ± .66	0.27 ± 0.68			
Image	STEP (N=17)	4.41 ± .49	4.29 ± .67	-0.12 ± 0.52	0.19	0.09	0.08
	UNSUP-PA (N=16)	4.44 ± .63	4.64 ± .50	0.20 ± 0.40			
	SUP-PA (N=16)	3.94 ± 1.01	4.34 ± .71	0.40 ± 0.94			
Health	STEP (N=17)	4.78 ± .35	4.69 ± .34	-0.09 ± 0.45	0.12	0.17	0.14
	UNSUP-PA (N=16)	4.60 ± .53	4.73 ± .49	0.13 ± 0.34			
	SUP-PA (N=16)	4.21 ± 1.01	4.60 ± .57	0.39 ± 1.09			
Overall	STEP (N=17)	4.25 ± .41	4.14 ± .49	-0.11 ± 0.46	0.35	0.08	0.07
	UNSUP-PA (N=16)	4.11 ± .59	4.30 ± .60	0.19 ± 0.26			
	SUP-PA (N=16)	3.79 ± .85	4.14 ± .54	0.35 ± 0.81			
Barriers							
Time	STEP (N=17)	3.33 ± 1.12	2.80 ± .95	-0.53 ± 0.87	0.99	0.11	0.33
	UNSUP-PA (N=16)	3.15 ± 1.22	3.02 ± 1.29	-0.13 ± 0.90			
	SUP-PA (N=16)	3.08 ± 1.16	3.04 ± 1.03	-0.04 ± 1.20			
Effort	STEP (N=17)	2.66 ± .76	2.27 ± .82	-0.39 ± 0.70	0.60	<0.001	0.51
	UNSUP-PA (N=16)	2.80 ± .85	2.23 ± 1.13	-0.57 ± 0.80			
	SUP-PA (N=16)	3.07 ± .73	2.38 ± .84	-0.69 ± 0.85			
Obstacles	STEP (N=17)	1.94 ± .56	1.81 ± .55	-0.13 ± 0.60	0.64	0.19	0.63
	UNSUP-PA (N=16)	1.98 ± .56	1.97 ± .82	-0.01 ± 0.76			
	SUP-PA (N=16)	2.19 ± .74	1.92 ± .66	-0.27 ± 0.83			
Overall	STEP (N=17)	2.59 ± .61	2.26 ± .60	-0.33 ± 0.59	0.70	<0.001	0.88
	UNSUP-PA (N=16)	2.63 ± .75	2.33 ± .89	-0.30 ± 0.63			
	SUP-PA (N=16)	2.80 ± .53	2.39 ± .63	-0.41 ± 0.71			

4.11 TREATMENT SATISFACTION

Overall, 98% of the participants reported that they would recommend this weight management program to others. In addition, 90% of participants reported that they would recommend the physical activity portion of the program to others. Ninety-two percent of participants reported being somewhat satisfied or very satisfied with the weight management program and 86% reported being somewhat satisfied or very satisfied with the physical activity portion of the program. Eighty-eight percent of participants in STEP reported being somewhat satisfied or very satisfied with their progress, while 82% of UNSUP-PA were somewhat satisfied or very satisfied and 100% of SUP-PA were somewhat satisfied or very satisfied with their progress. Treatment satisfaction data are reported in Table 17.

Table 17. Treatment Satisfaction

Question	Group	Would Recommend	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
Weight Management Program N, (%)	STEP (N=17)	17, (100%)	1, (6%)	1, (6%)	2, (12%)	13, (76%)
	UNSUP-PA (N=16)	15, (94%)	1, (6%)	2, (13%)	3, (19%)	11, (69%)
	SUP-PA (N=16)	16, (100%)	1, (6%)	0, (0%)	3, (19%)	13, (81%)
Physical Activity Program N, (%)	STEP	15, (88%)	1, (6%)	2, (12%)	5, (29%)	9, (53%)
	UNSUP-PA	14, (88%)	2, (13%)	0, (0%)	3, (19%)	11, (69%)
	SUP-PA	15, (94%)	0, (0%)	2, (13%)	4, (25%)	10, (63%)
Satisfaction with Progress N, (%)	STEP		1, (6%)	1, (6%)	2, (12%)	13, (76%)
	UNSUP-PA		1, (6%)	2 (13%)	3, (19%)	10, (63%)
	SUP-PA		0	0	8, (50%)	8, (50%)

4.12 INTERVENTION PROCESS MEASURES

Chi-square and one-way ANOVA's were used to examine group attendance, and physical activity participation for SUP-PA, UNSUP-PA, and STEP. Group attendance rates were similar for STEP (96.8 ± 7.1%), UNSUP-PA (94.1 ± 22.2%), and SUP-PA (92.4 ± 10.8%) (p=0.66).

SUP-PA engaged in 109 ± 49 minutes/week across the 12-week intervention with 9 participants achieving ≥85% of the total minutes of exercise prescribed for the 12-week intervention. Intervention physical activity data are presented in Table 16. SUP-PA was prescribed 3-5 days/week of physical activity in sessions of 10-60 minutes completed at an intensity of 60-75% heart rate maximum. 97.2% of the heart rates taken were above the 60% heart rate threshold. Participants exercised on the treadmill (55%), stationary cycle (9.5%), elliptical (14.3%) and adaptive motion trainer (21.2%). Data are illustrated in Figure 9. Physical activity prescription and physical activity participation are illustrated in Figure 10.

UNSUP-PA self-reported engaging in 170 ± 150 minutes/week of moderate-to-vigorous physical activity across the 12-week intervention according to weekly diaries. Individuals that failed to turn in a physical activity log book were counted as having zero minutes for that week of the intervention. Twelve participants in UNSUP-PA achieved the physical activity prescription (defined as achieving ≥85% of the total minutes of exercise prescribed for the 12-week intervention). Data are illustrated in Figure 11.

Adherence to the physical activity prescriptions was also analyzed based on diary data. Individuals that failed to turn in a physical activity log book were counted as having zero steps for that week of the intervention. STEP self-reported averaging 10,572 ± 2195 steps/day with 2916 ± 1672 brisk steps/day across the 12-week intervention. Twelve participants in STEP achieved the total step/day physical activity prescription (defined as accumulating ≥85% of the prescribed amount of total steps for the 12-week intervention) and 14 participants regularly achieved the brisk step/day goal (defined as accumulating ≥85% of the prescribed amount of brisk steps for the 12-week intervention). Data are illustrated in Figure 12 and 13.

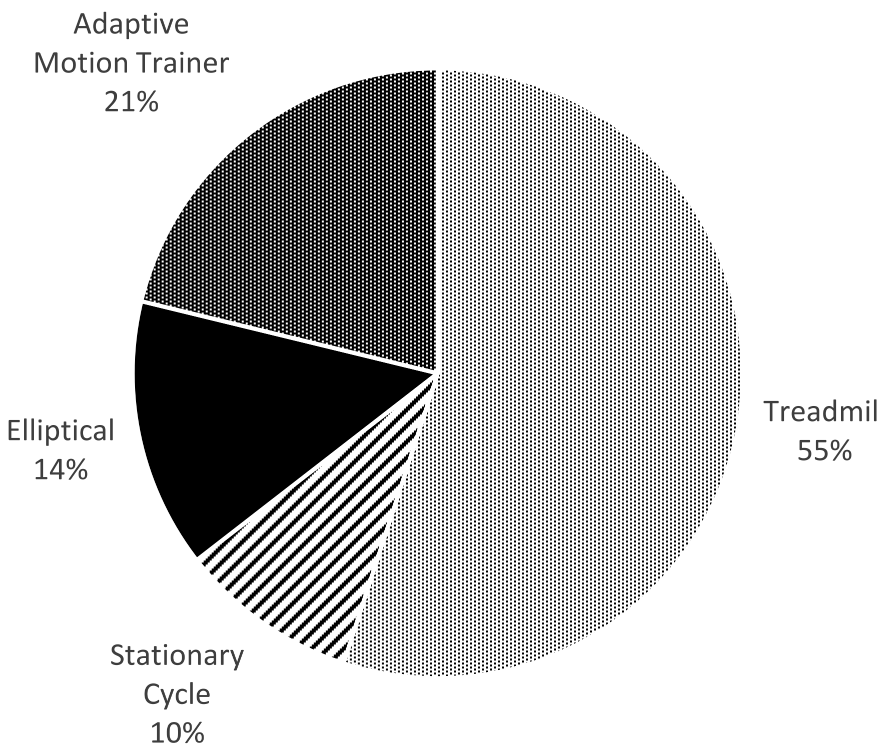


Figure 9. Supervised Exercise Equipment Use

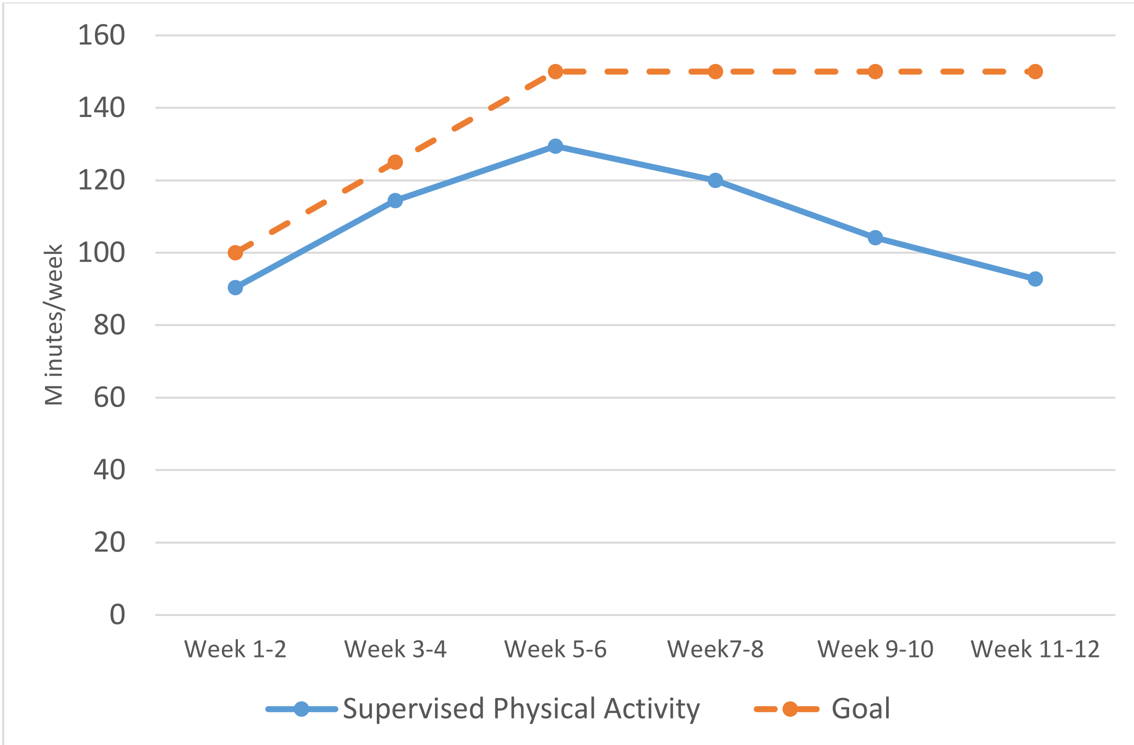


Figure 10. Objectively Measured Physical Activity via Observation for SUP-PA across the Intervention

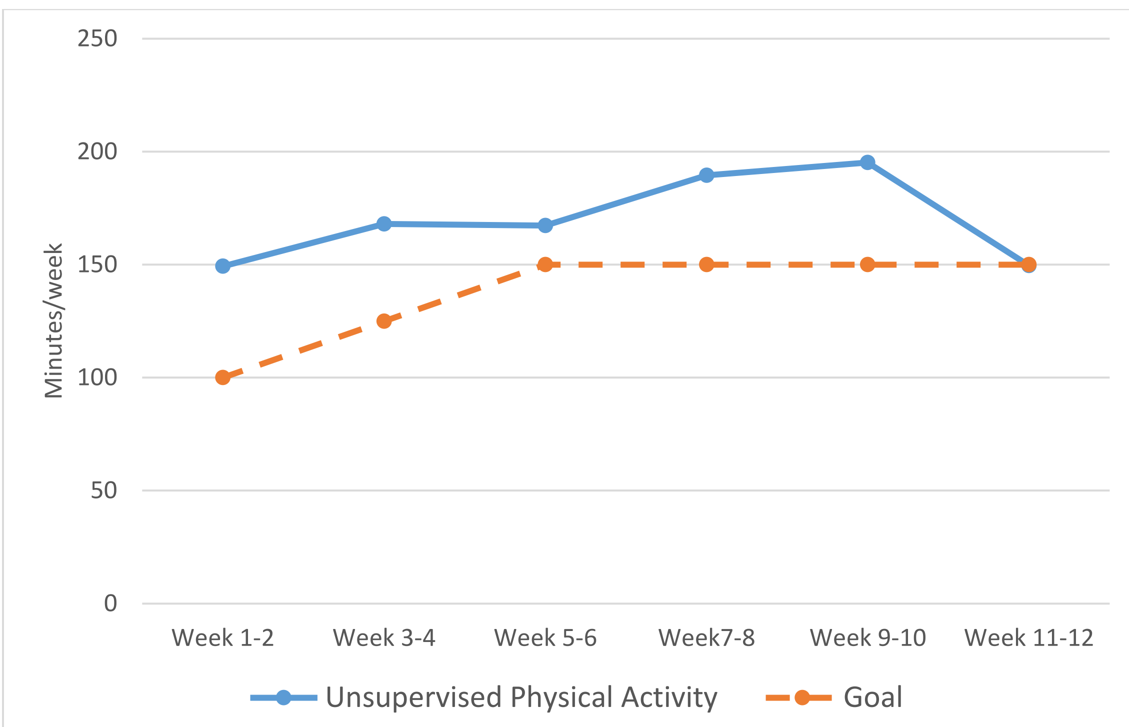


Figure 11. Self-Reported Physical Activity via Diary for UNSUP-PA across the Intervention

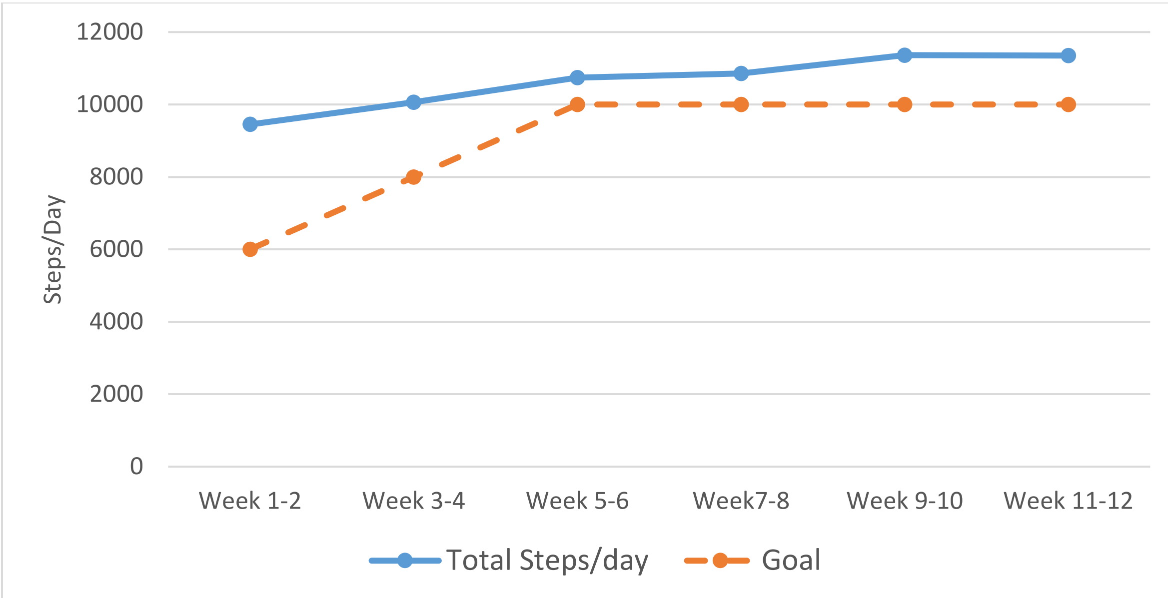


Figure 12. Self-Reported Total Steps/Day via Diary for STEP across the Intervention

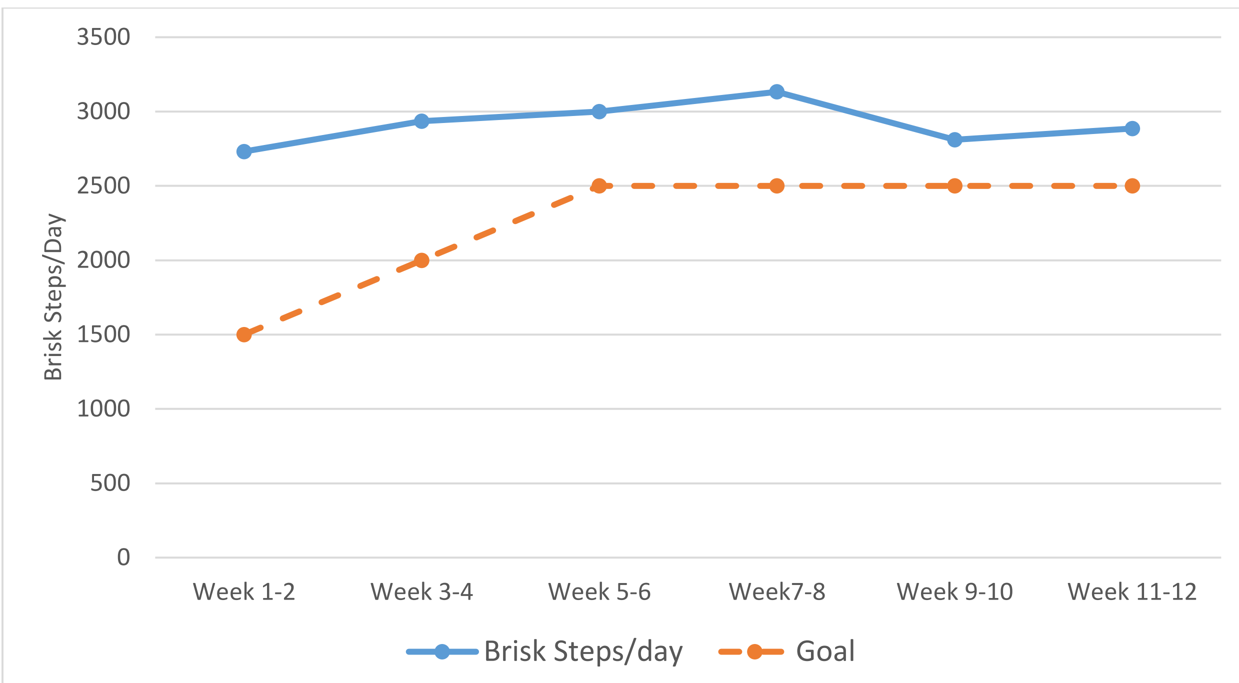


Figure 13. Self-Reported Brisk Steps/Day via Diary for STEP across the Intervention

Previous supervised exercise trials have been efficacy trials rather than effectiveness trials; thus, previous trials have only used data from individuals adhering to the physical activity prescription. To examine if a similar data analysis would change the outcomes of this study, we analyzed the data using only data from individuals who adhered to the physical activity prescription. Adherence was defined as completing 85% of the physical activity prescription or more. STEP had 12 adherers and 5 non-adherers, UNSUP-PA had 12 adherers and 4 non-adherers, and SUP-PA had 9 adherers and 7 non-adherers. When examining percent weight loss, there was a significant difference between adherers and non-adherers in STEP ($p<0.001$); however, there were no differences between adherers and non-adherers in UNSUP-PA ($p=0.55$) and SUP-PA ($p=0.56$). When examining cardiorespiratory fitness, there was a difference between adherers and non-adherers in STEP ($p=0.03$); however, there were no differences between adherers and non-adherers in UNSUP-PA ($p=0.92$) and SUP-PA ($p=0.99$). Data are illustrated in Figures 14 and 15.

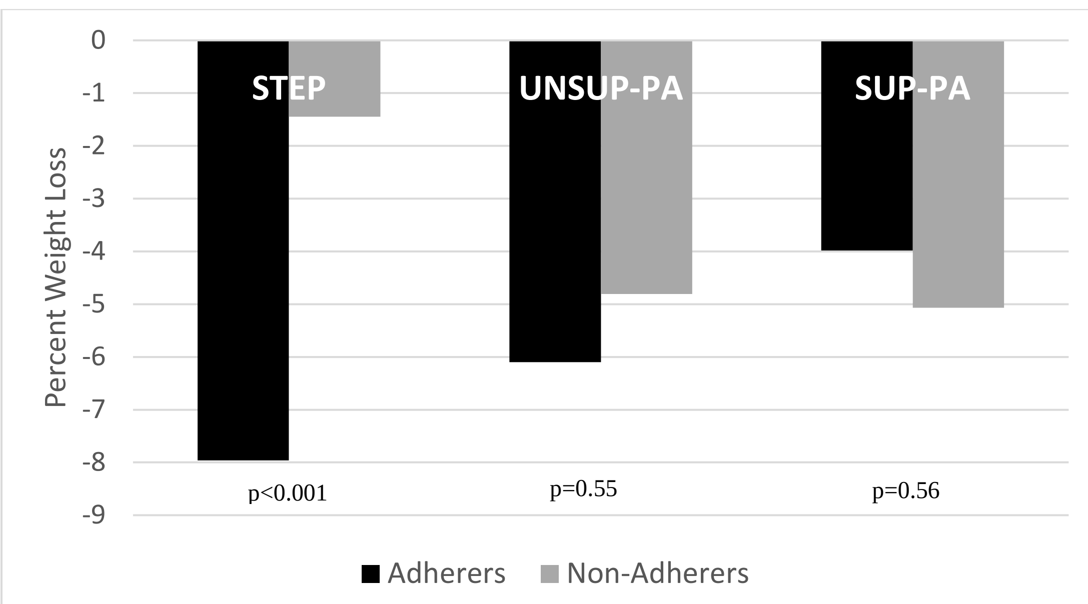


Figure 14. Percent Weight Loss by Adherers and Non-Adherers

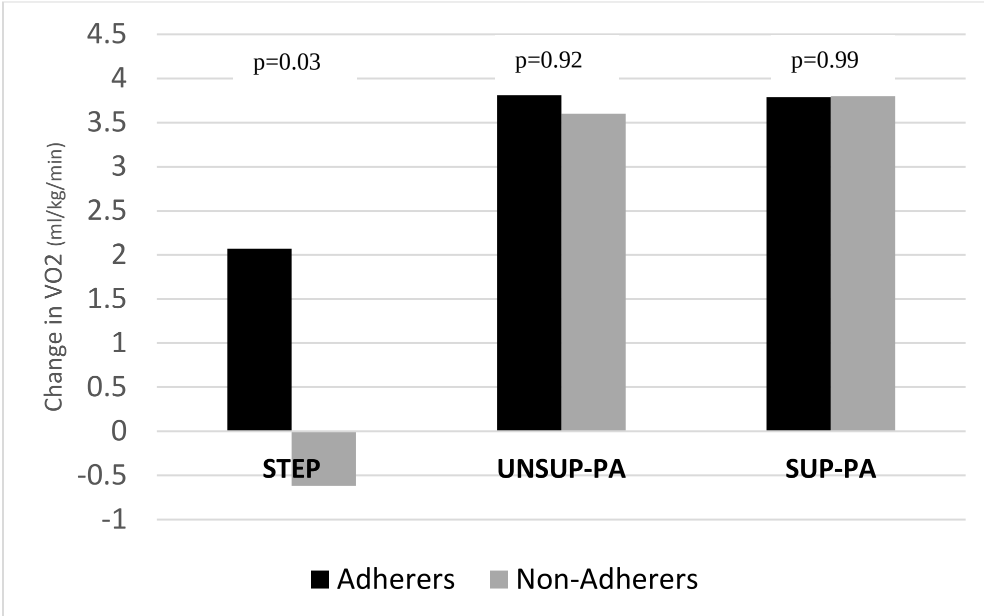


Figure 15. Change in Fitness by Adherers and Non-Adherers

5.0 DISCUSSION

This study was conducted to compare the effectiveness of a supervised physical activity program and two unsupervised physical activity programs combined with a standard behavioral weight loss intervention across 12-weeks in adults who were overweight or obese. Previous comparisons of supervised and unsupervised physical activity programs during weight loss interventions have yielded inconsistent changes in weight, fitness and physical activity.[19,21,22,24,36] Moreover, previous trials have lacked a comprehensive assessment of outcomes including objective measures of physical activity. The current investigation prescribed similar doses of physical activity to be completed in a supervised setting or an unsupervised setting to distinguish if physical activity behaviors and physiological responses would be different between the various interventions.

5.1 PARTICIPANT RETENTION

Forty-nine out of 52 (94.2%) participants completed the baseline and 12-week assessments. Attrition of one participant per group was observed. This level of retention is comparable or better than previous trials utilizing supervised exercise.[22,24,27,91,190] Attrition rates are typically higher in trials utilizing supervised exercise compared to studies prescribing unsupervised physical activity.[27,175,190,191] In a 12-week study utilizing a behavioral weight management program and supervised exercise, Verba and colleagues reported 75% retention.[190] Perri et al. reported 81.6% retention over a 6-month behavioral weight loss intervention with supervised exercise, concluding that individuals completing supervised exercise were more likely to drop-out compared to individuals completing unsupervised physical activity.[22] It is possible that supervised exercise is inconvenient for participants and increases individual time commitment leading to increased rates of attrition; however, the current study showed equal rates of attrition across all groups.

5.2 CHANGE IN PHYSICAL ACTIVITY

The primary aim of this study was to compare changes in MVPA completed in bouts of ≥ 10 minutes between STEP, UNSUP-PA, and SUP-PA across the 12-week intervention. This investigation demonstrated that STEP, UNSUP-PA, and SUP-PA were successful at increasing levels of MVPA completed in bouts of ≥ 10 minutes with no differences between groups (see Figure 7). It was hypothesized that SUP-PA would engage in the highest levels of MVPA compared to UNSUP-PA and STEP because supervised physical activity is considered the gold-standard for prescribing physical activity within research settings and all of SUP-PA's physical activity was supervised by an exercise physiologist to confirm proper exercise intensity. However, the current study demonstrated that prescribing physical activity that is unsupervised can be just as effective for increasing MVPA completed in bouts of ≥ 10 minutes.

MVPA, and more specifically MVPA completed in bouts of ≥ 10 minutes, are associated with improved long-term weight loss and weight maintenance.[13,14,137] While this study was only 12-weeks in duration, it is evident that all three physical activity prescriptions increased objectively measured MVPA. Previous trials comparing supervised and unsupervised programs within a weight loss trial did not objectively measure physical activity, [21-24] so the current study offers a unique contribution to the literature. However, it is unclear if the MVPA observed in this study would have continued over a longer period of time and further investigation is warranted.

To our knowledge this is one of the first studies to also assess changes in other forms of physical activity (MVPA, LPA, and SED) using objective measures when comparing a supervised program and an unsupervised physical activity program, specifically within a behavioral weight management program. Hypotheses related to physical activity behavior in this study were based on the ActivityStat hypothesis.[35] Because the physical activity prescription for SUP-PA specifically targeted MVPA completed in bouts of ≥ 10 minutes, it was hypothesized that SUP-PA would not have increases in LPA. Moreover, it was hypothesized that UNSUP-PA and STEP would increase LPA because of the lifestyle approach of these interventions. However, STEP, UNSUP-PA, and SUP-PA all had favorable increases in LPA across the 12-week intervention with no differences between groups. LPA is positively associated with improved weight loss outcomes.[137] These results indicate that during 12-week weight loss intervention, all three physical activity prescriptions produced similar increases LPA, which may promote future weight loss maintenance.

Sedentary behavior (SED) is another component from the physical activity spectrum that may affect weight loss outcomes. SED is associated with obesity and several cardiometabolic risk factors.[87,90,192,193] A previous trial conducted by Jakicic et al. focused on a calorie restricted diet and increased unsupervised MVPA, SED was also decreased.[100] In the current trial, it was hypothesized that SUP-PA may compensate for the increased structured physical activity by increasing SED. This aligned with the ActivityStat hypothesis.[35] However, objective measures of SED demonstrated that STEP, UNSUP-PA, and SUP-PA all decreased SED similarly. It is unclear if these decreases in SED, independent of other components of physical activity impacted weight loss or other outcomes assessed.

This study utilized a novel steps/day prescription utilizing a total steps/day count and a brisk steps/day recommendation. This recommendation was based on a secondary data analysis by Creasy et al.[178] finding that people who successfully lost weight during a behavioral weight loss intervention were taking approximately 10,000 steps/day with 2,500 to 3,000 brisk steps/day. Based upon this finding, participants in the STEP group were prescribed 10,000 steps/day with 2,500 brisk steps/day completed in bouts of ≥ 10 minutes. Using a steps/day recommendation may be more manageable for overweight and obese adults who were previously inactive. In addition, giving a daily step goal may positively promote behavior change daily. Objective physical activity data confirmed that STEP closely paralleled these recommendations throughout the 12-week intervention. In addition, other measures of physical activity were similar between STEP and the other two treatment groups. These results demonstrate that using a steps/day recommendation elicits similar changes in physical activity behaviors compared to unsupervised physical activity prescribed in minutes/day and a supervised exercise program prescribed in minutes/day. Therefore, future programs may utilize a similar steps/day recommendation to decrease the potential costs and burden of a supervised program.

Overall, all three treatment groups increased physical activity as prescribed during the 12-week intervention. Objectively measured physical activity confirmed that individuals were following the physical activity recommendations. There were no differences in the change in physical activity behaviors between the three treatment groups. Therefore, using unsupervised physical activity programs may be advantageous considering supervised programs can be burdensome, expensive, and lack generalizability. It is also important to note that UNSUP-PA increased MVPA without the use of any activity device and STEP increased MVPA using only a basic pedometer. Both unsupervised groups were anchored to moderate intensity physical activity using ratings of perceived exertion. Thus, when anchored properly and combined with a strong behavioral component, participants engaging in a behavioral weight loss intervention were able to increase physical activity without the need for close monitoring from study staff. Future trials and investigations may benefit from prescribing physical activity in a similar, unsupervised manner. Because all three treatment groups were successful at increasing positive physical activity, this gives researchers, programs, and institutions options to include physical activity with the context of a behavioral weight management program.

5.3 CHANGE IN WEIGHT, ANTHROPOMETRICS, AND BODY COMPOSITION

5.3.1 Change in Weight

This investigation demonstrated that STEP, UNSUP-PA, and SUP-PA successfully lost weight when physical activity was combined with a comprehensive weight management intervention (STEP: -5.3 ± 3.6 kg, UNSUP-PA: -5.1 ± 3.3 kg, SUP-PA: -3.8 ± 3.0 kg) with no differences between groups. These findings suggest that all three interventions are comparable for producing weight loss. This finding was contrary to the original hypothesis that suggested that SUP-PA would result in the most weight loss compared to UNSUP-PA and STEP.

Weight losses in this trial are comparable to previous behavioral weight loss interventions lasting 3-4 months in duration.[22-24,91] Results of the current study closely parallel the findings of Craighead and Blum which found that combining a behavioral weight management program with supervised exercise induced a weight loss of 5.0 ± 1.2 kg, while contracted exercise (unsupervised) induced a weight loss of 3.8 ± 1.4 kg.[23] The results of the study conducted by Craighead and Blum were limited because no formal physical activity participation data were reported.[23]

The weight loss results of the current study are also similar to the 12-week weight losses observed from Verba and colleagues,[190] and the 3-month weight losses in observed in a study conducted by Perri et al.[22] Both of these previous trials utilized supervised exercise and a strong behavioral weight management program.

Attainment of 5% weight loss is a reasonable goal for interventions targeting weight loss;[189] in addition, 5% weight loss is associated reduced weight-related health risk.[14] When further separating treatment groups into of >5% weight loss and <5% weight loss, STEP and UNSUP-PA had significantly more individuals achieving 5% weight loss compared to SUP-PA. It is unclear why STEP and UNSUP-PA had higher rates of individuals achieving 5% weight loss because physical activity (energy expenditure) and energy intake were not different between groups. Nonetheless, it is intriguing that both UNSUP-PA and STEP had higher achievement of this goal, and further investigation may be warranted.

Overall, the results of this study demonstrate that when combined with a standard behavioral weight loss intervention prescribing supervised physical activity in minutes/week, unsupervised physical activity in minutes/week, and unsupervised physical activity in steps/day produced similar amounts of weight loss. Thus, all three physical activity programs are feasible options for promoting weight loss when combined with a standard behavioral weight management program.

5.3.2 Change in Body Composition and Anthropometrics

Across the 12-week intervention STEP, UNSUP-PA, and SUP-PA lost similar amounts of fat tissue. These losses in fat mass were similar to a previous study of similar duration utilizing supervised exercise and a SBWP.[190] During behavioral weight loss interventions, individuals lose predominantly fat mass; however, some weight loss is due to losses in lean mass.[194] Trials have attempted to retain lean mass through aerobic exercise and resistance training; however, most individuals lose a small amount (13-28%) of lean mass.[46,194] In the current trial, UNSUP-PA and SUP-PA lost approximately 1 kg of lean mass while SUP-PA retained lean mass (p=0.06). Janssen et al. showed that supervised aerobic exercise coupled with a calorie restricted diet was the most efficacious strategy for retaining lean tissue compared to diet only and resistance training plus diet.[46] However, objectively measures physical activity did not differ by group in the current trial; thus, it is unclear why SUP-PA retained lean mass. A possible explanation is SUP-PA was coming to the PAWMRC 3-4 days per week and may have perceived that they were putting forth a high amount of exercise effort in the trial. Therefore, SUP-PA may not have adhered as closely to the dietary recommendations and relied heavily on the caloric expenditure of the exercise to promote weight loss; however, this was not supported by the energy intake data collected. Potentially a longer trial with objective measures of dietary intake are needed to help elucidate why supervised physical activity would promote lean mass retention compared to the unsupervised programs. Overall, the reasons why SUP-PA retained lean mass compared to UNSUP-PA and STEP remain uncertain and further investigation may be warranted.

STEP, UNSUP-PA, and SUP-PA reduced waist circumference (umbilicus and iliac crest) and hip circumference during the 12-week intervention with no differences between the groups. Changes in these anthropometric measurements are similar to other weight loss trials of similar duration.[190,191,195] It was hypothesized that SUP-PA would have the most favorable changes in anthropometric measures, however, STEP and UNSUP-PA had similar reductions in waist and hip circumference measures. It is possible that we did not see this effect because the intervention was too short and the diet blunted the effects of the physical activity on visceral adiposity. A longer trial may be needed to allow enough time to differentiate the benefits of the MVPA versus the effects of weight loss alone on visceral fat; however, in this 12-week trial supervised physical activity and unsupervised physical activity resulted in similar changes in anthropometrics.

5.4 CHANGES IN PHYSIOLOGICAL VARIABLES

5.4.1 Changes in Cardiorespiratory Fitness

A commonly reported benefit of increased physical activity is increased cardiorespiratory fitness (i.e., functional capacity). The results of this study demonstrate that STEP, UNSUP-PA, and SUP-PA all improved cardiorespiratory fitness during the 12-week intervention (STEP: 1.3 ± 2.4 ml/kg/min, UNSUP-PA: 3.8 ± 3.2 ml/kg/min, SUP-PA: 3.8 ± 1.6 ml/kg/min). Both UNSUP-PA and SUP-PA improved cardiorespiratory fitness more than STEP in response to the intervention. Because weight loss can potentially confound increases in relative oxygen consumption, data were also analyzed to examine changes in peak absolute oxygen consumption from the submaximal exercise test. Based on this analysis, SUP-PA and UNSUP-PA improved fitness while there was no change in fitness for STEP (SUP-PA: 0.22 ± 0.23 L/min, UNSUP-PA: 0.17 ± 0.24 L/min, STEP: -0.04 ± 0.19). There were no differences between SUP-PA and UNSUP-PA in either analysis. Thus, it appears that both unsupervised and supervised physical activity programs prescribed in minutes/week result in comparable increases in fitness. Perri et al. found that supervised exercise and home-based exercise improved relative oxygen consumption after 6 months of training (Supervised: 3.71 ml/kg/min, Unsupervised: 3.91 ml/kg/min).[22] In addition, Perri et al. found that absolute oxygen consumption improved in both the supervised and unsupervised physical activity programs after 6 months of training. These results mirror the results of the current study.

Previously, step/day recommendations have not resulted in increased cardiorespiratory fitness.[26] The current study attempted to increase cardiorespiratory fitness by utilizing a brisk step/day recommendation. While STEP did improve relative oxygen consumption, these improvements may partially be attributed to the weight loss because absolute oxygen consumption did not change. The reason why STEP did not improve fitness cannot be explained by differences in physical activity in this study and therefore warrants further investigation. However, this does suggest that there may be a blunted increase in absolute fitness when activity is prescribed as steps/day rather than minutes of MVPA/week.

Overall, the current study was successful at increasing cardiorespiratory fitness. This has important health implications because cardiorespiratory fitness is significantly associated with reduced risk of cardiovascular disease and mortality.[56-59] Moreover fitness is associated with improved health even in the presence of overweight and obesity. Contrary to our hypothesis, UNSUP-PA was able increase fitness at a similar magnitude compared to SUP-PA. This finding has important research and clinical implications. The current study demonstrates that given the proper behavioral intervention and physical activity prescription unsupervised physical activity can be just as beneficial as supervised physical activity for previously inactive overweight and obese adults.

5.4.2 Changes in Resting Heart Rate and Blood Pressure

STEP, UNSUP-PA, and SUP-PA all decreased resting heart rate during the 12-week intervention. It was hypothesized that SUP-PA would have a greater decrease in resting heart rate compared to UNSUP-PA and STEP; however, there were no differences between the groups. This is not surprising considering all three groups had similar changes in physical activity across the 12-week intervention.

STEP, UNSUP-PA, and SUP-PA decreased systolic and diastolic blood pressure over the course of the weight loss intervention. It was hypothesized that SUP-PA would have a greater decrease in resting blood pressure compared to UNSUP-PA and STEP; however, there were no differences between the groups. Decreases in systolic blood pressure were similar to other behavioral weight loss interventions utilizing calorie-restricted diets and physical activity.[19,21,196] Because obesity is a risk factor for elevated blood pressure,[175] it is important to emphasize that all three physical activity prescriptions lowered diastolic and systolic blood pressure. Therefore, using an unsupervised physical activity prescription coupled with a behavioral weight management program with a dietary component is a potential strategy to reduce resting blood pressure.

5.5 CHANGES IN DIETARY INTAKE AND EATING BEHAVIORS

Energy intake and eating behaviors were a critical component of this the behavioral intervention delivered in this study. All three groups significantly reduced caloric intake across the 12-week intervention. On average groups reduced energy intake by ~400 to 500 kcals/day. Changes in energy intake were similar to previous trials of similar duration.[190,196] In this study, participants were prescribed a reduced calorie diet (1200-1800 kcals/day) with 20-30% of intake from fat. This prescription is similar other studies utilizing calorie-restriction and physical to promote weight loss.[175,190,196] All three groups significantly reduced fat, carbohydrate, and protein intake across the 12-week intervention. However, percent change in macronutrient content was only significant for protein, which increased during the intervention. Relative changes in macronutrient content were similar to those reported in a study conducted by Rogers et al.[196] Changes in macronutrient intake were similar across all three treatment groups. By design, STEP, UNSUP-PA, and SUP-PA were given the same dietary recommendations and delivered the same weekly behavioral lessons. Thus, it is not surprising that all three groups had similar changes in energy intake and macronutrient intake.

The behavioral weight loss intervention also focused on improving eating behaviors that are associated with long-term weight loss success. Improvements in eating behaviors were similar as measured by the Eating Behavior Inventory (EBI) across all three treatment groups. Improvements in EBI scores were similar compared to Rogers et al., which utilized a similar 3-month behavioral weight loss intervention.[196]

Furthermore, eating behaviors as measured by the Three Factor Eating Questionnaire improved similarly across all three groups. All three groups improved dietary restraint, decreased disinhibition, and decreased hunger as expected with a behavioral weight loss intervention.[197,198] Increased cognitive dietary restraint and reduced disinhibited eating are associated during weight loss treatment are associated with improved weight loss and weight maintenance.[198] Therefore, the changes in the current study are indicative of long-term success. However, it is unclear if these changes would have persisted in a longer trial, and further investigation is warranted.

5.6 PROCESS MEASURES

All three groups had greater than 90% attendance to the weekly intervention meetings over the course of the 12-weeks with no difference between groups which is similar to attendance reported by Verba et al.[190] Perri et al. had approximately 80% adherence to the behavioral intervention (defined as attendance to more than 50% of intervention sessions).[22] It was hypothesized in previous supervised exercise trials that also utilized a weekly group meeting, that the supervised exercise group was overburdened with the time commitment of the study.[22] In the current study, this was not the case because SUP-PA attended just as many weekly group meetings as UNSUP-PA and STEP.

Based on self-report, UNSUP-PA and STEP had high adherence to the physical activity prescription throughout the 12-week intervention. SUP-PA had a lower adherence rate; however, SUP-PA’s exercise sessions were confirmed via observation rather than self-report. It is possible that actual adherence rates were lower in UNSUP-PA and STEP. The current study attempted to quantify physical activity participation across the intervention by objectively monitoring physical activity at week 4, 8 and 12 using the SenseWear device. Objectively measured physical activity at these pre-determined time-points demonstrated that UNSUP-PA and STEP were adherent to the physical activity prescription. In addition, SUP-PA was engaging in more physical activity than just the supervised exercise sessions. Future trials utilizing unsupervised physical activity programs should also use some method to confirm adherence (e.g., physical activity monitors, heart rate monitors, or GPS).

5.7 PHYSICAL ACTIVITY SELF-EFFICACY, EXPECTATIONS, AND BARRIERS

It was hypothesized that physical activity self-efficacy would improve over the 12-week intervention and that STEP and UNSUP-PA would have higher increases in self-efficacy compared to SUP-PA. However, this study failed to detect any significant changes in physical activity self-efficacy during the 12-week intervention. Previous literature has demonstrated that overweight women enrolling in a 6-month weight loss intervention utilizing unsupervised physical activity improved self-efficacy.[199] The current study also failed to detect significant changes in perceived future physical activity self-efficacy. It is unclear why there were no improvements in physical activity self-efficacy during this 12-week intervention.

There were significant increases in perceived self-efficacy to continue to walk briskly 1-mile across all three treatment groups with no differences between the groups. In addition there was a significant group effect for perceived self-efficacy to continue to achieve the physical activity goal over the next three months. Post-hoc analyses failed to detect the individual group differences; however, it appears that STEP and UNSUP-PA had higher reported self-efficacy compared to SUP-PA as hypothesized.

Expected outcomes and barriers for physical activity were assessed using a previously validated questionnaire.[200] There were no changes in the expected benefits for physical activity across the 12-week intervention with no differences between groups. Similarly, Gallagher et al. found that a 6-month behavioral weight loss intervention recommending unsupervised physical activity did not change image, health, or total benefits.[199] In the current study there were significant decreases in effort and overall barriers during the 12-week intervention. Gallagher et al. found that time, effort, obstacle, and total barriers decreased in response to a 6-month weight loss program.[199] While the current study did not find significant decreases in all barriers, it is important to note that all reported barriers either decreased or remained unchanged during the 12-week intervention. It has been hypothesized that supervised exercise is burdensome and inconvenient; thus, one would expect SUP-PA to report a potential increase in barriers. Yet, this was not observed in the current study. Thus, supervised and unsupervised physical activity appear to produce similar perceived responses for expected outcomes and barriers for physical activity.

5.8 CLINICAL IMPLICATIONS

The results of this study have important implications for both research and clinical settings. Based on the findings of this study, unsupervised physical activity programs were just as effective as a supervised training program for increasing MVPA and promoting weight loss during a behavioral weight management program. In addition, when unsupervised physical activity was prescribed in minutes/week (i.e., similar to the supervised program) improvements in cardiorespiratory fitness were similar to supervised physical activity prescribed in minutes/day. This finding demonstrates that requiring individuals to complete supervised physical activity may not result in better outcomes compared to prescribing unsupervised physical activity.

Supervised exercise trials offer numerous benefits for efficacy studies attempting to determine the effect of a controlled exercise dose on the desired outcome. However, supervised physical activity may be more expensive than unsupervised programs because of the need for additional staff to supervise the activity sessions and the need for facilities in which to conduct the supervised activity sessions. Supervised programs also lack generalizability outside of the research environment for participants who otherwise would not have access to a supervised program.

Furthermore, the ActivityStat hypothesis suggests that requiring supervised exercise may inadvertently reduce non-exercise physical activity or increase sedentary time.[35] Previous studies have failed to quantify compensation or changes in physical activity occurring outside of the supervised sessions that could either enhance or blunt the observed results. This study demonstrated that physical activity behaviors outside of the supervised exercise sessions were similar compared to the unsupervised groups with increased LPA and decreased SED. Ultimately the results of this study demonstrate that prescribing physical activity in a supervised or unsupervised manner elicits similar responses in physical activity, similar amounts of weight loss and similar improvements in fitness when coupled with a behavioral weight loss program.

Using a total steps/day goal along with a brisk step goal was just as effective as supervised exercise training at 60-75% heart rate maximum for increasing MVPA and eliciting weight loss. This finding has multiple public health implications. First, physical activity in the form of walking and brisk walking is an effective strategy for weight loss when enrolled in a behavioral weight management program. This message is important for all adults seeking to lose weight, but it may be even more important to individuals who have difficulty engaging in other forms of physical activity due to barriers such as lack of time, lack of resources, or for other various reasons.

In addition, there is an abundance of consumer-based physical activity monitors that are commercially available. The wearable activity monitor market is projected to continue to grow over the next 5 years.[201] These consumer-based monitors provide physical activity data in steps/day output, so the results of this study may be used to recommend physical activity prescriptions that are harmonious with these devices.

There were no statistically significant differences in the change of MVPA between all three treatment groups. However, SUP-PA increased MVPA completed in bouts $\geq$ 10 minutes by approximately 30 min/wk more than UNSUP-PA and 70 min/wk more compared to STEP. While these differences did not induce differences in the physiological responses, these differences may be clinically significant. This study may have been underpowered to detect these differences. In addition, it is possible that physiological outcomes not measured in this study were impacted by these differences in MVPA. Future studies should be adequately powered to detect clinically significant differences in MVPA. Moreover, future studies should use additional physiological measures to examine the potentially meaningful effects of these differences in MVPA.

Overall, supervised and unsupervised physical activity programs yielded similar results within a behavioral weight management program. Because supervised exercise programs are not always practical outside of research settings, it may be advantageous to utilize well-designed unsupervised programs which limit participant barriers and produce generalizable results.

5.9 LIMITATIONS AND FUTURE DIRECTIONS

Relatively few trials have been conducted to compare unsupervised physical activity to supervised physical activity during a behavioral weight loss intervention. While this trial adds to the current literature, the limitations of this study should be considered when interpreting the observed results.

1. First, the current study was only 12-weeks in duration. Because the study was only 12-weeks in duration, there may not have been enough time to detect a difference in weight loss between the groups. Previous literature has indicated that a calorie-restricted diet (creating a negative energy balance) is the primary cause of weight loss.[32,33] While physical activity can contribute to weight loss, given that this trial was only 12 weeks

in duration, physical activity may have had limited impact on the weight loss achieved. However, physical activity is strongly associated with weight maintenance. Thus, a longer trial would have been more conducive for comparing weight loss and weight maintenance.

2. A priori power analyses were based on change in MVPA at week 12. This study did not have sufficient power to observe group X time interactions using repeated measures. Future studies should seek to recruit enough participants to examine interaction effects using repeated measures analyses.
3. All three treatment groups were engaging in high amounts of physical activity at baseline (STEP: 35.4 ± 33.5 min/day, UNSUP-PA: 25.6 ± 36.0 min/day, SUP-PA: 28.0 ± 23.5 min/day). Participants self-reported not engaging in more than 60 minutes of structured physical activity per week during the initial eligibility screening. Thus, these participants must have been engaging in high amounts of lifestyle or occupational physical activity at the beginning of the study. Whether this influenced the results of this study is unclear and warrants further investigation.
4. Because of the nature of supervised exercise, SUP-PA had to come to the Physical Activity and Weight Management Research Center (PAWMRC) at least three times per week to engage in supervised physical activity. In addition, SUP-PA came to the PAWMRC once a week for the behavioral intervention lesson. The increased burden of travel time may have detracted from the effectiveness of the intervention. However, attendance to the behavioral intervention was similar across all three groups, and adherence to the physical activity prescription was also similar across groups.

Nonetheless, future studies may want to have multiple gym locations to make the supervised physical activity more convenient for participants.

5. By design, it was not possible to control for total contact time across all three groups. SUP-PA had 3-4 additional contacts with study staff per week. To reduce the potential contamination of this additional contact time, study staff was instructed to not talk to SUP-PA about intervention-related material during the supervised exercise sessions. Future studies should also attempt control for the additional contact time associated with supervised exercise.
6. Participants were prescribed 150 min/week of MVPA to match the physical activity guidelines. Future trials should also attempt to increase physical activity levels to parallel recommendations for long-term weight loss maintenance. It is recommended that individuals should be engaging in ~250 minutes of MVPA/week and this study only prescribed physical activity up to 150 minutes/week which may not be sufficient for weight maintenance.
7. By design, UNSUP-PA and STEP were only able to provide self-report physical activity data each week in the form of an activity log book, while SUP-PA's physical activity was directly observed by study staff. In order to minimize this limitation, the SenseWear device was worn at baseline week 4, week 8, and week 12 to measure physical activity objectively across all three groups throughout the intervention. These data were blinded to participants. Future studies should objectively measure physical activity throughout the intervention and provide participants with feedback using the objective data.

8. Different components of physical activity were comprehensively assessed in this study including SED, LPA, and MVPA. However, it is unclear if the total activity patterns between STEP, UNSUP-PA, and SUP-PA were different leading to differences in total energy expenditure. Future trials focusing on weight change outcomes, should use doubly labeled water to measure total energy expenditure.
9. The current study offers no explanation as to why STEP and UNSUP-PA had significantly more people achieve 5% weight loss. Future efforts should focus on examining individual level factors that may influence responses to these intervention approaches.
10. This study did not perform any formal cost-effectiveness analyses; however, future trials should incorporate these data to help both clinical and research institutions to make informed decisions on these programs.

5.10 SUMMARY

In summary, this study showed that unsupervised physical activity programs can be as effective as a supervised program for increasing MVPA during a standard behavioral weight loss intervention for adults who are overweight or obese. The observed increases in MVPA were also accompanied by reductions in body weight, % body fat, resting heart rate, blood pressure, and increases in cardiorespiratory fitness when physical activity was combined with a standard behavioral weight loss intervention utilizing calorie restriction. These findings were observed regardless of intervention condition (STEP, SUP-PA, and UNSUP-PA). While this trial was relatively short in duration, these results do offer initial evidence that unsupervised physical activity programs are just as successful at increasing physical activity compared to a supervised program.

This suggests that there are a variety of options to prescribe physical activity during a standard behavioral weight loss intervention all of which can induce weight loss. Whether the results of this study will translate across populations or during a longer intervention period warrant further investigation. However, this study provides compelling evidence that unsupervised physical activity prescribed in minutes/week and an unsupervised physical activity program prescribed in steps/day can increase physical activity equally compared to a supervised physical activity program producing similar physiological improvements in adults who are overweight or obese.

APPENDIX A

PHYSICAL ACTIVITY DATA FOR INDIVIDUALS WITH ≥ 4 DAYS/WEEK ≥10 HOURS/DAY

Table 18. Objectively Measured Physical Activity

Outcome	Groups	Assessment Periods				P-Values		
		Baseline	4 Weeks	8 Weeks	12 Weeks	Time	Group	Time X Group
Days of Wear Time	STEP (N=17)	6.8 ± 0.6	6.9 ± 0.3	6.5 ± 1.1	6.8 ± 0.4	0.09	0.84	0.71
	UNSUP-PA (N=16)	6.7 ± 0.9	6.8 ± 0.4	6.4 ± 0.8	6.8 ± 0.4			
	SUP-PA (N=12)	6.8 ± 0.6	6.9 ± 0.3	6.8 ± 0.5	6.6 ± 0.8			
Hours of Wear Time/Day	STEP (N=17)	14.3 ± 1.7	14.5 ± 1.4	14.4 ± 1.6	14.6 ± 1.6	0.44	0.68	0.90
	UNSUP-PA (N=16)	14.8 ± 1.0	14.9 ± 0.9	14.6 ± 1.2	14.8 ± 1.2			
	SUP-PA (N=12)	14.8 ± 1.3	15.0 ± 1.4	14.6 ± 1.1	14.7 ± 0.7			
SED (min/day)	STEP (N=17)	585.6 ± 113.6	579.2 ± 105.4	521.8 ± 126.3	524.7 ± 110.0	<0.001	0.26	0.99
	UNSUP-PA (N=16)	638.3 ± 106.4	621.3 ± 88.2	586.5 ± 103.0	582.1 ± 112.7			
	SUP-PA (N=12)	605.5 ± 91.8	589.5 ± 103.5	543.7 ± 84.8	547.4 ± 114.1			
LPA (min/day)	STEP (N=17)	189.3 ± 57.9	210.2 ± 62.2	252.7 ± 82.0	259.0 ± 65.3	<0.001	0.31	0.26
	UNSUP-PA (N=16)	174.0 ± 67.7	180.2 ± 66.7	199.8 ± 62.8	231.1 ± 81.2			
	SUP-PA (N=12)	205.1 ± 75.0	212.3 ± 69.2	231.7 ± 80.4	230.5 ± 80.7			
MVPA (min/day)	STEP (N=17)	60.9 ± 45.2	71.5 ± 33.3	76.9 ± 41.0	75.3 ± 40.2	<0.01	0.79	.099
	UNSUP-PA (N=16)	49.2 ± 44.3	63.3 ± 49.8	67.6 ± 53.4	64.8 ± 50.2			
	SUP-PA (N=12)	52.5 ± 42.6	72.3 ± 35.2	70.9 ± 47.2	73.2 ± 53.5			
Bouted MVPA (min/day)	STEP (N=17)	35.4 ± 33.5	42.8 ± 23.6	51.2 ± 33.5	47.0 ± 28.2	<0.001	0.85	0.92
	UNSUP-PA (N=16)	25.6 ± 36.0	38.3 ± 42.6	46.1 ± 45.5	41.7 ± 44.5			
	SUP-PA (N=12)	26.6 ± 23.6	43.5 ± 21.3	46.6 ± 29.9	50.1 ± 38.6			
Bouts of MVPA/Day	STEP (N=17)	1.6 ± 1.4	2.0 ± 1.1	2.1 ± 1.2	2.2 ± 1.3	<0.01	0.61	0.94
	UNSUP-PA (N=16)	1.2 ± 1.3	1.5 ± 1.2	1.8 ± 1.4	1.9 ± 1.6			
	SUP-PA (N=12)	1.2 ± 1.2	1.7 ± 1.0	1.7 ± 1.1	1.9 ± 1.9			
Intensity of MVPA	STEP (N=16)	4.4 ± 0.8	4.8 ± 0.9	4.9 ± 0.9	5.0 ± 1.1	0.01	0.45	0.77
	UNSUP-PA (N=11)	4.2 ± 0.6	4.7 ± 0.6	4.5 ± 0.8	4.5 ± 0.6			
	SUP-PA (N=11)	4.2 ± 0.3	4.5 ± 0.6	4.6 ± 0.7	4.7 ± 0.8			

SED: Sedentary Time (<1.5 METs)
LPA: Light-Intensity Physical Activity (≥1.5 METs to <3.0 METs)
MVPA: Moderate-to-Vigorous Physical Activity (≥3.0 METs in bouts of ≥1 minute)
Bouted MVPA: (≥3.0 METs in bouts of ≥10 minutes)
Intensity of MVPA: (average METs/ physical activity bout ≥10 minutes)

APPENDIX B

RECRUITMENT TELEPHONE SCREENING FORM

RECRUITMENT FORM:

Thank you for your interest in our program. My name is __________ and I am a student/staff member in the Department of Health and Physical Activity at the University of Pittsburgh. I would briefly like to tell you about this research program.

Procedure for Describing the Study and Obtaining Verbal Consent to Conduct the Telephone Screen: A description of the study will be read to participants, and this description includes important components of the informed consent process (see attached script). Individuals who express an interest in participating in this study will be told the following to obtain verbal consent:

- ***Investigators Component of Informed Consent:*** *This study is being conducted by Seth A. Creasy at the University of Pittsburgh. His mentor, Dr. John M. Jakicic from the Department of Health and Physical Activity will be overseeing this project.*
- ***Description Component of Informed Consent****: We are interested in recruiting 60 men and women to participate in this study. This study will focus on helping you lose weight through assisting you to make changes to your eating and activity behaviors. If you are eligible for this study you will complete measurements of your physical activity, weight, body fatness, fitness, blood pressure, and other factors that may change with your participating in this study. You will complete these measures at 0 and 12 weeks during this study. Physical activity will also be assessed at weeks 4 and 8. You will attend regular weight loss sessions during the intervention period that lasts 12 weeks. Also you will be randomly assigned to one of three intervention groups with randomization being similar to flipping a coin to decide what group you will be in. One of the groups will be asked to complete 12 weeks of supervised physical activity. This group will come to the Physical Activity and Weight Management Research Center near the University of Pittsburgh's Oakland Campus to complete these physical activity sessions. The other two groups will be asked to complete 12 weeks of home-based physical activity, which means you will do all physical activity on your own. The physical activity for the home-based groups will be recommended in minutes per week or steps per day.*

- *If you complete this study you can earn up to $95. If you are interested in participating in this study, I will need to ask you a few questions about your demographic background, physical health, and medical history to determine if you appear to be eligible to participate in this study. It will take approximately 5 minutes to ask you all of the questions. If we complete the interview, I will ask you for some specific information (your complete name, phone number and mailing address) so that we can contact you regarding your participation in this study. If eligible, we will then schedule for you to attend an orientation session that will explain all of the procedures of this study in greater detail.*
- ***Confidentiality Component of Informed Consent:*** *If your answer to a particular question tells me clearly that you will not be eligible for this study, I will stop the interview, and not ask you any more personal questions.*
- ***Right to Participate or Withdraw from Participation Component of Informed Consent:*** *Your responses to these questions are confidential, and the information related to your health history or current behaviors that you are about to give me will be*

destroyed after this interview even if you are found to be eligible.

Do you have any questions related to any of the information that I have provided to you? Staff member will answer any questions or will defer these questions to the Principal Investigator or Co-Investigator when appropriate prior to proceeding. If the individual would like to think about their participation prior to proceeding with the Phone Screen, they will be provided with the telephone number that they can call if they decide to participate in the future.

- ***Voluntary Consent Component of Informed Consent:*** *Do you agree that the procedures that will be used to conduct this Phone Screen have been described to you, all of your questions have been answered, and you give me permission to ask you questions now as part of the initial Phone Screen?* If "YES" indicate the participant's agreement with this statement on the top of the next page, and sign your name and date the form, and then complete the Phone Screen. If "NO", thank the individual for calling and <u>do not</u> complete the Phone Screen.

The caller gives verbal permission to conduct the Phone Screen: ☐ Yes ☐ No

Verbal Assent was given to:

____

Staff Member Signature

____

Date Verbal Assent was given

Completed by Principal Investigator:

Eligible based on telephone screening: ☐ Yes ☐ No

If "No", list reason for ineligibility: __________________________________

<u>Phone Screen Interview</u>

Screening:

1. Gender: ☐Male ☐Female
2.a. Age: ☐☐ **(18-55)** 2.b.Date of Birth: ☐☐/☐☐/☐☐

3. Current Weight: ☐☐☐ pounds
4. Current Height: ☐feet ☐☐inches

Office Use: BMI = _______ (25.0 to <40.0 kg/m^2)

5. Are you able to walk for exercise? ☐ **YES** ☐ No If "no" specify reason:____

6. Do you currently exercise regularly at least once per week at a moderate intensity for at least 20 minutes?
☐ Yes ☐ **NO**

If "yes" What types of exercise are you doing?________________________________
If "yes" How many days per week?____
If "yes" on average how many minutes per day do you exercise?__________________
If "yes" How long have you been exercising this way?__________________________

7. Have you ever been told by a doctor or other medical person that you have any of the following conditions? If "yes", Specify:

a. Heart Disease	☐ Yes	☐ **NO**	________________________
b. Angina	☐ Yes	☐ **NO**	________________________
c. Hypertension	☐ Yes	☐ **NO**	________________________
d. Heart Attack	☐ Yes	☐ **NO**	________________________
e. Stroke	☐ Yes	☐ **NO**	________________________
f. Diabetes (sugar)	☐ Yes	☐ **NO**	________________________
g. Cancer	☐ Yes	☐ **NO**	________________________

8. Do you have any joint, bone conditions, or any other medical condition that may limit your participation in a physical activity program?
If "yes", specify: ______________________________ ☐ Yes ☐ **NO**

9. Are you taking any prescription medications for depression or anxiety?
☐ Yes ☐ **NO**

11. Are you taking any medications for your blood pressure?
If "yes", specify: _________________________________ ☐ Yes ☐ **NO**

12. Are you taking any medications for your thyroid?
If "yes", specify: _________________________________ ☐ Yes ☐ **NO**

13. Are you taking any medications for the purpose of weight loss?
If "yes", specify: ________________________________ ☐ Yes ☐ **NO**

14. Are you taking any medications that may not be intended for weight loss, but you have noticed that the medication may affect your body weight?
If "yes", specify: ________________________________ ☐ Yes ☐ **NO**

15. Are you currently a member of another organized exercise or are you participating in an organized weight reduction program?

    If "yes", specify: ________________________________ ☐ Yes ☐ **NO**

16. Have you lost weight in the past 3 months? ☐ Yes ☐ **NO**

    If "yes", specify number of pounds:_____ Method used:______________
    Note: Ineligible if weight loss is ≥5% of current body weight or 15 pounds total

17. Have you undergone bariatric surgery? ☐ Yes ☐ **NO**

18. Are you currently being treated for an eating disorder? ☐ Yes ☐ **NO**

19. Are you currently participating in other research studies?

    If "yes", specify: ________________________________ ☐ Yes ☐ **NO**

20. Have you been a participant in a previous exercise or weight control study?

    If "yes", specify: ________________________________ ☐ Yes ☐ **NO**

21. Do you plan to spend any time out of town on vacation or business in the next 6 months that may affect your ability to participate in the study?

    If "yes", specify: ________________________________ ☐ Yes ☐ **NO**

22. Do you plan on relocating outside of the Greater Pittsburgh Area within the next 6 months?

    If "yes", specify: ______________________________ ☐ Yes ☐ **NO**

23. Are you currently using an activity tracker? (e.g., Fitbit, Jawbone Up, Shine, etc.)

    ☐ Yes ☐ **NO**

WOMEN ONLY COMPLETE THE FOLLOWING QUESTIONS

24. a. Are you currently pregnant? ☐ Yes ☐ **NO**

b. Have you been pregnant in the last 6 months? ☐ Yes ☐ **NO**

c. Do you plan on becoming pregnant in the next 12 weeks? ☐ Yes ☐ **NO**

APPENDIX C

ORIENTATION INVITATION

Dear Participant,

You recently contacted the Physical Activity and Weight Management Research Center at the University of Pittsburgh inquiring about our current research studies and programs. We are pleased to inform you that we are in the process of beginning our next research program, and based on the information that you provided to us at that time, it appears that you are eligible to participate.

As described to you briefly when you called to inquire about this research study, this program is designed to place study participants into 1 of 3 groups: (1) supervised physical activity (SUP-PA) prescribed in minutes per week plus behavioral intervention sessions, (2) unsupervised physical activity (UNSUP-PA) prescribed in minutes per week plus behavioral intervention sessions, or (3) Unsupervised physical activity prescribed in steps/day (STEP) plus behavioral intervention sessions. All of the groups will receive the same behavioral intervention sessions to promote weight loss. These programs will be available to you **at no cost**.

We would like to invite you to attend an orientation meeting on Wednesday, March 16th at 5:45 PM in Oak Hill Commons. We have enclosed a map to assist you in locating this building. Free parking for this orientation is available in the building lot (*please refer to the enclosed map*).

The meeting will last approximately 60-90 minutes.

Please bring a government issued picture identification (driver's license) with you to this meeting that has your name and birth date on it so that we can confirm your age for eligibility in this study.

Please confirm your attendance by calling 412-383-4038 or by emailing sethcreasy@pitt.edu. This may be the last orientation session for the study, so if you are able, please try to attend.

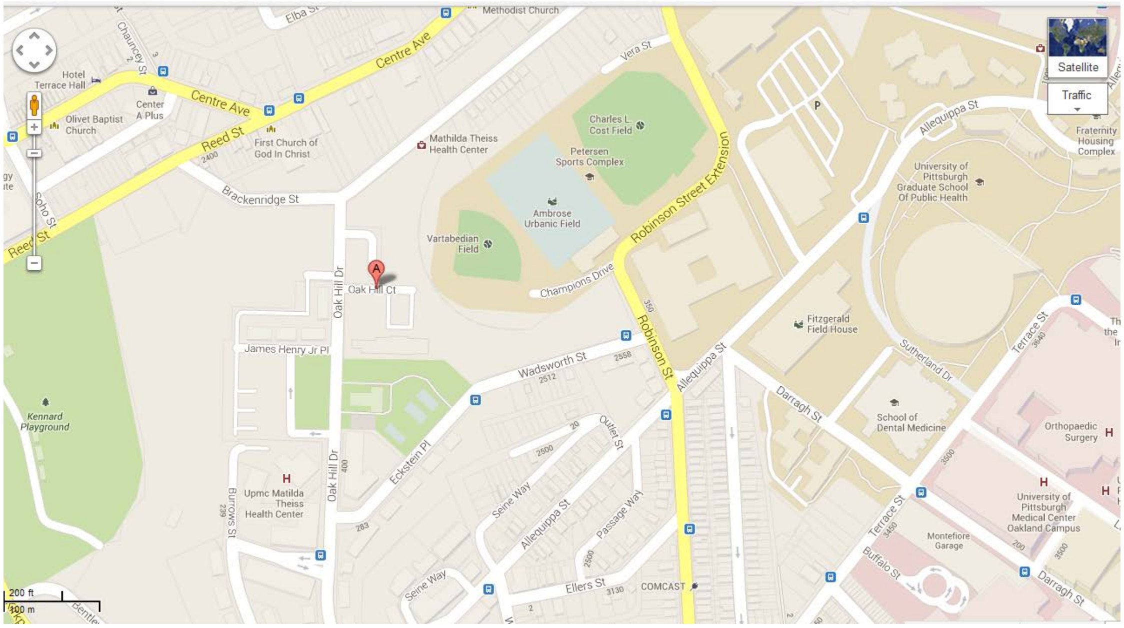
Congratulations on taking the first step to better health. We look forward to working with you!

Sincerely,

Seth A. Creasy, MS
Department of Health and Physical Activity
Physical Activity and Weight Management Research Center

Directions to the Physical Activity and Weight Management Research Center
Oak Hill Commons
32 Oak Hill Court
Pittsburgh, PA 15213 (mailing zip code 15261)
412-383-4020

NOTE: Because this is a new building this address may not show up when using your GPS. Thus, we recommend that you use the directions and map below.



From the North

- Take 279 South
- Take exit 2A to merge onto I-579 S/Veterans Bridge toward Veterans Bridge
- Continue to follow I-579 S
- Take the exit toward Parkway East (376)/Oakland/Monroeville
- Merge onto Boulevard of the Allies
- Exit onto Forbes Avenue
- Turn left onto Craft Avenue
- Turn left onto Fifth Avenue
- Take the first right onto Robinson Street
- Go past the 2nd stop sign at the top of the hill and turn left onto Wadsworth Street
- At the first stop sign, Oak Hill Drive, make a right
- Go to the 1st Stop Sign.
- Our building is just past this stop sign on the right, and the entrance to the parking lot is approximately 100 ft past the stop sign on the right.

From the East

- Take Parkway East (376)
- Take exit 73B to merge onto PA-885 N/Bates Street toward Oakland
- Turn left onto Boulevard of the Allies
- Turn right onto Craft Avenue
- Turn left onto Fifth Avenue
- Take the first right onto Robinson Street
- Go past the 2nd stop sign at the top of the hill and turn left onto Wadsworth Street
- At the first stop sign, Oak Hill Drive, make a right

- Go to the 1st Stop Sign.
- Our building is just past this stop sign on the right, and the entrance to the parking lot is approximately 100 ft past the stop sign on the right.

<u>From the South or West</u>

- Take the Parkway West (376) through the Fort Pitt tunnels and the Fort Pitt bridge
- Keep right to stay on Parkway West (376)
- Exit onto Forbes Avenue
- Turn left onto Craft Avenue
- Turn left onto Fifth Avenue
- Take the first right onto Robinson Street
- Go past the 2nd stop sign at the top of the hill and turn left onto Wadsworth Street
- At the first stop sign, Oak Hill Drive, make a right
- Go to the 1st Stop Sign.
- Our building is just past this stop sign on the right, and the entrance to the parking lot is approximately 100 ft past the stop sign on the right.

<u>From the South Side</u>

- Take Carson Street to the Birmingham Bridge
- Turn left onto Fifth Avenue
- Take the first right onto Kirkpatrick Street
- Turn right onto Bentley Drive
- Turn left onto Oak Hill Drive
- Go to the 2nd Stop Sign.

Our building is just past this stop sign on the right, and the entrance to the parking lot is approximately 100 ft past the stop sign on the right.

APPENDIX D

REACH ORIENTATION DOCUMENTATION

Table 19. Orientation Schedule

Orientation Scheduled	Number Invited	Number Attended	Number Consented
March 2, 2016	12	10	8
March 3, 2016	16	15	13
March 8, 2016	19	16	15
March 16, 2016	25	16	16
March 18, 2016	10	6	6
March 23, 2016	2	2	2
March 30, 2016	5	3	3
Totals	89	68	63

APPENDIX E

INTERVENTION SCHEDULE AND WEEKLY LESSONS

REACH STUDY

ALL meetings will be Tuesday @ 5:45pm

Weekly Meeting Schedule (Weeks 1 – 12)

Week	Meeting Date	Meeting Day	Lesson
*1	*April 12, 2016	Tuesday	Introduction
*2	*April 19	Tuesday	Developing and Implementing an Exercise Plan
3	April 26	Tuesday	Motivation and Goals
4	May 3	Tuesday	Tip the Balance
5	May 10	Tuesday	Evaluating Your Progress/ Assessment Results
6	May 17	Tuesday	Problem Solving and Barriers to Eating and Exercise
7	May 24	Tuesday	Thoughts
8	May 31	Tuesday	My Plate/ Dietician
9	June 7	Tuesday	Stimulus Control
10	June 14	Tuesday	Exercise Equivalents
11	June 21	Tuesday	Slippery Slope of Lifestyle Change
12	June 28	Tuesday	Factors Contributing to Long-term Success

Figure 16. Behavioral Intervention Meeting Schedule

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