THE EFFECTS OF 6 WEEKS OF HIGH INTENSITY INTERVAL TRAINING VS. MODERATE INTENSITY TRAINING ON CHANGES IN BODY COMPOSITION

by

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A THESIS

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THE EFFECTS OF 6 WEEKS OF HIGH INTENSITY INTERVAL TRAINING VS. MODERATE INTENSITY TRAINING ON CHANGES IN BODY COMPOSITION

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KINESIOLOGY
ABSTRACT

**Background:** It is important to identify strategies to promote exercise adherence and to identify an optimal exercise stimulus to prevent adverse health outcomes associated with obesity. Low-volume high-intensity interval training (HIIT) has recently been shown to improve a number of cardiometabolic health outcomes similarly to moderate intensity exercise training (MIT) despite requiring 1 hr of training per week for HIIT vs 6 hrs for ET. However, less is known about HIIT and its effects on body composition. **Purpose:** To compare the effects of six-weeks of HIIT vs MIT for improving body composition.

**Methods:** Subjects were 22 overweight sedentary males (Age: 20 ± 1.5, % fat: 31.8 ± 6.4). Cardiovascular fitness, peak power, and body composition were assessed at baseline and 6 weeks post training. **Results:** A significant time effect was observed for % body fat (P < 0.05), VO2 peak (P < 0.05), android fat (P < 0.01), and gynoid fat (P < 0.01). No significant improvements were observed for changes in lean tissue or peak power. No significant group x time interactions was observed between HIIT and MIT. **Discussion:** HIIT and MIT both led to significant improvements in multiple characteristics of body composition, including % fat, and android and gynoid fat deposition. These data suggest that despite a lower volume and training frequency, HIIT and MIT provided similar benefits for improving body composition measures in overweight adolescent males.

Key words: obesity, HIIT, MIT, body composition, android, gynoid
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INTRODUCTION

According to Ogden et al (2014), 78.6 million American citizens, or roughly 1/3 of the population are obese. This is important, as obesity is associated with increased prevalence of a number of chronic cardiometabolic diseases, including cardiovascular disease, dyslipidemia, and type 2 diabetes. Additionally, adiposity is also known to facilitate wide spread inflammation and exacerbate existing conditions. Therefore, as the number of people classified as overweight or obese is expected to rise (Ogden et al., 2014), it is important to identify, promote, and implement modes of exercise that can lead to weight loss and improve body composition. However, the majority of the population find it difficult to incorporate enough weekly exercise to improve body composition, often citing ‘a lack of time” as the primary barrier to participation in exercise (DiBonaventura & Chapman, 2008; Godin et al., 1994). One mode of training that has recently gained interest, due to its ability to improve many aspects of cardiometabolic health in a time efficient manner is High Intensity Interval Training, or HIIT.

HIIT is a mode of training consisting of brief intense work bouts of exercise coupled with active or passive recovery between each interval. The use of recovery periods allows an individual to perform repeated bouts of higher intensity workloads that are not achievable when performing continuous exercise training. While the benefits of HIIT have been well-documented in the literature for many years, more recent studies have revealed the potential for low volume HIIT to improve cardiovascular fitness.
similarly to moderate continuous exercise training performed at more than double the training volume as HIIT. For example, Burgomaster and colleagues (2006) saw increases in work capacity with as little as six HIIT sessions, while others (Dunn, 2009; Trapp, Chisholm, Freund, & Boutcher, 2008) have demonstrated increases in VO$_2$ peak with longer training protocols. HIIT studies that have assessed changes within skeletal muscle showed significant increases in citrate synthase and cytochrome oxidase, two mitochondrial enzymes responsible for increased oxidative capacity, following only six weeks of training (Gibala & McGee, 2008). Additionally, Tremblay (1994) and Macdougal (1998) also showed increases in several glycolytic enzymes, demonstrating improvements in anaerobic metabolic activity in addition to the previously observed aerobic adaptations. In addition to inducing adaptations that lead to improvements in fitness and performance, multiple studies have shown the potential for HIIT to improve cardiometabolic health. For example, Burgomaster, Helgerud, Talanian, and Whyte (as cited in Boutcher, 2010) demonstrated a 22-33% increase in insulin sensitivity in nondiabetic participants following 2-8 weeks of HIIT. Furthermore, HIIT interventions in type 2 diabetes revealed increases in insulin sensitivity as high as 46 and 58% (Boudou, Sobngwi, Mauvais-Jarvis, Vexiau, & Gautier, 2003; Mourier et al., 1997). A recent review by Weston (2014) examined studies comparing HIIT to MIT and subsequent changes on vascular health in patients with cardiometabolic disease. While only two studies (Molmen-Hansen et al., 2012; Tjønna et al., 2008) demonstrated decreases in blood pressure, each study (ten total) reviewed reported larger improvements in VO$_2$ max
in HIIT compared to MIT, and both groups improved endothelial function. In addition to improvements in insulin sensitivity, HIIT studies have also observed beneficial changes in blood lipids. Specifically, Tjonna et al, Molmen-Hansen et al, and Moholdt et al (as cited in Weston, 2014), showed that HIIT increases high density lipoprotein cholesterol (HDL-C), while lowering total triglycerides, and low density lipoprotein cholesterol (LDL-C).

While it has become clear that HIIT can improve multiple facets of cardiometabolic health, the effects of HIIT on body composition are less understood. It is well established that aerobic exercise can facilitate weight loss through the loss of fat mass (Baria et al., 2014; Davidson et al., 2009; Lee et al., 2013; Willis et al., 2012). Several studies have shown that MIT can result in weight loss through decreases in fat mass; however, there is also the potential for loss of lean mass (Kim, Tsujimoto, So, & Tanaka, 2015; Lemon & Nagle, 1980). The primary factors that contribute to loss in lean mass following this mode of exercise training are thought to be due to increased cortisol secretion with concurrent decreases in growth hormone and testosterone when moderate intensity aerobic exercise is performed. This is thought to alter protein turnover during recovery, in favor of greater protein degradation as compared to synthesis, leading to muscle loss and a reduced power output (Swank, as cited in Baechle & Earle, 2008). In contrast, high intensity exercise results in increased secretion of multiple anabolic hormones, especially growth hormone that promotes protein synthesis (Foster et al., 2012; Peake et al., 2014). For example, Foster et al found a 60 fold increase in growth
hormone following 20 minutes of HIIT exercise, which remained elevated for two hours during recovery (2012). Additionally, other studies have shown HIIT to decrease fat mass in the android (trunk) and gynoid (leg) regions with concurrent increases in lean mass. Boudou et al saw a 24% increase in leg lean tissue, along with a 44% decrease in abdominal fat, and 18% decrease in subcutaneous fat (2003). Trapp et al demonstrated increases in lean trunk tissue with a 10% decrease in abdominal fat (2008). These studies suggest that HIIT may provide a short term anabolic stimulus similar to intense resistance training while promoting fat loss in the android and gynoid regions. Thus, the purpose of this study was to further examine and compare the effects of 6 weeks of HIIT vs MIT on changes in body composition. We hypothesized that those in the HIIT group would lose more fat mass and increase lean mass greater than those in the MIT group.

METHODS

Participants

Participants were 28 overweight or obese males between the ages of 17 and 22. Inclusion criteria included sedentary (<30 minutes of exercise per week), overweight or obese (BMI 25-35 kg/m²), normal fasting glucose (fasting glucose <100mg/dl), and no use of medications that effect body composition or metabolism. Additional criteria included any significant diseases that impact the results of the trial, weight loss or gain of >10% of bodyweight within the past 6 months, current smokers, and unsuitable for intense exercise as determined by the PAR-Q questionnaire. The trial was approved by
the Institutional Review Board for human use at the University of Alabama at Birmingham. All participants provided written consent. Parents or legal guardians provided consent for participants between the ages of 17-18.

Study design

This study was a 6 week, single site, two parallel arm, randomized controlled trial comparing the effects of body composition between a HIIT and MIT exercise program. Participants were randomly assigned to either the HIIT or MIT program. There were 28 participants total (n=13 for MIT and n=15 for HIIT). Participants underwent a series of baseline tests, were randomized into the HIIT or MIT training groups, and were reassessed again post training.

Pre and Post testing protocols

Pre and post testing protocols occurred over a 2 day sequence. On day 1, the participants arrived to the lab fasted for their body composition and incremental VO\(_2\) peak test. Body composition measurements included total and region specific (trunk and leg) measurements for % body fat, total mass, fat mass (g), lean mass (g), and bone mineral content (g). Measurements were conducted via Dual X-Ray Absorptiometry (DXA). Subjects were scanned in light clothing while lying flat in the machine with their arms by their sides. Scans were analyzed with ADULT software version 1.33 (Lunar Radiation). The VO\(_2\) peak test was performed on an electronically braked cycle
ergometer (Monark 894E). Each participant pedaled at 50 watts for 3 minutes. For every minute after, resistance was increased 25 watts until the participant reached volitional exhaustion. O₂ uptake was measured via open circuit spirometry and analyzed through a metabolic testing cart (model 2900, Yorba Linda, CA, USA). The highest VO₂ value recorded during the last stage of the test was used as the VO₂ peak. Participants then completed a 30 second Wingate maximal anaerobic power test on Day 2. This test was performed on the same cycle ergometer. The resistance was determined using 0.075 kg/kg body wt. Data for this test was collected and analyzed through Monark Anaerobic Testing Software.

Exercise Training

MIT was performed on a Monark Cycle Ergometer. Participants performed 45-60 minutes of continuous exercise 5 days per week for 6 weeks at a workload of 55-65% of VO₂ peak (workload begin at 55% for 45 minutes, then progressed to 65% for 60 minutes). Workload was determined from a pre intervention VO₂ peak test. Heart rate values were recorded every 5 minutes for each MIT workout. HIIT was performed on an electronically braked cycle ergometer (Quinton Excalibur, Quinton Instrument Company, Bothell, WA). Training consisted of 20 minute sessions that included cycling 4 minutes at 15% of maximum anaerobic power, or Max-AP (defined as the peak power achieved during the Wingate Test) followed by 30 seconds of pedaling at 85% maximum power. This cycle was repeated 4 times, ending with a 2 minute “cooldown” phase at 15% Max-
AP. Workload was determined via pre intervention Wingate Testing. Workouts were conducted 3 days a week for 6 weeks, with at least 24 hours of recovery in between each HIIT bout.

Body Composition

Measures of body composition were assessed through DXA (Lunar Prodigy; GE Healthcare Lunar, Madison, WI). Specific measures of body composition included total fat mass, fat free mass, and percent body fat. Prodigy enCORE software establishes the lines for specific regions of fat. The android region includes the area between the ribs and pelvis. The gynoid region includes the hips and upper thighs. Subjects wore light clothing while lying in a supine position during their scans. The ADULT software version 1.33 (Lunar Radiation) was used to analyze the scans.

Statistical Analysis

Descriptive statistics were calculated for each treatment group (HIIT and MIT) at baseline and following six weeks of exercise training. All values are reported as means ± SD. The following equation represents how percent fat for the android and gynoid regions were calculated with DXA: \( \% \text{Fat} = \left( \frac{\text{Fat mass}}{\text{Fat mass} + \text{lean soft mass} + \text{bone mineral content}} \right) \times 100 \). Overall comparisons of change in body composition measurements and VO\textsubscript{2} peak were assessed using a two (time) x two (group) repeated
measures analysis of variance (ANOVA). Tukey’s post hoc analyses were applied when significant time x group interactions occurred.

RESULTS

A total of 28 participants enrolled in the study. The average age and BMI of the HIIT group was 20 ± 1.5 years and 30.0 ± 3.1 kg/m$^2$. The average age and BMI of the MIT group was 20 ±1.5 years and 29.0 ± 3.4 kg/m$^2$. The participant ethnic composition included 18 non Hispanic Caucasian, 8 African Americans, and 2 Hispanic. Five participants (2 from HIIT and 3 from MIT) withdrew from the study during the course of the treatment. Reasons for leaving the study included transportation problems, illness, job relocation, and an injury unrelated to the study.

Data describing the exercise training and weekly time commitment are displayed in Table 1. The average peak power for the interval portion of HIIT workouts was 810 ± 249 watts, while peak power averaged 140 ± 21 watts during recovery. These workloads correspond to 325% and 56% of VO$_2$ peak. The average heart rate for HIIT was 178± 9 beats per minute during the interval, and 140 ± 13 beats per minute during recovery. The average peak power for MIT was 138 ± 13 watts, or 55-65% of VO$_2$ peak. The average heart rate for MIT was 158 ± 11 beats per minute.
Baseline characteristics between HIIT and MIT are presented in Table 2.

Although participants were randomized into each group, HIIT participants had a greater baseline body fat percentage compared to their MIT counterparts (p= 0.0454). No other statistically significant differences in baseline differences were observed.

Table 2. Baseline Characteristics of Study Population

<table>
<thead>
<tr>
<th>Variable</th>
<th>HIIT</th>
<th>MIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>Age</td>
<td>20.0 ± 1.5</td>
<td>20.0 ± 1.5</td>
</tr>
<tr>
<td>Weight</td>
<td>94.3 ± 12.1</td>
<td>89.7 ± 15.8</td>
</tr>
<tr>
<td>BMI</td>
<td>30.0 ± 3.1</td>
<td>29.0 ± 3.4</td>
</tr>
<tr>
<td>VO2</td>
<td>35.7 ± 6.2</td>
<td>35.0 ± 6.5</td>
</tr>
<tr>
<td>Peak Power</td>
<td>891.0 ± 296.6</td>
<td>1022.4 ± 179.8</td>
</tr>
</tbody>
</table>
Data from each group were compared to assess changes over time (Table 3). Both treatment groups demonstrated improvements in VO\(_2\) peak (p=0.0164), % fat (p=0.004), gynoid fat (p=0.000), and android fat (p=0.008). Each group also displayed improvements in other measures of body composition, including trunk total mass (kg) (p=0.031), trunk fat (kg) (p=0.01), leg fat (kg) (p=0.01), and total fat mass (kg) (p=0.01). No significant improvements were seen for changes in trunk lean mass (p=0.839), leg lean mass (p=0.176), or peak power (p=0.5130). A significant difference in VO\(_2\) peak improvement was observed, such that MIT improved VO\(_2\) peak by 11.1% whereas HIIT only improved VO\(_2\) peak 2.8% (P = 0.0185). No other significant group differences were observed.

Table 3: Changes over time with 6 weeks of HIIT or MIT

<table>
<thead>
<tr>
<th></th>
<th>HIIT</th>
<th>MIT</th>
<th>P Value</th>
<th>time x group</th>
</tr>
</thead>
<tbody>
<tr>
<td>% fat</td>
<td>33.7 ± 6.9</td>
<td>32.8 ± 7.0</td>
<td>27.8 ± 4.5</td>
<td>26.2 ± 3.7</td>
</tr>
<tr>
<td>android</td>
<td>41.1 ± 9.1</td>
<td>38.9 ± 10.4</td>
<td>30.1 ± 6.2</td>
<td>27.5 ± 7.2</td>
</tr>
<tr>
<td>gynoid</td>
<td>34.9 ± 6.3</td>
<td>32.7 ± 6.1</td>
<td>30.0 ± 4.3</td>
<td>27.1 ± 3.7</td>
</tr>
<tr>
<td>Trunk tissue</td>
<td>37.1 ± 8.6</td>
<td>35.9 ± 8.9</td>
<td>28.6 ± 6.0</td>
<td>26.7 ± 5.6</td>
</tr>
<tr>
<td>trunk total</td>
<td>45.0 ± 6.5</td>
<td>44.6 ± 6.2</td>
<td>37.2 ± 5.6</td>
<td>36.1 ± 5.9</td>
</tr>
<tr>
<td>Trunk fat</td>
<td>16.6 ± 5.4</td>
<td>16.0 ± 5.2</td>
<td>10.5 ± 3.4</td>
<td>9.6 ± 3.2</td>
</tr>
<tr>
<td>Leg Tissue</td>
<td>32.3 ± 6.6</td>
<td>31.4 ± 6.4</td>
<td>29.1 ± 4.1</td>
<td>27.5 ± 3.0</td>
</tr>
<tr>
<td>Leg Fat</td>
<td>10.9 ± 3.3</td>
<td>10.6 ± 3.2</td>
<td>8.7 ± 2.8</td>
<td>8.1 ± 2.2</td>
</tr>
<tr>
<td>Total tissue</td>
<td>33.6 ± 7.1</td>
<td>32.8 ± 7.3</td>
<td>27.8 ± 4.5</td>
<td>26.3 ± 3.7</td>
</tr>
<tr>
<td>Total Fat</td>
<td>31.8 ± 9.2</td>
<td>30.7 ± 8.8</td>
<td>22.5 ± 6.8</td>
<td>20.7 ± 5.7</td>
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DISCUSSION

This study was designed to investigate the effects of HIIT vs MIT for improving body composition and cardiovascular fitness in a cohort of obese/overweight men. We predicted that the HIIT group would demonstrate superior changes in cardiovascular fitness and body composition. Following six weeks of training, both groups improved VO$_2$ peak, % body fat, and the android and gynoid areas of fat deposition. No significant changes were seen in lean mass. These findings suggest that while HIIT may not provide superior cardiorespiratory fitness or body composition changes to that of MIT, HIIT may be a more efficient way to improve these parameters in less than half the time of training. However, it does not appear HIIT can induce increases in lean mass with a concurrent loss of fat mass with as little as six weeks of training.

There is a substantial volume of literature validating the use of HIIT to improve cardiorespiratory fitness (Astorino, Allen, Roberson, & Jurancich, 2012; Gibala & McGee, 2008; Tjønna et al., 2008; Trapp et al., 2008; Weston et al., 2014; Wisløff et al., 2007). Studies have demonstrated 7-13% improvements in VO$_2$ max in as little as 2 weeks, 4-8% improvements in 6-8 weeks, and as much as 41-46% in improvements with 12-24 weeks of training (Boutcher, 2010). Similar to improvements seen in interventions lasting 6 weeks, we observed statistically significant improvements for VO$_2$ peak in our HIIT group (2.8%). In comparing HIIT versus MIT for improvements in VO$_2$ peak, some studies have noted superior increases in VO$_2$ peak for HIIT (Ciolac et al., 2010; Wisløff et al., 2007), yet others have observed no differences between the groups.
Contrary to these previous findings, we found greater improvements in VO$_2$ peak in our MIT group (11.1%) compared to those performing HIIT (2.8%). Reasons for the differences seen in VO$_2$ peak comparing HIIT and MIT may be due to the specificity of the training protocol. Longer HIIT sessions coupled with less intense intervals appear to provide greater increases in VO$_2$ peak alone and compared to MIT (Dunn, 2009; Trapp et al., 2008). Proposed mechanisms for the increases in VO$_2$ with HIIT are unclear. Some have shown that an important contributor lies with phosphocreatine degradation. Works by Trump et al and Putman et al (as cited in Boutcher, 2010) indicate that although phosphocreatine is the primary source for ATP resynthesis with initial sprints, a majority of the ATP produced throughout the workout is done so via oxidative phosphorylation. Other proposed mechanisms include enhanced stroke volume, increased oxidative capacity in mitochondria, and oxygen diffusion capacity in muscle (Helgerud et al., 2007).

HIIT has also been shown to improve body composition through the loss of fat mass (Boudou et al., 2003; Dunn, 2009; Trapp et al., 2008; Tremblay et al., 1994). The duration of a HIIT protocol, as well as baseline BMI are important determinants in the potency of fat loss. HIIT interventions lasting less than or equal to 6 weeks utilizing patients of normal body weight or BMI observed decreases in abdominal and subcutaneous fat, but these decreases were trivial (Burgomaster et al, Perry et al, and Talanian et al, as cited in Boutcher, 2010). However, the body weight characteristics (Table 1) of our sample size may have played a role as to why we saw significant losses
in fat mass through only a 6-week intervention. Investigations that used longer trials (8-24 weeks) with overweight or type 2 diabetic patients (Boudou et al., 2003; Tremblay et al., 1994) saw greater reductions in fat mass. In addition to seeing decreases in percent body fat, we also observed improvements in fat deposition, such that there were decreases in gynoid and android fat. These results are consistent with what is seen in other HIIT studies measuring changes in abdominal and subcutaneous fat (Mourier et al, 1997; Trapp et al, 2008). However, it should be noted that despite the HIIT group’s improvement in body composition from baseline, they were not superior to those of our MIT group, as both groups saw significant changes. Mechanisms to how HIIT facilitates fat loss are multifaceted. Many believe the energy expended during, as well the elevation of caloric expenditure post training are two important factors. This expenditure is thought to occur because of an increase in fat oxidation, with greater fatty acid transport and oxidation in the muscle (Burgomaster et al, 2005). Decreases in food intake due to blunted appetites may be another factor in fat loss. However, most of the science behind this potential factor has only been confirmed in rodent studies (Bilski et al, as cited in Boutcher, 2010). In addition to decreases in fat mass, some studies using DXA scans (Boudou et al., 2003; Trapp et al., 2008) have observed increases in lean mass with their HIIT groups. However, these changes were not found in our study.

Strengths of this study included robust measures of body composition and fat distribution, well-controlled exercise training performed under supervised conditions, and rigorous pre-exercise testing to optimize training protocols for each participant.
Limitations in this study include the absence of a non-exercise control group, which prevented us from determining causality from each exercise group for the improvements in cardiorespiratory fitness and body composition. Another limitation was the short duration of the study. HIIT studies reporting changes in lean mass utilized longer durations for their interventions.

In conclusion, HIIT and MIT are both effective modes of training to improve cardiorespiratory fitness and body composition. Though HIIT may not provide superior benefits than MIT, our results suggest that HIIT may be a more efficient way to improve fitness in less than half the time that is devoted to MIT. However, it is unclear whether or not HIIT may be an effective strategy to build lean mass. Further research is needed with the specificity of HIIT protocols to help determine the minimum amount of HIIT required for significant fat loss. While the concept of HIIT may lead to improvements in lean muscle tissue, only a couple of studies (Boudou et al., 2003; Trapp et al., 2008) have data to support this concept. Thus, more work is needed to support or dispel the notion that HIIT increases lean mass with simultaneous fat loss.
Figure 1: Changes in VO2 peak following 6 weeks of HIIT or MIT

Values are expressed as mL/kg/min.
Figure 2: Changes in % body fat following 6 weeks of HIIT or MIT

Changes in % Fat

Changes in % fat are expressed as a percentage (p=0.004).
Figure 3: Changes in regional fat displacement following 6 weeks of HIIT or MIT

Changes in android and gynoid fat deposition expressed as a percentage. Gynoid (p=0.000); Android (p=0.008)


APPENDIX A

INSTITUTIONAL REVIEW BOARD
Human Subjects Protocol (HSP)
Form Version: June 26, 2012

- You are applying for IRB review of the research described in this form.
- To avoid delay, respond to all items in order and include all required approvals and documents.
- To complete the form, click the underlined areas and type or paste in your text; double-click checkboxes to check/uncheck. For more tips, see www.uab.edu/irb/forms.
- Mail or deliver all materials to AB 470, 701 20th Street South, Birmingham, AL 35294-0104.

Indicate the type of review you are applying for:

- [x] Convened (Full) IRB or
- [ ] Expedited—See the Expedited Category Review Sheet, and indicate the
category(ies) here: [☐] 1 [☐] 2 [☐] 3 [☐] 4 [☐] 5 [☐] 6 [☐] 7

1. IRB Protocol Title: High Intensity Interval vs Moderate Intensity Training: Maximizing the benefits of exercise in overweight adolescents.

2. Investigator, Contacts, Supervisors
   a. Name of Principal Investigator: Gordon Fisher
      Degree(s)/Title: PhD BlazerID: grdnfs
      Dept/Div: Human Studies Mailing Address: EB-232J UAB ZIP: 35294
      Phone: 6-4114 Fax:   E-mail: grdnfs@uab.edu
   b. Name of Contact Person: Amy Thomas Title: Study Coordinator
      Phone: 5-9273
      E-mail: anysusan@uab.edu Fax: 5-7560
      Mailing Address (if different from that of PI, above): LHL 448

Investigator Assurance Statement & Signature
By my signature as Principal Investigator, I acknowledge my responsibilities for this Human Subjects Protocol, including:

- Certifying that I and any Co-Investigators or Other Investigators comply with reporting requirements of the UAB Conflict of Interest Review Board;
- Certifying that the information, data, and/or specimens collected for the research will be used, disclosed and maintained in accordance with this protocol and UAB policies;
- Following this protocol without modification unless (a) the IRB has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a participant(s);
• Verifying that all key personnel listed in the protocol and persons obtaining informed consent have completed initial IRB training and will complete continuing IRB training each year;
• Verifying that all personnel are licensed/credentialed for the procedures they will be performing, if applicable;
• Certifying that I and all key personnel have read the UAB Policy/Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, Institutional Officials, and Regulatory Agencies and understand the procedures for reporting;
• Applying for continuing review of the protocol at least annually unless directed by the IRB to apply more frequently;
• Conducting the protocol as represented here and in compliance with IRB determinations and all applicable local, state, and federal law and regulations; providing the IRB with all information necessary to review the protocol; refraining from protocol activities until receipt of initial and continuing formal IRB approval.

Signature of Investigator: ________________________________  Date: __

c. List all staff who will be involved with the design, conduct, and reporting of the research, their degree(s) and job title, and any additional qualifications. Include individuals who will be involved in the consent process. Repeat the table below for each individual.

Note. For studies involving investigational drugs, include all investigators who will be listed on FDA Form 1572 and attach a copy, if applicable. Send the IRB a copy of Form 1572 anytime you update the form with the FDA.

<table>
<thead>
<tr>
<th>Role:</th>
<th>Co- -OR- ☒Other –AND/OR- ☐Consent Process</th>
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</thead>
<tbody>
<tr>
<td>Full Name:</td>
<td>David B. Allison</td>
</tr>
<tr>
<td>Primary UAB Dept.:</td>
<td>School of Public Health Dean’s Office</td>
</tr>
<tr>
<td>Degree(s) / Job Title:</td>
<td>PhD</td>
</tr>
<tr>
<td>Additional Qualifications pertinent to the study:</td>
<td>Advisor</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Role:</th>
<th>Co- -OR- ☒Other –AND/OR- ☐Consent Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Name:</td>
<td>Andrew Brown</td>
</tr>
<tr>
<td>Primary UAB Dept.:</td>
<td>Office of Energetics</td>
</tr>
<tr>
<td>Degree(s) / Job Title:</td>
<td>PhD, Post-doc</td>
</tr>
</tbody>
</table>
Additional Qualifications pertinent to the study:
Role: ☐ Co- ☑ OR- ☑ Other – AND/ OR- ☐ Consent Process

Full Name: Michelle Bohon Brown
Primary UAB Dept.: Nutrition Sci
Degree(s) / Job Title: PhD, Post-doc

Additional Qualifications pertinent to the study:
Role: ☐ Co- ☑ OR- ☑ Other – AND/ OR- ☐ Consent Process

Full Name: Karen Keating
Primary UAB Dept.: Office of Energetics
Degree(s) / Job Title: PhD, Research Associate
Additional Qualifications pertinent to the study:
Role: ☐ Co- ☑ OR- ☑ Other – AND/ OR- ☐ Consent Process

Full Name: Amy Susan Thomas
Primary UAB Dept.: Office of Energetics
Degree(s) / Job Title: MPH, RD, Study Coordinator, Exercise Physiologist
Additional Qualifications pertinent to the study:
Role: ☐ Co- ☑ OR- ☑ Other – AND/ OR- ☐ Consent Process

Full Name: Corey Noles
Primary UAB Dept.: Office of Energetics
Degree(s) / Job Title: BS, Research Assistant, Exercise Physiologist
Additional Qualifications pertinent to the study:
Role: ☐ Co- ☑ OR- ☑ Other – AND/ OR- ☐ Consent Process
d. Is the principal investigator a student, fellow, or resident? □ Yes  ☑ No

If Yes, complete items below and obtain signature of faculty advisor or supervisor:

Supervisor's Name:  
Degree(s) / Job Title:  
Additional Qualifications pertinent to the study:  
Telephone:  
E-Mail:  
Signature:  

e. Describe the principal investigator's activities related to this protocol and provisions made by the PI to devote sufficient time to conduct the protocol:

As his first funded project as a new Assistant Professor, this project is a priority for the PI. Dr. Fisher will be hands-on for initial testing and exercise training sessions and will personally conduct biochemical analyses in addition to overall implementation of the protocol. He has made adequate allowances in his schedule to conduct this research.

f. Is medical supervision required for this research?  □ Yes  ☑ No

If Yes, who will provide the supervision?

☐ PI will provide  -OR- Name:  Telephone:  

If other than PI, obtain signature of person providing medical supervision:

Signature:  

3. Funding

Is this study funded?  ☑ Yes  □ No

If No, specify that costs of the study will be covered by funds from the UAB department or other source named:  

If Yes, attach one copy of completed application or request for funding sent to sponsor, and complete a-d.

a. Title of Grant or Contract: **High Intensity Interval Versus Moderate Intensity Training: Maximizing the Benefits of Exercise in Overweight Adolescents.**

b. PI of Grant or Contract: **Gordon Fisher**

c. Office of Sponsored Programs Proposal Number: **NA**
   (or enter "Pending" and provide upon receipt from OSP)

d. Sponsor, Funding Route (check and describe all that apply):
   - ☐ Gov’t Agency or Agencies—Agency name(s): _____
   - ☐ Department of Defense (DoD): Identify DoD component: _____
   - ☐ Department of Energy (DOE)
   - ☐ Department of Justice (DOJ)
   - ☐ Department of Education
   - ☐ NIH Coop. Group Trial—Group name: _____
   - ☑ Private Nonprofit (e.g., Foundation)—Name: **Coca-Cola Foundation**
   - ☐ Industry, investigator-initiated—Name: _____ Describe the funding arrangement: _____

   Note. **Western IRB** reviews industry-sponsored protocols unless the investigator initiated the research, or the study qualifies for expedited review or involves gene therapy.

- ☐ UAB Departmental/Division Funds—Specify: _____

4. **Conflict of Interest**—Human subjects research involving a disclosed financial interest is subject to IRB review following review by the Conflict of Interest Review Board.

   The following definitions are used for Item #4:

   **Immediate family** means spouse or a dependent of the employee. **Dependent** is any person, regardless of his or her legal residence or domicile, who receives 50% or more of his or her support from the public official or public employee or his or her spouse or who resided with the public official or public employee for more than 180 days during the reporting period.

   **Financial Interest Related to the Research** means financial interest in the sponsor, product or service being tested, or competitor of the sponsor.

   For each investigator and staff member involved in the design, conduct and reporting of the research (see Items 2.a. and 2.c.) answer the questions below: (Repeat the section below for each individual)

**Name: David B. Allison**

Do you or your immediate family have any of the following? (check all that apply)

- ☐ An ownership interest, stock options, or other equity interest related to the research of any value.
- ☐ Compensation related to the research unless it meets two tests:
   - Less than $10,000 in the past year when aggregated for the immediate family.
   - Amount will not be affected by the outcome of the research.
- ☐ Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- ☐ Board of executive relationship related to the research, regardless of compensation.
**Name: Gordon Fisher**

Do you or your immediate family have any of the following? (check all that apply)

- An ownership interest, stock options, or other equity interest related to the research of any value.
- Compensation related to the research unless it meets two tests:
  - Less than $10,000 in the past year when aggregated for the immediate family.
  - Amount will not be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship related to the research, regardless of compensation.

**Name: Andrew Brown**

Do you or your immediate family have any of the following? (check all that apply)

- An ownership interest, stock options, or other equity interest related to the research of any value.
- Compensation related to the research unless it meets two tests:
  - Less than $10,000 in the past year when aggregated for the immediate family.
  - Amount will not be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship related to the research, regardless of compensation.

If you checked any of the above, a financial interest disclosure has to be submitted to or currently be on file with the CIRB. A completed CIRB Evaluation has to be available before the IRB will conduct its review.

5. Locations Involved

   a. Describe the facilities available for the conduct of the research. For research on UAB campus, include building names and room numbers: **Exercise Physiology Lab School of Nursing GM019; Core Lab of Nutrition and Obesity Research Center, Webb Building 337; Core Lab of Diabetes Research Center, Webb Building 337; Clinical Research Unit, Jefferson Towers 15.**

   b. Indicate all "performance sites" that will provide space, services, facilities, potential or actual participants, or other support for this protocol.

   - The Kirklin Clinic (TKC)
   - University of Alabama Hospital (UAHosp)
   - The Children's Hospital of Alabama (TCHA)
   - Callahan Eye Foundation Hospital (CEFH)
   - UAB Highlands
   - Jefferson County Dept. of Health (JCDH)
   - Birmingham Veterans Affairs Medical Center (BVAMC)
   - General Clinical Research Center (GCRC)—inpatient
   - General Clinical Research Center (GCRC)—outpatient
General Clinical Research Center (GCRC) at The Kirklin Clinic (TKC)  
☑ Other (i.e., Any performance site not listed above, including those covered by subcontracts related to this protocol)—Describe: see 5a

c. Is this study a clinical trial requiring clinical services at one of the performance sites listed in Item b above?  
☐ Yes ☑ No  
If Yes, Fiscal Approval Process (FAP)-designated units complete a FAP submission and send to fap@uab.edu. For more on the UAB FAP, see www.uab.edu/ohr.

d. Is this a field study?  
☐ Yes ☑ No  
If Yes, describe the community and include information about how the community will be involved in the design, implementation and analysis of the research. This would include focus groups, training local facilitators/community health advisors:

e. Is the study to be undertaken within a school, business, or other institution that does not have an institutional review board?  
☐ Yes ☑ No  
If Yes, attach a statement of any contacts with and approvals from the appropriate institution officials.  
Note. Documentation of all such approvals must be received by the UAB OIRB before IRB approval will be issued.

f. Has this protocol or project been reviewed by another IRB, similar review board, or departmental review committee(s) that authorizes the use of its patient populations?  
☐ Yes ☑ No  
If Yes, provide name of the review board(s); ______ and for each board listed, enter either the date of latest approval(s) or “PENDING”: ______ or reasons not approved: ______. If this protocol is subsequently rejected or disapproved by another review board, the UAB IRB must be notified promptly.

Name: Michelle Bohon Brown

Do you or your immediate family have any of the following? (check all that apply)
☐ An ownership interest, stock options, or other equity interest related to the research of any value.  
☐ Compensation related to the research unless it meets two tests:
   • Less than $10,000 in the past year when aggregated for the immediate family.
   • Amount will not be affected by the outcome of the research.
☐ Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
☐ Board of executive relationship related to the research, regardless of compensation.
Name: Amy Susan Thomas
Do you or your immediate family have any of the following? (check all that apply)
☐ An ownership interest, stock options, or other equity interest related to the research of any value.
☐ Compensation related to the research unless it meets two tests:
  • Less than $10,000 in the past year when aggregated for the immediate family.
  • Amount will not be affected by the outcome of the research.
☐ Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
☐ Board of executive relationship related to the research, regardless of compensation.

Name: Karen Keating
Do you or your immediate family have any of the following? (check all that apply)
☐ An ownership interest, stock options, or other equity interest related to the research of any value.
☐ Compensation related to the research unless it meets two tests:
  • Less than $10,000 in the past year when aggregated for the immediate family.
  • Amount will not be affected by the outcome of the research.
☐ Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
☐ Board of executive relationship related to the research, regardless of compensation.

Name: Corey Noles
Do you or your immediate family have any of the following? (check all that apply)
☐ An ownership interest, stock options, or other equity interest related to the research of any value.
☐ Compensation related to the research unless it meets two tests:
  • Less than $10,000 in the past year when aggregated for the immediate family.
  • Amount will not be affected by the outcome of the research.
☐ Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
☐ Board of executive relationship related to the research, regardless of compensation.

Attach copies of approvals/disapprovals.

g. Will any of the participants be from the Birmingham Veterans Affairs Medical Center? ☐Yes ☒No
   If Yes, attach VA IRB approval or notification from the VA Research and Development Department that the study has been submitted to the VA IRB for review.

h. Will the study be conducted at or recruit participants from the Jefferson County Department of Public Health (JCDH)? ☐Yes ☒No
   If Yes, attach notification that the protocol has been approved by JCDH or the Alabama Department of Public Health IRB.

6. Multi-Site Studies
   a. Is the investigator the lead investigator of a multi-site study? ☐Yes ☒No
b. Is UAB a coordinating site in a multi-site study?  
   Yes  No

c. If you answered Yes to a or b, describe the management of information obtained in multi-site research that might be relevant to the protection of participants. Include, at a minimum, the following items:
   o  IRB approvals from other sites
   o  Unanticipated problems involving risks to participants or others. (For example, if there is an unanticipated problem involving risks to participants or others, which site is responsible for reporting it?)
   o  Interim results.
   o  Protocol modifications.

7. Drugs: Will any drugs or supplements be used/studied in this protocol?  
   Yes  No
   If Yes, attach the Drug Review Sheet.

8. Devices: Will any devices be studied in this protocol or used for a purpose other than for which they were approved by the FDA?  
   Yes  No
   If Yes, attach the Device Review Sheet.

9. Special Approvals
   a. Does this project involve the use of radioisotopes?  
      Yes  No
      If Yes, attach documentation of approval from the Radiation Safety Division.
   b. Does this project include patients with contagious infections (e.g., mumps, measles, chickenpox, TB, meningitis)?  
      Yes  No
      If Yes, attach documentation of approval from Chairman of the Infection Control Committee of the appropriate facilities.
   c. Does this project involve obtaining remnant biopsy or surgical material from the Department of Pathology or any other source?  
      Yes  No
      If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Anatomic Pathology Release of Pathologic Materials).
   d. Does this project require obtaining any remnant clinical laboratory specimens, body fluids, or microbiological isolates from the Department of Pathology or any other source?  
      Yes  No
      If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Laboratory Medicine Release of Pathologic Materials).
   e. Does this project use stored (existing) specimens from a repository?  
      Yes  No
      If Yes, attach documentation of approval for use of specimens, and describe how existing specimens are labeled: _____
10. Use of Specimens

Does this project involve collecting specimens from participants and storing them for future research?

☐ Yes ☑ No

If Yes, complete a-h. If no, skip to Item 11

a. How will specimens be obtained, processed, distributed, and stored?

b. How will specimens be labeled (e.g., unique identifier, medical record number, Social Security number, name, date of birth)?

c. How will clinical data associated with the specimens be collected and stored?

d. What participant-identifying information will be collected and linked to the specimens?

e. What steps will be taken to maximize the confidentiality of linked identifiers? For example, procedures could include using a password-protected computer database to link identifiers, with limited personnel knowledgeable of the password, or coded identifiers released without the ability to link to clinical data (also called "stripped" or "anonymized" specimens).

f. Will specimens be shared with other investigators in the future? ☐ Yes ☐ No

If Yes, what identifiers, clinical information and demographic information will be shared; or will the specimens be stripped of identifiers (i.e., anonymized)? Also if yes, outline your procedure for assuring IRB approval for release and use prior to release of specimens.

Note. Investigators who receive and/or use these specimens must document approval from the appropriate IRB(s) before the specimens may be released.

g. Will biological samples be stored for future use? ☐ Yes ☐ No

If Yes, indicate whether they will be used for the disease under study in this protocol or research on other diseases.

h. Is genetic testing planned? ☐ Yes ☐ No

If Yes, describe the planned testing here and see "DNA/Genetic Testing" in the Guidebook for consent requirements.
11. Gene Therapy
Does this project involve gene therapy or administering recombinant materials to humans? □ Yes □ No

If Yes, submit the Gene Therapy Project Review Panel Report –OR- If this is a vaccine trial that is exempt from the NIH Guidelines For Research Involving Recombinant DNA Molecules, submit the Protocol Oversight Review Form For Clinical Vaccine Trials.

12. HIPAA Privacy and Security
Will the PI or others obtain, review, or make other use of participants' "personal health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of health care)? □ Yes □ No

If Yes, complete a-e as described.

a. Will the data/information be stored or managed electronically (on a computer)? □ Yes □ No

b. Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution)? □ Yes □ No

If Yes, attach copy of privacy notices from institution/entity, and provide the name of institution/entity:

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If Yes, attach copy of privacy notices from institution/entity, and provide the name of institution/entity:
d. Indicate which of the listed identifiers would be associated/linkedin with the protected health information (PHI) used for this protocol.

- Names
- Geographic subdivisions smaller than a State
- Elements of dates (except year) related to an individual
- Telephone numbers
- Fax numbers
- Email addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers
- Device identifiers and serial numbers
- Biometric identifiers
- Web universal resource locators (URLs)
- Internet protocol address numbers
- Full-face photographic images
- Any other unique identifying number—Describe: ______

Note. Codes are not identifying as long as the researcher cannot link the data to an individual

- None—If None, skip to Item 13.

e. Choose one plan to describe your use of the personal health information:

- The data collected meet the specifications for a “limited data set”
  —Attach Data Use Agreement or Business Associate Agreement

- Research staff will obtain authorization from each patient to use the information
13. Purpose—in nontechnical, lay language

Summarize the purpose and objectives of this protocol, including any related projects, in one short paragraph.

This is a single site, 2 parallel arm, randomized, controlled trial comparing the effectiveness of a High Intensity Interval Training (HIIT) versus a continuous Moderate Intensity Training (MIT) program on cardiovascular and metabolic health outcomes in overweight adolescent males. The study will be conducted over a total of 8 weeks. 36 participants will be enrolled, with 18 randomized to HIIT and 18 randomized to MIT. Multiple measures will be performed at baseline and 6 weeks, including anthropometry, body composition, insulin sensitivity, cardiovascular fitness, free living physical activity, blood pressure, blood assays, and appetite sensations.

14. Background—in nontechnical, lay language

Summarize in 2-3 paragraphs past experimental and/or clinical findings leading to the formulation of this study. Include any relevant past or current research by the Principal Investigator. For drug and device studies summarize the previous results (i.e., Phase I/II or III studies).

Obesity and physical inactivity are associated with decreased insulin sensitivity and the development of type 2 diabetes. It has been reported that the more overweight or obese an individual is, the more likely they are to experience adverse metabolic/cardiovascular outcomes. It is well recognized that weight loss achieved through caloric restriction and/or exercise can improve insulin sensitivity and body composition in obese and overweight individuals; however it has also been shown that approximately one-third of those who lose weight will regain weight within one year following treatment. Therefore, it is important to identify novel strategies that will promote exercise adherence and identify an optimal exercise stimulus to prevent adverse metabolic and cardiovascular outcomes associated with obesity. Low-volume high-intensity interval training (HIIT) (repeated sessions of
brief intermittent exercise performed at intensities > 90% VO\textsubscript{2\text{max}}) has recently been shown to improve insulin sensitivity, glucose tolerance, cardiovascular fitness, and blood pressure similar to traditional endurance exercise (ET) despite requiring 1 hr of training per week for HIIT vs 6 hrs for ET. Given that ‘lack of time’ remains the most commonly cited barrier to regular exercise participation, HIIT training may be a potent time-efficient strategy to induce similar metabolic and cardiovascular adaptations typically associated with ET. Additionally, while the overall caloric expenditure is significantly less performing HIIT as compared to ET; vigorous exercise has been shown to significantly reduce hunger immediately following the session.

15. Participants (Screening and Selection)

a. How many participants are to be enrolled at UAB? 36
   If multi-center study, total number at all centers: _____

b. Describe the characteristics of anticipated or planned participants.
   Sex: Male
   Race/Ethnicity: Various
   Age: 17-19 yo
   Health status: Generally good health

Note. If data from prior studies indicate differences between the genders or among racial/ethnic groups in the proposed research or if there are no data to support or to negate such differences, Phase 3 clinical trials will be required to include sufficient and appropriate entry of gender and racial/ethnic subgroups so that trends detected in the affected subgroups can be analyzed. If ethnic, racial, and gender estimates are not included in the protocol, a clear rationale must be provided for exclusion of this information. If prior evidence indicates that the results will not show gender or racial differences, researchers are not required to use gender or race/ethnicity as selection criteria for study participants. They are, however, encouraged to include these groups. See Section II. Policy of the NIH POLICY AND GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH – Amended, October, 2001) for further details.

c. From what population(s) will the participants be derived?
   College and high school campuses in the Birmingham area.
   Describe your ability to obtain access to the proposed population that will allow recruitment of the necessary number of participants:
   **We will use flyers, posters, word-of-mouth, and classroom presentations to recruit participants.**
   Describe the inclusion/exclusion criteria:
**Inclusion criteria**
- Ages 17-19
- Male
- Body mass index (BMI) (25.0 – 35.0 kg/m²)
- Interested in improving health and fitness

**Exclusion criteria:**
- Weight loss or gain of >10% of body weight in the past 6 months for any reason.
- Currently taking medication that suppresses or stimulates appetite.
- History of prior surgical procedure for weight control or liposuction.
- Current smoker.

Any major disease, including:
- Active cancer or cancer requiring treatment in the past 2 years (except nonmelanoma skin cancer).
- Active or chronic infections, including self-reported HIV positivity and active tuberculosis.
- Diagnosed heart conditions.
- Uncontrolled hypertension: systolic blood pressure 160 mm Hg or diastolic blood pressure 95 mm Hg on treatment.
- Gastrointestinal disease, including self-reported chronic hepatitis or cirrhosis, any episode of alcoholic hepatitis or alcoholic pancreatitis within past year, inflammatory bowel disease requiring treatment in the past year, recent or significant abdominal surgery (e.g., gastrectomy).
- Asthma.
- Diagnosed diabetes (type 1 or 2), fasting impaired glucose tolerance (blood glucose 118 mg/dL), or use of any anti-diabetic medications.

- Conditions or behaviors likely to effect the conduct of the trial: unable or unwilling to give informed consent; unable to communicate with the pertinent clinic staff; unwilling to accept treatment assignment by randomization; current or anticipated participation in another intervention research project that would interfere with the intervention offered in the trial; likely to move away from participating clinics before trial completed; unable to walk 0.25 mile in 10 minutes.
- Currently taking antidepressant, steroid, or thyroid medication, unless dosage is stable (no change for 6 months).
• Any active use of illegal or illicit drugs.
• Excessive alcohol intake defined as an average consumption of 3 or more alcohol containing beverages daily.
• Unwilling to limit alcohol intake to \( \leq 2 \) drink per day (one drink = 4 oz. wine, 12 oz. beer, or ½ shot of liquor).
• Current exerciser (>30 min organized exercise per week).
• Indication of unsuitability of current health for exercise protocol (PARQ).
• Any other conditions which, in opinion of the investigators, would adversely affect the conduct of the trial.

d. If participants will comprise more than one group or stratification, describe each group (e.g., treatment/intervention, placebo, controls, sham treatment) and provide the number of participants anticipated in each group.

18 in the High Intensity Interval Training (HIIT) and 18 in the continuous Moderate Intensity Training (MIT)

e. Indicate which, if any, of the special populations listed below will be involved in the protocol. Include the Special Populations Review Form (SPRF) if indicated.

- Pregnant Women: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
- Fetuses: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
- Neonates/Nonviable Neonates: SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
- Prisoners: Attach SPRF—Prisoners
- Minors (<19 years old): Attach SPRF—Minors
- Employees or students at institution where research conducted
- Persons who are temporarily decisionally impaired
- Persons who are permanently decisionally impaired (e.g., mentally retarded)
- Non-English Speakers

For each box checked, describe why the group is included and the additional protections provided to protect the rights and welfare of these participants who are vulnerable to coercion: Minors: Parental verbal consent will be obtained for interested persons <19 years old prior to screening. In addition, all subjects will be given the clear opportunity to decline participation. Employees/students: the informed consent clearly states the protection of employees and students against career or grade manipulation.
f. List any persons other than those directly involved in the study who will be at risk. If none, enter "None": None

g. Describe the process (e.g., recruitment, chart review) that will be used to seek potential participants (e.g., individuals, records, specimens). Research recruitment by non-treating physicians/staff may require completion of Partial Waiver of Authorization for Recruitment/Screening. (See http://main.uab.edu/show.asp?durki=61981.)

Recruitment materials attached.

h. If you will use recruitment materials (e.g., advertisements, flyers, letters) to reach potential participants, attach a copy of each item. If not, identify the source (e.g., databases) from which you will recruit participants.

We will use flyers, posters, word-of-mouth, and classroom presentations to recruit participants.

i. Describe the procedures for screening potential participants.

Those that respond to the study telephone number will be asked for parent contact information. Parents will be read the Informed Consent over the phone by study personnel. Pending verbal consent of one parent or guardian (waiver of documentation), subjects will be contacted and screened for initial eligibility via telephone. Eligible subjects will be scheduled for a clinic visit, during which informed assent, fasting blood glucose, assessment of height, weight, and blood pressure, and completion of screening questionnaires (PARQ) will occur. Those subjects that pass the second level of screening will be scheduled for baseline measurements.

16. Protocol Procedures, Methods, and Duration of the Study—in nontechnical language

a. Describe the study methodology that will affect the participants—particularly in regard to any inconvenience, danger, or discomfort.

Participants will have their fingers pricked for blood glucose at the screening visit. Blood will be drawn during baseline and final testing (OGTT) via an antecubital catheter over a 2-hour period. Blood will also be drawn via catheter on Day 1 and Day 42 of the training period. During the VO2 Maximum testing there may be discomfort while wearing the mask to include dry mouth and a feeling of claustrophobia. Exercise training may induce delayed onset muscle soreness and fatigue.

b. What is the probable length of time required for the entire study (i.e., recruitment through data analysis to study closure)?

1.5 years

c. What is the total amount of time each participant will be involved?
8 weeks
d. If different phases are involved, what is the duration of each phase in which the participants will be involved? If no phases are involved, enter "not applicable."
Not applicable
e. List the procedures, the length of time each will take, and the frequency of repetition, and indicate whether each is done solely for research or would already be performed for treatment or diagnostic purposes (routine care) for the population. Insert additional table rows as needed.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Length of Time Required of Participants</th>
<th>Frequency of Repetition</th>
<th>Research (Res) – OR - Routine Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone screening</td>
<td>15 minutes</td>
<td>Once</td>
<td>Res</td>
</tr>
<tr>
<td>Final screening</td>
<td>30 minutes</td>
<td>Once</td>
<td>Res</td>
</tr>
<tr>
<td>Testing visit 1</td>
<td>3.5 hours</td>
<td>Twice</td>
<td>Res</td>
</tr>
<tr>
<td>Testing visit 2</td>
<td>45 minutes</td>
<td>Twice</td>
<td>Res</td>
</tr>
<tr>
<td>Testing visit 3</td>
<td>15 minutes</td>
<td>Twice</td>
<td>Res</td>
</tr>
<tr>
<td>Clinic visit for HIIT</td>
<td>20 minutes</td>
<td>18</td>
<td>Res</td>
</tr>
<tr>
<td>Clinic visit for MIT</td>
<td>60 minutes</td>
<td>30</td>
<td>Res</td>
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</tbody>
</table>

f. Will an interview script or questionnaire be used? Yes ☐ No ☑
If Yes, attach a copy.

g. Will participants incur any costs as a result of their participation? Yes ☐ No ☑
If Yes, describe the reason for and amount of each foreseeable cost.

h. Will participants be compensated? Yes ☐ No ☑
If Yes, complete i-v:
i. Type: (e.g., cash, check, gift card, merchandise): check
ii. Amount or Value: $600
iii. Method (e.g., mail, at visit): at visit
iv. Timing of Payments: (e.g., every visit, each month): $100 after baseline testing; $500 after final testing.
v. Maximum Amount of Payments per Participant: $600
17. Describe the potential benefits of the research.
The health benefits of regular exercise are well established. And yet it remains
difficult for many persons to find the time and circumstances that lead to engaging in
regular exercise of a magnitude and duration generally believed to convey health
benefits. Therefore, it is essential to develop novel strategies to help people achieve
these goals. Here we propose a time-efficient exercise alternative to reduce the risk of
comorbidities associated with adiposity while making adherence easier.

18. Risks
a. List the known risks—physical, psychological, social, economic, and/or legal—that
participants may encounter as a result of procedures required in this protocol. Do
not list risks resulting from standard-of-care procedures. Note. Risks included in
this protocol document should be included in the written consent document.

Physical risks include possible adverse reaction to the blood draws. These
can include lightheadedness or fainting, along with pain, bruising, or infection at the
injection site. During the VO2 Maximum testing there is a rare risk of ischemia or
cardiac arrest. During the Wingate Power Test and the exercise training protocol,
there is a potential risk of mild muscle soreness, an arrhythmia and fatigue.

b. Estimate the frequency, severity, and reversibility of each risk listed.

We expect adverse reactions to the blood draws to be rare, not severe, and
completely reversible. Any soreness or fatigue related to exercise is not
expected to be severe and is also completely reversible.

c. Is this a therapeutic study or intervention? ☑ Yes ☐ No

If Yes, complete the following items:

i. Describe the standard of care in the setting where the research will be
conducted: The standard of care for increased fitness in overweight and
mildly obese persons is exercise prescription.

ii. Describe any other alternative treatments or interventions: There are a myriad
of exercise modes and programs for persons desiring greater physical
fitness and health outcomes.

iii. Describe any withholding of, delay in, or washout period for standard of care
or alternative treatment that participants may be currently using: None. All
participants will be exercising.

d. Do you foresee that participants might need additional medical or psychological
resources as a result of the research procedures/interventions? ☐ Yes ☑ No

If Yes, describe the provisions that have been made to make these resources
available.
e. Do the benefits or knowledge to be gained outweigh the risks to participants? 

   Yes  [ ] No

If No, provide justification for performing the research: 

19. Precautions/Minimization of Risks

a. Describe precautions that will be taken to avoid risks and the means for monitoring to detect risks.

To prevent risks associated with the blood draws experienced phlebotomists, strict sterile technique, and applying pressure on the injection site will be utilized to minimize pain, infection, and bruising. Participants will be closely monitored during blood draws, and at the first sign of lightheadedness, clamminess, or fainting, they will be placed in a reclined position with legs elevated, and pulse and blood pressure will be assessed until they have recovered fully. To avoid exercise-related risks, all study personnel related to the exercise protocol are exercise physiologists, CPR and defibrillator certified. Subjects will be instructed in technique to avoid injury and minimize soreness. Subjects will be supervised during on-site exercise training.

b. If hazards to an individual participant occur, describe (i) the criteria that will be used to decide whether that participant should be removed from the study; (ii) the procedure for removing such participants when necessary to protect their rights and welfare; and (iii) any special procedures, precautions, or follow-up that will be used to ensure the safety of other currently enrolled participants.

   (i) Any participant experiencing a documented injury or other physical condition, the participant and the study coordinator can assess the situation and determine if the participant wishes to continue. If symptoms do not improve, the participant will be removed from the intervention. (ii) Participants requiring removal from the study will be notified promptly and instructed to discontinue the intervention (exercise). Referral to their primary care provider will be made if necessary, and the participant will be provided with results of any tests or measurements that are available as a result of their participation in the study. (iii) All currently enrolled participants will be continually monitored for adverse reactions or other problems.

c. If hazards occur that might make the risks of participation outweigh the benefits for all participants, describe (i) the criteria that will be used to stop or end the entire study and (ii) any special procedures, precautions, or follow-up that will be used to ensure the safety of currently enrolled participants.
(i) If a significant percentage of participants (at least 10%) of participants experience a serious adverse event, the study would be stopped. (ii) If the study were to be stopped, all currently enrolled participants would be contacted by telephone promptly and assessed for adverse reactions, as well as be scheduled for a final clinic visit for further assessment.

20. Informed Consent

a. Do you plan to obtain informed consent for this protocol?  ☑ Yes  ☐ No
   If Yes, complete the items below.
   If No, complete and include the Waiver of Informed Consent or Waiver of Authorization and Informed Consent, as applicable.

b. Do you plan to document informed consent for this protocol?  ☑ Yes  ☐ No
   If Yes, complete the items below.
   If No, complete the items below and include the Waiver of Informed Consent Documentation.

c. How will consent be obtained? The study coordinator will present the study on the phone to the parent of the potential participant <19 years old. Informed consent (waiver of documentation) will be obtained at that time. Next, the study coordinator will present the study at the screening visit and ample time will be allotted for all potential participants to ask questions and have them answered by study personnel. The consent form will be reviewed page by page, and again time will be allotted for questions and answers. Finally, when the study protocol and consent have been reviewed and all questions have been addressed, individuals agreeing to participate will sign the consent form (those <19yo will be assenting). Each participant will be emailed a copy of their signed consent form.

d. Who will conduct the consent interview? The study coordinator

e. Who are the persons who will provide consent or permission? Participants or their parent

f. What steps will be taken to minimize the possibility of coercion or undue influence? The study coordinator will stress that participation is strictly voluntary and is in no way required in order to receive any type of services at UAB. Only the study coordinator, witness, and potential participant will be involved in the consent process. No other parties will discuss the research with the participant or attempt to exert any undue influence.

g. What language will the prospective participant or the legally authorized representative understand? English
h. What language will be used to obtain consent? **English**

i. If any potential participants will be, or will have been, in a stressful, painful, or drugged condition before or during the consent process, describe the precautions proposed to overcome the effect of the condition on the consent process. If not, enter "no such effect."

**No such effect.**

j. If any project-specific instruments will be used in the consenting process, such as flip charts or videos, describe the instrument(s) here, and provide a copy of each. If not, enter "not used."

**Not used.**

k. How long will participants have between the time they are told about the study and the time they must decide whether to enroll? If not 24 hours or more, describe the proposed time interval and why the 24-hour minimum is neither feasible nor practical. **Participants will be told about the study in their telephone screening interview; again at the screening visit. The screening consent and visit will take place at least 24 hours after the phone explanation. The study consent and baseline visit will take place at least 24 hours after the screening visit. Additionally, the study consent form will be emailed on the same day as the screening telephone visit, to allow additional time for the participant to review before signing. Parents of interested participants, 19yo will be told about the study on the phone, and allowed whatever length of time they desire to decide. Parents will also be emailed a copy of the informed consent.**

21. Procedures to Protect Privacy
Describe the provisions included in the research to protect the privacy interests of participants (e.g., others will not overhear your conversation with potential participants, individuals will not be publicly identified or embarrassed).

**Telephone screening will be conducted in the study coordinator’s private office, Webb Building has several small private rooms for participant interviews. No sensitive conversation will take place in public areas where the discussion may be overheard. Clinic staff will not make any statement where others can hear that might reveal personal information about the participant, study requirements, etc.**

22. Procedures to Maintain Confidentiality
a. Describe the manner and method for storing research data and maintaining confidentiality. If data will be stored electronically anywhere other than a server maintained centrally by UAB, identify the departmental and all computer systems used to store protocol-related data, and describe how access to that data will be limited to those with a need to know.
Paper records will be stored in a locking file cabinet in a locked office in the Exercise Physiology Lab, which is secured at all times (access restricted by key card). Electronic data will be stored on the School of Public Health server and computers, which are firewall protected, encrypted, and password-restricted. The servers are monitored at all times for outages. Secured login IDs, granted on a need-to-know basis, are required to access confidential information.

b. Will any information derived from this study be given to any person, including the subject, or any group, including coordinating centers and sponsors?  ☐ Yes ☒ No

If Yes, complete i-iii.
  i. To whom will the information be given? ______
  ii. What is the nature of the information? ______
  iii. How will the information be identified, coded, etc.? ______

23. Additional Information

In the space below, provide any additional information that you believe may help the IRB review the proposed research, or enter "None."

None