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Development And Validation Of A Scale To Measure Fear Of Physical Response To Exercise Among Overweight And Obese Adults

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DEVELOPMENT AND VALIDATION OF A SCALE TO MEASURE FEAR OF PHYSICAL RESPONSE TO EXERCISE AMONG OVERWEIGHT AND OBESE ADULTS

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HEALTH EDUCATION AND HEALTH PROMOTION

ABSTRACT

Fear-avoidance beliefs have been correlated with disability and physical function in populations with pain, but research has primarily focused on the impact of these beliefs on daily functioning, not leisure time physical activity. Current screening tools focus on a specific type or source of pain, making them inadequate for assessing fear of exercise-induced pain. The purpose of this study was to develop and establish preliminary validity of a scale to measure fear of physical response to exercise among overweight and obese adults. Additionally, the study sought to assess the relationships between scale responses and body mass index, physical activity level and daily pain.

The study employed a two-phase design. The first phase of the study employed formative methods including focus groups, expert reviews and cognitive interviews to gather data and cultivate an item pool which was used to develop a quantitative scale. This phase of the study resulted in a 16-item scale, designed to measure weight-specific, musculoskeletal and cardio-respiratory fears.

The second phase of the study consisted of administering the scale and validation measures to weight loss participants (n=125). Validation measures included questions assessing physical activity, pain, medical conditions and demographic information. Principle component analysis was conducted and a two-factor solution offered the best fit of the items: weight-specific fears and cardio-respiratory fears accounted for 34.5% and

30% of the variance in scale scores. Additional analysis indicated there were significant differences in cardio-respiratory subscale scores based on physical activity level (p=.006). Body mass index was a significant predictor of total scale score (p=.002) and weight-specific subscale scores (p=.001). Pain, as measured by the Pain Disability Index, was a significant predictor of total scale scores (p=.000), as well as scores on the weight-specific subscale (p=.001) and the cardio-respiratory subscale (p=.007).

The results of this study suggest that there may be a relationship between weight and fear-avoidance beliefs related to exercise. More work is needed, however to examine how the beliefs of overweight and obese individuals differ from those of sedentary, normal-weight individuals. Additionally, more research is needed to explore how medical conditions influence fear-avoidance beliefs among overweight and obese individuals.

Keywords: fear-avoidance; physical activity; obesity; scale development

DEDICATION

To my husband, Greg, and my beautiful son, Shepard. Thank you for your unending love and support.

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I would like to thank my committee for all of the guidance and support you offered throughout this process. Each of you helped in a special way, and this project would not have been successful without wisdom for all of you. Thank you, also, to the *EatRight* team; not only for your help with this project, but for being a constant source of support and encouragement throughout this journey. I would also like to thank my entire family for all of your love and guidance. I would never have made it through this without you.

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LIST OF ABBREVIATIONS

ACSM	American College of Sports Medicine
ANOVA	Analysis of Variance
BIA	Bioelectrical Impedance
BMI	Body Mass Index
BRFSS	Behavioral Risk Factor Surveillance System
CAQ	Cardiac Anxiety Questionnaire
CDC	Centers for Disease Control and Prevention
CVR	Content Validity Ratio
DOMS	Delayed Onset Muscle Soreness
FABQ	Fear Avoidance Beliefs Questionnaire
LBP	Low Back Pain
NHANES	National Health and Nutrition Examination Survey
NHLBI	National Heart Lung and Blood Institute
PCA	Principle Component Analysis
TSK	Tampa Scale for Kinesiophobia
USDHHS	United States Department of Health and Human Services
VAS	Visual Analog Scale

CHAPTER 1

INTRODUCTION

Statement of the Problem

Physical activity is associated with multiple health benefits, including decreased risks for heart disease, diabetes, and colon and breast cancers (US Department of Health and Human Services (USDHHS), 2008). Regular activity is also a key factor in maintaining a healthy body weight, and preventing loss of muscle mass during weight loss (National Heart Lung and Blood Institute (NHLBI), 2000; USDHHS, 2008; USDHHS, 1996). Physical activity enhances psychological well being through reducing anxiety and depression (Paluska & Schwenk, 2000).

Despite the multiple benefits of exercise, physical activity levels have declined over the last 40 years, due in part to environmental changes such as occupational activity and a heavy reliance on motorized transportation (French, Story & Jeffery, 2001; Hill, Wyatt, Reed & Peters, 2003). Leisure time has increased for most Americans over the last 20 years, and with this has come an increase in active leisure time activities such as cycling and hiking; however, these increases have been surpassed in the general population by a larger increase in sedentary activities such as television viewing and computer time (Sturm, 2004). Physical inactivity, along with poor diet was found to be the second leading actual cause of death in 2000, with 400,000 (16.6%) deaths attributed to these modifiable behaviors (Mokdad, Marks, Stroup & Gerberding, 2004).

Significance of the Problem

Physical Activity Defined

The Behavioral Risk Factor Surveillance System (BRFSS), a telephone health survey administered by the Centers for Disease Control and Prevention (CDC), classifies physical activity level based on self-report of weekly physical activity. Prior to October 2008, adults reporting 30 minutes or more of moderate to vigorous activity on five or more days of the week, or 20 minutes or more of vigorous activity on three or more days of the week were classified as meeting recommendations. Those individuals engaging in ten minutes or more of moderate or vigorous activity each week, but not meeting full recommendations were classified as insufficiently active. Those individuals engaging in less than ten minutes of moderate or vigorous activity each week were classified as inactive. According to results from the 2007 BRFSS, only 48.8% of adults in the US were meeting the recommendations for physical activity. Additionally, 37.7% of adults were insufficiently active, and 13.5% were completely inactive (CDC, 2008).

In October 2008, the CDC updated the recommendations for physical activity. It is now recommended that adults get at least 150 minutes of moderate-intensity physical activity, or at least 75 minutes of vigorous activity each week. In addition, adults should participate in strength training activities a minimum of two days each week (USDHHS, 2008).

These new recommendations differ from the previous recommendations in several ways. First, the revised guidelines differentiate between sources of activity. *Baseline activity* refers to activity performed during an individual's daily routine. These activities may include lifting and bending during daily routines. *Health-enhancing physical*

activity refers to activity above and beyond routine activities that are performed to burn additional calories and increase health. Physical activity, as referenced in the 2008 guidelines, refers specifically to health-enhancing physical activity. The second difference in the new guidelines is the allowance of more variability in frequency and duration of activity. Rather than specifying that an individual must get 30 minutes of activity on five days, these recommendations allow for fewer days of activity with longer durations, as long as the weekly total is 150 minutes (USDHHS, 2008).

Another change to these recommendations is the addition of dose-response acknowledgements. The guidelines acknowledge that health benefits can be seen with a minimum of 150 minutes of moderate-level activity each week. However, more substantial benefits can be seen with 300 minutes of activity each week. To reflect these additional recommendations, there are now four categories of activity: inactive, low activity, medium activity and high activity. *Inactivity* is defined as engaging in no activity above baseline activities. *Low activity* is defined as engaging in more activity than baseline, but less than 150 minutes each week. *Medium activity* is defined as engaging in between 150 and 300 minutes of activity ach week. *High activity* is defined as engaging in 300 minutes or more of activity each week. Health benefits increase with each category (USDHHS, 2008).

The CDC and American College of Sports Medicine (ACSM) define moderate intensity activities as those that increase the heart rate to 50-70% of maximum heart rate. This generally includes activities such as brisk walking, mowing the lawn, or bicycling on a flat terrain at a 5-9 mph speed. Vigorous intensity is defined as exercise raising the

heart rate to 70-85% of maximum heart rate. This includes activities such as jogging, playing tennis or swimming laps (ACSM, 2006).

Physical Activity Disparities

Physical inactivity appears to be disproportionally high among some demographic groups. The percentage of adults reaching recommended activity levels increases with education level. For adults with less than a high school education, 38.4% met the recommendations in 2007, compared to 54% of college graduates. Similar discrepancies can be seen among racial groups. Caucasian adults are more likely to get sufficient activity than African Americans or Hispanic adults (51.7%, 40.4%, and 42.1% respectively). Additionally, 47% of females met recommendations compared to 50.7 % of men (CDC, 2008).

Another population that is particularly at-risk for sedentary lifestyle is individuals who are overweight and obese. Although regular physical activity is a primary treatment strategy for weight loss, exercise can be a particularly difficult behavior for this population to initiate. A commonly cited deterrent to physical activity is pain (Clark, 1999; Grubbs & Carter, 2002). Sedentary individuals who begin to increase physical activity will often experience pain as a result of increased movements. This pain can be worse in people who are overweight or obese since extra body weight can induce joint pain due to the extra force exerted on the joints (Melissas, J., Kontakis, G., Volakakis, E., Tsepetis, T., Alegakis, A., & Hadjipavlou, A. 2005; Nevitt & Lane, 1999; Tukker, Visscher & Picavet, 2009).

Overweight and obese individuals have also been found to experience increased symptoms of exertion over sedentary individuals of normal weight. This includes a higher heart rate and percentage of cardiovascular capacity used compared to a normal-weight person when performing an equal amount of work. This may result in a higher rate of perceived exertion (RPE) and decreased enjoyment of activity (Ekkekakis & Lind, 2006).

Physical Activity in Treatment of Overweight and Obesity

The NHLBI recommended that lifestyle change be the first line of treatment for overweight and obesity, with pharmacotherapy and surgical options being used only in cases where diet and exercise changes fail (NHLBI, 2000). Dietary changes can take on many forms, but most result in some form of calorie restriction. Dietary changes such as reducing portion sizes or restricting the intake of certain food groups or nutrients are often used to decrease calorie intake and establish a negative energy balance.

Increased physical activity, through routine daily activity and structured exercise is the second component to lifestyle changes. Increasing activity will aid in establishing a negative energy balance by increasing the number of calories burned, and reducing risk factors by improving insulin regulation and decreasing blood pressure and cholesterol (NHLBI, 2000; USDHHS, 1996).

While dietary changes have been found to have the most impact on initial weight loss, exercise has been found to have a significant impact on maintenance of weight loss (Hill, 2006; Hill & Wyatt, 2005; Wing 1999). Reports from the National Weight Loss database indicated that 90% of individuals who lost 30 pounds or more and sustained the

loss at least one year reported that they engaged in moderate intensity exercise an average of one hour each day. Registry participants reported expending an average of 11830 kJ (2826 calories) each week (Klem, Wing, McGuire, Seagle & Hill, 1997).

Finding ways to increase exercise adherence among overweight and obese individuals is an important goal for weight loss and improvement of health indicators in this population. Addressing potential barriers to exercise early in course of treatment is a common recommendation for increasing adherence, however there is a lack of literature that addresses the role of weight on specific barriers such as pain and pain-related fear.

Conceptual Framework

As an individual initiates a new exercise program, he or she will commonly experience some form of exercise-induced pain. This pain may take the form of joint pain or cardiovascular discomfort from increased heart rate and increased respiratory rate. After exercise, the pain experienced may be from sore muscles or joint stiffness. ACSM encourages health care providers and fitness professionals to describe muscle soreness and pain after exercise as the body adapting to new movements. Individuals who are new to exercise should be prepared to experience some pain, and understand that pain is not always a sign of injury or harm (ACSM, 2006).

The fear-avoidance model proposes that individuals can interpret pain in two ways (Lethem et al., 1983). If pain is perceived as a normal part of the exercise process, the individual will find ways to cope with the pain and continue with the activity. If the individual perceives pain as a warning sign of harm, he or she may begin a process of activity avoidance that will lead to continued sedentary behavior. High fear-avoidance

beliefs have been found to be correlated with the level of pain an individual reports, as well as the level of physical disability reported. Fear-avoidance beliefs have also been showed to be negatively correlated with results of physical function tests (Crombez et al., 1999; Geisser et al., 2000; George et al., 2007; Swinkels-Meewise et al., 2006).

How an individual interprets pain experienced during and after exercise is influenced by a variety of factors. Literature suggests that age is inversely correlated with fear-avoidance beliefs. Younger adults have been found to have higher pain-related fear than older adults (Aikens et al., 1999; Cai, 2007; Fleet et al., 1997). Current literature shows less consistent results with gender differences, however. While some studies have found men to have higher fear-avoidance beliefs, others have found no differences between genders (Aikens et al., 1999; Aikens et al., 2001; Cai, 2007; Coudeyre et al., 2007; Fleet et al., 1997).

Figure 1 depicts the study's hypothesized conceptual model of fear of physical response to exercise. While there are no data on the role of body mass index (BMI) on fear-avoidance beliefs, it is hypothesized that weight will be correlated with pain-related fear due to the close relationship between weight and pain. It is hypothesized further that given overweight individuals are at an increased risk for co-occurring disorders including joint pain and

cardiovascular problems, this may cause some to fear that pain from exertion is a sign of harm.

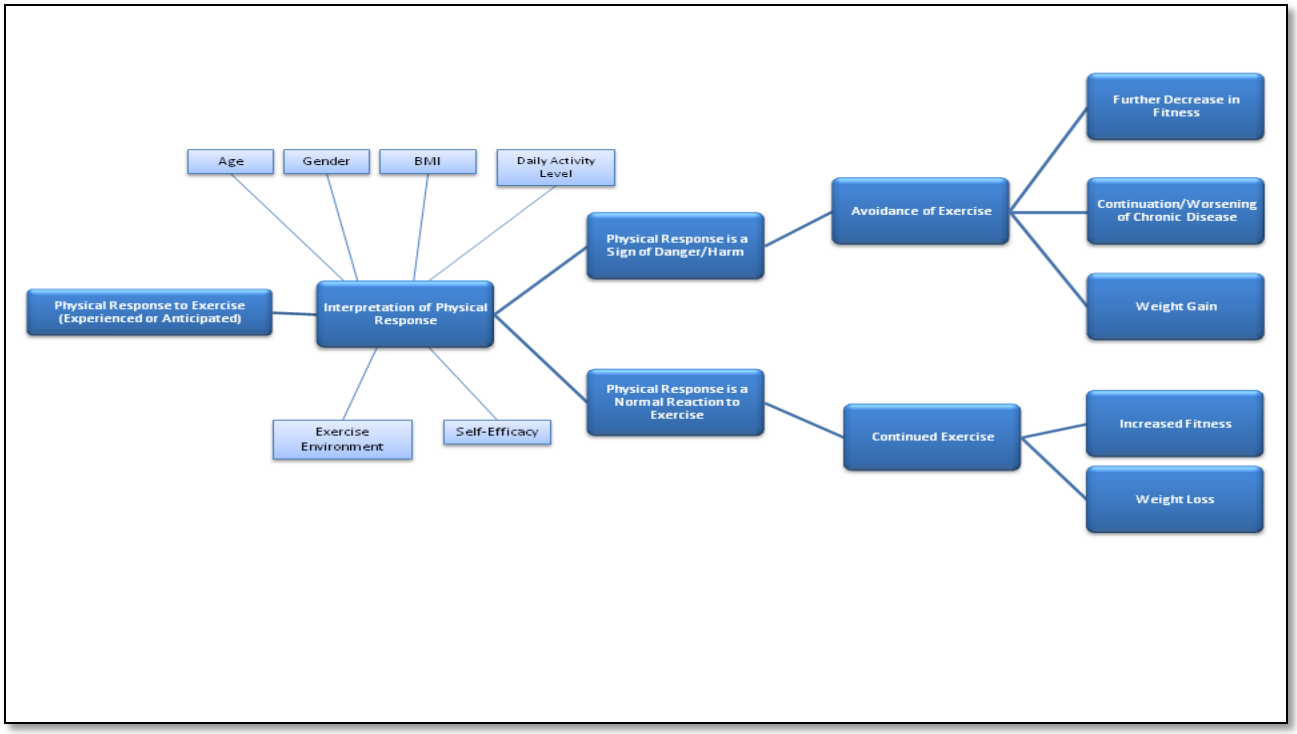

Figure 1: Conceptual Model of Fear of Physical Response to Exercise

Other variables in the model that may impact an individual's perception of pain are related to the external treatment environment. Those individuals who are closely monitored during exercise may feel safer with the pain they experience (Bunketorp, Lindhane, Carlsson & Stener-Victorin 2006). Research related to the treatment of fear-avoidance beliefs indicated that a graded-exposure treatment was most beneficial in lowering fear-related pain (Philips, 1987; Vlaeyen et al, 2001; Woods & Asmundson, 2008). Offering a safe, gradual exposure to exercise may serve to both limit exercise-induced pain, and reduce the fear associated with this pain.

Also, limiting pain and pain-related fear serve to increase a person's level of self-efficacy. Bandura (1977) defined self-efficacy as an individual's confidence in his or her

ability to perform a given behavior. Therefore, increasing an individual's self-efficacy to safely exercise will increase the likelihood of continued activity.

Gaps in the Literature

Existing literature has primarily examined the role of fear-avoidance beliefs in disease-specific population, such as arthritis or back pain (Cai, Pua, & Lim, 2007; Coudeyre, Tubach, Rannou, Baron, Coriat, Brin, Revel, et. al, 2007; Crombez, Vlaeyen, Heuts, & Lysens, 1999Elfving, B., T. & Grooten, 2007). No studies have examined the role of weight in fear-avoidance beliefs. Overweight and obesity often compound pain symptoms in conditions such as arthritis, and pain has been found to be more prevalent in some overweight populations, such as elderly populations (Andersen et al., 2003; Heim, et al., 2008; Patterson, Frank, Kristal & White, 2004). The close relationship between pain and weight points to the need for additional research in the area of fear-avoidance beliefs among overweight and obese populations.

The second gap in the literature is in the area of screening tools. Existing screening tools primarily address musculoskeletal pain (Kori, Miller & Todd, 1990; Waddell, 1993). There are no assessments that address other exercise-specific responses that could induce fear. These include cardiovascular responses such as increased heart rate and shortness of breath. In addition, existing tools focus on routine daily activity such as bending or lifting, but none address moderate or vigorous level activities. More research is needed in the area of exercise-specific screening tools that could be used for moderate or vigorous level exercise. Screening patients who are at greatest risk due to high fear avoidance beliefs prior to exercise prescription will allow healthcare providers

to identify potential barriers to exercise and confront these issues in the early phases of treatment.

Additionally, the primary outcomes examined by existing literature are disability and physical function using cross-sectional study designs. Recently, more prospective studies have been conducted to explore the predictive qualities of fear-avoidance beliefs on disability levels (Lee, Chiu & Lam, 2007; Linton, Buer, Vlaeyen & Hellsing, 2000). No literature has explored the impact of fear-avoidance beliefs on leisure-time physical activity. A screening tool that measures fear of exercise-induced pain could be used to evaluate the predictive nature of fear-avoidance beliefs in moderate and vigorous level activities.

Purpose of the Study

The purpose of this study was to design and explore the initial validity of a scale to measure fear of physical response to exercise among overweight and obese adults. The scale addressed physical responses including increased heart rate and musculoskeletal pain. In addition, this study explored the relationship between BMI and pain-related fears.

Research Questions

RQ1: What is the underlying factor structure of the items on the scale?

RQ2: What is the internal consistency and temporal stability of the resulting component structure?

RQ3: Is there a significant difference in scale responses based on physical activity level?

RQ4: Is there a significant relationship between responses to the scale and BMI?

RQ5: Is there a significant relationship between responses to the scale and pain, as measured by the Pain Disability Index?

Study Design

This study followed a two-phase design. The first phase, scale development, used qualitative methods to generate and revise the item pool. Focus groups were used to generate the initial item pool. An expert panel then reviewed the items and offered feedback on clarity and relevance of items. After further item revisions based on the panel's feedback, cognitive interviews were used to test for comprehension and ease of use. Results of these interviews were used to further refine the item pool, instructions and scale format.

The second phase of the study, scale validation, used a cross-sectional survey design. This was accomplished by distributing the scale to patients of multiple weight loss clinics at the University of Alabama at Birmingham (UAB). Results of the scale distribution were used to conduct principle component analysis. The resulting component structure was interpreted according to the hypothesized conceptual model, and tested for validity and temporal stability.

Assumptions

The following assumptions were made in this study:

1. Study participants were asked to complete self-report measures for physical activity level and pain. It was assumed that participants were accurate in reporting this information.
2. It was assumed that study participants were fairly representative of patients seeking weight loss treatment at the University of Alabama at Birmingham (UAB).

Limitations

The following are limitations that were inherent to this study because of study design:

1. Study participants were recruited from a sample of patients seeking medically-supervised weight loss treatment. Generalizations of the findings of this study are limited to individuals seeking treatment for weight loss.
2. The exploration of weight and exercise-related fear was conducted using a cross-sectional design. No causation can be assumed from this approach. The research only shows if a relationship is present, but no knowledge was gained as to the causal nature of that relationship.
3. Participation in this survey was voluntary. Therefore results may not be representative of individuals who declined to participate.
4. Participants were asked to respond to questions that rate their perceptions on pain, fear and activity avoidance. There is a potential that participants gave favorable responses, leading to a social desirability bias.

Chapter Summary

Physical activity levels have been decreasing over the last 40 years. Inactivity is associated with increased risk for diseases including diabetes and heart disease. A common barrier to physical activity is pain. The fear-avoidance model proposes that fear of pain is as much of a barrier to activity as the physical pain itself. Pain-related fear has been shown to be a predictor of disability and physical function in patients with chronic pain and cardiovascular disease; however the role of weight in fear-related pain has not been examined. Because individuals with a high BMI are more likely to experience pain when initiating a new exercise routine they may also be at higher risk for pain-related fear.

Current screening tools are inadequate for addressing some physical responses to exercise such as cardiovascular concerns. Existing measures focus primarily on musculoskeletal pain, and only address physical activity in reference to daily activities such as lifting or bending. This study addressed these limitations by developing and validating a scale to measure fear of physical response to exercise.

CHAPTER 2

REVIEW OF THE LITERATURE

The primary purpose of this study was to develop and establish some preliminary validity of a scale designed to measure fear of exercise-induced pain for use with adults who are overweight and obese. This literature review used electronic databases including PubMed and PsycInfo. The first phase of the search used key words including *barriers, exercise, fear, avoidance, pain,* and *physical activity*. Terms were searched alone and in various combinations. The second phase of the search included more specific search terms generated from the results of the first phase, as well as references cited in literature from the first phase. Terms used during the second phase included *kinesiophobia, Tampa Scale for Kinesiophobia* and *Fear-Avoidance Beliefs Questionnaire*.

This chapter describes existing recommendations for exercise prescription in overweight and obese populations as well as current literature in the area of obesity and pain. A review of pain-related fear is discussed, followed by a review of the primary outcomes described in fear-avoidance literature. Tools for measuring fear-avoidance beliefs, along with limitations of these tools are also reviewed.

Physical Activity Considerations for Obesity

The CDC recommends that adults get at least 150 minutes of moderate activity or 75 minutes of vigorous activity, or an equivalent combination each week (USDHHS, 2008). For individuals who are overweight or obese, ACSM (2006) suggests the primary mode of activity focus on aerobic activities that use large, major muscle groups. They

also recommend individuals begin with moderate intensity exercises, with longer durations and high frequencies, specifically 45 to 60 minutes, on five to seven days each week. Once this pattern is established, participants should begin working toward increasing intensity.

Sedentary individuals who begin to increase physical activity and exercise will often experience pain as a result of increased movements. This pain can be worse in people who are overweight or obese (Melissas, J., Kontakis, G., Volakakis, E., Tsepetis, T., Alegakis, A., & Hadjipavlou, A. 2005; Nevitt & Lane, 1999; Tukker, Visscher & Picavet, 2009). Extra body weight can induce joint pain due to the extra force exerted on the joints. They may also experience increased symptoms of exertion over sedentary individuals of normal weight (Ekkekakis & Lind, 2006).

Recently, studies have examined special considerations in exercise prescriptions when working with overweight and obese individuals. These studies have examined variables including exercise intensity and duration, psychological markers such as stress and enjoyment, and the role each of these plays in exercise adherence. Results have shown that obese individuals beginning exercise at a reduced intensity and increased frequency and duration gained fitness and lost weight at a rate comparable to that of higher intensity groups (Cox, Burke, Gorely, Beilin & Puddey, 2003; Jakicic, Marcus, Gallagher, Napolitano, & Wang, 2003). These findings offer hope and provide the opportunity for overweight and obese individuals to begin an exercise routine at a level that increases self-efficacy by minimizing physical barriers such as pain and overexertion, as well as psychological barriers such as pain-related fears.

Obesity and Exercise Exertion. Ekkekakis and Lind (2006) examined the role of intensity in exercise prescription of overweight women. In their study, they compared the differences in exercise intensity between two groups of women; one of normal weight (n=9) and one of women with BMIs equal to or higher than 25 kg/m^2 (n=16). In addition to physical factors of intensity, the researchers also examined the perceptual difference of the intensity between the two groups. Participants were asked to complete rate of perceived exertion (RPE) and please-displeasure ratings while walking at a self-selected pace, and again at a prescribed pace, which was a 10% increase from the self-selected pace. The primary purpose of the study was to examine differences in pleasure-displeasure ratings, as well as perceived exertion ratings between the two study groups. Results indicated that women in the overweight group used more cardiovascular capacity to conduct the same amount of work as the women of normal weight, and, as expected, achieved peak heart rate faster than normal weight women. The study also showed that overweight women consistently ranked their activity higher on the RPE scale. One speculation was that this increased use of cardiovascular capacity could be the reason for the higher RPE, as the overweight group felt more physical strain due to the more intense cardiovascular work. Another speculation was that because the heart had to work harder to conduct the same level of work, and the resulting heart rate was higher, a lighter intensity of workload was necessary for prescribing exercise that falls within the recommended light to moderate guidelines for deconditioned individuals when the participant is overweight or obese. The results also indicated that women who were of normal weight maintained the ratings of pleasure-displeasure throughout both the self-imposed and prescribed portions of the trial. Women who were overweight, however,

showed a decrease in these ratings throughout the course of the prescribed portion of walking. Ekkekakis and Lind (2006) also stated that their findings could partially explain past findings that showed overweight and obese individuals had lower adherence levels to exercise, as many of the studies that reported these findings had prescribed, rather than self-imposed, exercise goals. These results also support the idea that overweight and obese individuals may have more negative experiences with exercise. These negative experiences need to be addressed during the exercise prescription process to increase self-efficacy and adherence level with exercise among this group.

Obesity and Pain. A commonly cited barrier to physical activity is pain. Literature suggests that overweight and obesity may increase an individual's risk of pain. Andersen, Crespo, Bartlett, Bathon, and Fontaine (2003) used data from the third National Health and Nutrition Examination Survey (NHANES III) to examine the relationship between BMI and knee, hip, and back pains among adults 60 years and older. Results showed that prevalence of all three types of pain increased with BMI. For hip pain, incidence of pain increased from 10.4% in underweight participants to 23.3% in participants meeting criteria for class III obesity. For knee pain, prevalence rates increased from 12.1% in underweight individuals to 55.7% in participants meeting criteria for class III obesity. For back pain, pain incidence increased from 20.2% in underweight participants to 26.1% in participants meeting criteria for class III obesity (Andersen et al., 2003).

In the first known prospective study in this area, Heim, Snijder, Deeg, Seidell, and Visser (2008) examined pain reports among 55-85 year old participants of the Longitudinal Aging Amsterdam Study at baseline (n=2,000), and 3 year (n= 1478) and 6

year (n= 1271) follow-up. Participants with higher BMIs showed increased risks for pain at baseline and at both follow-up points. Results showed odds ratios (OR) for pain of 2.16 confidence interval (CI) (1.32–3.54) in men and 1.93 (1.26–2.95) in women when comparing the highest with the lowest quartile of BMI at baseline. Comparison of the participants without pain at baseline showed that those in the highest quartile of BMI had increased odds for incident pain after three years of follow-up. When comparing the highest quartile of BMI to the lowest, OR for pain were 2.23 (1.08–4.61) in men and 1.86 (0.88–3.93) in women. Odds ratios for pain after six years of follow-up were 2.34 (1.17-4.72) for men and 2.78 (1.36-5.70) for women in the highest BMI quartile.

The primary limitation of these studies is that they only included elderly populations. No literature is available that examines the relationship of weight and pain on young or middle-aged adults. If overweight and obese individuals have a higher propensity for exercise-induced pain, and experience more extreme cardiovascular responses to exercise, they may interpret these as signals that exercise is unsafe. This may result in higher fear-avoidance beliefs, which may contribute to exercise attrition. The current study measured pain in all participants, which adds to the existing literature by examining the relationship between pain, weight and exercise avoidance in adults aged 20-65 years of age.

Pain as a Psychological Barrier

Although pain is traditionally viewed as a physical barrier to exercise, it has been examined as a psychological barrier as well. Lethem et al. (1983) were among the first to write of fear-avoidance and its role in pain-related conditions. The authors described a

model in which pain-related behaviors continued in the absence of physical symptoms. The term fear-avoidance was used to describe the idea that an individual interprets pain experienced during and after movement as a warning sign that the body is in danger. In an effort to prevent injury or harm, the individual will avoid movement. Kori, Miller and Todd (1990) were the first to describe 'kinesiophobia', or fear of movement, as a phobia-level fear. They proposed that chronic pain often stemmed more from "phobic processes than neurological processes- it is more a response to fear than to actual pain" (p. 35). These irrational fears evolve from a feeling of vulnerability to injury. The reaction to this fear, in the form of avoidance of movement often serves to perpetuate the cycle of pain and avoidance, rather than leading to a healing process. By avoiding movement, muscle and joint pain becomes worse and daily function declines.

Although the fear-avoidance model was originally developed in populations with musculoskeletal pain, it has also been applied to individuals with cardiac-related fear. Heart-focused anxiety is a term that has been used to describe fear of cardiac-related stimuli due to a perceived negative consequence. For example, an individual may perceive increased heart rate as indication of a heart attack. This fear has been found to be associated with an attention to, and avoidance of, cardiac-related activity (Aikens et al., 2001; Aikens et al., 1999; Fleet et al., 1998).

The fear-avoidance model proposes that the way in which an individual interprets pain will lead to continued activity or avoidance of activity (Lethem et al., 1983; Vlaeyen & Linton, 2000). An individual's first cognitive process after experiencing pain is to interpret the pain and assess its significance. If the pain is experienced as a normal process, the individual does not fear the pain and will confront it and recover. If the

person experiences a more negative appraisal of the pain, however, he or she may react with negative coping mechanisms, specifically catastrophic thinking, which is considered a precursor of fear-avoidance beliefs. Once the individual begins to fear the pain, he or she will avoid activity that is believed to cause the pain. In addition to avoidance, the fear will often lead to a hypervigilance of pain-related movements. Individuals may become more aware of movements that are believed to cause pain, and therefore spend a larger than normal amount of time worried about these movements. This hypervigilance can lead to impairments in coping with daily stressors and an inability to perform daily tasks.

Avoidance of movement is a predictive behavior rather than a responsive one. Movements are avoided based on the belief that they will cause pain, not based on the experience of pain itself. This results in the individual allowing fewer interactions with a movement that is expected to cause pain. This results in fewer opportunities for the individual to perform activities and learn that they do not always cause pain. When this level of avoidance is reached, a loss of daily function often occurs. Loss of functioning, along with the preoccupation of pain-related fear, often results in psychological impairments such as depression or irritability.

The process of avoiding the fear-inducing activity has been termed the disuse syndrome (Kori, Miller and Todd, 1990). This term is used to refer to two facets of disuse: physical deconditioning due to reduced muscle use, and impairments in muscle coordination which can lead to guarded movements. Physical deconditioning refers to general decline in physical fitness due to avoiding activity that is thought to cause pain. Impairments in muscle coordination refer to problems that can be seen in activities such as walking. In the case of chronic pain such as back pain, an individual may

overcompensate some movements to protect against pain, which can lead to gait impairments or other losses in physical function. Disability and the loss of physical function have been the primary focus of much of the research in fear-avoidance beliefs to date.

Pain-Related Fear and Disability, Physical Function

Fear of pain has repeatedly been shown to have a relationship with disability and loss of physical function in patients with pain conditions (Tables 1 & 2). Pain-related fear has also been shown to be a better predictor of disability than pain intensity (Vlaeyen et al., 1995; Waddell et al., 1993).

Table 1: Pain- Related Fear and Disability

Author	Sample	Fear Measure	Disability Measure	Correlation Coefficient	P
Crombez et al., 1999	Chronic LBP N=35	TSK FABQ-W FABQ-PA TSK PASS	RDQ RDQ	r = .56 r = .63 r = .51 r = .43 r = .13	p < .001 p < .001 p < .001 p < .01 NS
Swinkels-Meewise et al., 2006	Acute LBP N= 96	TSK	RDQ	r = .43	p < .001
George et al., 2007	Exercise-induced DOMS (Shoulder) N=42	TSK FPQ-III	DASH	r = .405 r = .487	p < .01 p < .01

Table 2: Pain-Related Fear and Physical Function

Author	Sample	Fear Measure	Physical Function Test	Correlation Coefficient	P
Crombez et al., 1999	Chronic LBP N=35	TSK FABQ-W FABQ-PA TSK	Trunk Extension/Flexion 5.5 kg lift	r = -.40 r = -.10 r = -.45 r = -.49	p < .01 NS p < .01 p < .01

		PASS		r = -.33	p < .05
Swinkels-Meewise et al., 2006	Acute LBP N= 96	TSK	7 kg lift	r = -.35	p < .001
George et al., 2007	Exercise-induced DOMS (Shoulder) N=42	TSK FPQ-III	Maximum velocity isometric contraction	r = .06 r = .332	NS p < .05
Geisser et al., 2007	Chronic LBP N=133	TSK-2	PILE		
			Floor-Waist	Avoidance r = -.30	p < .001
				Fear r = -.14	NS
			Waist-Shoulder	Avoidance r = -.31	p < .001
				Fear r = -.29	p < .001
			Bicycle Ergometry	Avoidance r = -.09	NS
				Fear r = .15	p < .05

Crombez et al. (1999) conducted a three-pronged study to evaluate the effect of pain-related fear on both self-reported disability and physical function. The objective of the first study (*N*=35) was to examine the role of pain-related fear in self-reported disability. Participants with chronic back pain were recruited from a pain clinic and a rehab unit of Katholieke Universiteit at Leuven in Belgium. Eleven males and 24 women, with a mean time of 6.7 years from the onset of back pain, completed measures of pain-related fear, current pain intensity, negative affect, and disability. Disability was significantly correlated with pain-related fears (r=0.51-0.63, *p*<. 001), but not with pain intensity (r=0.21) or negative affect (r=0.26).

The second phase of this study (n= 38) examined pain-related fear and physical function. Participants in this phase of the study included patients referred for chronic back pain. The mean age of this group was 40.84 years (*SD*=10.02), and was 34% male. Measures of pain-related fear, pain severity, pain anticipation and negative affect were assessed for ability to predict performance on a trunk extension test. Two of the three pain-related fear measures showed significant correlations with peak performance on the trunk extension test.

The third phase of this study examined both self-reported disability and physical function. Participants were 31 chronic back pain patients with a mean age of 41.61 years (SD= 10.7). Participants completed measures to assess pain-related fear, negative affect, pain catastrophizing, disability and pain onset. Prior to engaging in the physical function test, participants were asked to rate their pain using a visual analog scale (VAS). After completion of a weight lifting task in which the participants were instructed to lift and hold a 5.5kg bag, they were asked to rate the increase in pain over the initial level reported using the same VAS. As expected, self-reported disability was correlated with pain-related fear measures ($r = .43$, $p < .001$).

This group of studies contributes to the hypothesis that pain-related fear predicts disability and physical functioning by controlling for pain intensity. Previous studies correlated fear of pain with physical function, but it was not clear that tests had not been terminated due to pain intensity. By controlling for intensity, this study furthered the evidence that pain-related fear contributed to activity avoidance.

A number of studies have found evidence to support the effects of pain-related fear in self-reported disability among acute cases of back pain as well. Swinkels-Meewisse et al. (2006) examined the relationship of pain-related fear and physical function among participants suffering from acute low back pain (LBP). Participants were 176 adults with an onset of LBP in the previous four weeks. Prior to a physical function test, participants completed measures of current pain (VAS), disability, pain-related fear and pain catastrophizing (Tampa Scale for Kinesiophobia and Fear-Avoidance Beliefs Questionnaire). Participants were instructed to lift a 7 kg bag with both hands from a position on the floor onto a table, and back to the floor. As in previous studies with

chronic back pain, pain-related fear was shown to be a significant predictor of disability (β= 0.35, p=. 003), as was current pain intensity (β= 0.27; p= 0.012). Pain-related fear was also found to be a significant predictor for physical function (β=-0.27, p=0.021).

Although much of the research in the area of fear-avoidance beliefs has been carried out with LBP patients, pain-related fear has also demonstrated a role in impaired functioning among individuals with other pain-related conditions as well. Heuts et al. (2004) examined the role of pain-related fear in daily functioning of osteoarthritis patients. Results showed that pain-related fear was negatively associated with daily functioning, and was found to be a significant predictor of daily functioning when assessed alone and with pain measures (β=0.30 p<0.001, β= 0.36, p<0.001 alone; β=0.2, p<0.001 with knee and hip pain measures). When entered with pain measures, the model accounted for 38% of variance in daily functioning.

Geisser, Haig and Theisen (2000) examined the relationship between pain-related fear and both a lifting test and submaximal cardiac test, along with rate of perceived exertion (RPE) and heart rate. Pain-related fear measures were significantly correlated with submaximal cardiac test (r= .15, p<.05) and physical function test (r=-.29 to r= -.31, p<.001).

Pain-Related Fear and Physical Activity

Despite the number of studies that have examined the role of pain-related fear in disability and physical function, very few have examined the role of pain-related fear in leisure time physical activity. Physical activity is often prescribed as treatment for chronic pain conditions, however little is known about the effect of pain-related fear on

moderate or vigorous levels of physical activity. In the only study found on this topic, Elfving et al. (2007) studied the relationship of fear-avoidance and physical activity in individuals suffering with low back pain. The study used a cross-sectional design to survey patients diagnosed with chronic, non-specific LBP in a primary-care setting. Participants' self-reported levels of physical activity were used to categorize participants as high or low physical activity. Patients with low physical activity were found to have significantly higher fear-avoidance scores than those in the high physical activity group. Odds ratios for low physical activity ranged from 4 to 8.5 for medium to high pain-related fear scores ($p < 0.05$). These findings lend initial support for the idea that individuals may avoid physical activity due to pain-related fear. There are limitations of this study, the most notable of which are the cross-sectional design and use of self-report for physical activity measure. While a relationship was found, no statement can be made as to the causal relationship of pain on exercise avoidance. More work is needed in examining the role of acute pain and exercise-induced pain in physical activity avoidance.

Only one study was found that addressed the role of pain-related fear in exercise-induced pain in a generally healthy sample. George et al. (2007) recruited 42 participants who had no history of neck or back pain and were not currently participating in regular weight training activity. Participants completed measures of anxiety, fear of pain and pain catastrophizing. Participants were then taken through a shoulder fatigue procedure, which was intended to induce delayed-onset muscle soreness (DOMS). After 24 hours, participants were asked to report their current level of pain (clinical pain score), as well

as undergo a physical function test of pain and a muscle force test. They also completed a disability measure, as well as a second pain-related fear questionnaire.

Fear of pain, as measured prior to DOMS induction, accounted for 16% ($p= 0.008$) of the variance in clinical pain, and 10% ($p= 0.047$) of variance in evoked pain tests. Fear of pain and clinical pain scores accounted for 50% ($p=0.001$) of the variance in disability. This study did not report findings for predictability of disability based on fear of pain while controlling for pain intensity. It is interesting to note that this study measured fear of pain before and after DOMS induction, using two different measures. Both measures were significantly correlated with each other ($r=. 410$, $p <0.01$) and with self-reported disability ($r=. 487$, $p<0.01$ & $r= .405$, $p<0.01$). While these results are moderate, they do show potential for a relationship between pain-related fear and exercise-induced pain outcomes. More research is needed on the role of pain-related fear in physical activity levels and exercise avoidance among individuals with exercise-induced pain.

Assessment of Pain-Related Fear

Pain-related fear is commonly assessed using fear-avoidance questionnaires. Two questionnaires commonly cited in pain-related fear research are the Tampa Scale for Kinesiophobia (TSK; Kori et al., 1990) and the Fear-Avoidance Beliefs Questionnaire (FABQ; Waddell et al., 1993). The TSK and FABQ have been used together and separately to assess pain-related fear and both have been shown to be significant predictors of disability (Table 1) and physical function (Table 2).

The TSK (Appendix A) is a 17-item scale that measures fear of injury, or re-injury due to movement. Each item is scored on a Likert-style scale ranging from 1 (strongly disagree) to 4 (strongly agree). Four of the items are negatively worded and reversed scored. Total scores range from 17 to 68, with higher scores representing higher fear of movement. The scale was originally developed for use in LBP, but has been used to measure pain-related fear in populations with arthritis, fibromyalgia and neck pain (Cleland, Fritz & Childs, 2008; Heuts, et al., 2004; Roelofs, Goubert, Peters, Vlaeyen & Crombez, 2004).

Several versions of the TSK exist including a Dutch translation, a shortened version and two-factor and four-factor models. French, France, Vigneau, French, & Evans (2007) examined the psychometric properties of the original 17-item English version of the TSK. They examined the internal consistency, construct validity and factor structure of the scale using a sample of back and neck pain patients. Cronbach's alpha for the total scale was α=.84. Construct validity was measured by obtaining correlation between the TSK and other measures of pain-related fear. Correlation coefficients were obtained for the Pain Catastrophizing Scale (r= .51), the FABQ physical activity subscale (r= .53) and work subscale (r =.35), the Beck Depression Inventory (r = .34), the State-Trait Anxiety Inventory (r =.28), the Quebec Back Pain Disability Scale (r =.30), the Million Visual Analog Scale (r =.39), and a pain-intensity visual analog scale (r =.23). All correlations were significant at $p<.001$.

Cleland et al. (2008) found similar results when they examined the psychometric properties of the TSK among a group of neck pain patients. Cronbach's alpha for the scale was reported to be α= .89. This study also examined construct validity using

correlation coefficients of the TSK and other scales of fear-related pain and self-reported disability. Coefficients were measured for the FABQ-PA ($r = .44$, $p < .001$), FABQ-W ($r = .45$, $p < .001$), Neck Disability Index ($r = -.05$, NS), and the numeric pain rating scale ($r = .24$, $p < .001$). This study also examined test-rest reliability over a 2-4 day period. Test-retest reliability was reported as .80.

The Fear-Avoidance Beliefs Questionnaire (Waddell, Newton, & Henderson, 1993; Appendix B) is an 11 question scale. Responses range from 0 to 6, with higher scores indicating higher levels of fear-avoidance. The scale has two subscales: physical activity (FABQ-PA) and work (FABQ-W). The physical activity subscale consists of 4 items and the work subscale consists of 7 items. Waddell et al. reported test-retest reliability of $r = 0.88$. Jacob, Baras, Zeev, and Epstein (2001) reported Cronbach's alpha for the physical activity subscale as $\alpha = .70$ and for the work subscale as $\alpha = .89$. McCracken, Gross, Aikens and Carnrike (1996) examined correlates of FABQ scores with other pain measures. Total FABQ scores correlated significantly with measures of disability ($r = 0.52$, $p < .001$), avoidance behavior ($r = 0.46$, $p < .01$) and help-seeking behavior ($r = .46$, $p < 0.01$). The correlation between FABQ scores and pain severity was not significant ($r = 0.28$).

Limitations to Existing Scales

The primary limitation to both of these scales is the range of pain they address. Pain is referred to as deriving from a single-source, often stemming from a routine activity or injury. These scales are not easily adaptable to pain sources such as exercise that may produce multiple types of pain. For example, someone initiating exercise may

experience both cardiovascular and musculoskeletal pain. These different types of pain may need to be assessed differently. Additionally, the source of the pain is not addressed. While the FABQ addresses work-specific pain, other causes or influences of pain are not addressed. Addressing specific influencing variables such as age may lend additional insight into the best way to address fear-avoidance beliefs. Similarly, weight is not addressed in any of the existing tools. Including items that specifically address weight will allow healthcare providers to more adequately assess the cause of the fear, and be better prepared to work with the individual to address these fears.

Chapter Summary

A review of the literature indicated a relationship has been identified between fear-avoidance beliefs and avoidance of movement based on both musculoskeletal pain and cardiovascular symptoms. The current body of literature supports the idea that overweight and obese individuals experience different physiological and psychological responses to exercise than normal weight individuals. If individuals who are overweight or obese experience higher levels of perceived exertion and increased pain during exercise, they may also experience higher levels of pain-related fear with exercise.

While assessment tools have been developed to measure these beliefs in multiple injury-specific populations, no instrument has been developed to measure the impact of weight on these beliefs. Additionally, no instrument is available to measure pain-related fear in exercise-induced pain. The purpose of this study is to develop an instrument to measure fear of exercise-induced pain in individuals who are overweight or obese. The

study will use an exploratory mixed methods approach to develop items and examine the component structure, internal consistency and temporal stability of the items in the scale.

CHAPTER 3

METHODOLOGY AND RESULTS: SCALE DEVELOPMENT

Purpose of Study

The purpose of this study was to develop and establish some preliminary validity of a scale to measure fear of physical responses to exercise among overweight and obese adults. The scale was based on the following three measures that have been validated in populations with chronic and acute pain and cardiac conditions: the Tampa Scale of Kinesiophobia (TSK; Kori et al., 1990), the Fear Avoidance Beliefs Questionnaire (FABQ; Waddell et al., 1993), and the Cardiac Anxiety Questionnaire (CAQ; Eifert et al., 2000). The TSK and FABQ were originally designed to measure pain-related fear in individuals with low back pain (LBP), but have been modified for use in studies with arthritis, fibromyalgia and whiplash (Bunketorp, Lindh, Carlsson, & Stener-Victorin, 2006; Goubert, Crombez, Van Damme, Vlaeyen, Bijttebier, & Roelofs 2004; Heuts, Vlaeyen, Roelofs, de Bie, Aretz, van Weel,& van Schayck, 2004; Lee, Chiu, & Lam, 2007). Many studies modified the scales by changing condition-specific wording to reflect the condition of the study sample. For example, the phrase "back pain" would be replaced with "arthritis" to measure pain-related fear in patients with arthritis. Although this method led to validation in many studies, Goubert et al. (2004) pointed out that pain-related fear may affect individuals with different types of pain in different ways, and interpretation of scale scores may differ for different patient groups. Modifying the

scales to reflect these differences may lead to more valid measurements. For this reason, this study addressed scale development from the initial phases of development, rather than only validating the existing tools with a new sample.

This study consisted of two phases: scale development and scale validation (Figure 2). Scale development involved generating items, analysis of content validity, and cognitive interviews. Scale validation included principle component analysis and analysis of temporal stability and internal consistency of the resulting components. It also included analysis of differences in scale responses among differing physical activity levels, weight, gender, age and pain levels. This chapter discusses the methodology and results of the scale development phase of the study.

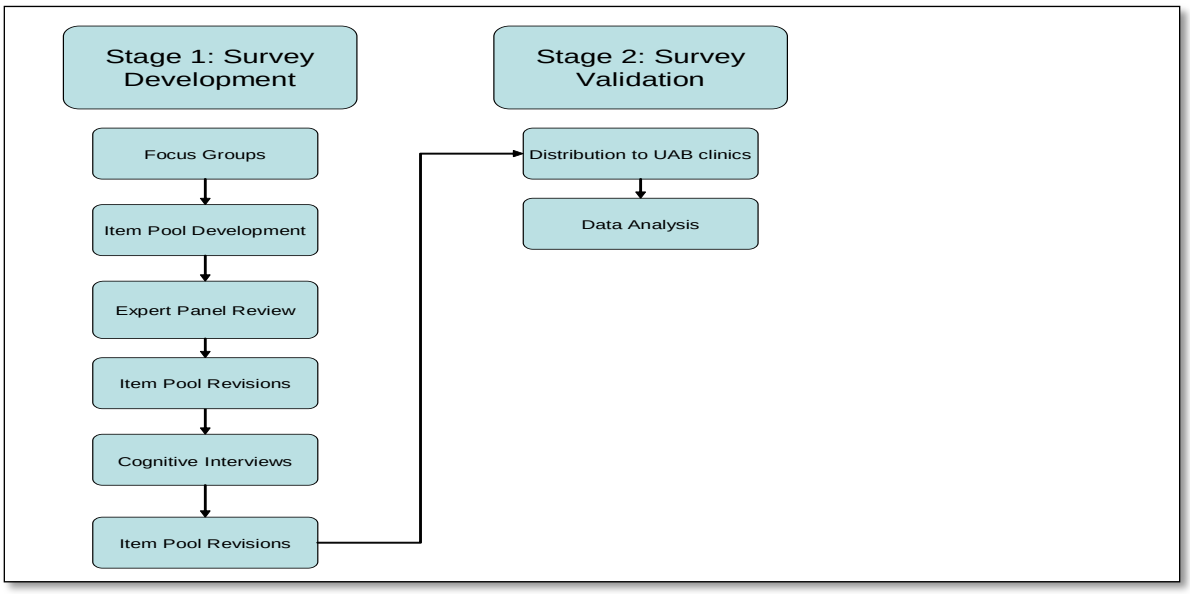

Figure 2: Study Flowchart

Scale Development

Participants

Participants for the scale development phase of the study were recruited from the EatRight Risk Reduction and Optifast clinics at the University of Alabama at Birmingham (UAB). Both of these weight loss clinics operate within the UAB Department of Nutrition Sciences. The Risk Reduction clinic is designed for individuals at high risk for, or already diagnosed with, medical conditions associated with a high BMI). These diagnoses may include diabetes, hypertension, hyperlipidemia, polycystic ovarian syndrome, and arthritis. Individuals seen in this clinic complete an evaluation that includes a resting metabolic rate assessment, lab work, a nutrition assessment, fitness assessment, medical history and physical. Treatment plans for patients in the Risk Reduction clinic may include individualized nutrition and exercise plans, referral to physical therapy or other rehabilitative services, and prescription medication. Individuals in this clinic may be self-referred or referred by a primary care or other specialty physician. Treatment goals may include weight loss, improved health indicators or preparation for other weight loss programs including surgical options.

The Optifast program is designed for individuals who need to lose 50 pounds or more. Individuals in this program follow a very low calorie diet, typically ranging from 800 to 1000 calories each day. The program focuses on behavioral adaptations of ineffective diet and exercise habits. A physician, registered dietician, exercise trainer and psychologist monitor patients. Participants are seen on a weekly basis by members of the treatment team. They also attend weekly classes that focus on increasing nutrition and exercise knowledge, as well as addressing behavioral components including emotional

eating, stress management and assertiveness. Like the Risk Reduction clinic, treatment goals for Optifast participants may include weight loss, improved health indicators, or preparation for other weight loss treatments such as surgery.

Participants in both clinics have a wide range of BMIs. While some Risk Reduction participants may have a BMI that falls in the normal range, the majority of patients in both clinics have BMIs higher than 25 kg/m^2.

This study was approved by the UAB Institutional Review Board and informed consent was obtained from each participant (Appendix C, D).

Participant Recruitment

A query of electronic patient records was conducted to find patients who met preliminary eligibility. The query used the following variables to determine preliminary eligibility: patient last name, patient first name, patient status, patient age, current BMI, and patient gender. Patient status, which indicates the program in which the patient is enrolled, was filtered to include only patients in the Optifast or Risk Reduction programs. Patient age was filtered to include only those patients aged 20-65 years. Current BMI, which gives patients' BMI at the most recent visit, was filtered to include only those patients with BMI measurements of 25-60 kg/m^2. The query resulted in 368 potentially eligible patients. The mean age of potentially eligible Optifast participants was 48.47 years, and the mean BMI was 34.92 kg/m^2. The mean age of potentially eligible Risk Reduction patients was 45.88 years, and the mean BMI was 38.90kg/m^2. Seventy percent of potentially eligible Optifast participants were female and 83.26% of potentially eligible Risk Reduction participants were female.

Patients were called or emailed to introduce the study and assess interest in participation. If the patient agreed to participate, screening questions were asked to validate eligibility criteria (Appendix E). Individuals who agreed to participate were sent informed consent information by mail or email, depending on their preference. Informed consent was reviewed with each participant when they arrived to participate and they were given time to ask questions and sign the consent before measurements were taken.

Inclusion Criteria

The primary inclusion criterion for the scale development phase of the study was a BMI of 25 kg/m^2 or above. Because an extreme BMI could skew results as outliers, an upper limit of 60 kg/m^2 was set for BMI.

Exclusion Criteria

Individuals who were under instructions to avoid physical activity or limit exercise due to a medical condition were excluded. These instructions may influence participants' perception of the safety of exercise and therefore skew responses. Individuals under the age of 20 and over age 65 were also excluded from this study. Individuals with cognitive impairment or serious mental illness, as determined by a diagnosis of a psychotic disorder, developmental delay or cognitive impairment due to dementia, which would impair comprehension of survey items or physical activity recall, were also excluded from the sample.

Measures

Body Mass Index. Participants' weight was taken at the time they participated in the study. Patients were weighed in light clothing without shoes, using a Tanita digital scale (Model #BWB500A). Height was measured using a wall-mounted stadiometer. Research staff was trained on the protocol used for measuring height and weight (Appendix F). BMI was calculated using the formula kilograms/meters^2.

Body Composition. Body composition was measured using bioelectrical impedance (BIA). This method assesses body composition by passing a weak electric current through the body and measuring resistance. The current travels through various tissues at different rates, and uses this information to estimate fat, fat-free mass, and body water. For this study, BIA was measured using the Tanita digital scale (Model #BWB500A). To ensure the most accurate measure of body composition participants were instructed not to eat or drink four hours prior to measurement and to avoid strenuous activities including exercise the day of participation.

Physical Activity. Physical activity was measured using the physical activity questions from the Behavioral Risk Factor Surveillance System (BRFSS; CDC, 2008; Appendix G). This set of questions asked participants if they engaged in moderate level activity during a normal week. If they responded yes, they were asked how many days per week they participated in these activities and the length of time the sessions lasted. This series of questions was then repeated for vigorous level activity. Responses were divided into four categories: (1) inactivity (2) low activity (3) medium activity (4) high activity, based

on the current CDC recommendations. Inactivity was defined as engaging in no activity above baseline activities. Low activity was defined as engaging in more activity than baseline, but less than 150 minutes each week. Medium activity was defined as engaging in 150 to 299 minutes of activity each week. High activity was defined as engaging in 300 minutes or more of activity each week (USDHHS, 2008).

This set of questions relies on self-report of activity levels, which introduces inherent limitations over objective methods of measurement (Table 3). The primary limitations of self-report measures are the possibilities of recall bias and social desirability. When compared to markers such as doubly-labeled water and accelerometers, self-report measures often show an overestimation of activity level, particularly in reports of moderate level activity. Yore et al. (2007) reported test-retest reliability for a survey based on BRFFSS physical activity questions for two different time periods. Participants completed the survey 1-5 days after the initial survey, and again 10-19 days after the initial survey. Test-retest reliability for the first to second survey were higher than those for the first to third surveys (k=0.53 vs. 0.35 for moderate activity, k= 0.86 vs. 0.80 for vigorous activity and k=0.84 vs. 0.67 for total recommended activity). When compared to accelerometers, validity of the questions was k=0.31 for moderate level activity, k= 0.17-0.26 for vigorous activity, and k=0.19-0.23 for total recommended activity. These findings are in line with those of Sallis and Saleans (2000), who reported an analysis of seven self-report physical activity measures for adults. For total physical activity, they found validity of self-report measures against accelerometers to range from 0.14 to 0.50. It should be noted, however, that while the

questionnaire used by Yore et al. (2007) contained the questions used in the BRFSS survey, additional questions were added that do not appear in the final BRFSS survey.

Another type of self-report measure that is used in physical activity literature involves a single-item measure. This type of assessment is often used when questionnaires need to be brief, or when physical activity is not the primary outcome. Many of these questions are intended to determine if participants are active or inactive. For example, Schechtman et al., (1991) described the use of the single-item, "Do you currently participate in any regular activity or program (either on your own or in a formal class) designed to improve or maintain your physical fitness?" While this question did show significant correlation to biological markers including BMI and lipid values, it does not allow for the exploration of various intensities or types of physical activities that is possible with multiple-item measures.

A major strength of self-report measures is the low cost and ease of use that make them a common assessment tool for many exercise studies. Other methods of measuring activity, including accelerometers and heart rate monitoring are often cost-prohibitive and require increased training for study staff and increased education and reporting time for participants.

Another advantage of the BRFSS questions is the self-administered design. Measures such as the 7 day physical activity recall (PAR; Sallis, et al., 1985) have shown acceptable psychometric properties. The limitation for this measure, in relation to this study, was the requirement of an interviewer to administer the measure. The intent of this study was to design a self-administered measure that could be completed by

participants in a clinic setting. The introduction of a measure that cannot be self-administered limits accessibility to participants.

Table 3: Feasibility of physical activity measures

Physical Activity Measure	Strengths	Limitations
Doubly-labeled water	• High reliability/validity	• Time requirement for participants • Training for staff and participants • Cost
Accelerometer	• Ability to determine intensity and duration of activity	• Time requirement for participants • Training for staff and participants • Cost
Pedometer	• Ease of use • Cost	• Decreased validity • No ability to determine intensity of activity
Activity journal	• Ability to assess frequency, intensity, duration and mode of activity • Limits recall bias • Cost	• Social desirability • Time required for participant
Multiple-item questionnaire	• Ability to assess frequency, intensity, duration and mode of activity • Ease of use • Time-efficient • Self-administered • Cost	• Recall bias • Social desirability
Single-item questionnaire	• Ease of use • Time-efficient • Cost	• Inability to assess frequency, intensity, duration and mode of activity • Social desirability

Pain. Pain from conditions including chronic back pain, arthritis or fibromyalgia was measured due to the fact that being overweight or obese can worsen these conditions, and many times pain from these conditions is made worse with the initiation of a new exercise routine. Pain was measured using the Pain Disability Index (PDI; Pollard, 1984; Appendix H). This scale asked participants to measure the effect of pain on various

aspects of life including family and home responsibilities, recreation, social activities, occupation, sexual behavior, and life-support activities. Participants were asked to rate the effect of pain on a scale of 0 to 10, with 0 indicating no disability at all, and 10 indicating total disability. The scale was scored by adding the responses to the seven categories. Scores range from 0-70, with higher scores indicating greater disability. This scale was chosen due to its focus on general impairment rather than pain level at a specific point in time.

Tait, Chibnall and Krause (1990) found the scale to have a single factor structure, which accounted for 56% of the variance in scores. Cronbach's alpha for the scale was reported as 0.86. Using the median score of the scale (score=46) as a cut-off, the authors split participants into low or high pain categories. PDI scores were compared to scores on multiple assessments that measured psychological distress, pain description, disability and pain history. Significant differences were found between the high and low PDI groups in the categories of psychological distress, pain description and disability ($p<.001$ for all 3 categories).

Tait et al. (1990) reported test-retest reliability to be lower than expected (r=.44). This was reported as a two-month test-retest design, however the time between first and second testing ranged from 11 days to 307 days. Gronblad et al. (1993) reported much higher results using a one week test-retest (ICC=0.91). Authors noted that these higher results may have been a result of a more homogenous sample in relation to the data collected by Tait et al. (1990), as well as a more uniform time between first and second testing.

Item Development Process

Scale development was based on the 8-step development process outlined by DeVellis (1991). This 8-step process includes the following stages: (1) determine clearly what is to be measured (2) generate an item pool (3) determine the format for measurement (4) have initial item pool reviewed by experts (5) consider inclusion of validation items (6) administer items to a development sample (7) evaluate the items (8) optimize scale length.

The following portion of this chapter outlines the specific data collection techniques and sample characteristics for each of the stages of the scale development phase of the study.

Determination of Measurement Constructs: Focus Groups

The primary goal of the scale of interest was to measure pain-related fear. Although this type of fear has been measured in multiple chronic and acute pain populations, it has never been measured in generally healthy overweight or obese populations. Constructs that may be related to pain-related fear among individuals in this group include musculoskeletal barriers such as joint and muscle pain, as well as cardio-pulmonary barriers including shortness of breath, increased heart rate and increased perceived exertion.

Focus groups were held to determine constructs that should be included in the initial item pool. Groups were conducted until responses were repetitive and no new information was gained. A total of three focus groups were held before saturation was reached. Groups were held in the Webb Nutrition Sciences building, as study

participants were familiar with this setting. Informed consent was obtained, groups were audio taped and the moderator and an assistant took notes.

Audiotapes were transcribed and checked with notes taken during the groups. MaxQDA was used to code transcriptions and identify themes from each group. A report was generated that outlined the major themes that emerged from each group. Each participant received a copy of the report from the group in which they participated and they were asked to confirm that the results were accurate. Themes of all three groups were merged to identify recurring themes. Recurring themes that emerged across all focus groups were used to develop scale items (Krueger, 1988; Stewart & Shamdasani, 1990).

Incentives

Krueger (1994) suggested using monetary incentives that are within the budget of the project, yet valuable enough to convey the importance of participation. For this study, participants were given $15 gift cards for participating in the focus groups.

Focus Group Participants

Focus group participants were recruited from the list of potentially eligible participants created from the query of electronic records. After initial eligibility was determined in the query, participants were called to assess interest in participation and to determine full eligibility.

The number of participants in each group ranged from six to eight individuals, with 21 total participants. Demographic characteristics of the focus group members are

shown in Table 4. Seventy-six percent of participants were female. The mean age of participants was 48.57 years (±11.64). The mean BMI of group members was 40.63 kg/m^2 (±8.42), and the mean body fat percentage was 46.20% (±7.75).

Table 4: Demographic characteristics of focus group members

	Mean (*SD*)	*N*=21 (%)
Age (years)	48.57 (±11.64)	
Gender		
Female		76.2%
Male		23.8%
Ethnicity		
African American		28.6%
Caucasian		66.7%
Hispanic		4.8 %
Education		
High School or Equivalent		14.3%
Some College		23.8%
Bachelor's Degree		23.8%
Master's Degree		19.0%
Professional Degree (MD, JD, etc)		14.3%
Other		4.8%
BMI (kg/m^2)	40.63 (±8.42)	
Overweight		9.5%
Class I Obesity		19.0%
Class II Obesity		28.6%
Class III Obesity		42.9%
Body Fat	46.20 % (±7.75)	

Physical Activity. Total minutes of activity were calculated by adding the average number of moderate-intensity and the average number of vigorous-level intensity minutes. The mean number of total minutes of activity was 64.5 (±41.56) minutes each week (Table 5). Nine percent of participants were categorized as inactive, and 28.57% of participants were categorized as low activity. Nineteen percent of group members were categorized as medium activity and 23.84% were categorized as high activity.

Table 5: Physical activity levels of focus group participants

Physical Activity Category	n	N=21 (%)
Inactive	2	9.5%
Low Activity	6	28.57%
Medium Activity	4	19.04%
High Activity	5	23.84%
Missing Data	4	19.04%

Pain. Participants were asked to rate the level of disability they experienced in each of seven areas. Scores for each category ranged from 0, meaning no disability, to 10, meaning total disability, with the total score ranging from 0-70. The total score mean was 9.43 (±14.06). The means and standard deviations of each area are presented in Table 6.

Table 6: Pain disability index scores of focus group participants

Area	Mean (SD)
Family/Home Responsibilities	1.57 (± 2.23)
Recreation	2.10 (± 2.88)
Social Activity	1.43 (± 2.69)
Occupation	1.57 (± 2.50)
Sexual Behavior	1.38 (± 2.65)
Self-Care	.71 (± 1.49)
Life-Support Activities	.67 (± 1.11)
Total Score	9.43 (± 14.06)

Focus Group Themes

Focus groups began with broad questions such as identifying common physical responses to exercise. These were followed by more specific questions of perceptions and interpretations of these responses (Appendix I; Krueger, 1994; Stewart & Shamdasani, 1990). The initial set of questions included six questions. A seventh question related to lifestyle physical activity was added as a result of discussion during the first focus group.

Types of Physical Responses to Exercise

Three primary types of physical responses were discussed: cardio- respiratory responses, pain responses, and energy level. Cardio-respiratory responses included increased heart rate, labored breathing or shortness of breath, and clammy hands or numbness in extremities. Pain responses included joint pain or stiffness and muscle pain including soreness and strained muscles. Discussion about energy level related to a feeling of fatigue during and immediately after exercise, and an increase in overall energy level after a consistent exercise routine has been established.

Safety of Physical Responses to Exercise

Specific Symptoms. When asked to identify differences between safe and unsafe physical responses to exercise, some participants named specific responses which they categorized as always indicating danger. These included numbness in hands and/or feet, clammy hands, dizziness, and blurred vision.

Severity/Duration of Symptoms. Many members reported that they based interpretations of responses such as joint pain or chest pain on the degree or extremity of the response. Group members discussed that some level of pain or discomfort is to be expected with exercise; however, pain or discomfort that does not go away after a period of time, or is worse than what has been experienced during past exercise sessions, could be a sign of injury. Participants noted that there is a "different kind of pain" that signals injury or unsafe conditions. One member noted, "I used to exercise a long time ago, so I know what it felt like to begin with, compared to what it feels like now. And it is definitely not

the same." Other participants noted that the expectation of pain prevented them from working hard enough to experience pain. One group member stated, "I've never felt any pain like that because I've never pushed myself that hard. I don't want to hurt, so I don't push hard enough."

Similar ideas were voiced in relation to pain responses. Participants stated that exercise will often cause deep breathing, but that there is a difference between breathing heavy and shortness of breath. One participant noted, "I feel okay if I am tired, but I usually catch a second wind. It's when I can't catch that second wind that I know I've gone too far."

Differences in Overweight and Normal Weight Responses

Two primary themes emerged when participants were asked about differences in the way the bodies of normal weight and overweight individuals react to exercise. First, most groups members agreed that overweight and obese individuals experienced more extreme responses to exercise than normal weight individuals. Group members reported that they believed normal weight individuals were more tolerant to pain, and had more stamina, which made exercise easier for them. Words such as "heightened" and "exaggerated" were commonly used when describing the responses of overweight and obese individuals. Group members noted that these more intense responses may be due to deconditioning, poor circulation or decreased muscle tone, but all noted that these responses decreased as weight decreased.

The second theme that emerged was the importance of the role of psychological responses to exercise. One member, who reported being active when she was younger

and at a healthy weight, stated that she felt resentful and frustrated that she could not do the same activities she could do previously. Many members reported getting frustrated with exercise because they felt that they could not keep up in a group setting, or they felt they had to exercise at a level that was not intense enough for weight loss. Others noted that safety concerns dampened motivation to exercise. One participant noted that he felt he was "too heavy to walk," but also noted that he thought that this was "just an excuse because I'm too heavy because I don't walk." Many members felt that these psychological concerns about exercise were concerns that an individual of normal weight would not experience.

Difference in Interpretation of Physical Response to Exercise

Participants were asked to discuss possible differences in the way normal weight individuals and overweight individuals may interpret physical responses to exercise. The primary theme that emerged from this discussion related to an over-reaction to pain or cardio-respiratory responses. One participant stated "the overweight person thinks he's dying." Participants in each group stated that this over-reaction to physical responses stems, in part, from a fear of weight-related risk factors. Many participants reported that knowing they were at an increased risk for heart attack and stroke due to their weight made them more aware of physical responses during and after exercise. One participant described an experience in which she thought that she was "having the heart attack [my doctor] said I would have." But noted that she felt that, "the normal weight person, they know that it's okay." This fear of risk factors tended to be especially relevant to trying new activities. Participants noted that while they may feel comfortable doing a routine

exercise such as walking, they would not feel safe trying new exercises such higher intensity aerobic exercises or weight training.

Some group members noted that this fear is often used as an excuse to avoid exercise. One participant discussed thoughts that overweight and obese individuals are "always thinking about pain." She pointed to this as the reason that some overweight or obese individuals may overlook a potentially dangerous reaction, thinking that it is a result of weight rather than a medical condition. But she also noted that this is a reason many overweight individuals avoid exercise, explaining that they are in a constant state of pain, so they avoid intentionally increasing this pain through exercise. Other group members discussed thinking that exercise was unsafe due to their weight and found that they would talk themselves out of exercising by saying they needed to lose weight before they could exercise safely.

Factors Influencing Physical Safety

When asked to discuss factors that influenced feelings of comfort or safety with exercise, two primary themes emerged: medical clearance and supervised exercise. Group members reported feeling safer after receiving medical clearance to exercise. This clearance ranged from having a physician tell the individual what exercises were physically safe or unsafe, to undergoing an exercise stress test.

The second theme, supervised exercise, ranged from working with a personal trainer to having frequent interactions with a physician or other medical staff while initiating an exercise program. Many participants noted that while they felt safe doing familiar exercise such as walking, they were not comfortable trying new exercises such as

resistance training or increasing their exercise intensity without supervision from a trainer. While some participants felt safe in a gym setting that was staffed with personal trainers, others noted they felt more comfortable in a medical setting or a setting where personnel specialized in working with individuals who are overweight and obese. One difference of opinion that was of interest was related group-based exercise classes. While some participants felt safer in a group setting than exercising alone, others felt that the group setting fostered a feeling of needing to "keep up," which they felt was not physically safe for individuals who are overweight or obese. While all agreed that working with a trainer individually was the ideal situation, some participants noted that they felt safer to determine their own intensity while exercising alone than follow directions of an instructor in the context of a group setting.

Item Pool Development

Based on the literature review and the themes that emerged from the focus group discussions, an initial pool of potential scale items was developed. The initial pool consisted of 32 items (Appendix J). Items were designed as declarative statements and directions asked respondents to rank their agreement or disagreement to each statement using a five-point Likert- type scale. The Likert-type scale included the following options: (1) strongly disagree; (2) disagree; (3) neither agree or disagree; (4) agree; (5) strongly agree.

Expert Panel Review

Once items were developed, the initial scale was reviewed by a panel of experts to analyze content validity (DeVellis, 1991). Ten experts in the fields of obesity, physical

activity, scale development, and fear-avoidance beliefs were asked to complete the review. Five experts completed the review, for a 50% response rate. Members of the panel completed an on-line instrument that that asked them to rate each item based on the item's relevance for measuring the construct of fear of physical response to exercise (Appendix K). Each item was scored as 'essential,' 'useful but not essential,' or 'not necessary,' based on how well it measured the construct. Additionally, the instrument allowed the reviewers to give input on the clarity of the items and offer suggestions for changes in wording. The relevance ratings were used to calculate a content validity ratio (CVR). This ratio was presented by Veneziano and Hooper (1997) as a method of quantifying content validity of health behavior scales. Originally developed by Lawshe (1985) for use in employment testing, the ratio uses the following formula to find a numeric value for content validity:

$$CVR = \frac{(n_e - N/2)}{N/2}$$

CVR= content validity ratio, n_e = number of panelists rating item as essential, N = total number of panelists.

Table 7 shows the minimum CVR value that must be obtained for an item to be statistically significant at the $p<.05$ level. Five individuals completed the initial review, resulting in a CVR value of 0.99 as the minimum requirement for statistical significance. Of the 32 scale items, only one reached statistical significance (Table 8). This item was "I need to limit the amount of exercise I do because of my weight" (CVR= 1). Three additional items had a CVR value of 0.6, indicating that four of five respondents rated these items as essential, however due to the small number of reviewers these items did not reach significance. A review of open-ended feedback provided by reviewers showed

that many believed the items offered a valuable screening tool, but many were confused as to the exact construct they were assessing. In addition to this confusion, some reviewers appeared unclear about the rating system of 'essential,' 'useful but not essential,' or 'not necessary.'

Table 7: CVR value for an item to be considered valid at a $p<.05$ level

Number of Panelist	Minimum Value
5-7	0.99
8	0.78
9	0.75
10	0.62
11	0.59
12	0.56
13	0.54
14	0.51
15	0.49
20	0.42
25	0.37
30	0.33
35	0.31
40	0.29

Table 8: Content validity results of first expert review

CVR	Item
CVR= 1	Q31. I need to limit the amount of exercise I do because of my weight.
CVR= 0.6	Q16. I need to lose weight before I can exercise safely. Q26. If I experience discomfort while exercising it is a sign that I need to stop exercising. Q27. There are some exercises that are unsafe for me because of my weight.
CVR= 0.2	Q5. I'm afraid that I may harm myself if I exercise. Q9. When I experience discomfort during or after exercise it is a signal from my body that I should not exercise. Q10. Exercise is safe for a person my weight. Q11. When I exercise, I often worry that I may have a heart attack. Q12. It is not safe for people who are overweight or obese to exercise. Q15. My weight puts additional stress on my body that makes it unsafe for me to exercise.

	Q19. I will feel safe exercising if my doctor tells me I need to. Q21. If I experience discomfort while exercising it is a sign that I am in danger Q22. I will feel safe exercising if a medical professional shows me how. Q30. I am safe to continue exercising after I experience pain if that pain goes away as soon as I stop exercising.
CVR= -0.2	Q1. My weight makes it dangerous for me to exercise. Q2. The pain that I experience during exercise would probably get better if I exercised more often. Q4. If exercise aggravates a previous injury, then exercise should be avoided. Q6. Exercise is dangerous for my heart. Q7. It is unsafe for me to do the same exercises as a person of normal weight. Q13. Activities that result in sweating or heavy breathing make me feel unsafe. Q14. People who are overweight or obese need to start exercising at a slower pace than people who are normal weight. Q17. My weight makes it unsafe for me to try new physical activities. Q18. It is not safe for me to increase my activity level until I lose weight. Q20. It is not safe for people who are overweight or obese to exercise alone. Q28. I feel safe trying new exercises. Q29. It is not safe for me to do some exercises because of my weight. Q32. When I feel discomfort or pain from activity, it is difficult for me to focus on anything else.
CVR= -.06	Q23. I experience less pain when I lose weight, which means exercise is safer when I lose weight. Q25. I feel safe planning my exercise routine on my own.
CVR= -1	Q3. Pain always means I have injured my body. Q8. I feel safe exercising on my own. Q24. I feel safer exercising when someone else exercises with me.

Based on these low CVR results, the decision was made to do a second round of expert reviews. Three primary changes were made to the review prior to the second evaluation. First, the results of the first round of reviews were used to condense the original 32 items to 20 (Table 9). This was done by reviewing open-ended feedback. Items that were noted to be repetitive were condensed to single items, and wording

changes were made based on specific recommendations from reviewers. Second, to aid in clarity, items were divided into subscales based on themes of the items. These subscales included general weight-related fear of exercise, fear of musculoskeletal pain and fear of cardio-respiratory responses to exercises. Finally, revised directions were developed to clarify the construct of fear of physical response to exercise (Appendix L). These revised directions gave general instructions for completing the review, as well as additional instructions specific to each subscale.

Table 9: Items included in second round of expert interviews

General Fear
1. I need to limit the amount of exercise I do because of my weight.
2. I need to lose weight before I can exercise safely.
3. There are some exercises that are unsafe for me because of my weight.
4. I'm afraid that I may harm myself if I exercise.
5. My weight puts additional stress on my body that makes it dangerous for me to exercise.
6. It is not safe for me to do some exercises because of my weight.
7. My weight makes it dangerous for me to try new physical activities.
Fear of Musculoskeletal Pain
8. The pain that I experience during exercise would probably get better if I exercised more often.
9. If exercise aggravates a previous injury, then it is a sign that I should not exercise.
10. Pain always means I have injured myself.
11. If I experience pain or discomfort while exercising it is a sign that I need to stop exercising.
12. I am safe to continue exercising after I experience pain if that pain goes away as soon as I stop exercising.
13. Just because exercise causes muscle or joint pain does not mean it is dangerous.
14. Pain lets me know when to stop exercising so that I don't injure myself
15. No one should have to exercise when it causes pain
Fear of Cardio Respiratory Responses
16. When I exercise, I often worry that I may have a heart attack.
17. Exercise is dangerous for my heart.
18. Exercises that result in sweating or heavy breathing make me feel unsafe.
19. When I experience discomfort during or after exercise it is a signal from my body that I should not exercise.
20. I cannot do exercises that raise my heart rate because they are dangerous for me.

Nineteen new panelists were asked to complete the online review. Twelve individuals completed the review, and an additional two individuals rated only the first six items. This resulted in a minimum CVR value of 0.51 for those items rated by 14

reviewers and 0.56 for those items rated by 12 reviewers. Four items had CVR values that reached statistical significance. These items were 'I need to lose weight before I can exercise safely;' 'I am afraid that I may harm myself if I exercise;' 'When I exercise, I often worry that I may have a heart attack;' and 'Exercises that result in sweating or heavy breathing make me feel unsafe.'

While traditional scale development standards are to keep only those items with CVRs that reach statistical significance, Veneziano and Hooper (1997) noted that those items with positive CVR values should also be further examined. They recommended keeping items with a positive CVR value for further development since this indicates that at least half the reviewers rated the item as essential. Thirteen items had CVR values that were positive after the second round of expert reviews. The open-ended feedback for these items was reviewed, and if specific recommendations for item improvement could be followed the item was retained for further development. One specific piece of feedback that appeared repeatedly was item redundancy. Multiple reviewers noted that while they thought several items tapped into an essential variable, they did not know which specific item they thought was the best to measure the variable. Feedback indicated one of several items should be included, but all related items were marked 'useful but not necessary.' For example, one reviewer stated, "This seems to capture the same construct as [a previous item] so I would choose one or the other- either will work." As a result, the reviewer rated both items 'useful but not essential.' When this feedback was given items were combined or one item was deleted. Table 10 shows all changes that were made to the item pool as a result of the second round of expert reviews. A total

of 16 items were retained for the cognitive interview stage of cognitive scale development (Appendix M).

Table10: Changes made to scale after 2nd CVR

Item Number	Item	Change	Reason for change
6	It is not safe for me to do some exercises because of my weight.	Item Deleted	Redundant with item 3
8	The pain that I experience during exercise would probably get better if I exercised more often.	Item Deleted	Assumes pain is experienced by all respondents.
15	No one should have to exercise when it causes pain	Item Deleted	Unclear wording: 'have to'
5	My weight puts additional stress on my body that makes it dangerous for me to exercise.	Deleted 'additional'	Leading wording
7	My weight makes it dangerous for me to try new physical activities.	Changed to 'My weight makes me scared to try new physical activities.'	Change to better relate to fear.
9	If exercise aggravates a previous injury, then it is a sign that I should not exercise.	Changed to 'If exercise makes a previous injury worse, then I am afraid that continuing to exercise could harm me.'	Reading level and to make item better relate to harm.
10	Pain always means I have injured myself.	Changed to 'Pain during exercise means I am injuring myself.'	Make present tense and to specify exercise-induced pain.
11	If I experience pain or discomfort while exercising it is a sign that I need to stop exercising.	Deleted 'or discomfort' Inserted 'in my muscles or joints	Consistency in wording Specificity
12	I am safe to continue exercising after I experience pain if that pain goes away as soon as I stop exercising.	Inserted 'muscle or joint'	Specificity
14	Pain lets me know when to stop exercising so that I don't injure myself.	Inserted 'in my muscles or joints'	Specificity
18	Exercises that result in sweating or heavy breathing make me feel unsafe.	Changed to 'make me sweat or breath heavy.'	Reading level
19	When I experience discomfort during or after exercise it is a signal from my body that I should not exercise.	Inserted 'such as heavy breathing or increased heart beat'	Specificity
20	I cannot do exercises that raise my heart rate because they are dangerous for me.	Changed to 'should not'	Remove extreme wording

Cognitive Interviews

The third stage of scale development was to conduct cognitive interviews, which were used to reduce response error by identifying portions of the scale that were unclear or potentially misunderstood by respondents. Interviews followed a verbal probing model (Willis, 1999; Willis, DeMaio & Harris-Kojetin, 1999). In this model, the interviewer follows a series of probes to explore the respondents' understanding of key terms and concepts asked in the scale. This model offers a more structured format than traditional think-aloud interviews, in which respondents are instructed to voice their thought patterns while responding to scale items with very little input from the interviewer. For this study a set of scripted probes was written for the scale directions, answer choices, and each scale item (Appendix N). Participants were asked general questions related to the meaning of each item by asking them to paraphrase or reword items. Additional, more specific, probes focused on questions raised during the expert panel review. These additional probes related to the meaning of specific terms in items or how rewording items would change responses. Participants were also asked to rank how easy or difficult each item was to answer using a 4- point scale in which 1 referred to very easy and 4 referred to very difficult.

Incentives

Individuals participating in cognitive interviews received a $15 gift card for their participation.

Participants

For this stage of development, inclusion criteria were modified. Willis (1999) recommended including a wider range of sampling in cognitive interviewing to ensure that response error is reduced in those intended to be screened out by the scale. To accomplish this, criteria for BMI was not used for inclusion and individuals not participating in the weight loss programs were recruited. Ten cognitive interviews were conducted in two rounds of five interviews. Four men and six women participated. Sixty percent of respondents were Caucasian. Full demographic characteristics of the sample are presented in table 11. Six participants were current participants of an EatRight program; two were participants of the Risk Reduction clinic and the other four participated in the Optifast program. Non-EatRight participants were normal weight individuals chosen to reflect a range of demographic characteristics and activity levels.

Table 11: Demographic information of cognitive interview participants

	Mean (SD)	Percentage of Total
Gender		
Male		40%
Female		60%
Ethnicity		
African American		40%
Caucasian		60%
Age (years)	43.40 (16.14)	
Education		
Vocational/Technical School		10%
Some College		10%
Bachelor's Degree		50%
Master's Degree		20%
Other (Associate's Degree)		10%
BMI (kg/m^2)	31.71 (9.43)	
Normal Weight		30%
Overweight		20%
Class I Obesity		30%

Class II Obesity		10%
Class III Obesity		10%
BIA	34. 24 (9.86)	
EatRight Program Participation (current enrollment status)		
Risk Reduction Clinic		20%
Optifast		40%
Non-participant		40%
Pain Disability Index	1.70 (± 2.90)	
Weekly Physical Activity Minutes	226.50 (187.77)	
Physical Activity Category		
Inactivity (no activity over baseline)		10%
Low (less than 150 minutes/week)		30%
Medium (150-299 minutes/week)		30%
High (300 minutes or more/week)		30%

First Round of Interviews

The participants were first asked to provide feedback related to their initial impressions when given the scale. They were asked to address issues including color, layout, print size and length. Most of the feedback in the first round reflected the idea that the scale appeared to be a typical survey with a recognizable format and answer set. Participants were then asked to read the directions and answer choices and restate each of these in their own words. All participants' responses were similar, with the exception of the restatement of answer choice three: 'neither agree nor disagree.' While some participants responded that this choice reflected not having an opinion, others believed it meant they were unsure of their response. This was addressed in the second round of interviews by adding another prompt to the interview (Table 12). The additional prompt read: "What do you think 'neither agree nor disagree' means?" An additional follow-up prompt was also added which read, "Is this the same as unsure?"

To assess the need for additional directions for different sections of the scale, participants were given two versions of the scale. The first included one set of general directions with the 16 items presented as one continuous list. The second version divided the 16 items into three sections, each with directions specific to that set of questions. The first set of questions was presented with the same general directions given in the first version of the scale. The second set of questions gave the same instructions, but with the addition of the phrase, "the following questions relate to pain in your muscles or joints." The third set of questions was also presented with the general directions, but with the addition of the phrase, "the following questions relate to your thoughts about how your heart and lungs may feel during or after exercise." Participants were asked to choose which version of the scale they preferred and if their answers would change based on the difference in directions. Two of the initial five respondents noted that the additional directions seemed redundant and unnecessary given the specificity of the questions. The remaining three reflected that their answers would not change based on the additional directions, but noted that the additional directions helped to frame the questions and direct their thinking for the questions that followed. One of the participants noted that although she liked the additional directions, they made the overall layout less appealing because it felt cluttered. As a result of this, additional white space was added to the area around the directions before the second round of interviews.

Other changes after the first set of interviews reflected discrepancies in interpretation of item 15, which read: "When I experience discomfort such as heavy breathing or increased heart beat during or after exercise it is a signal from my body that I should not exercise." The primary discrepancy was whether this question reflected a need

to avoid exercise temporarily or permanently. The original intent of this question was to reflect a long-term avoidance. The first set of interviews included a prompt to ask participants if their answer would change if the question read: "I should not continue exercising." While most participants responded that this would change their answer, there was still some discrepancy in interpretation. To address this in the second round of interviews, an additional prompt was added to assess interpretation if the wording was changed to state: "I am not ready for exercise."

The final change made after the first round of interviews related to the order of the cardio-respiratory items. Respondents noted that some of these items appeared to be very similar, and that they would answer them similarly. When asked about specific wording however, some respondents noted that there were small differences in the questions. The order of these items was changed after the first round of interviews to separate similar questions and prevent respondents from answering based on apparent redundancy.

Table 12: Changes made after cognitive interviews

Changes made after first five interviews	
Scale Layout	Additional white space added between sections in 2nd version (additional directions) to increase initial appeal.
Scale Directions and Answer Choices	Additional interview prompt added: • "What do you think 'neither agree nor disagree' means? • "Does [neither agree nor disagree] mean the same as 'unsure'?
Scale Items	Additional interview prompts added: • Item 15: "How (if at all) would you answer this question differently if the statement was reworded so that the end of the statement read "…I am not ready to exercise?"
	Item 15: Phrase 'discomfort such as'

	removed.
	Items 12-16: Reordered cardio-respiratory items to separate similar questions
Changes made after second five interviews	
Scale Directions/Answer Choices	Second version of scale (additional directions) chosen as final version
Scale Items	Item 5: phrase 'physical activity' replaced with 'exercise.'
Validation Measures	Checklist of medical conditions added to list of validation measures

Second Round of Interviews

After the second set of five interviews the responses were analyzed and the scale was further revised. The second version was decided to be the best version for use. While no participants reported that the additional directions would change their answers, more individuals voiced that the additional directions made the scale easier to use. Those who preferred the version with fewer directions reported that they thought the additional directions were unnecessary, but did not take away from the scale. The only change in wording was made to item five. The initial version of this item read: "My weight makes me scared to try new physical activities." The phrase 'physical activities' was replaced with the word 'exercise.' This change was made for two reasons. First, it was noted that all other items referred to exercise and not physical activity. Secondly, respondents consistently reported that changing this wording made a change in the way they interpreted the question. Most respondents noted that they felt 'physical activity' related to a broader set of activities than 'exercise.' Changing this wording kept all items parallel and prevented confusion and differences in interpretation. Sixteen items were included in the final scale after the second round of interviews (Appendix O).

The final change after the second set of interviews related to the set of validation measures that was used in the scale validation phase of the study. Many respondents made comments that their answers to items would be different if they had experienced various medical problems. For example, many participants noted that their ranking for cardio-respiratory items would probably differ if they had experienced a heart attack or other heart problem. For this reason, a checklist of various medical conditions was added to the set of validation measures (Appendix P).

Chapter Summary

The purpose of this study was to design and explore the initial validity of a scale to measure fear of physical-response to exercise for use with adults who are overweight and obese. This chapter discussed the scale development process which included focus groups, expert review and cognitive interviews. Focus group participants were recruited from the EatRight Weight Management programs at the University of Alabama at Birmingham. Three focus groups with a total of 21 participants were conducted to examine themes of fear-avoidance beliefs, exercise and weight. Discussions from the focus groups were transcribed and analyzed to find themes that should be included in the initial item pool.

The thirty-two items included in the initial pool were sent to a panel of experts in the fields of obesity, exercise and fear-avoidance beliefs. Each panel member scored the items based on relevance to measuring the concept of fear of physical response to exercise, as well as wording and clarity. Construct validity was measured using a construct validity ratio. Due to low statistical significance the scale items were revised,

along with directions for the expert panel review. The revised materials were sent to a new panel of experts in the same fields. Responses from the second expert review were used to further revise the scale, and 16 items were kept for the final development phase of cognitive interviews.

Two rounds of five cognitive interviews were conducted with individuals of various ages, educational levels, weight and activity levels. Responses from these interviews were used to make final revisions to the scale's layout, instructions, items and response options. The final version consisted of 16 items with a five-point Likert-type scale response set.

CHAPTER 4

METHODOLOGY AND RESULTS: SCALE VALIDATION

Participants

Participants for the scale validation phase of the study were recruited from the EatRight Risk Reduction and Optifast clinics at the University of Alabama at Birmingham (UAB). These were the same clinics used to recruit participants for the scale development phases of the scale. Both of these weight loss clinics operate within the UAB Department of Nutrition Sciences. This study was approved by the UAB Institutional Review Board and informed consent was obtained from each participant.

Inclusion Criteria

The primary inclusion criterion for the scale validation phase of the study was a BMI of 25 kg/m^2 or above. Because an extreme BMI could skew results as outliers, an upper limit of 60 kg/m^2 was set for BMI.

Exclusion Criteria

Individuals who were under instructions to avoid physical activity or limit exercise due to a medical condition were excluded. These instructions may influence participants' perception of the safety of exercise and therefore skew responses. Individuals under age 20 and over age 65 were also excluded from this study. Individuals

with cognitive impairment or serious mental illness as determined by a diagnosis of a psychotic disorder, developmental delay or cognitive impairment due to dementia that would impair comprehension of survey items or physical activity recall were also excluded from the sample.

Participant Recruitment

Each week the schedules for all clinics were reviewed to find patients who met initial eligibility criteria. These criteria included age and BMI. Patients who were determined to meet these criteria were contacted to introduce the study, determine full eligibility, and assess willingness to participate. If the patient was willing to participate he or she was sent a copy of the informed consent by email or mail, depending on the participant's preference. When the participant arrived at the scheduled appointment he or she was given an opportunity to ask questions related to the study and then signed the informed consent (Appendix R). Participants were then given the scale validation tools and instructed to complete the instrument while waiting to see the scheduled provider.

Distributing consent documents prior to in-person contact was used due to IRB guidelines of giving participants a minimum of 24 hours to review informed consent prior to participation. As a result of this procedure and clinic schedules, patients were seen one to three times before the researcher was typically able to establish contact. This led to difficulty recruiting participants in the initial phases of treatment, prior to any intervention or education related to physical activity. After three months of using this recruitment process, an IRB amendment was granted that allowed the 24 hour period to

be waived. At this point, patients could be recruited and participate during the same clinic visit.

The revised recruitment protocol allowed for charts to be reviewed when patients arrived for their scheduled appointments. Potentially eligible participants were approached by the researcher who introduced the study and determined complete eligibility. If the patient was interested in participating, he or she was given the informed consent and was given time to read the consent and ask questions. They were then given the validation tool and completed it while they were waiting to see the scheduled provider.

Incentives

Participants were given a voucher for five dollars toward any UAB EatRight product or service for their participation.

Measures

Body Mass Index

Participants' weights were recorded from their medical record on the day of participation. Patients were weighed in light clothing without shoes, using a Tanita digital scale (Model #BWB500A). Height was also taken from the medical record. Height was measured using a wall-mounted stadiometer. All clinic staff members are trained on the protocol used for measuring height and weight (Appendix F). BMI was calculated using the formula kilograms/meters^2.

Body Composition

Body composition was measured using bioelectrical impedance (BIA). This method assesses body composition by passing a weak electric current through the body and measuring resistance. For this study, BIA was measured during the clinic visit using the Tanita digital scale (Model #BWB500A).

Physical Activity

Physical activity was measured using the physical activity questions from the 2008 Behavioral Risk Factor Surveillance System (BRFSS; CDC, 2008; Appendix G). This set of questions asked participants if they participated in moderate level activity during a normal week. If they responded yes, they were asked how many days per week they participated in these activities and the length of a typical session. This series of questions was then repeated for vigorous level activity. Responses were divided into four categories: (1) inactivity (2) low activity (3) medium activity (4) high activity, based on the current CDC recommendations. *Inactivity* was defined as engaging in no activity above baseline activities. *Low activity* was defined as engaging in more activity than baseline, but less than 150 minutes each week. *Medium activity* was defined as engaging in 150 to 299 minutes of activity each week. *High activity* was defined as engaging in 300 minutes or more of activity each week (US Department of Health and Human Services, 2008).

Pain

Pain was measured using the Pain Disability Index (PDI; Pollard, 1984; Appendix H). This scale asked participants to measure the effect of pain on various aspects of life

including family and home responsibilities, recreation, social activities, occupation, sexual behavior, and life-support activities. Participants were asked to rate the effect of pain on a scale of 0 to 10, with 0 indicating no disability at all, and 10 indicating total disability. The scale was scored by adding the responses to the seven categories. Scores range from 0-70, with higher scores indicating greater disability. This scale was chosen due to its focus on general impairment rather than pain level at a specific point in time.

Demographic Information

Participants completed a demographic questionnaire that asked for information related to gender, race and education level. The questionnaire also asked participants which EatRight programs they were involved with and how long they had been involved in each program.

Medical Conditions

Participants were given a list of medical conditions and asked to indicate if they had ever been told they had any of these conditions (Appendix P). These conditions included musculoskeletal conditions and cardiopulmonary conditions, as well as other unassociated conditions. This list was placed at the end of the validation tool to prevent leading the participants' answers by causing them to think about potentially painful conditions before answering the fear avoidance scale items.

Data Management

All data were entered into a Microsoft Excel spreadsheet on a secure server. Participants' first and last names were used to track which patients had been identified as potentially eligible, if they agreed to participate, and the date of participation, if applicable. Participants signed a log verifying their receipt of the incentive. Study data were entered in a separate file, in which all study participants were assigned a unique identifier. No identifying information was entered with study data. All electronic data was stored on a server maintained by UAB. All computers used by the researchers were connected to a TCP/IP local area network and were behind appropriate firewalls. Data entry was verified by having two research assistants each check 12 data entries. This accounted for a total verification of 20% of all data. Excel files were exported into SPSS 15.0 for data analysis.

Statistical Analysis

The following portion of this chapter outlines the statistical analysis used for each of the five research questions (RQ).

RQ1: What is the underlying component structure of the items on the scale?

Principle component analysis (PCA) is a statistical technique used to reduce large sets of variables into smaller subsets of variables that are related in some way. PCA is an exploratory process used in the early stages of research when the goal is to describe and summarize data by finding correlated variables. In scale development these subsets, or components, include items that correlate with each other and are relatively independent of other components. PCA extracts components in such a way that the first component

explains the most variance in item responses. After the first component, subsequent components are extracted based on the percentage of variance explained by each.

The Kaiser-Meyer-Olkin test of sampling adequacy was first used to determine if correlations were adequate for component analysis. According to this test of sampling adequacy, correlations of .60 or above are necessary for PCA (Tabachnick & Fidell, 1996).

Because PCA is based on correlation, a large sample size is necessary for obtaining reliable results. Inadequate sample size can lead to over fitting of data, resulting in items loading on components that are not a true fit (Tabachnick & Fidell, 1996). This results in Type I error when items are retained when they should not be. A small sample may also lead to inaccurately low component loadings, resulting in Type II error when items are deleted from the scale when they should be retained. When a small sample is used it is difficult to determine if low component loadings should be interpreted as a need to delete that item, or if the item should be retained for further development.

Despite the agreement that sample size is a key determinant for reliable use of PCA, there is much debate as to the number of subjects required for an accurate analysis. There are two primary sampling patterns in the debate over sample size: minimum total sample size and subject to item ratio. Comrey and Lee (1992) give the following, widely accepted guidelines for sample size adequacy in PCA: 50-very poor, 100-poor, 200-fair, 300- good, 500- very good and 1,000 or more- excellent. Other commonly cited rules include a range of minimum total sample sizes including N= 50 (Barrett & Kline, 1981), N= 200 (Comrey, 1973) and N= 400 (Aleamoni, 1973).

The primary debate against absolute sample size recommendations lies in the complexity of scales for which PCA is used. There are no stipulations based on scale size, complexity of component structure, or magnitude of correlations. For this reason, many authors have recommended focusing more on subject to item ratio. Nunnally's (1978) 10:1 ratio is a widely-accepted rule, which recommends 10 subjects for each 1 item in the PCA. Gorsuch (1983) and Hatcher (1994) both report specific guidelines when ratios as small as 5:1 can be used, but both note that higher ratios are generally more advisable.

Guadagnoli and Velicer (1988) cited a lack of empirical evidence for commonly used recommendations for sample size in PCA. They used a Monte Carlo procedure to explore the circumstances under which sample size influenced component analysis. They examined four variables: total sample size, number of variables/items, number of components and component saturation. They explored the influence of these variables on the stability of component pattern, as measured by the difference between sample component pattern and the population component pattern (g^2). The authors manipulated the four sample size characteristics to explore a range of situations derived from combinations of the following criteria: total sample size of 50, 100, 150, 200, 300, 500 or 1,000; the number of variables ranged from 36-144; the number of components was three, six, or nine; and the component loadings were .40, .60 or .80.

Results indicated that the most influential factor on component pattern stability was component saturation or factor loading. Total sample size had a greater influence on component pattern than other variables, but this was only the case when component loadings were low (.40). When component loadings were moderate to high (.60-.80),

total sample size, number of items and number of components were not related to the difference between sample component patterns and population component patterns.

The analysis also described the influence of the four sample size characteristics on Type I and Type II error. Results showed a tendency for PCA to under define components (Type II error), but this was only at the low level of component loading. When component loading was .80, Type I error was not seen in any case. When component loading was .60, Type I error did not occur for any sample with a total sample size of 100 or above. Type I error increased when the component loading decreased to .40, with the highest reported Type I error rate being 9%. Type II error was more frequent, but showed the same patterns based on the strength of component loading.

The authors concluded that existing subject to item ratios have no substantial basis and that total sample size is the more important of the two sample size characteristics when determining the appropriate sample needed to conduct PCA. Total sample size needed is contingent on the strength of component loadings, however, and component saturation should be considered before making a decision about the sample size needed, or the adequacy of conducting PCA on a small sample. Based on the results, the authors made the following recommendations: (1) component patterns may be interpreted as accurate with any sample size if the average component loading is above .60 and there are four or more variables on the component; (2) if components have lower loadings but there are a higher number of variables per component (10-12), results should be accepted when the total sample size is at least 150; (3) if there are fewer than 4 variables on a component and loadings are less than .60, a total sample of 300-400 is necessary.

Osborne and Costello (2004) replicated this study using the same data set. Using the same methodology, the authors furthered the analysis by examining both the independent and combined impacts of total sample size (N) and subject to item ratio on PCA stability. Results indicated a similar pattern of influence, with item loading having the most impact on component pattern stability. As item loading increased average squared discrepancy decreased (g^2), as did Type II error. Additionally, as item loading scores increased agreement (kappa) between sample and population patterns also increased. When analyzed together, neither total N nor subject to item ratio was a significant predictor of pattern stability. When analyzed separately, total N was significantly related to pattern stability, as well as agreement and Types I and II errors. Subject to item ratio showed a significant inverse relationship with pattern stability and Type I error when analyzed without total N.

Authors also noted several interaction effects that were seen in the analysis. Most notable were the interaction between component loadings and the total N, the interaction between component loading and the ratio of subjects to items, and the interaction between total N and the ratio of subjects to variables. Both the component loading x total N and component loading x subject to item ratio interactions indicated that while pattern stability, agreement and error rates were all influenced by component loadings, the influence decreased as total N and the subject to item ratio increased. Similarly, the total N x subject to item ratio interaction indicated that while higher subject to item ratios were generally associated with better pattern stability and decreased error rates, this influence decreased as the total N increased. Authors concluded that while the overall results

replicated those of Guadagnoli and Velicer (1988), the interactions found in this analysis warranted a more complex interpretation of sample size needed for a reliable PCA.

The initial recruitment goal for this study was 300 to allow for a full factor analysis, but the time frame of this study presented challenges for obtaining a sample this large. Although there were an adequate number of potentially-eligible patients, the researcher was not able to establish contact with many of them prior to their appointment. Additionally, many patients who agreed to participate when contacted prior to their appointment either cancelled or did not show for their appointment. Based on the literature review of PCA, a minimum total sample size of 100-150 could be deemed appropriate for this study, based on expected component loadings of ≥.60, with 16 items that were designed in three hypothesized subscales of 5-6 items each. Because PCA is more exploratory in nature, it was decided to conduct the analysis with the existing 125 samples.

PCA and common factor analysis procedures commonly use rotation to increase interpretability if there is more than one component. Because the goal of PCA is to reduce items to relevant subsets, interpretability is a key aspect when analyzing the resulting factor structure (Tabachnick & Fidell, 1996). Orthogonal rotation is a class of rotation in which the components are not correlated. All components are statistically independent of one another (DeVellis, 1991). Varimax orthogonal rotation minimizes the complexity of components by maximizing the variance of loadings on each component (Tabachnick & Fidell, 1996). An item loading of .60 was used as a cut-off for retaining items.

RQ2: What is the internal consistency and temporal stability of the resulting component structure?

Internal consistency was analyzed using Cronbach's alpha coefficients (Cronbach, 1951). Coefficient alpha was examined for each component to determine the factor's internal consistency so subscale scores could be summed for a composite score. An alpha score of .70 was considered adequate for summating component scores. The change in coefficient alpha if items were deleted was also examined to determine the effect of elimination of each item on the stability of the factor structure of each subscale.

Temporal stability was determined using a test-retest design. The original study design included retesting 10% of participants two weeks after initial participation. To limit time burden, the participants were only asked to complete the 16 items of the newly-developed scale, rather than the entire original assessment during the re-test. Correlations between item responses on the first and second administrations were analyzed for consistency of responses over time. Test-retest correlations of $r \geq .70$ were determined to be reliable over time.

RQ3: Is there a difference in scale responses based on physical activity level?

A one-way analysis of variance (ANOVA) was used to evaluate the differences between scores on each of the scale components and physical activity level. ANOVA is a statistical technique used to compare differences between two or more means. A one-way ANOVA compares the differences between one dependent variable and one independent variable that has three or more levels. For this analysis, scale scores were

entered as the dependent variable. The four physical activity categories were entered as the levels of the independent variables.

Physical activity was measured by calculating the total number of minutes each participant reported during a typical week. This was done by multiplying the number of days of moderate level activity by the typical time spent engaged in moderate activity each day. The number of days of vigorous activity was multiplied by the typical time spent engaged in vigorous activity each day. These two values were then added to calculate the total minutes of activity each week. This value was then categorized using the following CDC classification: *inactive:* 0-9 minutes/week; *low activity:* 10-149 minutes/week; *medium activity:* 150-299 minutes/week; *high activity:* $\geq$ 300 minutes/week. These 4 levels of activity were used as the levels of the independent variable.

ANOVA is based on several assumptions related to the distribution of the sample (Tabachnick & Fidell, 1996). The ANOVA analysis assumes a normal distribution and is sensitive to outliers. An exploratory analysis of the physical activity variable was conducted using SPSS version 15.0 software (SPSS Inc. Chicago, IL) to examine the distribution of scores and screen for outliers. The ANOVA analysis also assumes homogeneity of variance. If sample size within each cell is equal, this assumption is considered to be met. ANOVA also assumes that relationships between variables are linear. Non-linear relationships will reduce the power of the analysis. Linearity was tested by looking at the scatter plots of dependent variables.

A significant F-statistic indicates that there is a significant difference in at least one of the levels of the independent variable. To further assess which levels have

significant differences, post hoc tests were conducted (Dawson & Trapp, 2004; Gravetter & Wallnau, 2007). For this study the Sheffe post hoc test was used to determine the differences in scale scores among physical activity levels.

RQ4: Is there a significant relationship between responses to the scale and BMI?

Bivariate correlation was used to assess the relationship between BMI and scale scores. Correlation is used to assess the strength of association between two continuous variables. No inference can be made as to the causality of resulting relationships, but the existence and strength of a relationship can be assessed. Pearson correlation coefficients were calculated to examine the relationships between three variables: BMI and score on the weight-specific subscale; BMI and score on the cardio-respiratory subscale; and BMI and total scale score.

A bivariate regression analysis was also conducted to assess the predictive ability of BMI on the scale scores. Regression analysis assesses the predictive nature of one variable on another by finding the best linear fit between the means of the X and Y variables and minimizing the variance of the distance between data points. The results give a linear equation that allows for prediction of the dependent variable when the value of the independent variable is known.

RQ5: Is there a significant relationship between responses to the scale and pain, as measured by the Pain Disability Index?

Responses to the seven areas on the PDI were added together to calculate a total PDI score, with possible scores ranging from 0-70. Bivariate correlations were used to

assess the relationship between total scores on the PDI and the fear-avoidance subscales and total score. Pearson correlation coefficients were calculated to analyze the relationships between three scores: total PDI scores and weight-specific subscale scores; total PDI scores and cardio-respiratory subscale scores; and total PDI scores and total fear avoidance scale scores. A bivariate regression analysis was also conducted to determine the predictive ability of PDI scores on fear avoidance scale scores.

Results

The following section of this chapter discusses the results of the scale validation phase of this study. General results related to sample characteristics and demographic information are presented first, followed by results for each of the five guiding research questions.

Participants

A total of 125 individuals participated in the measurement study. Table 13 shows complete demographic information for the validation sample. The mean age of participants was 48.67 (±10.11) years. Seventy-four percent of participants were female, and 67% were Caucasian. There was no significant difference on total scale scores between males and females (p= .236). Thirty-two percent of all respondents had a Bachelor's degree. Thirty- three percent of participants were currently enrolled in the Risk Reduction program, and 55% were enrolled in the Optifast program. The mean BMI of participants was 37.23 (± 7.46) kg/m^2, and the mean body fat percentage was 43.66% (± 7.93).

Table 13: Demographic characteristics of validation participant

	Mean (SD)	n	N= 125 (%)
Age	48.67 (10.11)		
Height (in)	65.97 (3.72)		
Weight (lb)	232.97 (54.37)		
Body Mass Index (kg/m^2)	37.21 (7.43)		
BIA (%)	43.66 (7.93)		
Gender			
Male		32	25.6%
Female		93	74.4%
Ethnicity			
African American		36	28.8%
Caucasian		84	67.2%
Asian		3	2.4%
Hispanic		2	1.6%
Level of Education			
High School or Equivalent		5	4%
Voc/Tech School		5	4%
Some College		20	16%
Bachelor's Degree		41	32.8%
Master's		35	28%
Doctoral Degree		4	3.2%
Professional Degree (MD, JD, etc)		12	9.6%
Other		3	2.4%
Current Program			
Risk Reduction Clinic		42	33.6%
Optifast		69	55.2%
Lifestyle		14	11.2%
Length of time in current program			
Less than 1 month		30	30%
1 month-3 months		52	52%
4 months-6 months		11	11%
7 months-1 year		16	16%
Over 1 year		16	16%
Previous Program			
Risk Reduction Clinic		8	6.4%
Optifast		9	7.2%
Lifestyle		18	14.4%
Fitness		1	0.8%
None		89	71.2%
Length of time in previous program			
Less than 1 month		8	6.4%

1 month-3 months		14	11.2%
4 months-6 months		4	3.2%
7 months-1 year		3	2.4%
Over 1 year		7	5.6%
Does not apply		88	70.4%

RQ1: What is the underlying component structure of the items in the scale?

Principle component analysis was used to explore the component pattern of the 16 items included in the scale. A review of the data showed one participant had outlying scores for items 12-16. This participant was excluded from the analysis to normalize the distribution of the scores. This resulted in a total sample size of N=124 for the PCA. The Kaiser-Meyer-Olkin test of sampling adequacy was .84, indicating sufficient correlations between the items to justify the use of PCA. The scale was hypothesized to have three factors that emerged from the scale development phase of the study: weight-specific fears, musculoskeletal fears, and cardio-respiratory fears. A three-component structure with varimax rotation was forced to reflect this design in the examination of the component loadings of the items.

Component 1 included six items, all of which were originally included in the weight-specific fears section of the scale. All six items exceeded the minimum component loading of ≥0.60 needed for retention. Component 2 was composed of the five items originally designed for the musculoskeletal section of the scale. Only three of these items met the component loading criteria of .60. Item 9, *I am safe to continue exercising after I experience muscle or joint pain if that pain goes away as soon as I stop exercising*, had a component loading of .586. Item 10, *Just because exercise causes muscle or joint pain does not mean it is dangerous*, had a component loading of .496. Component 3, cardio-respiratory fears, included the five items originally included in the

cardio-respiratory section of the scale. All five items exceeded the minimum component loading of .60 needed for retention.

Due to the low component loading scores on component 2, a second PCA was conducted that excluded items 7-11. A two-component structure was forced on the remaining items (Table 14). All 11 items had component loadings of ≥0.60 in the resulting component pattern. After varimax rotation the first component accounted for 34.5% of the total variance and the second component accounted for an additional 30% of the total variance. These results indicate that a two component structure offers the best fit for the scale in the current form accounting for 64.5% of the variance in fear related to exercise among this sample.

Table 14: Component loadings for 2 component structure

Item	Component	
	1	2
I need to lose weight before I can exercise safely.	.712	.245
There are some exercises that are unsafe for me because of my weight.	.788	.086
I am afraid that I may harm myself if I exercise.	.827	.202
My weight puts stress on my body that makes it dangerous for me to exercise.	.851	.030
My weight makes me scared to try new exercises.	.809	.110
If exercise makes a previous injury worse, then I am afraid that continuing to exercise could harm me.	.738	.093
Exercises that make me sweat or breathe heavy make me feel unsafe.	.220	.742
Exercise is dangerous for my heart.	.126	.914
When I exercise, I often worry that I may have a heart attack.	.085	.772
I should not do exercises that raise my heart rate because they are dangerous for me.	.097	.876
When I experience heavy breathing or increased heart beat during or after exercise it is a signal from my body that I should	.118	.854

not exercise.		

The PCA resulted in the weight-specific subscale consisting of six items, with a possible score range of 6 – 30. The mean score for this subscale was 13.72 (± 5.39). The cardio-respiratory fear subscale consisted of five items, with a possible score range of 5 – 25. The mean score for this subscale was 7.49 (± 2.57). The total scale consisted of 11 items, with a possible score range of 11 – 55. The mean total score for this sample was 19.78 (± 6.57).

RQ2: What is the internal consistency and temporal stability of the resulting component structure?

Internal consistency. The coefficient alpha of the first component, weight-specific fears, was α= .88 and α= .85 for the second component, cardio-respiratory fears. The internal consistency of the components was not significantly affected by elimination of any item. These high internal consistency results indicate that summated scores of both components could be used to represent meaningful subscales scores. The internal consistency of all scale items was also evaluated. For the total scale, α=.86, indicating that scores for the entire scale could be summated for a total score.

Temporal stability. Seventeen participants completed the test-retest portion of the study. One participant was excluded from the analysis based on outlying scores on the cardio-respiratory scale, so the total sample size for the test –retest analysis was N=16 (12.9% of the total sample). One participant did not answer one item on the weight-specific fears subscale at the first administration, so only 15 scores (12.1% of the total sample) were

used to calculate the correlations of this component. Time between scale administrations ranged from 14- 35 days, with the mean time of 20.59 (±7.2) days. Table 15 shows mean scores on both administrations of the scales, as well as correlation coefficients for the scales. The correlation between test-retest responses for the weight-specific fear component was *r*= .77, exceeding the minimum required for the subscale to be considered reliable over time. The test-retest correlation of the cardio-respiratory fear component was lower than expected however, with *r*=.42, indicating that responses to these items changed significantly between the two administrations. A review of the individual items indicated that none of the five items on this subscale had a significant correlation between the two administrations. Correlation coefficients for the five items ranged from .26-.59.

Table 15: Test-retest correlations

Component	Mean (SD) of First Administration	Mean (SD) of Second Administration	*r*
Weight-specific fears	16.20 (5.24)	12.63 (3.76)	.77
Cardio-respiratory fears	7.31 (2.15)	7.00 (2.19)	.42

RQ3: Is there a difference in scale responses based on physical activity level?

The mean physical activity minutes per week was initially 252.14 (±299.44) minutes. A review of the sample distribution for physical activity revealed violations of the assumption of normality. The distribution had a skewness of 2.35 and kurtosis of 7.17. Box plots revealed four outlying scores ranging from 1080-1740 minutes/week. These scores were determined to be an extreme overestimation of activity and were therefore removed from the analysis. The mean after eliminating these outliers was 214.65 (±214.43) minutes/week. Skewness and kurtosis for the distributions were still

higher than desired (1.31 and 1.34, respectively), but more acceptable than previously noted.

One participant omitted a question in the weight-specific fears section of the scale. A second participant was omitted for extreme scores on the cardio-respiratory scale. These two omissions, along with the elimination of the four outlying physical activity scores resulted in n=119 for the ANOVA analysis with the weight-specific subscale and n=120 for the ANOVA analysis with the cardio-respiratory subscale.

The one-way ANOVA for physical activity category and weight-specific scale scores indicated there were no significant differences between scale responses based on physical activity level ($F=2.49$, $p=.06$). The ANOVA analysis for physical activity category and cardio-respiratory subscale indicated that there was significant difference in scores between at least two of the physical activity levels ($F= 4.42$, $p = .006$). The Sheffe post hoc test indicated that the group with a *medium* level of physical activity had significantly more weekly activity than the group with an *inactive* level of physical activity (mean difference = 2.13, $p=.022$). The group of participants in the *high* level of physical activity also had a significantly higher level of weekly activity than the group in the *inactive* level of physical activity (mean difference = 2.17, $p=.015$).

RQ4: Is there a significant relationship between responses to the scale and BMI?

Scores from the 124 participants were used to calculate Pearson correlation coefficients (r) for each of three relationships. One participant was omitted from the correlation analyses with total scale scores and weight-specific subscale scores due to missing data. This resulted in n=123 for these two correlations.

A statistically significant positive correlation was seen between BMI and total scale score (r = .276, p=.002), indicating that as BMI increased, total scores on the fear-avoidance scale increased. There was also a significant positive correlation between BMI and the weight-specific fears subscale (r = .307, p= .001), indicating that scores on this subscale increased as BMI increased. Although these correlations are statistically significant, they are weaker than expected. Also unexpected was the lack of significant correlation between BMI and the cardio respiratory subscale scores (r = .073, p= .419).

Bivariate regression analysis indicated that BMI was a significant predictor of total scale score (F= 10.0, p = .002) and weight-specific fear subscale score (F= 12.57, p= .001), but not cardio-respiratory subscale scores (F=.658, p = .419) (Table 16). The resulting regression equation for BMI and total scale score was Total Score = 10.67 +.244 (BMI), indicating that for every one unit increase in BMI, total scale scores will increase by .244 points. This accounted for 7.6% of the total variance in scale scores. The resulting regression equation for BMI and the weight-specific fear subscale was Weight-Specific Fear= 5.42 + .222 (BMI), indicating that for every one unit increase in BMI, weight-specific scale score will increase by .222 points. This accounted for 9.4% of the total variance in the subscale scores.

Table 16: Regression statistics for BMI and PDI

Predictor Variable	Fear Avoidance Score	F	p	R^2
BMI	Total Scale Score	10.01	.002	.076
	Weight-Specific Scale	12.57	.001	.094
	Cardio-Respiratory Scale	.658	.419	.005
PDI	Total Scale Score	13.89	.000	.103

	Weight-Specific Scale	12.06	.001	.091
	Cardio-Respiratory Scale	7.63	.007	.059

RQ5: Is there a significant relationship between responses to the scale and pain, as measured by the Pain Disability Index?

Scores from the 124 participants were used to calculate Pearson correlation coefficients for each of three relationships. With the omission of the one entry with missing data, n=123 for the correlations involving the weight-specific subscale and total scale score. The correlation involving the cardio-respiratory fear subscale had n=124.

The mean total PDI score was 10.73 (± 13.92). Correlation analysis indicated a significant positive correlation between total PDI score and the weight-specific subscale (r = .301, p = .001). There was also a significant positive relationship between total PDI score and total fear avoidance scale score (r = .321, p = .000). Similar to the correlations between BMI and the fear avoidance scale scores, these correlations are lower than expected despite their significance. Unlike the correlations with BMI however, there was a significant correlation between total PDI score and the cardio-respiratory subscale (r = .243, p=.007).

Bivariate regression analysis indicated that total PDI score was a significant predictor of total scale score (F= 13.89, p = .00) and weight-specific fear subscale score (F= 12.06, p= .001), as well as cardio-respiratory subscale scores (F= 7.62, p =.007) (Table 16). The resulting regression equation for PDI and total scale score was Total Score = 18.15 +.151 (PDI), indicating that for every one unit increase in PDI scores, total scale scores will increase by .151 points. This accounted for 10.3% of the total variance in scale scores. The resulting regression equation for PDI scores and the weight-specific

fear subscale was Weight-Specific Fear= 12.46 + .116 (PDI), indicating that for every one unit increase in PDI, weight-specific scale score will increase by .116 points. This accounted for 9.1% of the total variance in subscale scores. Finally, the regression equation for PDI scores and cardio-respiratory subscale scores was Cardio-Respiratory Scale Scores= 7.01 + .045 (PDI), indicating that for every one unit increase in PDI scores, cardio-respiratory subscale scores will increase by .045 points. This accounted for 5.9% of the variance in subscale scores.

Chapter Summary

This chapter described the methodology and results of the scale validation phase of this study. Participants from the UAB EatRight Risk Reduction and Optifast clinics were recruited to complete the scale that was developed during the previous phase of the study. Participants completed the 16 items of the newly-developed scale, as well as validation scales including the Pain Disability Index, BRFSS physical activity questionnaire and a list of medical conditions.

The initial recruitment goal for factor analysis was 300 participants, but recruitment challenges made this goal difficult during the time frame of this study. As a result, data analysis was conducted with a total of 125 participants. Although this is a smaller sample size than desired, it was determined that this was an adequate sample size for PCA given the high component loadings, number of items per component, and the exploratory design of the analysis.

Principle component analysis revealed that a two-component structure was the best fit for the items in their existing form. These two components consisted of the six

items in the weight-specific fears subscale and the five items in the cardio-respiratory fears subscale. Both subscales showed good internal consistency, leading the researcher to deem them appropriate for summating item responses for a cumulative score. Temporal stability, as measured by a test-retest design, showed lower than expected stability of scores over time.

The differences in scores based on physical activity level were examined using an ANOVA. Results indicated a significant difference in scores on the cardio-respiratory subscale, based on physical activity level. Post hoc testing revealed that the significant differences in subscale scores occurred between the *inactive* and *medium activity* groups and between the *inactive* and *high activity* groups. There were no significant differences on the weight-specific subscale between different physical activity levels.

Finally, the correlation of scale scores with total PDI scores and BMI indicated a significant positive relationship between scores on the weight-specific subscale and total PDI scores as well as BMI. There was also a significant positive relationship between the total fear avoidance scale scores and PDI scores, as well as BMI. Scores on the cardio-respiratory subscales were significantly correlated with total PDI scores but not BMI.

CHAPTER 5

DISCUSSION

The purpose of this study was to develop a scale to measure fear of physical response to exercise among overweight and obese adults. Additionally, the study sought to explore the validity of the scale through principle component analysis as well as internal consistency and temporal stability analyses. This study was also designed to examine the relationships between fear-avoidance beliefs and weight, physical activity level and pain. This chapter reviews the findings of this study and discusses the research limitations as well as implications for future research.

Discussion of the Findings

Scale Development

Three focus groups with a total of 21 participants were used to develop the concepts to be measured in the scale. When asked to describe the differences in physical responses to exercise between normal weight and overweight/obese individuals, the primary theme that emerged was that overweight and obese individuals have a heightened, more extreme physical reaction to exercise. This is in line with previous studies that have shown that a higher cardiovascular response to exercise among overweight adults (Hills, Byrne, Wearing and Armstrong, 2005: Hulens, Vansant, Claessens, Lysens and Muls, 2003; Mattsson, Larsson and Rossner, 1997).

In addition to describing the differences in terms of what physical responses were experienced, this study also asked participants to explore how these responses are interpreted differently between normal weight and overweight/obese individuals. Participants described exaggerated interpretations of fear and increased focus on the responses than would be expected from normal weight individuals. While multiple studies have found a difference in affective response to exercise between weight groups, the researcher is unaware of any that have explored the source of these differences. Existing studies used quantitative scales of pleasure/displeasure (Ekkakis and Lind, 2006; Ekkakis, Lind and Vazou, 2010), or mood state batteries (Carels, Berger and Darby, 2006) to measure affective state. While the latter often includes screening for tension or anxiety, it does not specify whether or not the anxiety is caused by the exercise. Rather, most have evaluated the effect of exercise in improving or changing general mood state, and have not addressed exercise-induced anxiety. While participants of these focus groups did endorse similar mood improvements related to exercise, they also expressed a separate fear that occurred as a direct result of exercise. Identifying exercise-induced fears and differentiating these from other psychological barriers to exercise such as social physique anxiety may lead to more tailored treatments and better adherence to exercise prescription.

Expert review. An expert review was used to assess construct validity of the scale. Ten experts in the fields of obesity, physical activity and fear-avoidance beliefs were asked to review the scale using an on-line assessment tool. The response rate of 50% was much lower than anticipated and made it difficult for items to reach statistical significance. For

an item to be determined significant with five reviewers, the CVR must equal 0.99. This means all reviewers must agree that an item is essential for it to be retained. To allow for variance in opinion, 19 panelists were asked to complete the survey in the second round of expert reviews. Twelve individuals completed the review, and an additional two individuals reviewed only the first six items. This required CVR results of .56 (12 reviewers) and .51 (14 reviewers) to be significant. This allowed for more discussion and difference of opinion between reviews before an item was qualified as non-significant.

The second challenge with the review was that most of the reviewers were unfamiliar with the CVR and did not fully understand what they were ranking. Many reviewers believed they were ranking the items' usefulness on the scale as a whole, rather than the items' relevance to the construct of fear-avoidance of exercise. This emphasized the need for more detailed instructions and clarity in scale design during the development process. The results of the first expert review show that it can be difficult to determine if the item is in need of revision or if the reviewers need more clarity on CVR assessment. This is best highlighted by the fact that the only item that reached significance in the first review was deleted from the scale due to a negative CVR value after the second review.

These results also highlight the importance of reviewing open-ended responses to the expert review in addition to CVR values. Because many reviewers were not aware of how the CVR was calculated, they did not understand that unless an item was marked as *essential* it was not included in the CVR calculation. Review of open-ended comments showed that many of the items marked as *useful but not essential* were items that reviewers felt should be included, but needed revisions to the wording. Another common scenario was that a reviewer marked two items as *useful but not essential*, but noted in

the open-ended response that one of the two should be retained, but they did not have a preference as to which was retained.

Scale Validation

Principle component analysis. Principle component analysis (PCA) was used as an exploratory technique for examining the component structure of the 16 items included in the final scale. PCA indicated a two-component structure offered the best fit for the items in the current form. This was unexpected because the items eliminated were all the items that were designed to measure fear of musculoskeletal pain, a type of pain that emerged as a common fear-eliciting response to activity during the scale development phases of the study.

Of the five musculoskeletal pain items, only three had factor loadings ≥ 0.60 (moderate saturation) that was set as the retention level for the study, but the two additional items did closely approach the retention level, with component loadings of .586 and .496. Further exploration of the internal consistency of this scale led the researcher to eliminate the items for the current study since coefficient alpha for the component did not reach the desired .70 ($\alpha = .67$).

One reason for these findings may be the small sample size used for the analysis. While a sample size of 125 is adequate for an exploratory analysis, a larger sample could give more definitive results. A small sample can lead to Type II error in which item loadings are erroneously low, when a larger sample would show higher loadings. A challenge in interpreting component loadings with a small sample is that the researcher must decide if low loadings indicate a need to remove the items, or if they should be

retained for further development. Given the focus group discussions related to musculoskeletal pain and the component loadings that closely approached significance, it is the researcher's opinion that these items are useful in measuring exercise specific fear-avoidance beliefs. These items should be more fully developed and analyzed using a larger sample before a final decision to eliminate them is made.

Temporal stability. A second issue of interest from the scale validation phase of this study was the low test-retest correlations. While the test-retest results for the weight-specific subscale were acceptable (r = .77), the results for the cardio-respiratory subscale were not (r = .42). This may have been due, in part to the intervention participants received between test administrations and differences in the programs in which the participants were enrolled. Fourteen of the 17 (82.4%) individuals who completed the second test administration were enrolled in the Optifast clinic. Participants in this clinic are seen on a weekly basis, and receive both individual and group intervention at each appointment. Since the average time between administrations was 20 days, these participants could have received as many as three individual interventions and three group interventions between test administrations. Much of this intervention is related to physical activity, including education on heart rate and heart rate response to exercise. Although participants may not have lost enough weight to reduce weight-specific fears during this time period, they may have received enough education and physical activity intervention to change the scores on the cardio-respiratory scale.

The remaining participants were enrolled in the Risk Reduction clinic, and are seen on a less frequent schedule, typically once every two to four weeks. The

intervention offered in this clinic is individual, but some participants receive additional group intervention if they choose to enroll in another group-based program. Because there were only three participants from this clinic that completed the second test administration, it is not possible to compare their results directly to those in the Optifast program.

These differences in interventions may be especially true for individuals in the first weeks of treatment, when they are highly motivated and potentially actively engaged in increasing their activity level. They may be more likely to try new activities when given guidelines from healthcare providers and may experience success with these, reducing their fear level. Those patients in later phases of treatment may already be established in activity patterns or less motivated to try new activities, so their answers may be more stable over time.

Future validation of this scale should take this treatment effect into account and oversample individuals in the Risk Reduction clinic to allow for a more accurate comparison. Another alternative would be to conduct both administrations prior to program enrollment, before any intervention takes place. Additionally, it would be beneficial to explore differences between participants who are early in the treatment process and participants who are in later phases of treatment.

Body mass index. BMI was significantly correlated with total scale scores and scores on the weight-specific fears subscale, but not with the cardio-respiratory subscale. Bivariate regression analysis also showed that BMI was a significant predictor of both total scale scores and weight-specific scale scores, but not cardio-respiratory scale scores. The

ANOVA also showed that BMI accounted for 7.6% of the variance in total scale scores and 9.4% of the variance in the weight-specific subscale scores. The relationship between BMI and weight-specific scale scores was in the direction predicted by the researcher, although not as high as expected. These results indicate that while there is a relationship between BMI and scale scores, there are other factors that influence scale scores.

One of the other factors influencing scale scores may have been medical conditions. Cognitive interview participants often noted that their responses would have changed if they had experienced a cardiac event or if they had a joint disease such as arthritis. Future research should further explore the interaction between weight and medical conditions. For example, examining fear-avoidance beliefs among cardiac rehab patients who are overweight may show that weight has a larger influence in this population than among generally healthy overweight individuals.

Additionally, this study included only individuals with a BMI of $\geq$25 kg/ m^2. The correlation between BMI and fear-avoidance beliefs may be stronger if normal weight participants have lower scores than found among the current sample. This study also excluded individuals with a BMI of <60 kg/m^2. Exploring the fear avoidance beliefs of individuals in higher BMI ranges may also lead to a higher correlation between BMI and fear, especially cardio-respiratory fears. Because individuals with BMIs >60 kg/m^2 may have more extreme cardio-respiratory responses to exercise, fear avoidance beliefs may higher among this population. Future research should compare fear-avoidance beliefs among a wider range of BMI levels, including normal weight sedentary individuals and overweight individuals, as well as all levels of obesity.

Pain disability index. The PDI had a significant positive correlation with total scale scores, as well as both of the subscale scores. This is in line with previous studies that reported finding fear of pain to be more predictive of disability than pain intensity (Vlaeyen, 2000; Vlaeyen, 1995). The results of the bivariate regression indicated that all scale scores could be predicted from PDI scores. This could be helpful in a clinical practice setting where having knowledge of patients' pain levels could indicate a need to screen for fear-avoidance beliefs as well.

Limitations of the Study

Study Design

The associations between fear-avoidance beliefs, weight and physical activity level found in this study are inherently limited to due the cross-sectional nature of this study design. Due to this design, no inference can be made to the causality of weight or physical activity level on fear-avoidance belief, or the influence of these beliefs on weight and activity. Future research should explore these associations through a longitudinal design. One recommendation for this would be to measure fear-avoidance beliefs prior to exercise prescription and weight loss treatment. Assessing the influence of fear-avoidance beliefs on program adherence and outcomes would give a more complete picture of the role these beliefs may play in exercise avoidance.

A second limitation to this study was the use of self-reported physical activity measures. Self-report measures have been shown to overestimate activity (Sallis and Saleans, 2000), and the reported activity levels of the validation sample suggest this may

have been the case in this study. The average weekly minutes of moderate activity reported was 172 minutes, and the average weekly minutes of vigorous activity reported was 82 minutes. This put 25% of respondents in the medium activity category (150-300 minutes/week) and 31% in the high activity category (≥300 minutes/week). After elimination of the four outliers the mean was 215 minutes/week, with 25% of respondents in the medium activity category and 28% in the high category. These results are higher than national averages reported by the CDC, which indicate that only 48.8% of adults participated in the recommended amount of weekly physical activity (CDC, 2008).

Because overweight and obese individuals experience more exertion during activity than normal weight individuals, overestimation of activity may be more pronounced among overweight and obese individuals (Hills, Byrne, Wearing and Armstrong, 2005; Mattsson, Larsson and Rossner, 1997). While overweight individuals may have higher amounts of moderate or vigorous level activity during a typical day due to low cardiovascular fitness and higher body weight, it is important to differentiate between daily activities that are difficult due to weight, and activities that are intended as exercise. Future research should measure fear-avoidance beliefs in relation to more objective measures of physical activity. Using methods such as pedometers or accelerometry in combination with activity journaling could give a more accurate picture of the true relationship between exercise level and fear-avoidance beliefs. Additionally, incorporating measures of fitness, in addition to measures of activity level may lead to a more clear understanding of the relationship between scale scores and exercise patterns by allowing for exploration of fear of progression or higher intensity exercises.

Implications for Future Research

Further Scale Development

Given the current sample size, the researcher plans to continue to recruitment in an effort to more fully validate the tool. Further validation will include exploratory and confirmatory factor analyses of the items, as well as revisions to the test-retest design noted earlier in this chapter. The researcher also plans to more fully explore the relationship between scale responses and gender and age. Additionally, the list of medical conditions will be compared with responses to explore the influence of these on scale responses. Because these conditions were frequently referenced during the cognitive interview phase of the study, it will be important to see if these function as a predictor in the relationship between weight, physical activity, pain and fear-avoidance beliefs.

Measurement is the basic foundation of research in the science of health behavior. Therefore, continued development of a screening tool for exercise-specific fear avoidance beliefs is essential for the early identification of these beliefs. Because fear avoidance beliefs are predictive rather than reactive, it is important that these beliefs be identified early in the treatment process. Fear avoidance assessments may prove to be a valuable asset in preventive care. By conducting fear avoidance screenings with individual who are at risk for hypokinetic diseases, tailored interventions can be designed to increase activity levels prior to the onset of disease.

Assessment tools will also be useful in the secondary and tertiary treatments of overweight and obesity, as these are settings in which patients often present for treatment with habits that have been developing over a long period of time. By the time an

individual seeks medical attention for weight-related health issues, he or she may have already reached the point of avoiding movement and exercise due to fear of pain. For this reason, early recognition of fear avoidance beliefs in overweight and obese individuals is important for prescription of an exercise routine that is tailored to their specific needs, which, in turn, may lead to increased self-efficacy and improvements in program retention and adherence.

Treatment of Fear Avoidance Beliefs

When asked to discuss how exercise-induced anxiety could be decreased, the most common response in focus groups was supervision. While some specifically noted that they felt safer in a medical facility, others noted that working with a physical therapist or personal trainer on an individual basis in a gym setting was enough to decrease fear. Many participants noted that having a physician tell them they were healthy enough to exercise would reduce fear to some extent, but still felt unsafe because they were not certain what level of exertion was safe. Many also noted that an exaggerated focus on pain and cardio-respiratory responses caused them to fear that responses were symptoms of a heart attack or other health condition that they had been warned of due to their weight. These results suggest a role for targeted exercise recommendations that specifically address fear avoidance beliefs associated with exercise.

Literature on low back pain treatment indicates two approaches to treatment of fear avoidance beliefs that have shown promising results. The first of these treatments, graded exercise, was first described by Fordyce et al (1973) as an operant conditioning

approach to back pain treatment. The authors described pain as a learned behavior, and as such treatment should be focused on reducing the pain behaviors and increasing "well" behaviors. The primary goals of the treatment outlined in this study were not to reduce pain, but rather to decrease pain behaviors including medication intake and avoidant behaviors, and to increase "well" behaviors including walking and engaging in social and work activities. The procedure involved coaching the patient through an exercise protocol based on quotas established during an initial assessment process. The quota for the first exercise session was set at a point below the pain threshold. Reinforcement from the therapist was only given in the event that the task was performed to the quota level. Reinforcement came in the form of a rest break and encouragement or attention from the therapist. Once the quota was reached, it was increased for the next session. If the quota was not reached, the therapist recorded the session results without encouragement. The task was completed at the same level during the next exercise session.

The second treatment, graded exposure therapy, has been established as a plausible alternative to graded exercise and has seen increasing acceptance in physical therapy fields in recent years (George Fritz, Balosky, and Donald, 2003; George, Zeppieri, 2009). First described by Philips (1987), this treatment approach combines direct contact with the fear-inducing behavior as well as patient education. The goal is to lead patients to confront their fear in such a way that they experience success with performing the behavior pain-free. The primary difference between graded exposure and graded exercise is the condition for progression of exercise. Graded exercise progresses the exercise when the quotas set for a given exercise is met. In contrast, graded exposure progresses the exercise when the fear-avoidance level is reduced. In a typical graded

exposure protocol, a patient is presented with potentially fear-inducing stimuli. In back pain treatment this often includes a series of activities requiring lifting or bending. The patient rates which activities they fear most, and performs the activity to the level they can with no fear. During the next session, the patient completes the activity at the same level and completes a fear-avoidance questionnaire. If the fear level has decreased from the previous visit, the frequency, duration and intensity of the exercise is increased by at least 10% during the next visit. The therapist reinforces the confrontation of the fear, as well as the completion of the activity. If the fear level has not decreased, the activity is repeated at the same level during the next session. The role of the therapist in this instance is to reinforce the importance of confronting the fear and completing the activity. In addition to the exercise sessions, patients are given written educational material that explains the physiological components of back pain and prevention/treatment constructs of back pain. Patients are given readings to complete between sessions and a portion of each session is spent reviewing the reading. This process is repeated until the patient no longer reports fear of the activity (George and Zeppieri, 2009).

There is a paucity of research on clinical use of graded exposure due to its recent adaptation to clinical use with physical therapists. The primary limitation of existing research in relation to exercise-specific fear avoidance is the focus on activities of daily living (ADLs) rather than exercise intended for weight loss and fitness. For example, most of the existing literature relates case studies where the exercise sessions consisted of standing to fold laundry or lifting a load of laundry from floor to table. Future research should develop interventions that address fear-inducing exercises such as walking on a treadmill and offer patient education on heart rate response and muscle strain. Using the

same techniques of confrontation and positive reinforcement may prove helpful in allowing patients to experience higher heart rates or muscle fatigue and see successful outcomes with reduced fear.

Chapter Summary

This chapter discussed the results of this study and implication for future research. The PCA revealed a two-component structure, with an emerging third component with three items meeting the cutoff criterion and two additional items that closely approached the cutoff of .60. Given that the items in this scale related to musculoskeletal pain, which was a commonly-cited source of fear-inducing pain among focus group participants, these items will be further developed with larger samples sizes in future research. The lower-than expected test-retest results may be due, in part to differences in program interventions and the length of time participants had been involved in the program. Future research should take these differences into account and explore the impact of these two factors on the stability of scores over time.

Total scale scores were significantly correlated with pain, as measured by total PDI scores. BMI also showed a positive correlation with total scale scores, and scores on the weight-specific fears subscale, but not with scores on the cardio-respiratory subscale. Future research should examine scale scores on a wider range of BMIs to further explore the differences between responses of normal weight individuals and overweight/obese individuals.

The next steps for validation of this scale will include continued recruitment in an effort to obtain a sample large enough for confirmatory factor analysis. Additionally, co-

occurring medical conditions will be more thoroughly investigated to assess the impact of these conditions on fear avoidance beliefs in the presence and absence of obesity.

In addition to continued validation of a screening tool for exercise-specific fear avoidance beliefs, treatment protocols to counter these beliefs should be explored. Two promising alternatives include graded exercise treatment and graded exposure treatment, which have both been used in treatment of fear-avoidance beliefs in low back pain.

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APPENDIX A

TAMPA SCALE OF KINESIOPHOBIA

Ratings: 1- Strongly Disagree
2- Disagree
3- Agree
4- Strongly Agree

	Statement	Rating
1	I'm afraid that I might injure myself if I exercise	
2	If I were to try to overcome it, my pain would increase	
3	My body is telling me I have something dangerously wrong	
4	My pain would probably be relieved if I were to exercise	
5	People aren't taking my medical condition seriously enough	
6	My accident has put my body at risk for the rest of my life	
7	Pain always means I have injured my body	
8	Just because something aggravates my pain does not mean it is dangerous	
9	I am afraid that I might injure myself accidentally	
10	Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	
11	I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	
12	Although my condition is painful, I would be better off if I were physically active	
13	Pain lets me know when to stop exercising so that I don't injure myself	
14	It's really not safe for a person with a condition like mine to be physically active	
15	I can't do all the things normal people do because it's too easy for me to get injured	
16	Even though something is causing me a lot of pain, I don't think it's actually dangerous	
17	No one should have to exercise when he/she is in pain	

(Kori, Miller & Todd, 1991)

APPENDIX B

FEAR-AVOIDANCE BELIEFS QUESTIONNAIRE

Here are some of the things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 to say how much physical activities such as bending, lifting, walking or driving affect or would affect *your* back pain.

	Completely disagree			Unsure			Completely agree
1. My pain was caused by physical activity……..	0	1	2	3	4	5	6
2. Physical activity makes my pain worse…….	0	1	2	3	4	5	6
3. Physical activity might harm my back……..	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse…...	0	1	2	3	4	5	6

The following statements are about how your normal work affects or would affect your back pain

	Completely disagree			Unsure			Completely agree
6. My pain was caused by my work or by an accident at work……	0	1	2	3	4	5	6
7. My work aggravated my pain……	0	1	2	3	4	5	6
8. I have a claim for compensation for my pain……	0	1	2	3	4	5	6
9. My work is too heavy for me……..	0	1	2	3	4	5	6
10. My work makes or would make my pain worse……..	0	1	2	3	4	5	6
11. My work might harm my back……..	0	1	2	3	4	5	6
12. I should not do my normal work with my present pain…….	0	1	2	3	4	5	6
13. I cannot do my normal work with my present pain……...	0	1	2	3	4	5	6
14. I cannot do my normal work till my pain is treated……..	0	1	2	3	4	5	6
15. I do not think that I will be back to my normal work within 3 months.	0	1	2	3	4	5	6
16. I do not think that I will ever be able to go back to that work……...	0	1	2	3	4	5	6

Scoring

Scale 1: fear-avoidance beliefs about work – items 6, 7, 9, 10, 11, 12, 15.

Scale 2: fear-avoidance beliefs about physical activity – items 2, 3, 4, 5.

(Waddell, 1993)

APPENDIX C

INSTITUTIONAL REVIEW BOARD APPROVAL FOR THE STUDY

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on October 26, 2010. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56 and ICH GCP Guidelines.

Principal Investigator:	WINGO, BROOKS
Co-Investigator(s):	ARD, JAMY D EVANS, RETTA R ROY, JANE SNYDER, SCOTT W
Protocol Number:	**X081208014**
Protocol Title:	*Development of a scale to measure fear of exercise-induced pain in overweight and obese adults*

The IRB reviewed and approved the above named project on 11-11-09. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review.

IRB Approval Date: 11-11-09

Date IRB Approval Issued: 11-11-09

Marilyn Doss

Marilyn Doss, M.A.
Vice Chair of the Institutional Review
Board for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

470 Administration Building
701 20th Street South
205.934.3789
Fax 205.934.1301
irb@uab.edu

The University of
Alabama at Birmingham
Mailing Address:
AB 470
1530 3RD AVE S
BIRMINGHAM AL 35294-0104

APPENDIX D

SCALE DEVELOPMENT
INFORMED CONSENT FORMS

Informed Consent-Focus Group

University of Alabama at Birmingham
School of Public Health
Department of Health Behavior

TITLE OF RESEARCH: Development of a scale to measure fear of exercise-induced pain in overweight and obese adults

IRB PROTOCOL NUMBER: X081208014

INVESTIGATOR: Brooks C. Wingo, MSW

SPONSOR: UAB Department of Health Behavior

Explanation of Procedures

You are being asked to participate in a research study that examines how people interpret pain that is experienced during and after exercise. Before beginning the focus group, we will measure your height and weight to determine if you are eligible to take part in this study. We will also ask you to complete questionnaires related to exercise and daily level of pain.

In a group format, you will be asked to discuss your knowledge, beliefs, and experiences about exercise, and how your body reacts to exercise. The purpose of this group discussion is to identify areas of exercise that people may fear, or responses to exercise that make people avoid exercising again in the future. The results of this discussion will be used to develop a questionnaire for weight loss patients. The group discussion session will be approximately 1 to 2 hours in duration.

If you decide to participate, you will be asked questions (in a group format of approximately 10 people) related to your exercise habits and the various types of pain you may have felt while exercising. The focus groups will be recorded using a digital voice recorder. However, recordings will not be publicly aired or distributed and will be kept in a secure space in which only the principal investigator and select research staff have access. All information obtained will be used entirely for the purpose of this study. Focus group and individual activity information will be reported only for groups of participants. Results of individuals will not be reported.

Participant's Initials:_____

UAB – IRB
Consent Form Approval 12/23/08
Expiration Date 12/23/09

Risks and Discomforts
There are no major risks or discomforts associated with participating in this study. However, there is a risk is associated with potential loss of privacy. Participants will be asked to give responses to questions in a group setting. Some individuals may experience discomfort speaking in front of a group and/or having their responses recorded.

Benefits
There may be no personal benefit from your participation in this research; however, your participation may provide valuable information to the public health community about how to assess patients' fears associated with exercise.

Alternatives
Participants may request that detailed written notes are taken rather than recorded (if this is requested, the participant must answer questions in an individual interview rather than a group discussion). Another alternative would be not to participate in the study.

Confidentiality
After the focus group, the digital voice recordings will be downloaded onto a secure computer, then deleted from the digital recorder. The data will be stored and protected on a secure UAB server, accessible to research personnel only. All audio recordings will be destroyed upon completion of the study.

Information obtained about you for this study will be kept private to the extent allowed by law. However, the following groups will be able to view your medical records and have access to private information that identifies you by name: the Office for Human Research Protections (OHRP) and UAB's Institutional Review Board (IRB). The results of the research may be published for scientific purposes. These results will include a summary of what we observe. However, your identity will not be given out. In addition, if you are UAB employee or student, your employer will not be notified of your participation in this study without your consent.

Refusal or Withdrawal Without Penalty
Your taking part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will

Participant's Initials:_____

not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution or the EatRight Weight Management Program.

What if you are a UAB Employee? Taking part in this research is not a part of your UAB duties, and refusing will not affect your job or relationship with UAB. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you are a UAB Student? You may choose not to be in the study or you may withdraw (stop) from the study at any time before it is over. This will not affect your class standing or grades at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation
There is no cost to you for taking part in this study.

Payment for participation in Research
If you are eligible for this study and you choose to participate, you will receive a $15 debit card for your participation in the group discussion meeting.

Questions
If you have any questions, concerns, or complaints about the research, please contact Brooks Wingo. She will be glad to answer any of your questions 205-996-5029. You may also contact her advisor, Dr. Monica Baskin at 205-975-5704.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Ms. Sheila Moore. Ms. Moore is the Director of the Office of the Institutional Review Board for Human Use (OIRB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816. If calling the toll -free number, press the option for "all other calls" or for an operator/attendant and ask for extension 4-3789.Regular hours for the Office of the IRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal right
You are not waiving any of your legal rights by signing this informed consent.

Participant's Initials:_____

Signatures

Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.

Signature of Participant Date

Signature of Investigator Date

Signature of Witness Date

Signature of person obtaining consent (if other than the investigator). Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant Name:_____
Research Protocol: Development of a scale to measure fear of exercise- induced pain in overweight and obese adults

UAB IRB Protocol Number: **X081208014**
Principal Investigator: Brooks C. Wingo, MSW

Sponsor: UAB Dept of Health Behavior

What health information do the researchers want to use? All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, The Children's Hospital of Alabama, Callahan Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant:_____ Date:_____
or participant's legally authorized representative:_____ Date:_____
Printed Name of participant's representative:_____
Relationship to the participant:_____

UAB Consent Form – Cognitive Interview

University of Alabama at Birmingham
School of Public Health
Department of Health Behavior

TITLE OF RESEARCH: Development of a scale to measure fear of exercise-induced pain in overweight and obese adults

IRB PROTOCOL NUMBER: **X081208014**

INVESTIGATOR: Brooks C. Wingo, MSW

SPONSOR: UAB Department of Health Behavior

Explanation of procedures:
You are being asked to participate in a research study that examines how people interpret pain that is experienced during and after exercise. Before beginning the interview, we will measure your height and weight to determine if you are eligible to take part in this study. We will also ask you to complete questionnaires related to exercise and daily level of pain.

In a one-on-one format, you will be asked to read the instructions, questions and answer choices for a questionnaire that is being developed. You will then be asked questions about the clarity and ease of use of the questionnaire. The interview session will be approximately1 hour in duration.

All opinions you give will be used to improve the questionnaire for future use. All information obtained will be used entirely for the purpose of this study.

Risks and Discomforts
There are no major risks or discomforts associated with participating in this study. However, there is a risk is associated with potential loss of privacy. Participants will be asked to give responses to questions, some individuals may experience discomfort speaking with the researcher in an individual setting.

Benefits
There may be no personal benefit from your participation in this research;

Participant's Initials_____

UAB – IRB
Consent Form Approval 12/23/08
Expiration Date 12/23/09

however, your participation may provide valuable information to the public health community about how to assess patients' fears associated with exercise.

Alternatives
The only alternative would be not to participate in the study.

Confidentiality
Data will be stored and protected on a secure UAB server, accessible to research personnel only. All audio recordings will be destroyed upon completion of the study.

Information obtained about you for this study will be kept private to the extent allowed by law. However, the following groups will be able to view your medical records and have access to private information that identifies you by name: the Office for Human Research Protections (OHRP) and UAB's Institutional Review Board (IRB). The results of the research may be published for scientific purposes. These results will include a summary of what we observe. However, your identity will not be given out. In addition, if you are UAB employee or student, your employer will not be notified of your participation in this study without your consent.

Refusal or Withdrawal Without Penalty
Your taking part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution or the EatRight Weight Management Program.

What if you are a UAB Employee? Taking part in this research is not a part of your UAB duties, and refusing will not affect your job or relationship with UAB. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you are a UAB Student? You may choose not to be in the study or you may withdraw (stop) from the study at any time before it is over. This will not affect your class standing or grades at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation
There is no cost to you for taking part in this study.

Payment for participation in Research
If you are eligible for this study and you choose to participate, you will receive a $15 debit card for your participation in the interview.

Participant's Initials_____

Questions
If you have any questions, concerns, or complaints about the research, please contact Brooks Wingo. She will be glad to answer any of your questions 205-996-5029. You may also contact her advisor, Dr. Monica Baskin at 205-975-5704.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Ms. Sheila Moore. Ms. Moore is the Director of the Office of the Institutional Review Board for Human Use (OIRB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816. If calling the toll -free number, press the option for "all other calls" or for an operator/attendant and ask for extension 4-3789.Regular hours for the Office of the IRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal right
You are not waiving any of your legal rights by signing this informed consent.

Signatures

Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.

Signature of Participant Date

Signature of Investigator Date

Signature of Witness Date

Signature of person obtaining consent (if other than the investigator). Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant Name:_____ UAB IRB Protocol Number: X081208014

Research Protocol: Development of a scale to measure fear of exercise- induced pain in overweight and obese adults

Principal Investigator: Brooks C. Wingo, MSW

Sponsor: UAB Department of Health Behavior

What health information do the researchers want to use? The researchers are interested in your participation in the EatRight program. All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, The Children's Hospital of Alabama, Callahan Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant:_____ Date:_____
or participant's legally authorized representative:_____ Date:_____
Printed Name of participant's representative:_____
Relationship to the participant:_____

APPENDIX E

SCALE DEVELOPMENT
PARTICIPANT RECRUITMENT PHONE SCRIPTS

Focus Group Script

Hello, my name is Brooks Wingo and I work with the EatRight program at UAB. I am a student here, and I am conducting a study to look at the role of pain, and pain-related fear in exercise adherence. The goal of the study is to develop a measurement tool that will help healthcare providers better address fears related to starting a new exercise program.

The portion of the study that I would like for you to participate in is a focus group. Our group discussion will take between 1 – 2 hours. We will measure your height and weight, but that is the only physical measures or test that will be performed. The group will be held at the Webb Nutrition Sciences building. As a thank you, you will receive a $15 gift certificate for participating in the group.

Participation in this study is completely voluntary, and your decision to participate will not affect your treatment in anyway. If you agree to participate, all information will be kept confidential and you can ask questions or stop at any time.

To make sure you are eligible to participate, I need to ask you a few questions. The questions will take about 3 minutes. Before we start, do you have any questions for me?

How old are you (today)? [Must between 20 and 65]

Are you currently under a doctor's instructions to avoid physical activity or exercise? (Must answer no)

What is your weight at this time?

Eligible - Thank you, you are eligible. We have scheduled two groups, and you may choose which one works best for you. The days/times are_____. Which one would work best for you?

Would you prefer an email or phone call reminder?

I will send you papers that explain the study in more detail, please look over these. When you arrive for the group we will go over these and you will have time to ask any questions you may have. What is the best way to send these to you (email, fax or mail)?

If you have any additional questions or need to reschedule please contact me at 996-5029.

Not eligible – Thank you for your time and interest in this study. Unfortunately, you are not eligible for this study at this time.

Cognitive Interview Script

Hello, my name is Brooks Wingo and I work with the EatRight program at UAB. I am a student here, and I am conducting a study to look at the role of pain, and pain-related fear in exercise adherence. The goal of the study is to develop a measurement tool that will help healthcare providers better address fears related to starting a new exercise program.

The portion of the study that I would like for you to participate in is an interview in which you will give me feedback about a new questionnaire that is being developed. I will ask you to read the items and answer questions about your understanding of the questions being asked. The interview will take between 30 minutes and 1 hour. We will measure your height and weight, but that is the only physical measures or test that will be performed. The interview will be held at the Webb Nutrition Sciences building. As a thank you, you will receive $15 for participating in the group.

Participation in this study is completely voluntary, and your decision to participate will not affect your treatment in anyway. If you agree to participate, all information will be kept confidential and you can ask questions or stop at any time.

To make sure you are eligible to participate, I need to ask you a few questions. Before we start, do you have any questions for me?

How old are you (today)? [Must between 20 and 65]

Are you currently under a doctor's instructions to avoid physical activity or exercise? (Must answer no)

Eligible - Thank you, you are eligible. Let's set up a time when we can get

together.

When is a good day and time for you?

Would you prefer an email or phone call reminder?

I will send you papers that explain the study in more detail, please look over these. When you arrive for the interview we will go over these and you will have time to ask any questions you may have. What is the best way to send these to you (email, fax or mail)?

If you have any additional questions or need to reschedule please contact me at 996-5029.

Not eligible – Thank you for your time and interest in this study. Unfortunately, you are not eligible for this study at this time.

APPENDIX F

HEIGHT AND WEIGHT MEASUREMENT PROTOCOL

Height

Height is measured in US customary units to the nearest 0.25 inch. Instruct the participant to remove shoes and headgear and to stand erect with feet flat on the floor and both heels together. Feet should be touching the 2x4 board mounted on the base of the wall. The participant stands erect with back, shoulder blades, and buttocks in contact with the wall. The participant's weight should be evenly distributed on both feet, and arms remain relaxed at the sides with palms facing inward.

Ask the participant to inhale deeply and maintain a fully erect position without altering the load on the heels. Bring the height board snugly, but not tightly, on the top of the participant's head. Record height to nearest 0.25 in.

Weight

Body weight measurements are taken to the nearest 0.5 lb. Instruct the participant to remove shoes, headgear, coat, etc., and heavy items in the pockets (e.g., keys or wallets) in order to be weighed in light indoor clothing. All body weights are measured on a digital scale, which is placed on a firm, level surface.

Ask the participant to stand in the center of the scale platform, since standing off-center may affect the weight measurement. The participant should stand with arms relaxed at the sides, head erect, and eyes looking straight ahead.

Make sure the scale reads "0" before the participant stands on the measurement platform. When the digital readout stabilizes, record the observed weight to the nearest 0.5 lb.

APPENDIX G

BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM PHYSICAL ACTIVITY QUESTIONNAIRE

1. When you are at work, which of the following best describes what you do?
    a. Mostly sitting or standing
    b. Mostly walking
    c. Mostly heavy labor or physically demanding work
    d. Don't know / Not sure

We are interested in two types of physical activity – vigorous and moderate. Vigorous activities cause large increases in breathing or heart rate while moderate activities cause small increases in breathing or heart rate.

2. Now, thinking about the **moderate** physical activities you do when you are not working in a usual week, do you do moderate activities for at least 10 minutes at a time, such as brisk walking, bicycling, vacuuming, gardening, or anything else that causes small increases in breathing or heart rate?

    a. Yes
    b. No
    c. Don't know/Not sure

If "Yes," answer the next 2 questions, otherwise skip to question 3.

2a. How many days per week do you do these moderate activities for at least 10 minutes at a time?

___ Days per week

___ Do not exercise at least 10 minutes weekly

__ Don't know/Not sure

2b. On days when you do moderate activities for at least 10 minutes at a time, how much total time per day do you spend doing these activities?

___: ___ ___ Hours and minutes per day

__ Don't know/Not sure

3. Now, thinking about the **vigorous** physical activities you do when you are not working in a usual week, do you do vigorous activities for at least 10 minutes at a time, such as running, aerobics, heavy yard work, or anything else that causes large increases in breathing or heart rate?
    a. Yes
    b. No
    c. Don't know/Not sure

If "Yes," answer the next 2 questions.

3a. How many days per week do you do these vigorous activities for at least 10 minutes at a time?

___ Days per week

___ Do not exercise at least 10 minutes week

__ Don't know/Not sure

3b. On days when you do vigorous activities for at least 10 minutes at a time, how much total time per day do you spend doing these activities?

___: ___ ___ Hours and minutes per day

__ Don't know/Not sure

APPENDIX H

PAIN DISABILITY INDEX

For the 7 areas listed below, please circle the number on the scale which describes the level of disability you typically experience. A score of "0" means no disability at all, and a score of "10" indicates that all of the activities which you would normally do have been totally disrupted or prevented by your pain over the past week. Circle "0" if a category does not apply to you.

Family/Home Responsibilities: This category refers to activities related to the home or family. It includes
chores or duties performed around the house (e.g. yard work, house cleaning) and errands or favors for other family members (e.g. driving the children to school.

0 1 2 3 4 5 6 7 8 9 10
No Disability *Mild* *Moderate* *Severe* *Total Disability*

Recreation: This category includes hobbies, sports, and other similar leisure time activities.

0 1 2 3 4 5 6 7 8 9 10
No Disability *Mild* *Moderate* *Severe* *Total Disability*

Social Activity: This category refers to activities which involve participation with friends and acquaintances other than family members. It includes parties, theater, concerts, dining out, and other social functions.

0 1 2 3 4 5 6 7 8 9 10
No Disability *Mild* *Moderate* *Severe* *Total Disability*

Occupation: This category refers to activities that are a part of or directly related to one's job. This includes non-paying jobs as well, such as housewife or volunteer worker.

0 1 2 3 4 5 6 7 8 9 10
No Disability *Mild* *Moderate* *Severe* *Total Disability*

Sexual Behavior: This category refers to the frequency and quality of one's sex life.
0 1 2 3 4 5 6 7 8 9 10
No Disability *Mild* *Moderate* *Severe* *Total Disability*

Self-Care: This category includes activities which involve personal maintenance and independent daily living (e.g. taking a shower, driving, getting dressed).
0 1 2 3 4 5 6 7 8 9 10
No Disability *Mild* *Moderate* *Severe* *Total Disability*

Life-Support Activity: This category refers to basic life-supporting behaviors such as eating and sleeping.

0	1	2	3	4	5	6	7	8	9	10
No Disability		*Mild*		*Moderate*			*Severe*		*Total Disability*	

(Pollard, 1984)

APPENDIX I

FOCUS GROUP QUESTIONS

1. When thinking about exercise such as brisk walking, jogging, aerobic classes, or swimming, what are some typical physical responses you experience during or after exercise? These can be things you have experienced in the past, or things that you expect to experience from exercise.

2. What are some factors that would make you think responses to exercises are safe? What are some factors that would make you think responses are signaling some form of danger?

3. How are physical responses to exercise different between overweight and normal weight individuals?

4. How might a physical response be interpreted differently for an overweight person and a normal weight person? For example, would an increased heart rate mean the same thing for an overweight person as it would for a normal weight person?

5. Is exercise safe for people who are overweight?
    a. For those who have lost weight: Do you feel safer exercising since losing weight? Why?
    b. For those who have not lost weight yet: Do you think you will feel safer exercising if you lost weight? Why?

6. Tell me about any circumstances or situations that make you feel safer exercising? Tell me about any circumstances or situations that make you feel less safe exercising?

APPENDIX J

INITIAL ITEM POOL

1. My weight makes it dangerous for me to exercise.
2. The pain that I experience during exercise would probably get better if I exercised more often.
3. Pain always means I have injured my body.
4. If exercise aggravates a previous injury, then exercise should be avoided.
5. I'm afraid that I may harm myself if I exercise.
6. Exercise is dangerous for my heart.
7. It is unsafe for me to do the same exercises as a person of normal weight.
8. I feel safe exercising on my own.
9. When I experience discomfort during or after exercise it is a signal from my body that I should not exercise.
10. Exercise is safe for a person my weight.
11. When I exercise, I often worry that I may have a heart attack.
12. It is not safe for people who are overweight or obese to exercise.
13. Activities that result in sweating or heavy breathing make me feel unsafe.
14. People who are overweight or obese need to start exercising at a slower pace than people who are normal weight.
15. My weight puts additional stress on my body that makes it unsafe for me to exercise.
16. I need to lose weight before I can exercise safely.
17. My weight makes it unsafe for me to try new physical activities.
18. It is not safe for me to increase my activity level until I lose weight.
19. I will feel safe exercising if my doctor tells me I need to.
20. It is not safe for people who are overweight or obese to exercise alone.
21. If I experience discomfort while exercising it is a sign that I am in danger.
22. I will feel safe exercising if a medical professional shows me how.
23. I experience less pain when I lose weight, which means exercise is safer when I lose weight.
24. I feel safer exercising when someone else exercises with me.
25. I feel safe planning my exercise routine on my own.
26. If I experience discomfort while exercising it is a sign that I need to stop exercising.
27. There are some exercises that are unsafe for me because of my weight.
28. I feel safe trying new exercises.
29. It is not safe for me to do some exercises because of my weight.
30. I am safe to continue exercising after I experience pain if that pain goes away as soon as I stop exercising.
31. I need to limit the amount of exercise I do because of my weight.
32. When I feel discomfort or pain from activity, it is difficult for me to focus on anything else.

APPENDIX K

EXPERT REVIEW TOOL

Physical Response to Exercise: Expert Review

1. Scale Directions

Please provide comments and/or suggestions for the scale directions.

*** 1. Directions: Read each of the following statements and rank your agreement or disagreement using the scale Strongly Disagree (1), Disagree (2), Neither Agree or Disagree (3), Agree (4), or Strongly Agree (5).**

2. Item Pool

Please rate each item as Essential, Useful but not Essential, or Not Necessary. Use the text box below for any suggestions for revisions or general questions/comments about the item.

*** 2. My weight makes it dangerous for me to exercise.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 3. The pain that I experience during exercise would probably get better if I exercised more often.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

Physical Response to Exercise: Expert Review

*** 4. Pain always means I have injured my body.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 5. If exercise aggravates a previous injury, then exercise should be avoided.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 6. I'm afraid that I may harm myself if I exercise.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

Physical Response to Exercise: Expert Review

*** 7. Exercise is dangerous for my heart.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 8. It is unsafe for me to do the same exercises as a person of normal weight.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 9. I feel safe exercising on my own.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

Physical Response to Exercise: Expert Review

*** 10. When I experience discomfort during or after exercise it is a signal from my body that I should not exercise.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

3. Item Pool-continued

*** 11. Exercise is safe for a person my weight.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

Physical Response to Exercise: Expert Review

*** 12. When I exercise, I often worry that I may have a heart attack.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 13. It is not safe for people who are overweight or obese to exercise.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 14. Activities that result in sweating or heavy breathing make me feel unsafe.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

Physical Response to Exercise: Expert Review

*** 15. People who are overweight or obese need to start exercising at a slower pace than people who are normal weight.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 16. My weight puts additional stress on my body that makes it unsafe for me to exercise.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 17. I need to lose weight before I can exercise safely.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

Physical Response to Exercise: Expert Review

*** 18. My weight makes it unsafe for me to try new physical activities.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 19. It is not safe for me to increase my activity level until I lose weight.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 20. I will feel safe exercising if my doctor tells me I need to.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

4. Item Pool-continued

Physical Response to Exercise: Expert Review

*** 21. It is not safe for people who are overweight or obese to exercise alone.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 22. If I experience discomfort while exercising it is a sign that I am in danger.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 23. I will feel safe exercising if a medical professional shows me how.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

Physical Response to Exercise: Expert Review

*** 24. I experience less pain when I lose weight, which means exercise is safer when I lose weight.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 25. I feel safer exercising when someone else exercises with me.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 26. I feel safe planning my exercise routine on my own.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

Physical Response to Exercise: Expert Review

*** 27. If I experience discomfort while exercising it is a sign that I need to stop exercising.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 28. There are some exercises that are unsafe for me because of my weight.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 29. I feel safe trying new exercises.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

Physical Response to Exercise: Expert Review

*** 30. It is not safe for me to do some exercises because of my weight.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

5. Item Pool- continued

*** 31. I am safe to continue exercising after I experience pain if that pain goes away as soon as I stop exercising.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

Physical Response to Exercise: Expert Review

*** 32. I need to limit the amount of exercise I do because of my weight.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

*** 33. When I feel discomfort or pain from activity, it is difficult for me to focus on anything else.**

- ◯ Essential
- ◯ Useful, but not essential
- ◯ Not necessary

Comments and/or Suggestions for Revisions

6. Response Choices

Please provide comments and/or suggestions for revisions for the response set.

34. All questions will use the following response set:
Strongly Disagree
Disagree
Neither Agree or Disagree
Agree
Strongly Agree

7. General Comments

Physical Response to Exercise: Expert Review

Please give general feedback and/or suggestions on the scale.

35. General Feedback

APPENDIX L

REVISED DIRECTIONS FOR SECOND EXPERT REVIEW

The purpose of this scale is to measure fear of negative consequences from exercise among individuals who are overweight or obese. This is a fear of any physical reaction to exercise, such as fear of injury or harm resulting from participating in exercise. This fear may arise from direct experiences with exercise in the past, or from anticipated responses to exercise that are expected though never experienced. Additionally, the scale is intended to measure avoidance of exercise resulting from this fear.

Specifically, this scale is intended to measure two types of physical responses to exercise: musculoskeletal pain or injury, and cardio-respiratory responses. Musculoskeletal responses include pain or injury such as joint pain, sprains or pulled muscles. Cardio-respiratory responses include increased heart rate, shortness of breath, or sweating.

There are three groups of questions in this scale. The first relates to general fear of physical consequences of exercise and the role weight plays in this fear. It is also intended to measure avoidance of exercise based on this fear. The second relates specifically to fear of musculoskeletal pain or injury and exercise avoidance resulting from this fear. The third relates specifically to fear of cardio-respiratory responses and exercise avoidance resulting from this fear.

You are being asked to rate how essential each item is for measuring the three components of this scale. Please rate each item as essential, useful but not essential, or not necessary based on the item's ability to measure the related component of fear of physical response to exercise and exercise avoidance based on this fear. Additionally, please provide feedback on the clarity and wording of the scale directions, items, and answer choices in the text boxes provided.

APPENIDIX M

ITEM POOL USED IN COGNITIVE INTERVIEWS

1. I need to lose weight before I can exercise safely.
2. There are some exercises that are unsafe for me because of my weight.
3. I'm afraid that I may harm myself if I exercise.
4. My weight puts stress on my body that makes it dangerous for me to exercise.
5. My weight makes me scared to try new exercises.
6. If exercise makes a previous injury worse, then I am afraid that continuing to exercise could harm me.
7. Pain during exercise means I am injuring myself.
8. If I experience pain in my muscles or joints while exercising, it is a sign that I need to stop exercising.
9. I am safe to continue exercising after I experience muscle or joint pain, if that pain goes away as soon as I stop exercising.
10. Just because exercise causes muscle or joint pain does not mean it is dangerous.
11. Pain in my muscles or joints lets me know when to stop exercising so that I don't injure myself.
12. When I exercise, I often worry that I may have a heart attack.
13. Exercise is dangerous for my heart.
14. Exercises that make me sweat or breath heavy make me feel unsafe.
15. When I experience heavy breathing or increased heart beat during or after exercise it is a signal from my body that I should not exercise.
16. I should not do exercises that raise my heart rate because they are dangerous for me.

APPENDIX N

COGNITIVE INTERVIEW SCRIPT

Cognitive Interview Introduction: I am going to give you a survey that is being developed for use in weight loss clinics. The purpose of this interview is to give us an idea of how easy the survey is to understand. We will go over the directions to the survey, and then we will go through each question and the answer choices. How you would answer each of the questions is not important at this time. So your responses to the questions will not be recorded. After reading each question, I will ask you a series of questions about how you came up with your answer. So I may ask you to reword the question in your own words, or I may ask you if any phrases were unclear to you. Your responses to these questions will help to revise the survey so that it is easier to use. Do you have any questions before we get started?

Initial Thoughts: To get started can you tell me what you think when you first look at the survey? Please let me know what you are thinking about the way it looks, the colors, or any other thoughts you have when you first look at the survey.

Now, take a few minutes to read through the survey. I would like for you to read all of the directions and each question to yourself.

(Give participant 2nd version with sub-scale directions) Now, please look over this version of the survey, which has a different set of directions.

Which survey did you find easier to answer?

Did the difference in directions make a difference to the way you answered any of the questions?

Please read the directions to yourself.

Directions: Read each of the following statements. Then rank your response to each statement using the following choices: (1) Strongly Disagree; (2) Disagree; (3) Neither Agree nor Disagree; (4) Agree; (5) Strongly Agree

- Can you tell me, in your own words, what these directions are asking you to do?
- Are there any words or phrases in these directions that are unclear?

Please read the first question to yourself. (For each question, have participant read the statement to themself and then ask them the questions).

Q1: I need to lose weight before I can exercise safely.

- Tell me what you think this statement means
- In this statement, what does the word "safely" mean to you?
- Are there any words or phrases in this statement that are unclear?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q2: There are some exercises that are unsafe for me because of my weight.

- Tell me what you think this statement means.
- In this statement, what does the word "unsafe" mean to you?
- How would your answer change (if at all), if the word "some" was removed from this statement?
- Are there any words or phrases in this statement that are unclear?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q3: I am afraid that I may harm myself if I exercise.

- Tell me what you think this statement means.
- In this statement, what does the word "harm" mean to you?
- Are there any words or phrases in this statement that are unclear?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q4: My weight puts stress on my body that makes it dangerous for me to exercise.

- Tell me what you think this statement means.
- In this statement, what does the word "stress" mean to you?
- In this statement, what does the work "dangerous" mean to you?
- Are there any words or phrases in this statement that are unclear?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q5: My weight makes me scared to try new physical activities.

- Tell me what you think this statement means.
- What does the phrase "new physical activities" mean to you?
- How would your answer change (if at all) if the term "physical activity" was replaced with the term "exercise" in this statement?
- Are there any words or phrases in this statement that are unclear?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q6: If exercise makes a previous injury worse, then I am afraid that continuing to exercise could harm me.

- Tell me what you think this statement means.
- Are any words or phrases in this question unclear?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q7: Pain during exercise means I am injuring myself.

- Tell me what you think this statement means.
- What does the term "injuring" mean to you?
- Are any words or phrases in this question unclear?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q8: If I experience pain in my muscles or joints while exercising, it is a sign that I need to stop exercising.

- Tell me what you think this statement means.
- In this question, what does the term "muscle or joint pain" mean to you?
- In this statement, what does the phrase "stop exercising" mean to you? (Follow-up prompt: Does it mean stop that particular exercise session or stopping exercise all together, such as not exercising again in the future; does is mean stop until the pain goes away, or stop completely)
- Are any words or phrases in this question unclear?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q9: I am safe to continue exercising after I experience muscle or joint pain, if that pain goes away as soon as I stop exercising.

- Tell me what you think this statement means.
- Are any words or phrases of this statement unclear to you?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q10: Just because exercise causes muscle or joint pain does not mean it is dangerous.

- Tell me what you think this statement means.
- In this statement, what does the word "dangerous" mean to you?
- Are any words or phrases of this statement unclear to you?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q11: Pain in my muscles or joints lets me know when to stop exercising so that I don't injure myself.

- Tell me what you think this statement means.
- How (if at all) would you answer this question differently if the phrase "so that I don't injure myself" were taken out?
- Are any words or phrases of this statement unclear to you?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q12: When I exercise, I often worry that I may have a heart attack.

- Tell me what you think this statement means.
- In this statement, what does the word "often" mean to you?
- Are any words or phrases of this statement unclear to you?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q13: Exercise is dangerous for my heart.

- Tell me what you think this statement means.
- In this statement, what does the word "dangerous" mean to you?
- Are any words or phrases of this statement unclear to you?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q14: Exercises that make me sweat or breath heavy make me feel unsafe.

- Tell me what you think this statement means.

- How do you define “breath heavy?”
- Are any words or phrases of this statement unclear to you?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q15: When I experience heavy breathing or increased heart beat during or after exercise it is a signal from my body that I should not exercise.

- Tell me what you think this statement means.
- How (If at all) would you answer this question differently if the statement was reworded so that end of the statement ready “…should not continue exercising.”
- Are any words or phrases of this statement unclear to you?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

Q16: I should not do exercises that raise my heart rate because they are dangerous for me.

- Tell me what you think this statement means.
- How do you define “raise my heart rate?”
- How high would your heart rate need to be to make you feel danger?
- Are any words or phrases of this statement unclear to you?
- On a scale of 1-4, with 1 = very easy, 2 = somewhat easy, 3 = somewhat difficulty, 4 = very difficult, how easy was this item to rank?

APPENDIX O

FINAL SCALE USED FOR VALIDATION

Directions: Read each of the following statements. Then rank your response to each statement using the following choices: (1) Strongly Disagree; (2) Disagree; (3) Neither Agree nor Disagree; (4) Agree; (5) Strongly Agree

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. I need to lose weight before I can exercise safely.	1	2	3	4	5
2. There are some exercises that are unsafe for me because of my weight.	1	2	3	4	5
3. I am afraid that I may harm myself if I exercise.	1	2	3	4	5
4. My weight puts stress on my body that makes it dangerous for me to exercise.	1	2	3	4	5
5. My weight makes me scared to try new exercises.	1	2	3	4	5
6. If exercise makes a previous injury worse, then I am afraid that continuing to exercise could harm me.	1	2	3	4	5

Directions: The following questions relate to pain in your muscles or joints. Read each of the following statements. Then rank your response to each statement using the following choices:
(1) Strongly Disagree; (2) Disagree; (3) Neither Agree nor Disagree; (4) Agree; (5) Strongly Agree

7. Pain during exercise means I am injuring myself.	1	2	3	4	5
8. If I experience pain in my muscles or joints while exercising, it is a sign that I need to stop exercising.	1	2	3	4	5

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
9. I am safe to continue exercising after I experience muscle or joint pain if that pain goes away as soon as I stop exercising.	1	2	3	4	5
10. Just because exercise causes muscle or joint pain does not mean it is dangerous.	1	2	3	4	5
11. Pain in my muscles or joints lets me know when to stop exercising so that I don't injure myself.	1	2	3	4	5

Directions: The following questions relate to your thoughts about your heart and lungs may feel during or after exercise. Read each of the following statements. Then rank your response to each statement using the following choices: (1) Strongly Disagree; (2) Disagree; (3) Neither Agree nor Disagree; (4) Agree; (5) Strongly Agree

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
12. Exercises that make me sweat or breathe heavy make me feel unsafe.	1	2	3	4	5
13. Exercise is dangerous for my heart.	1	2	3	4	5
14. When I exercise, I often worry that I may have a heart attack.	1	2	3	4	5
15. I should not do exercises that raise my heart rate because they are dangerous for me.	1	2	3	4	5
16. When I experience heavy breathing or increased heart beat during or after exercise it is a signal from my body that I should not exercise.	1	2	3	4	5

APPENIDIX P

MEDICAL CONDITION CHECKLIST

Have you ever been told that you have any of the following medical conditions? (Please check all that apply)

High blood pressure

Coronary artery disease

Heart disease other than coronary artery disease

Heart attack

Stroke

Mitral valve prolapse

Heart murmur

Pulmonary hypertension

COPD

Asthma

Diabetes

High Cholesterol

Acid Reflux or GERD

Crohn's Disease

Celiac

Chronic Kidney Disease

Fibromyalgia

Arthritis

Joint pain other than arthritis

Plantar Fasciitis

Osteoporosis

Herniated Disk

Degenerative Joint Disease

Sleep Apnea

Chronic Sinusitis

Polycystic Ovarian Syndrome (PCOS)

Migraines

Chronic Fatigue Syndrome

APPENIDIX Q

SCALE VALIDATION
INFORMED CONSENT FORMS

UAB Consent Form –Scale Validation

University of Alabama at Birmingham
School of Public Health
Department of Health Behavior

TITLE OF RESEARCH: Development of a scale to measure fear of exercise-induced pain in overweight and obese adults

IRB PROTOCOL NUMBER: **X081208014**

INVESTIGATOR: Brooks C. Wingo, MSW

SPONSOR: UAB Department of Health Behavior

Explanation of procedures:
You are being asked to participate in a research study that examines how people interpret pain that is experienced during and after exercise. Before beginning the questionnaire, we will measure your height and weight to determine if you are eligible to take part in this study.

If you decide to participate, you will be asked to complete a series of questionnaires. These will include questions regarding your usual exercise habits, medical conditions, your daily level of pain, and you thoughts about pain that is caused by exercise. The purpose of this study is to examine the usefulness of these questionnaires in weight loss treatment. The time required for completing these questionnaires is approximately 30 minutes.

Risks and Discomforts
There are no major risks or discomforts associated with participating in this study. However, there is a risk is associated with potential loss of privacy. Participants will be asked to give responses to questions, some individuals may experience discomfort answering questions about pain.

Benefits
There may be no personal benefit from your participation in this research; however, your participation may provide valuable information to the public health

Participant's Initials: _____

UAB-IRB
Consent Form Approval 11-11-09
Expiration Date 11-11-10

community about further understanding how to assess patients' fears associated with exercise.

Alternatives
The only alternative would be not to participate in the study.

Confidentiality
Data will be stored and protected on a secure UAB server, accessible to research personnel only.

Information obtained about you for this study will be kept private to the extent allowed by law. However, the following groups will be able to view your medical records and have access to private information that identifies you by name: the Office for Human Research Protections (OHRP) and UAB's Institutional Review Board (IRB). The results of the research may be published for scientific purposes. These results will include a summary of what we observe. However, your identity will not be given out. In addition, if you are UAB employee or student, your employer will not be notified of your participation in this study without your consent.

Refusal or Withdrawal Without Penalty
Your taking part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution or this program.

What if you are a UAB Employee? Taking part in this research is not a part of your UAB duties, and refusing will not affect your job or relationship with UAB. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you are a UAB Student? You may choose not to be in the study or you may withdraw (stop) from the study at any time before it is over. This will not affect your class standing or grades at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation
There is no cost to you for taking part in this study.

Participant's Initials: _____

Payment for participation in Research
If you are eligible for this study and you choose to participate, you will receive a $5 gift card good toward the purchase of any UAB EatRight product or service.

Questions
If you have any questions, concerns, or complaints about the research, please contact Brooks Wingo. She will be glad to answer any of your questions 205-996-5029. You may also contact her advisor, Dr. Monica Baskin at 205-975-5704.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Ms. Sheila Moore. Ms. Moore is the Director of the Office of the Institutional Review Board for Human Use (OIRB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816. If calling the toll -free number, press the option for "all other calls" or for an operator/attendant and ask for extension 4-3789.Regular hours for the Office of the IRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal right
You are not waiving any of your legal rights by signing this informed consent.

Signatures

Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.

Signature of Participant Date

Signature of Investigator Date

Signature of Witness Date

Signature of person obtaining consent (if other than the investigator). Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant Name:_____ UAB IRB Protocol Number: X081208014

Research Protocol: Development of a scale to measure fear of exercise-induced pain in overweight and obese adults

Principal Investigator: Brooks C. Wingo, MSW

Sponsor: UAB Department of Health Behavior

What health information do the researchers want to use? The researchers are interested in your participation in the EatRight program. All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, The Children's Hospital of Alabama, Callahan Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant:_____ Date:_____
or participant's legally authorized representative:_____ Date:_____
Printed Name of participant's representative:_____
Relationship to the participant:_____

UAB Consent Form –Scale Validation Retest

University of Alabama at Birmingham
School of Public Health
Department of Health Behavior

TITLE OF RESEARCH: Development of a scale to measure fear of exercise-induced pain in overweight and obese adults

IRB PROTOCOL NUMBER: **X081208014**

INVESTIGATOR: Brooks C. Wingo, MSW

SPONSOR: UAB Department of Health Behavior

Explanation of procedures:
You are being asked to participate in a research study that examines how people interpret pain that is experienced during and after exercise. Before beginning the questionnaire, we will measure your height and weight to determine if you are eligible to take part in this study.

If you decide to participate, you will be asked to complete a questionnaire. This questionnaire will include questions regarding your thoughts about pain that is caused by exercise. The purpose of this study is to examine the usefulness of this questionnaire in weight loss treatment. The time required for completing this questionnaire is approximately 10 minutes.

Risks and Discomforts
There are no major risks or discomforts associated with participating in this study. However, there is a risk is associated with potential loss of privacy. Participants will be asked to give responses to questions, some individuals may experience discomfort answering questions about pain.

Benefits
There may be no personal benefit from your participation in this research; however, your participation may provide valuable information to the public health community about further understanding how to assess patients' fears associated with exercise.

Participant's Initials: _____

UAB-IRB
Consent Form Approval 11-11-09
Expiration Date 11-11-10

Alternatives
The only alternative would be not to participate in the study.

Confidentiality
Data will be stored and protected on a secure UAB server, accessible to research personnel only.

Information obtained about you for this study will be kept private to the extent allowed by law. However, the following groups will be able to view your medical records and have access to private information that identifies you by name: the Office for Human Research Protections (OHRP) and UAB's Institutional Review Board (IRB). The results of the research may be published for scientific purposes. These results will include a summary of what we observe. However, your identity will not be given out. In addition, if you are UAB employee or student, your employer will not be notified of your participation in this study without your consent.

Refusal or Withdrawal Without Penalty
Your taking part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution or this program.

What if you are a UAB Employee? Taking part in this research is not a part of your UAB duties, and refusing will not affect your job or relationship with UAB. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you are a UAB Student? You may choose not to be in the study or you may withdraw (stop) from the study at any time before it is over. This will not affect your class standing or grades at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation
There is no cost to you for taking part in this study.

Payment for participation in Research
If you are eligible for this study and you choose to participate, you will receive a $5 gift card good toward the purchase of any UAB EatRight product or service.

Participant's Initials: _____

Questions
If you have any questions, concerns, or complaints about the research, please contact Brooks Wingo. She will be glad to answer any of your questions 205-996-5029. You may also contact her advisor, Dr. Monica Baskin at 205-975-5704.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Ms. Sheila Moore. Ms. Moore is the Director of the Office of the Institutional Review Board for Human Use (OIRB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816. If calling the toll -free number, press the option for "all other calls" or for an operator/attendant and ask for extension 4-3789.Regular hours for the Office of the IRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal right
You are not waiving any of your legal rights by signing this informed consent.

Signatures

Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.

Signature of Participant	Date
Signature of Investigator	Date
Signature of Witness	Date
Signature of person obtaining consent (if other than the investigator).	Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant Name:_____

UAB IRB Protocol Number: X081208014

Research Protocol: Development of a scale to measure fear of exercise-induced pain in overweight and obese adults

Principal Investigator: Brooks C. Wingo, MSW

Sponsor: UAB Department of Health Behavior

What health information do the researchers want to use? The researchers are interested in your participation in the EatRight program. All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, The Children's Hospital of Alabama, Callahan Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant:_____ Date:_____
or participant's legally authorized representative:_____ Date:_____
Printed Name of participant's representative:_____
Relationship to the participant:_____