2012

Factors Associated with Participant Retention in a Behavioral Weight Loss Study

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FACTORS ASSOCIATED WITH PARTICIPANT RETENTION IN A BEHAVIORAL WEIGHT LOSS STUDY

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A DISSERTATION

Submitted to the graduate faculty of The University of Alabama at Birmingham,
in partial fulfillment of the requirements for the degree of
Doctor of Philosophy

BIRMINGHAM, ALABAMA

2012

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ABSTRACT

Participant retention in longitudinal research is gaining increasing attention. By identifying factors associated with participant retention, programs can be better designed to promote effective weight loss. This study examines factors associated with participant retention. The Anderson Behavioral Model provided the conceptual framework for the study. The sample consisted of secondary data abstracted from the research records of 316 participants in the University of Alabama at Birmingham cohort of the Look Action for Health in Diabetes (AHEAD) trial. The Look AHEAD trial is a randomized controlled trial designed to investigate the long-term effects of interventions aimed at producing weight loss in adult participants with type 2 diabetes. Variables measured at baseline and annually through follow-up year-five were abstracted and evaluated for association with participant retention using bivariate and multivariate statistics. Overall retention in the Look AHEAD trial was very high (89% - 93%) for a 5-year period. Bivariate testing showed individuals significantly more likely to be retained were greater than 60 years of age, possessed lower levels of depression, had lower body mass index (BMI), had hemoglobin A1c ranging from 7.0% to 8.9%, and had higher health status scores. There were no significant differences in retention by gender, race, education level, income, marital status, or treatment assignment. Multivariable models found age greater than 60 years, lower BMI, and hemoglobin A1c ranging from 4.0% to 8.9% to be significant predictors of greater retention. Retention in behavioral weight-loss programs

is associated with greater efficacy. Study findings provide insight into subgroups of individuals who are at risk for attrition, and an exploration of changes in longitudinal research retention strategies.

Keywords: Participant retention, Attrition, Dropout, Weight loss, Predictors

DEDICATION

This work is dedicated to my family and friends who have continuously supported me in reaching this very personal goal. My family and friends understood when I spent hours writing this dissertation, time that could have been spent with them. They understood when I could not visit as often as I wanted. They understood when vacations, meals, and shopping trips, with them, were delayed. They understood, supported, and loved me throughout this journey.

ACKNOWLEDGMENTS

Dr. Karen Meneses is the first person I would like to thank. I am truly grateful for her enthusiasm, her unending encouragement, and her resolute dedication to my success. I am also indebted to my committee members, Drs. Andres Azuero, Michelle Martin, Linda Moneyham, and James Shikany, whose unwavering support and encouragement has inspired me to always be a cheerleader for others. Thank you for all you have done for me and for your patient service on my dissertation committee.

On this journey, Dr. Beth Lewis was supportive of my decision to go back to school and she has continually made me aware of opportunities that will enhance my research endeavors. Thank you, Dr. Lewis. I thank all of the Look AHEAD Research Group Members at the Birmingham, Alabama clinical site. You make working together fun.

I thank, Dr. Erica Pryor, for holding on to a paper I had written for one of her classes seven years earlier, sharing it with me and saying, "Look how far you have come!" Thank you, Dr. Pryor, for continuing to encourage me.

To my classmates, Donna Dunn, Jennifer McLeod, Emily Jones, Cindy Joiner, and Thuy Lam, I have enjoyed meeting you and getting to know you. Without the supportive telephone chats, emails, and dinner dates, I would have been lost. I also thank my workplace friends – Sheikilya Thomas for her coffee walks and chats, Christie Oden for her impeccable data keeping ability and her assistance, Jennifer Wammack for proofreading, catching my many typographaphical errors and for being my friend, and

Margaret Pike, Isabelle Joffrion, and Beverly Powell for being my cheerleaders. I would also like to thank my long-time friends, Casey Azuero for saying "go ahead, take a class, what have you got to lose?", Eileen Helms for our coffee dates, Kay Vance for never giving up on inviting me to the lake, Audrey Wrenn for using her motivational interviewing skills on me to keep me moving forward, and my running buddy, Pat Perry, who has listened to me for miles and miles and miles, and encouraged me every step of the way! I am thankful to Judy Zaritt for always picking up the phone and for being a great listener.

I am grateful to my mother, Helen Clagg, who has inspired me to cross the finish line by stating, "I hope you finish this thing before I die." Finally, I thank my husband Mike, our children Jason, Jackie, Jillian, and my daughter in law – Jackie, for sticking with me through all the good times and bad, and helping to keep me sane, and never failing to lift my spirits.

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CHAPTER 1

INTRODUCTION

Participant retention is vital to the success of a clinical trial to ensure that the study results and conclusions bear scientific validity. Although successful participant retention is typically not the primary variable studied in a clinical trial, it is a major concern for researchers conducting such trials because attrition can potentially compromise research findings. Clinical research studies vary by setting, type and duration of intervention, and number of participants; thus, it is important to identify common factors related to retention across study variations. To date, a consistent set of factors associated with participant retention has not yet been identified (Moroshko, Brennan, & O'Brien, 2011). By identifying factors related to retention in clinical trials, specifically clinical weight-loss trials, findings, and outcomes can have the potential to improve retention and to promote evidence-based approaches for weight loss in the future.

In weight-loss clinical trials, researchers consistently report poor participant retention that has not improved appreciably for more than 20 years (Goldberg & Kiernan, 2005), often with drop-out proportions of 45% or higher (Clark, Niaura, King, & Pera, 1996; Coday et al., 2005). Factors related to retention among participants who enroll in behavioral weight-loss clinical trials are increasingly important to study. Participant retention is of particular importance for obesity treatment programs because previous

research has shown that when participants remain engaged in a weight-loss program, the likelihood of achieving the target weight-loss goal is enhanced (Ho, Nichaman, Taylor, Lee, & Foreyt, 1995). The ideal outcome of a clinical trial promoting weight loss with a behavioral intervention is not only participant retention, but also the achievement of a targeted weight-loss goal. Identifying factors related to participant retention may facilitate targeted interventions to prevent drop-out and enable participants to remain engaged in order to gain the necessary skills to achieve weight loss and weight maintenance (Moroshko et al., 2011).

A few weight-loss intervention studies examined predictors of participant attrition, but only baseline data related to demographic and psychological variables were considered for describing sample characteristics and evaluating treatment outcomes (Clark et al., 1996; Honas, Early, Frederickson, & O'Brien, 2003). Researchers developing weight-loss studies spend much of their effort on study design and weight-loss outcomes rather than adapting existing or developing new theoretical models related to participant retention (Moroshko et al., 2011; Shumaker, Dugan, & Bowen, 2000). Because participant retention is not typically the primary outcome of a behavioral weight-loss study, this dissertation adds to the scant body of knowledge through use of a theoretical framework to guide the examination of factors associated with participant retention in a behavioral weight-loss study.

Purpose

The purpose of this research study is to examine factors associated with participant retention over time. Specifically, the relationship of gender, race, age,

education, income, marital status, depression, health status, body mass index (BMI), and hemoglobin A1c to participant retention is explored. In addition, follow-up visit characteristics are examined as factors associated with participant retention in the Look Action for Health in Diabetes (AHEAD) Study at the Birmingham, Alabama clinical site.

Significance of the Problem

The Center for Information and Study on Clinical Research Participation (CISCRP) reported a trend toward poor volunteer retention in research, citing that only one in four research participants remain with a study until completion (CenterWatch, 2005). Additionally, the Institute of Medicine (2009) reported that poor participation has been documented over the past decade. Inadequate funding in federally-funded clinical trials is cited as a reason for poor participation (Institute of Medicine, 2009). Participation in scientific research is thought to be declining due to increasing rates of refusal and lack of eligible participants (Galea & Tracy, 2007). Due to the lack of eligible individuals willing to participate in research studies, it is particularly important to retain participants once enrolled in clinical trials. The shortage of scientific research devoted to objectively quantifying retention factors associated with successful participant retention in clinical trials poses an additional problem for researchers.

Conceptual Framework

The Andersen Behavioral Model provided the theoretical underpinning to examine factors associated with retention in a longitudinal weight-loss study. The Andersen model was originally developed in the 1960s to understand why families use

health services (Andersen, 1995). This model is intended to predict and explain health service use by suggesting that individuals are predisposed to use health services by factors which facilitate or hinder use, and their need for care (Andersen, 1995). The Andersen Model incorporates three main components in the framework: *predisposing*, *enabling*, and *need* factors. Figure 1 shows the relationships among the components of the model.

First, Andersen (1995) posited that *predisposing* characteristics represent characteristics that exist before the onset of illness. These characteristics are typically non-modifiable and include demographics such as age, gender, and race/ethnicity. Second, *enabling* characteristics are those characteristics that can facilitate or impede health care service use. These characteristics include organizational factors, financial factors, and social relationships such as income, health insurance, travel time, and waiting time to see a health care provider. Third, *need* characteristics represent professional judgment regarding an individual's health status such as an objective measure of the need for care. For example, BMI and hemoglobin A1c represent objective measures that may illustrate the severity of obesity and diabetes, thus prompting a health care practitioner to refer an individual for care. According to Andersen (1995), *need* factors might also represent an individual's subjective assessment of their need for service, such as perceived health status.

Evidence shows that the Andersen model is better suited to predicting use of discretionary services than to its original purpose of predicting use of formal health services (Mitchell & Krout, 1998). A clinical trial promoting weight loss through behavioral change could be viewed as a discretionary service available to eligible

participants who are willing to enroll. Thus, the Andersen Model was selected as the conceptual framework for this research study because of its potential to guide the identification of factors associated with participant retention in a clinical trial of weight loss.

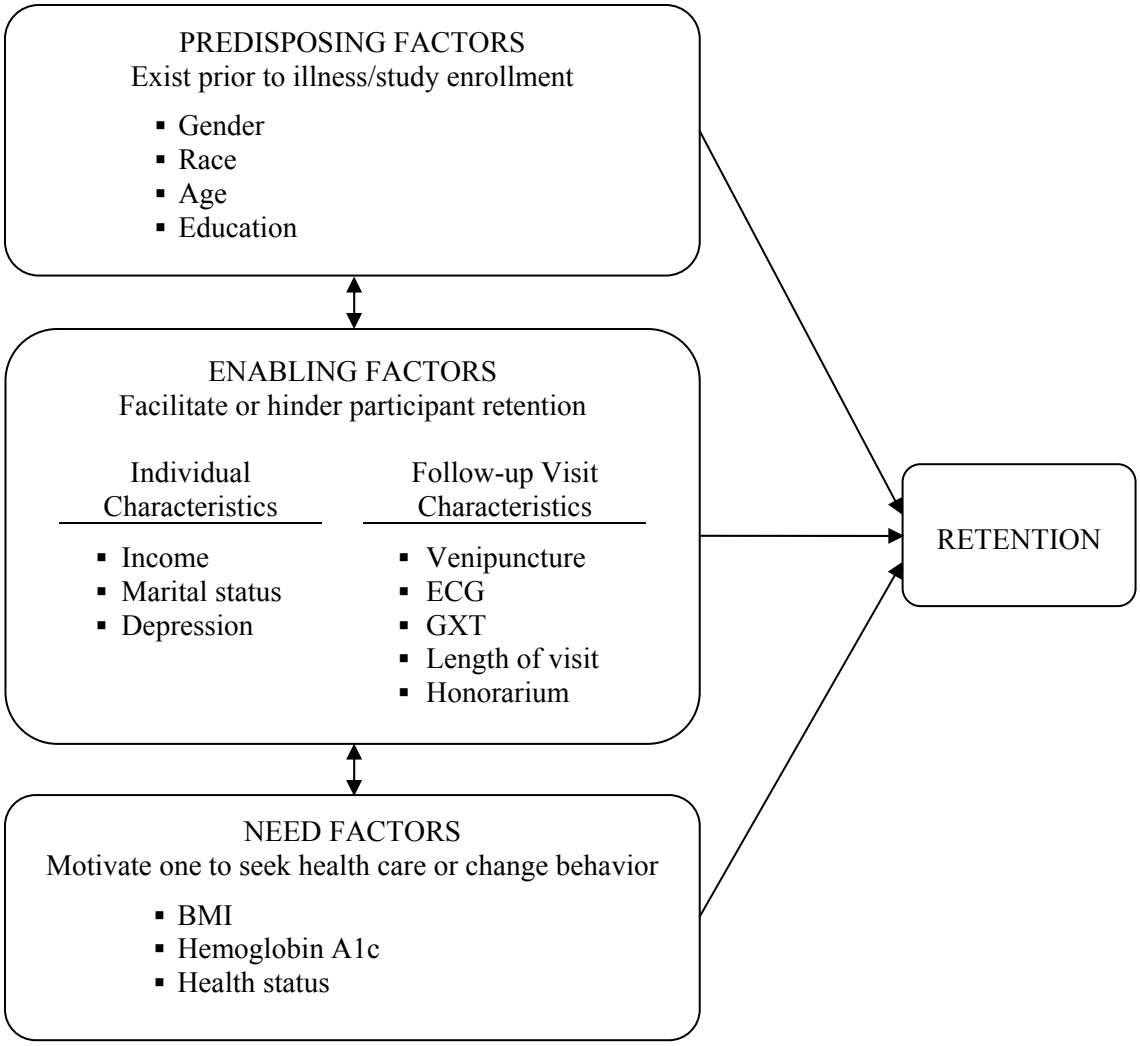

Figure 1. Conceptual model of retention in a weight-loss study. Study Framework Adapted from the Andersen Behavioral Model (1995).

For the purposes of this research study, predisposing factors are gender, race, age, and education. Enabling factors cover both individual characteristics and follow-up visit characteristics. Individual characteristics include income, marital status, and depression. Follow-up visit characteristics include blood tests measuring lipid levels and blood glucose levels, electrocardiograms (ECGs), graded exercise tests (GXTs), length of visit, and honorarium. Need factors include BMI, hemoglobin A1c, and health status. Need factor variables encompass objective measures related to the severity of obesity and diabetes along with self-perceived and reported health status. Need factors may prompt an individual to seek the benefits of participating in a clinical trial with an intervention to promote weight loss.

Specific Aim

The primary aim of this research study was to describe factors (i.e., predisposing, enabling, and need) associated with participant retention in a clinical trial of a behavioral weight-loss intervention among overweight or obese adult individuals with type 2 diabetes.

Research Questions

Research Question 1

How do predisposing factors, specifically gender, race, education, and age, relate to participant retention over time?

Research Question 2

How do enabling factors, specifically income, marital status, and depression, relate to participant retention over time?

Research Question 3

How do need factors, specifically, BMI, hemoglobin A1c, and health status, relate to participant retention over time?

Research Question 4

How do additional enabling factors, specifically study procedures, length of visit, and honorarium, relate to participation over time?

Definition of Terms

The following terms were defined conceptually and operationally for the purpose of this dissertation research.

Age: The part of life from birth to a given time. Age is identified in years of life, and data were obtained via participant response from the research study record.

Body mass index: A key index for relating weight to height; calculated using the body mass index formula (weight in kilograms divided by height in meters squared; kg/m^2). Height and weight measurement data were obtained from the research study record.

Depression: A condition diagnosed when at least five of the following symptoms are present: depressed mood, diminished interest or pleasure in most all activities, significant change in weight or appetite, significant change in sleep pattern, psychomotor

agitation, fatigue or loss of energy, feelings of worthlessness or inappropriate guilt, impaired ability to concentrate or indecisiveness, recurrent thoughts of death or suicide. These symptoms must be present during the same 2-week period and represent a change from a previous level of functioning. Depression was measured using the Beck Depression Inventory and results were obtained from the research study record.

Electrocardiogram: A procedure where electrodes are placed on the chest, arms, and legs and attached to a machine that records the electrical activity of the heart. Electrocardiogram was dichotomized as *Yes* or *No*, indicating whether a participant received the procedure, and data were obtained from the research study record.

Gender: Male or female. Either of the two major forms of individuals that occur in many species and that is distinguished respectively as male or female. Gender was self-identified, and data were obtained via participant response from the research study record.

Graded Exercise Test: A procedure commonly known as a stress test. It is typically performed on a treadmill. Exercise intensity is increased in stages so that an individual's heart rate, blood pressure, electrocardiogram, and oxygen consumption can be evaluated in response to increasing exercise. Graded exercise test was dichotomized as *Yes* or *No*, indicating whether a participant received the procedure in conjunction with an annual study visit, and data were obtained from the research study record.

Health status: A participant's subjective evaluation of his or her current level of health. Health status was quantified and data were obtained via participant response from the research study record.

Hemoglobin A1c: Glycosylated hemoglobin. The hemoglobin A1c test measures the level of hemoglobin A1c in the blood. The value is expressed as a percentage representing the average blood glucose concentrations for the preceding 2 to 3 months. Higher levels are indicative of poor blood glucose control. Hemoglobin A1c values were obtained from the research study record.

Honorarium: A monetary award, measured in U.S. dollars, to compensate a participant for the burden of an annual study visit, such as time or travel. Honorarium was dichotomized as *Yes* or *No*, indicating whether a participant received an honorarium, and data were obtained from the research study record.

Income: The amount of monetary or other returns, either earned or unearned, accruing over a given period of time. Income is reported in U.S. dollars, and data were obtained via participant response from the research study record.

Length of Visit: The amount of time taken for a participant to complete an annual study visit. Length of visit was estimated based on the number of exam forms and procedures to be completed at a specific annual study visit. Length varied by exam year, and data were obtained from the research study record.

Marital status: Married or not married (single, widowed, or divorced); the legal standing of a person in regard to his or her marriage state. Marital status was classified as either married or not married, and data were obtained via participant response from the research study record.

Obesity: A condition characterized by an excessive amount of body fat. Class I obesity = BMI 30.0 kg/m^2 - 34.9 kg/m^2; class II obesity = BMI 35.0 kg/m^2 - 39.9 kg/m^2; and class III obesity = BMI $\geq$ 40.0 kg/m^2

Overweight: A weight in excess of the normal for age, height, gender, and build. A BMI of 25.0 kg/m^2 - 29.9 kg/m^2

Race: White or Black; a category of humankind that share certain distinctive physical traits. Race was classified as either White or Black, and data were obtained via participant response from the research study record.

Retention: The completion of a scheduled annual study visit within the study visit window. Participants who complete each visit within the allowable visit window are considered retained for that visit. Participants who do not complete a particular scheduled visit within the allowable study visit window, but do complete the next scheduled visit, are not considered retained for the visit that they missed, but are considered retained for the next attended scheduled visit. Thus, retention can fluctuate over time and across visits. Retention was reported as a percentage of participants enrolled who then completed each follow-up visit.

Venipuncture: A procedure where a needle is inserted into a vein. Venipuncture was used to collect blood for analysis. Venipuncture was dichotomized as *Yes* or *No*, indicating whether a participant received the procedure in conjunction with an annual study visit, and data were obtained from the research study record.

Assumptions

The assumptions for this study were as follows:

1) Retention can be accurately measured over time.
2) Predisposing factors can be reported and accurately measured.
3) Enabling factors can be reported and accurately measured.

4) Need factors can be reported and accurately measured.

5) Retention behaviors are influenced by multiple factors arising from multiple interacting systems.

CHAPTER 2

REVIEW OF LITERATURE

The purpose of this chapter is to review the literature related to retention and attrition as related to gender, race, age, education, income, marital status, depression, BMI, hemoglobin A1c, and follow-up visit characteristics. Second, the interrelationships among predisposing factors, enabling factors, and need factors relating to participant retention are reviewed. Finally, gaps in research literature relating to participant retention are summarized.

Search Methodology

The author used a systematic approach to search the literature to identify research studies about participant retention in clinical trials, and more specifically participant retention in weight-loss clinical trials. The publication dates were delimited to January 1, 1990 - December 30, 2010. The search was limited to research studies written in the English language, and research of adult populations in the United States. The following databases were used in the search: *PubMed, Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and PsycINFO*. The search consisted of a variety of key words and phrases such as *retention*, *attrition*, *dropouts*, *participant retention*, *retention and obesity*, *predictors of attrition*, and *predictors of retention*. The primary focus was to identify articles addressing participant retention and predictors of

attrition in studies with a behavioral intervention promoting weight loss. A secondary focus was to identify articles in which participant retention or attrition was the phenomenon of interest and the outcome variable. Also, relevant manuscript references were scanned for any additional, relevant publications.

The searches yielded 1,802 articles. The author reviewed titles for first level screening, and identified 292 potential articles that included the search terms. The second level screening encompassed the review of abstracts with the aim of identifying studies that included predictors of participant retention in weight-loss programs with a behavioral weight-loss intervention component. A secondary aim in the second level screening was to identify empirically-tested retention strategies. Two hundred seventy-seven articles were eliminated because the principal outcome of interest was a topic other than participant retention in a behavioral weight-loss study or the retention strategies were not scientifically tested.

Of the remaining 15 studies, 2 were eliminated because they were conducted using a non-U.S. population; 1 was eliminated because the parent study involved participants with anorexia enrolled in an eating disorder treatment program. Of the 12 remaining studies, 3 articles describing empirical testing of two retention strategies, persistence, and the inclusion of a run-in period were included. Although the research described in these three articles did not involve a weight-loss intervention, they were included in this review because they scientifically tested retention strategies. The nine remaining articles are discussed in this review. The authors of these articles explore relationships between individual factors and the factors that had an impact on retention.

Retention

Nine studies examined retention in weight-loss intervention trials. Retention in behavioral weight-loss clinical trials was conducted by investigators working with the Behavior Change Consortium, and reported by Coday and colleagues (2005). The Behavior Change Consortium investigators conducted focus groups at 15 university-based research sites to determine barriers to retention in behavioral intervention research. The focus group participants included principal investigators and project coordinators who were asked what specific retention strategies they used. They identified eight retention strategies: (1) emphasizing benefits of participation; (2) minimizing respondent burden; (3) providing incentives or small tokens of appreciation; (4) giving tangible support; (5) being patient yet persistent; (6) being flexible; (7) enlisting support from others and provide social support; and (8) maintaining a good tracking system. Coday and colleagues also reported the retention results (68.6% - 85%) of six studies that related to specific lifestyle changes of diet and physical activity. Lower retention was associated with longer treatment duration; the study with the lowest retention (68.6%) was 24 months in duration, while the study with the highest retention (85%) was 12 months in duration (Coday et al., 2005). The longer the duration of the weight-loss program, the more difficult it was to retain participants. The authors concluded that future behavioral intervention trials could benefit from an examination of participant retention factors.

A term related to retention is attrition. Attrition occurs when participants fail to continue with study follow-up and leave the study completely. Participants who begin a study and miss one or more follow-up visits, but ultimately complete the study, could be

considered retained. The literature indicates definitions of retention and attrition are typically identified from the perspective of the study goals outlined in the study protocol.

Davis and Addis (1999) examined predictors of attrition rather than predictors of retention. They reviewed how investigators defined the term 'attrition' in 20 studies of behavioral treatment programs, and found no clear definition of attrition across the studies. Davis and Addis found that some studies operationally defined attrition using the number of study sessions participants attended while other studies based the definition of attrition on participant report of sessions attended. Participant reported attrition included those participants who announced that they were terminating a study prior to completion. The authors concluded that until predictors of attrition are further identified and appropriate strategies to reduce attrition are developed, retention in behavioral treatment programs will continue to be challenging.

Clark and colleagues (1996) examined whether the pre-treatment variable *depression* and health behavior variables *smoking status* and *exercise habits*, would predict attrition from a 26-week clinical program that included a very low-calorie diet and behavior modification therapy overseen by a multidisciplinary team. Participants included 143 adult males and females. The authors measured attrition by counting the total number of sessions attended. Results showed participants who attended more sessions were significantly less depressed, nonsmokers, older, exercisers, and had a greater BMI.

Teixeira and colleagues (2004) explored predictors of attrition by examining baseline behavioral and psychosocial variables such as dieting history, dietary intake, exercise self-efficacy, and quality of life differences between participants with successful

weight loss and participants without successful weight loss in a behavioral weight management program. The sample consisted of 158 overweight and obese females, ranging from 40-55 years of age, enrolled in a 16-week lifestyle weight-loss program aimed at improving diet and increasing physical activity. The participants were followed for one year after treatment. The authors measured attrition by classifying participants who did not complete assessments at the 16-month follow-up visit as non-completers. Thirty percent of the participants did not complete follow-up visits. Significant predictors of attrition were greater number of previous weight-loss attempts, poorer quality of life, greater initial weight, and fewer exercise minutes.

While maintaining retention is a goal of researchers, reducing attrition is an equal priority for researchers. High attrition presents a serious problem for researchers conducting clinical trials involving long-term behavioral weight-loss interventions. Both the internal and external validity of research findings can be threatened by participants who are lost to follow-up or refuse to continue to participate in the clinical trial. In light of the effort and cost of recruiting participants, similar cost and effort should be directed to retaining participants (Aitken, Gallagher, & Madronio, 2003).

In summary, behavioral treatment programs and studies varied in the way they operationally defined the term attrition. This variation is problematic in attempts to identify reliable, consistent predictors of attrition. The following sections present a review of the literature examining the variables included in the present study.

Predisposing Factors

Predisposing factors are fixed factors and exist prior to study enrollment. Predisposing factors investigated as predictors of retention were age, race, gender, and education.

Age

Honas and colleagues (2003) investigated age, race, marital status, and sex as potential demographic determinants of attrition among 866 adult participants enrolled in a clinic-based weight management program in a medical center in the Midwest. The program consisted of meal replacement shakes and weekly behavioral meetings. Overall retention for the 16-week program was 69%. Seventy-six percent of participants, age 51 – 60 years old, completed the program. Significantly fewer participants less than 40 years of age completed the weight-loss program compared to those age 40 – 50 years 60% ($p < 0.001$) and 68% ($p < 0.05$) respectively. The authors found that participants 50 years of age and younger had a significant risk for dropout compared to participants older than 50 years old ($p = 0.04$). They concluded that age was a significant demographic determinant of attrition.

As previously described, Clark and colleagues (1996) investigated whether pretreatment depression, activity level, smoking, and health status would predict attrition from a 26-week obesity treatment program among 143 adult participants enrolled in a clinical weight-management program. While not a primary endpoint, they also examined age as a demographic factor that may influence retention. The researchers found that

older participants attended more sessions than younger participants (p <0.001). The mean age of participants was 42 years.

Fabricatore and colleagues (2009) examined baseline characteristics of demographic, weight-related, and psychological variables as predictors of attrition in a 52-week randomized controlled clinical trial that combined pharmacotherapy and behavior therapy for weight loss. The participant sample consisted of 224 obese adult males and females randomized into one of four groups: (a) sibutramine alone; (b) lifestyle modification alone; (c) combined sibutramine and lifestyle modification therapy group; and (d) sibutramine plus brief therapy. Attrition was defined as failure to complete the week 52 assessment visit. Retention at one year was 82.6%. The authors found older age was significantly related to greater retention (p = 0.03).

In summary, authors of the three studies consistently found that younger age was associated with higher attrition.

Race

Race was examined as a potential variable affecting retention and attrition in two studies. Glasgow and colleagues (2007) conducted a randomized controlled trial aimed at delivering a weight-loss intervention over the internet. They enrolled a total of 2,311 adult males and females. The intervention and randomization consisted of a basic 6-week online self-help weight-loss program with or without a goal-setting intervention and a nutrition education intervention. Using data collected at a baseline assessment, they created an individually-tailored weight-loss plan based on participant responses to health history, prior weight-loss attempts, motivators for weight management, perceived barriers

to change, social support, body image, nutritional habits, and physical activity questions. Participants were initially provided with a basic weight-loss program guide, and received emailed newsletters with tailored action plans at one week, three weeks, and six weeks post-baseline. The authors report that approximately 48% of the participants provided information through a 12-month follow-up survey. The authors found that Blacks versus non-Blacks were less likely to continue with the internet-based weight-loss program ($p = 0.03$).

In the previously-described study, Honas and colleagues (2003) found Black participants were more likely to drop out of the 16-week, clinic-based weight-loss program compared with White participants ($p < 0.05$). Both studies found White participants were more likely to be retained in the weight-loss program than Black participants.

Gender

Of the studies identified for this literature review, data regarding gender as a predictor of retention are sparse and results are conflicting. Honas et al. (2003) found that females had greater likelihood of attrition ($p < 0.05$), while Glasgow et al. (2007) found the opposite, with females more likely to remain in the weight-loss program ($p = 0.006$). Fabricatore and colleagues (2009) found no significant difference in retention between male and female participants.

Education

In a previously-described study conducted by Fabricatore and colleagues (2009), education as a predictor of attrition was examined. The participants were randomized into four cohorts: (a) weight-loss pharmaceutical only; (b) lifestyle modification only; (c) a combination of both; or (d) weight-loss pharmaceutical and a brief lifestyle modification session. The investigators found that education was a marginally significant variable related to retention ($p = 0.05$). Participants with some college and those who graduated from college were more likely to be retained when compared to those with a high school education or less.

Summary of Predisposing Factor Variables

Researchers found that predisposing factors, such as age, gender, race, and education level may have an impact on retention in clinical trials focusing on weight loss (Fabricatore et al., 2009; Glasgow et al., 2007; Honas et al., 2003). Of the few studies that examined these predisposing factors, younger age, black race, and lower education levels were associated with attrition. The results for gender were equivocal. The studies were few, and a small number of significant associations were found. Thus, the demographic variables most often collected may be used as the basis of future investigations that examine attrition.

Enabling Factors

Enabling factors are defined as factors that potentially impede or enhance participation in a clinical trial. Enabling factors can include income, marital status,

depression, and follow-up visit characteristics. Unlike predisposing factors, enabling factors can change over time.

Income

Income levels are reported frequently in published manuscripts and although income levels may influence participant retention, none of the studies reviewed for this dissertation reported participant income as relating to participant retention or attrition.

Marital Status

Marital status may influence participant retention. Two studies examined the relationship between marital status and retention. Fabricatore and colleagues (2009) found no significant difference in retention between married and non-married participants. The second study by Honas and colleagues (2003) classified marital status into three groups: (a) married, (b) single, and (c) divorced. Honas and colleagues (2003) found divorced females were more likely to drop out of clinical research and weight-loss programs ($p < 0.05$) than married or single participants.

Goldberg and Kiernan (2005) conducted a descriptive study employing motivational interviewing techniques to reduce ambivalence during group-based orientation sessions prior to randomization in a behavioral weight-loss trial. The study sample included 162 overweight and obese adults, ages 25-80 years, living in a major metropolitan area. Participants were asked to present for a follow-up visit every 6 months for a period of 18 months. The authors implemented motivational interviewing techniques to address retention in a behavioral weight-loss trial. The authors reported

71% of their participants were married and, overall, the study maintained a very high retention of 96%. However, the authors did not explore or report retention differences between married and non-married participants.

Depression

Previous study results suggested that baseline depression levels may have an impact on retention (Clark et al., 1996). The presence of depressive symptoms at pretreatment or pre-randomization may indicate risk for attrition (Clark et al., 1996). Clark and colleagues found that higher levels of baseline depression were significantly associated with lower retention ($p = 0.014$). Texeira et al. (2006) also found that baseline depression was associated with poor adherence, as measured by the number of sessions attended (Teixeira et al., 2006). In a third study, Fabricatore and colleagues (2009) reported baseline depression was significantly related to poor participant retention ($p = 0.02$).

Goldberg and Kiernan (2005) administered the Beck Depression Inventory (BDI) during screening. Based on previous knowledge citing depression with poor adherence to protocols, those individuals identified as depressed were considered ineligible. The actual retention for the Goldberg and Kiernan (2005) study was high at 96%; however, the overall goal of that descriptive study was to reduce ambivalence towards participating in a weight-loss program prior to randomization. Even though effective screening techniques may be a key to successful retention in clinical trials, the strength of behavioral weight-loss programs lies in the ability to generalize the results to a broader population (Coday et al., 2005). Deeming depressed participants as not eligible for a

weight-loss study is problematic in the sense that is limits the ability of the findings to be generalized. Results from the Goldberg and Kiernan (2005) study can only be generalized to a population of adult, obese individuals who were not depressed.

The literature reviewed for this dissertation showed that participants experiencing lower levels of depression are more likely to be retained in weight-loss programs than those participants experiencing higher levels of depression (Clark et al., 1996; Fabricatore et al., 2009; Teixeira et al., 2004).

Follow-up Visit Characteristics

The published papers reviewed for this dissertation did not explore the relationship between follow-up visit characteristics and participant retention.

Summary of Enabling Factors

Enabling factors such as marital status and depression have an impact on participant retention in clinical trials focusing on weight-loss (Clark et al., 1996; Fabricatore et al., 2009; Teixeira et al., 2004). Published papers exploring the relationship between income, study follow-up visit characteristics, and retention were not found in the literature search for this dissertation.

Need Factors

Need factors can be defined as the signs and symptoms of disease that can trigger an individual's decision to seek health care. Elevated BMI, elevated hemoglobin A1c

levels, and health status were examined as need factors, potentially prompting an individual to seek intervention through a weight-loss program.

Body Mass Index

Carels et al. (2003) sought to confirm and extend predictors of attrition in a sample of 44 obese postmenopausal females participating in a 6-month, 24-session weight-loss intervention. The authors investigated whether baseline characteristics were associated with program completion. The authors found that unsatisfactory early weight loss and poor session attendance were indicators of unfavorable treatment outcomes. In seeking to identify predictors of attrition and failure to lose weight during treatment, the researchers found greater BMI, poor body image, and greater expectations for program success were positively related to poor attendance (Carels et al., 2003). The authors found poor attendance to be associated with unsatisfactory early weight loss, diminished quality of life, and low self-efficacy. The authors concluded that attrition and failure to lose weight led to poor treatment outcomes.

Fabricatore and colleagues (2009) explored the relationship between BMI and participant retention but did not find a statistically significant difference ($p = 0.22$). Clark and colleagues (1996) examined the relationship between BMI and retention. The investigators found that BMI was a significant predictor of retention. Participants with a greater baseline BMI attended more sessions as compared with those with a lower baseline BMI ($p = 0.012$). Teixeira and colleagues (2004) found the opposite results. Participants with a greater BMI were significantly less likely to complete the weight-loss program compared with participants with a lower BMI ($p < 0.001$).

Hemoglobin A1c

Hemoglobin A1c has not been examined as a variable related to retention in the literature. However, in a comprehensive review of thirteen behavioral weight management studies, Davis and Addis (1999) demonstrated that higher levels of symptom severity variables predicted attrition. Symptom severity variables in the Davis and Addis (1999) review were self-reported levels of pain, depression, and anxiety. Although hemoglobin A1c is not a symptom of illness in the same sense as pain, depression, and anxiety, an elevated hemoglobin A1c is a clinical sign indicative of illness severity. As previously stated, higher levels of symptom severity have been shown to predict attrition (Davis and Addis, 1999).

Health Status

Self-perceived health status has not been examined as a variable related to participant retention in the literature. However, the previously described study by Glasgow and colleagues (2007), found that the enrollment of individuals with a chronic illness, such as diabetes, was higher when compared to those without a chronic illness. These results potentially suggest that the presence of a chronic condition may motivate individuals to initiate participation in a weight-loss study. However, Glasgow and colleagues did not find any differences related to retention among those with and without chronic conditions.

Summary of Need Factor Variables

Baseline BMI may or may not be indicative of participant retention in behavioral weight-loss programs. The results of the literature reviewed relating baseline BMI to participant retention were equivocal. Hemoglobin A1c was not specifically examined as a predictor of retention in the literature reviewed for this dissertation. Although health status may influence enrollment in a weight-loss study, further investigation of this need factor variable is warranted. Need factor variables may be used as the basis of future investigations that examine participant retention.

Retention Strategies

Two retention strategies, (a) a run-in period and (b) persistence, were identified as successful retention strategies in three studies (Cotter, Burke, Stouthamer-Loeber, & Loeber, 2005; Kleschinsky, Bosworth, Nelson, Walsh, & Shaffer, 2009; Ulmer, Robinaugh, Friedberg, Lipsitz, & Natarajan, 2008). While the identified studies did not pertain to research involving behavioral weight loss, they are included in this review because they were the only studies identified in the literature that objectively quantified specific retention strategies.

Run-in Period

Ulmer and colleagues illustrated the importance of a run-in period and its effect on retention (Ulmer et al., 2008). A run-in period is a useful technique not only for the participant but also for the researcher seeking participants who will remain actively engaged in the research (Hunt & White, 1998). During the run-in period, the potential

participant is typically asked to adhere to a regimen similar to the intervention in the protocol. After the run-in period, the researcher is able to assess adherence to a proxy protocol. The assumption is that those participants who are unable to adhere to a shorter duration proxy protocol will be less likely to adhere to a long-term protocol (Robiner, 2005). Ulmer and colleagues (2008) found the use of a run-in-period significantly reduced drop-out ($p < 0.001$).

Persistence

Two studies used persistence in callbacks to improve retention (Cotter et al., 2005; Kleschinsky et al., 2009). Kleschinsky et al. (2009) used telephone calls for contacting participant for follow-up. The participants were repeat driving under the influence (DUI) offenders who consented to be contacted one year after completion of a two-week residential program ($n = 704$). The mean number of telephone callback attempts required for a 70.1% follow-up completion was 8.6; however, after 60% of the participants had been contacted, the remaining participants required significantly more calls to complete the follow-up interview ($p < 0.001$). The mean number of telephone callback attempts needed to complete interviews after the 60% threshold was 21.9 callbacks. The response continued to increase until the researchers reached 40 callbacks. The data from this study indicated the percentage of return for callbacks did not level off until after 20 calls and only after 40 calls did the potential return for additional calls not justify the added effort.

Cotter et al. (2005) examined the development of disruptive behavior disorders among 177 adolescent boys enrolled in a longitudinal study. The researchers were

specifically interested in investigating the influence of less persistence on retention. They set cutoff contact attempt points at 5, 10, and 20 calls, and compared the results to the actual retention, which consisted of unlimited contact efforts. Results showed that if contact attempts were halted after 10 call attempts, nearly one-third (32%) of the participants would have been lost to follow-up, and if stopped after 20 call attempts, 12% of the participants would have been lost. Thus, these studies showed that persistence in callback for particularly difficult participants can result in an improved retention.

Gaps in the Retention Literature

Published literature on predictors of retention in clinical trials is limited. Identifying consistent predictors of retention is difficult considering differences in study design, setting characteristics, and lack of homogeneity of the enrolled participants. Current reviews are limited by the lack of clinical trials focusing specifically on participant retention. Existing literature consists of primarily professional observations and case study reports rather than systematic scientific evaluations.

Identifying predictors of retention in clinical trials focused on weight loss may enable researchers to identify participants at risk for attrition, as well as target retention strategies to enhance participant retention throughout the study. Enhanced participant retention will not only improve the validity of study conclusions, it may also enhance the attainment of targeted weight-loss goals for participants.

Sustaining participant retention is problematic for longitudinal behavioral weight-loss intervention studies. Retention in weight-loss programs is a challenging endeavor

especially in light of the fact that retention for behavioral weight-loss programs has not improved much in the past 20 years (Goldberg & Kiernan, 2005).

CHAPTER 3

METHODOLOGY

This chapter describes the methodology of this research study and includes the research design, protection of human subjects, data collection, instruments, and data analysis. This dissertation is based on a subset of Look AHEAD data. The analyses performed herein were not conducted at the Look AHEAD Data Coordinating Center.

Research Design

The research design is a secondary analysis of data collected from the Look AHEAD trial at the University of Alabama at Birmingham (UAB) site. The Look AHEAD trial will be referred to as the parent study in this dissertation. The parent study is a multicenter randomized controlled clinical trial. Participant enrollment began in 2001 and the trial is currently in its tenth year of follow-up, and examines the effects of an intensive lifestyle intervention aimed at weight loss and weight maintenance over an extended period. Nationwide, the parent study includes 5,145 overweight or obese individuals diagnosed with type 2 diabetes. Participants were randomized into one of two arms: (a) an intensive lifestyle intervention group with a focus on weight loss or (b) a comparison group receiving standard diabetes education. The parent study objective was to determine whether participation in a lifestyle intervention was effective in reducing the incidence of serious cardiovascular disease events in overweight adults with type 2

diabetes. Additional information contained in Appendix A describes elements of the parent study, including how the original sample was obtained, a description of the setting, and data collection procedures. The parent study design and study participants are described in detail in a published manuscript (Ryan et al., 2003).

Dissertation Research Study: Sample and Setting

The sample for this dissertation research study consisted of data abstracted from research records of 316 participants enrolled at the UAB site between October 1, 2001 and April 30, 2004. The mean age of the sample was 59 years (*SD* = 6.5 years), with a range of 45 to 76 years. The majority of the sample was White (73%) and female (60%). Detailed demographic variables of interest are further described in chapter 4. Data at the UAB site are housed in the School of Medicine, Department of Medicine, Division of Preventive Medicine (DOPM).

Protection of Human Subjects

The parent study received initial Institutional Review Board (IRB) approval on May 23, 2001 and has been continually approved on an annual basis (Appendix B). The dissertation research study received initial approval from the UAB IRB on May 18, 2011 and was renewed on May 1, 2012. Confidentiality was ensured by not collecting Protected Health Information (PHI), and by using a participant acrostic and a unique study identification number, maintaining all data and records in locked storage areas accessible only to the parent study project staff, and password protecting computer data

files. Participants will not be personally identified in any scientific reports generated by the study.

Data Collection

From existing participant study records, data were abstracted from baseline and follow-up study visits for all participants enrolled in the parent study at the UAB site. The data were recorded on the Data Collection form (Appendix C) and entered into the IBM Statistical Package for the Social Sciences (SPSS) version 19 (2010). In order to maintain data quality, 10% of the records were randomly selected and assessed for data entry accuracy.

Study Variables

The main outcome variable for the dissertation research study was retention. For each participant, at each follow-up year, a binary indicator was coded indicating participant attendance within a specific follow-up visit window. For example, if a participant did not present for a follow-up visit within two months following his or her scheduled annual visit, the visit was considered missed and coded with a zero.

Predisposing Factor Variables

Predisposing factor variables of race, gender, age, and education were collected from the Screening form and the Myself and My Family form completed during screening and at baseline. The Myself and My Family form contained a question asking about the level of education, *What is the most education you have completed?* The

education item instructed the participant to identify only one item indicating the highest level of schooling attained. The parent study had 11 categories of various education levels, accounting for some college or some graduate school and a category noted as "other", directing the participant to fill in the blank. However, for this dissertation research study, education was coded into four categories: (a) high school diploma or less than high school education; (b) associate degree; (c) bachelor degree; and (d) graduate degree. The categories were collapsed from 11 in the parent study to four in this dissertation study due to the small numbers in each of the 11 categories.

Enabling Factor Variables

Enabling factors are those factors which may facilitate or hinder participant retention. In this research study, enabling factors include both individual characteristics and follow-up visit characteristics.

Individual characteristics. Enabling factor variables of income, marital status, and depression were collected at baseline, and annually for 4 years. These variables were not collected in the parent study during follow-up year 5.

Income. In the parent study, an income related questionnaire stated, "*In the past twelve months, how much did you and others currently living in your household earn from all sources?"* The parent study had nine categories indicating various levels of income: (a) under $10,000; (b) $10,000 - $19,999; (c) $20,000 - $29,999; (d) $30,000 - $39,999; (e) $40,000 - $49,999; (f) $50,000 - $59,999; (g) $60,000 - $69,999; (h)

$70,000 - $79,999; and (i) $80,000 or more. Due to fewer numbers in the present study, income was coded into five categories: (a) <$10,000; (b) $10,000 - $49,999; (c) $50,000 - $79,999; (d) $80,000 or more; and (e) refused. Refusing to answer the question was not an option on the form in the parent study. However, 14% - 16% of the sample population did not answer this question on the questionnaire at some point in time.

Marital status. The item addressing marital status in the parent study questionnaire directed the participant to choose the most appropriate category: (a) never married; (b) married; (c) divorced; (d) widowed; (e) separated; or (f) living in a marriage-like relationship. In this dissertation study, the marital status variable was dichotomized into two categories: (a) married and (b) not married. The marital status variable was dichotomized in the present study due to limited numbers in each category described in the parent study.

Depression. The Beck Depression Inventory (BDI) was used to assess depression levels in the parent study. The BDI is a 21-item, self-report instrument measuring the severity of depression. Each of the 21 items on the BDI has a set of four possible responses. For example, the statement selections for the first item are (a) I do not feel sad; (b) I feel sad; (c) I am sad all the time and I can't snap out of it; and (d) I am so sad or unhappy that I can't stand it. The responses are assigned a score ranging from 0 to 3. The participant was asked to consider each statement and choose the one that best described how he or she felt in the past week. The total score was computed by summing the item scores. Higher scores indicated a greater level of depression. This instrument

has been widely used in the literature and has reported high reliability. The test-retest reliability correlation across a one-week period was 0.93 and the internal consistency coefficient alpha was 0.92 (Beck, Steer, & Brown, 1996). In the present study, depression scores were abstracted from participant study records and documented on a data collection form.

Follow-up visit characteristics. In addition to the individual characteristics that change over time and hinder or facilitate participant retention, follow-up visit characteristics also served as enabling factors. The specific visit characteristics included data collection measures (i.e., venipuncture, ECG, and GXT), honorarium, and length of visit.

Venipuncture, ECG, GXT and Honorarium. The data collecting procedures were performed at varying time points per the parent study protocol. For example, venipuncture was performed at baseline and annually for the first 4 years. The ECGs and GXTs were collected at baseline, year 1, year 2, and year 4. The honorarium of $100 was distributed to study participants in follow-up year 3, year 4, and year 5. Four visit characteristics (i.e., venipuncture, ECG, GXT, and honorarium) were assigned a binary indicator and coded as 0 if the characteristic did not occur in that follow-up year or 1 if it did occur in the follow-up year.

Length of visit. This enabling factor, study-visit characteristic, was defined as the usual time it took to complete an annual follow-up visit. The length of visit varied for

each year. For example, in the first year of follow-up, the length of visit was approximately 3 hours; whereas, the fifth follow-up year visit was approximately 1 hour.

Need Factor Variables

The need factor variables measured in this study included: BMI, hemoglobin A1c, and health status. Weight and health status were collected at baseline and annually for 5 years. This information was abstracted from multiple parent study forms including the Blood Pressure, Waist, Height, and Weight form; the Thoughts and Feelings form; and the Laboratory Report form. For the present study, these results were recorded on the Data Collection form.

BMI. In the present study, BMI was divided into four categories: (a) overweight individuals had a BMI between 25.0 kg/m^2 and 29.9 kg/m^2; (b) class I obese individuals had a BMI between 30.0 kg/m^2 and 34.9 kg/m^2; (c) class II obese individuals had a BMI between 35.0 kg/m^2 and 39.9 kg/m^2; and (d) class III obese individuals had a BMI greater than or equal to 40 kg/m^2.

In the parent study, body weight was measured in the morning, after voiding, but before breakfast using a calibrated digital scale. Participants were asked to wear light clothing to the study visits. Additionally, they were asked to remove their shoes, jackets, and to empty their pockets prior to weighing. BMI was calculated by dividing weight in kilograms (kg) by height in meters (m) squared (kg/m^2). The weight was abstracted from the participant study record and recorded on the Data Collection form.

In the parent study, height was measured in centimeters using a wall-mounted stadiometer. Participants stood erect underneath the head plate with their backs to the stadiometer, their feet together, and their heels positioned against the wall. They were then asked to look straight ahead and position their heads in the Frankfort horizontal plane, an imaginary line passing through the external ear canal and across the top of the lower bone of the eye socket. After positioning, the movable head plate was lowered so that it was resting on the participant's head. The participant's height was recorded to the nearest half centimeter on the Blood Pressure, Waist, Height, and Weight form. The height measurement was abstracted from the participant study record and recorded on the Data Collection form.

Hemoglobin A1c. Laboratory specimens were collected at baseline and annually for four years. The specimens were collected and processed by a certified laboratory technician. For analysis, specimens were shipped to Northwest Lipid Research Laboratories located at the University of Washington in Seattle. The results from the hemoglobin A1c assay were documented and delivered to the clinical sites on a Laboratory Report form. Hemoglobin A1c percentages were abstracted from the Laboratory Report form and recorded on the Data Collection form.

Multiple measures were used in the parent study to assess quality of life and health status; however, the instruments used were not scored at the clinical site and therefore not available for the present study. For the present study, health status was assessed using the Feeling Thermometer Rating Scale (FT). The FT is a self-report instrument and provides a single value ranking current health status. The FT is a visual

analogue scale resembling a thermometer. It has graduations ranging from 0 (*worst imaginable health state*) to 100 (*best imaginable health state*). Participants were instructed to rate their health status by drawing a line to the number on the scale that best represented their health status. The FT is a widely used utility measure that provides a numerical expression of participant's current health state. The FT has been used in previous research and has demonstrated validity and reliability (Baldassarre, Arthur, Dicenso, & Guyatt, 2002; Puhan et al., 2005; Schunemann Goldstein, Mador, McKim, Stahl, & Griffith, 2006; Schunemann Norman, Puhan, Stahl, Griffith, & Heels-Ansdell, 2007). The number representing the participant's health status was collected at baseline and annually for 5 years and reported on the parent study's Thoughts and Feelings form. This number was abstracted from the Thoughts and Feelings form and recorded on the Data Collection form in the present study.

Although not included in the three-factor model for retention, a variable of interest also extracted from participant study records was group assignment (intervention vs. comparison/control). This information was collected to test for an association between group assignment and retention. In summary, a listing of study variables and how they were operationalized are presented in Table 1.

Table 1

Study Variables and Operational Definitions

Variable	Factor	Operational Definition
Retention	Primary outcome	Binary indicator (attended within study visit window/did not attend within study visit window), measured every year
Gender	Predisposing	Binary indicator (Male/Female), measured at baseline
Race	Predisposing	Binary indicator (White/Black), measured at baseline
Age	Predisposing	Numerical variable measured at baseline and computed for the follow-up years. Recoded into ordinal categorical variables for analysis.
Education	Predisposing	Ordinal categorical variable measured at baseline
Income	Enabling	Ordinal categorical variable measured year 1—year 4
Marital Status	Enabling	Categorical variable measured year 1—year 4
Depression	Enabling	Numerical variable recoded into ordinal categorical variable for analysis measured year 1—year 4
Venipuncture	Enabling	Binary indicator (yes/no), measured year 1—year 4
ECG	Enabling	Binary indicator (yes/no), measured year 1—year 4
GXT	Enabling	Binary indicator (yes/no), measured year 1—year 4
Honorarium	Enabling	Binary indicator (yes/no), measured 1—year 4
Length of visit	Enabling	Numerical variable recoded into ordinal categorical variable for analysis measured year 1—year 5
BMI	Need	Numerical variable recoded into ordinal categorical variable for analysis measured year 1—year 5
HbA1c	Need	Numerical variable recoded into ordinal categorical variable for analysis measured year 1—year 4
Health status	Need	Numerical variable recoded into ordinal categorical variable for analysis measured year 1—year 5
Group assignment	Additional variable of interest	Binary indictor recorded at baseline (intervention group/comparison group)

Data Analysis

Data were analyzed using the IBM SPSS version 19 (2010). To answer the research questions, descriptive statistics and generalized estimating equations (GEE) analyses were performed for all variables to assess whether individual factors, enabling factors, and need factors were associated with participant retention. GEE refers to a statistical methodology that extends generalized linear models such as logistic regression for use in longitudinal data analyses. Logistic regression is a widely-popular modeling technique for binary outcomes. The expected value of a binary outcome is its probability of occurrence. Logistic regression allows estimation of regression-type models that predict a transformation of the expected probability (referred to as the logit transformation) as a linear function of some explanatory variables. Once a model has been estimated, interpretation of the effect of each explanatory variable on the outcome is commonly expressed as an odds ratio, with its associated confidence interval and p-value. However, for inferences to be valid, the independence assumption needs to hold, which requires the cases used in the analysis be statistically independent of each other. With repeated measures or longitudinal data, because the outcome is measured repeatedly on the same participants, the assumption of independence is not likely to hold. If fitted to longitudinal data, a logistic regression is likely to result in biased odds ratios, confidence intervals, and p-values, which would invalidate any inferences. GEE incorporates the correlation among repeated measures in the model estimation algorithms, resulting in more appropriate odds ratios, confidence intervals, and p-values than those resulting from a common logistic regression analysis assuming independence.

A relatively small proportion of missing data in this study was imputed using the Last-Observation-Carried-Forward (LOCF) method. Some missing data were the result of those participants attending some, but not all, follow-up visits over the 5-year period, or declining to provide information on a variable, such as income. However, other missing data were attributed to the parent study design, as data on all variables were not collected at each follow-up year. For example, income, marital status, depression, and hemoglobin A1c were not measured during the fifth year of follow-up. The largest percent of missing values on a single variable was 9.2% for income.

Using LOCF, for a missing visit, the data available from the last visit were carried forward in order to provide estimates of the participant's missing data. LOCF is one of a number of methods that can be used to impute missing data in longitudinal analysis. Its main advantage is ease of implementation. However, because it may reduce variability, its principal shortcoming is the possibility of increasing type I errors. Additional complex statistical techniques to handle missing data are beyond the scope of this dissertation and will be considered as directions for future research.

Data Analysis Strategy

First, descriptive statistics were computed to summarize the baseline data for all continuous variables and categorical variables. Continuous variables are expressed in terms of means, standard deviations, and ranges. Categorical variables are expressed in terms of frequencies and percentages. Second, bivariate tests of association were conducted incorporating two variables: retention and each of the predictor variables, controlling for year, to estimate and test a time-averaged effect. The year indicator

variable was used as a control variable in the models, because it measures the exposure to a missed visit. For example, the more years an individual is a participant in a study, the higher the chances the individual might miss a study visit. In addition to the time averaged effect, an interaction with year analysis for each predictor was examined to test if the predictor effect varied by year. Finally, in order to answer the research questions, within each factor category, all factors as predictors were put into a multivariable model, controlling for year, for a more comprehensive examination of the variables as predictors of retention.

Descriptions of the main analytical strategies are listed below by research question.

Research Question 1

How do predisposing factors, specifically gender, race, education, and age, relate to participant retention over time?

Cross tabulations between participant retention at each follow-up year and each of the predisposing factor variables (gender, race, education, and age) were computed. An initial set of GEE models was used to conduct bivariate tests of association between retention and each of the predisposing factor variables, controlling for year. The aim of the bivariate analyses was to estimate and test the effect of each predisposing factor individually on retention, across the 5-year follow-up period. Next, a second set of GEE models was fitted for each predisposing factor variable, but including a year-by-factor interaction, in order to determine whether the effect of the predisposing factor on retention varied by year. Finally, all predisposing factors as predictors, as well as a year

variable, were put into a single GEE model for a more comprehensive examination of the predisposing factors as predictors of retention. Odds ratios and confidence intervals were calculated for the predictor variables in the GEE models. A p-value of less than 0.05 was considered statistically significant.

Research Question 2

How do enabling factors, specifically income, marital status, and depression, relate to participant retention over time?

Cross tabulations between participant retention at each follow-up year and each of the enabling factor variables (income, marital status, and depression) were computed. An initial set of GEE models was used to conduct bivariate tests of association between retention and each of the enabling factor variables, controlling for year, in order to estimate and test the effect of each enabling factor individually on retention, across the 5-year follow-up period. Next, a second set of GEE models was fitted for each enabling factor variable, but including a year-by-factor interaction, in order to determine whether the effect of the enabling factor on retention varied by year. Finally, all enabling factors as predictors, as well as a year variable, were put into a single GEE model for a more comprehensive examination of the enabling factors as predictors of retention. Odds ratios and confidence intervals were calculated for the predictor variables in the GEE models. A p-value of less than 0.05 was considered statistically significant.

Research Question 3

How do need factors (BMI, hemoglobin A1c, health status) relate to participant retention over time?

Cross tabulations between participant retention at each follow-up year and each of the need factor variables (BMI, hemoglobin A1c, health status) were computed. An initial set of GEE models was used to conduct bivariate tests of association between retention and each of the need factor variables, controlling for year, in order to estimate and test the effect of each need factor individually on retention, across the 5-year follow-up period. Next, a second set of GEE models was fitted for each need factor variable, but including a year by factor interaction, in order to determine whether the effect of the need factor on retention varied by year. Finally, all need factors as predictors, as well as a year variable, were put into a single GEE model for a more comprehensive examination of the need factors as predictors of retention. Odds ratios and confidence intervals were calculated for the predictor variables in the GEE models. A p-value of less than 0.05 was considered statistically significant.

Research Question 4

How do follow-up visit characteristics (study procedures, honorarium, and length of visit) relate to participation over time?

Cross tabulations between participant retention at each follow-up year and each of the follow-up visit variables (study procedures, honorarium, and length of visit) were computed. An initial set of GEE models was used to conduct bivariate tests of association between retention and each of the study follow-up visit characteristic

variables, controlling for year, in order to estimate and test the effect of each follow-up visit characteristic individually on retention, across the 5-year follow-up period. Next, a second set of GEE models was fitted for each follow-up visit characteristic variable, but including a year-by-factor interaction, in order to determine whether the effect of the follow-up visit characteristic on retention varied by year. Finally, all follow-up visit characteristics as predictors, as well as a year variable, were put into a single GEE model for a more comprehensive examination of the follow-up visit characteristic as predictors of retention. Odds ratios and confidence intervals were calculated for the predictor variables in the GEE models. A p-value of less than 0.05 was considered statistically significant.

An additional analysis was conducted for the group assignment variable as a predictor of retention. A GEE model was fitted to test the association between retention and group assignment, controlling for year, in order to estimate and test the effect of group assignment on retention across the 5-year follow-up period. A second GEE model tested a year-by-group assignment interaction in order to determine whether the effect of group assignment on retention varied by year.

CHAPTER 4

RESULTS

Sample Characteristics at Baseline

Participant records were reviewed and data were abstracted for a 5-year period of participation. The sample consisted of records from 316 participants of whom 190 (60.1%) were female and 126 (39.9%) were male. The mean age of the sample was 59.1 years (*SD* = 6.53 years; range 45 – 75 years). The sample was predominately White (*n* = 232, 73.1%) and married (*n* = 223, 70.6%). A majority of the participants reported having either a high school diploma or a college degree (*n* = 143, 44.3%) and (*n* = 134, 42.4%), respectively. Participants reported income levels greater than or equal to $50,000/year (*n* = 150, 47.5%), while 115 participants (36.4%) reported income less than $50,000/year, and 51 participants (16.1%) did not respond to the income item on the self-administered questionnaire.

Additional characteristics of the sample included mean BMI of 35.6 kg/m^2 (*SD* = 5.80 kg/m^2; range 25.5 kg/m^2 – 53.1 kg/m^2), mean hemoglobin A1c 7.2% (*SD* = 1.2%; range 4.9% – 11.9%), health status score 76.6 (*SD* = 14.1; range 0 – 100), and depression score 6.0 (*SD* = 4.8; range 0–26). Tables 2 and 3 summarize the baseline sample characteristics.

Table 2

Sample Characteristics at Baseline (N=316)

Continuous Variables	M	*SD*	Range
Age, years	59.0	6.5	45-76
BMI, kg/m^2	35.6	5.8	25.5–53.1
Hemoglobin A1c, %	7.2	1.2	4.9–11.9
Health status	76.6	14.2	0-100
Depression score	6.0	4.8	0-26

Table 3

Sample Characteristics at baseline (N=316)

Categorical Variables	Frequency	Percent
Treatment Assignment		
Comparison Group	161	50.9
Intervention Group	155	49.1
Gender		
Female	190	60.1
Male	126	39.9
Race		
White	232	73.1
Black	84	26.9
Marital status		
Married	226	71.6
Not Married	90	28.4
Income		
<$10,000 – 49,999	115	36.4
$50,000 - $79,999	83	26.3
≥$80,000	67	21.2
Refused	51	16.1
Education		
HS Diploma or <HS	152	47.1
AS Degree	33	10.4
BA/BS Degree	79	25.0
Graduate Degree	55	17.4

The research questions were aimed at exploring predisposing factors, enabling factors, and need factors as they related to participant retention over time. Predisposing factors, those factors which exist prior to study enrollment, include gender, race, age, and education. Enabling factors are those which facilitate or hinder participant retention, including income, marital status, and depression level. Enabling factors also include

follow-up visit characteristics, such as whether or not venipunctures, ECGs, and GXTs were performed, length of annual study visit, and whether an honorarium was given after an annual study visit. Need factors, those factors which motivate participants to seek health care or change behavior, include BMI, hemoglobin A1c, and health status information.

Research Question 1

The outcomes of Research Question 1 are displayed in the following set of tables. Table 4 presents descriptive statistics of the predisposing factors at baseline and reflects how they relate to participant retention over time. Table 5 presents the bivariate tests of association for each of the predisposing factors. Table 6 presents the results from the multivariable model. All models included follow-up year as a controlling variable. Finally, the results will be discussed separately in order of gender, race, education level, and age.

Table 4

Predisposing Factors and Participant Retention Over Time: Baseline Sample (N=316)

Variable	Y1	Y2	Y3	Y4	Y5
Attended Visit N (%)	282 (89.2)	282 (89.2)	293 (92.7)	282 (89.2)	291 (92.1)
Gender					
Female	165 (86.8)	168 (88.4)	177 (93.4)	166 (87.4)	175 (92.1)
Male	117 (92.9)	114 (90.5)	116 (92.1)	116 (92.1)	116 (92.1)
Race					
White	210 (90.5)	207 (89.2)	218 (94.0)	209 (90.1)	214 (92.2)
Black	72 (85.7)	75 (89.3)	75 (89.3)	73 (86.9)	77 (91.7)
Age (at baseline)					
45-59	146 (85.4)	145 (84.8)	155 (90.6)	150 (87.7)	155 (90.6)
60-76	136 (93.8)	137 (94.5)	138 (95.2)	132 (91.0)	136 (93.8)
Education					
HS Diploma or <HS	133 (87.5)	133 (87.5)	136 (89.5)	132 (86.8)	137 (90.1)
AS Degree	26 (78.8)	27 (81.8)	32 (97.0)	30 (90.9)	31 (93.9)
BA/BS Degree	70 (88.6)	71 (89.9)	73 (92.4)	69 (87.3)	72 (91.1)
Graduate Degree	53 (96.4)	51 (92.7)	52 (94.5)	51 (92.7)	51 (92.7)

Table 5

Bivariate Longitudinal Models – Predisposing Factors (Controlling for Follow-up Year)

	Time-averaged effect			Interaction with year		
Variable	Odds Ratio	95% CI	*p*	χ^2	*df*	*p*
Gender						
Female	0.63	0.34-1.15	0.132	6.768	4	0.149
Male	Ref	—	—			
Race						
White	1.39	0.77-2.50	0.274	5.599	4	0.231
Black	Ref	—	—			
Age						
45-59	0.65	0.47-0.88	0.006	5.607	4	0.230
60-76	Ref	—	—			
Education						
HS Diploma or <HS	0.53	0.20-1.39	0.198	14.564	12	0.266
AS Degree	0.37	0.12-1.17	0.090			
BA/BS Degree	0.49	0.18-1.37	0.173			
Graduate Degree	Ref	—	—			

Table 6

Multivariable Model for Retention using Predisposing Factors as Predictors

	Time—averaged effect		
Variable	Odds Ratio	95% CI	*p*
Gender			
Female	0.88	0.47 – 1.57	0.618
Male	Ref	—	—
Race			
White	0.28	0.70 – 2.51	0.383
Black	Ref	—	—
Age			
45-59	0.68	0.49 – 0.95	0.023
60-76	Ref	—	—
Education			
HS Diploma or <HS	0.51	0.18 – 1.39	0.185
AS Degree	0.45	0.14 – 1.46	0.184
BA/BS Degree	0.47	0.16 – 1.42	0.183
Graduate Degree	Ref	—	—

Gender

The sample consisted of 316 participants, of which 126 (39.9%) were male and 109 (60.1%) were female. Male attendance at annual clinic visits was 90% or greater over a 5-year period. Female attendance was slightly lower than male attendance in

follow-up year 1 (86.8%), year 2 (88.4%), and year 4 (87.4%). During follow-up year 3, 93.4% of the original cohort of females attended the annual clinic visit, whereas 92.1% of males attended. At follow-up year 5, both males and females attended at 92.1%. Across the 5 years, there were no significant differences in the odds of retention by gender (OR for females/males = 0.63; 95% CI [0.34, 1.15]; $p = 0.132$). Also, a non-significant test of year-by-gender interaction (χ^2 (4) = 6.768, $p = 0.149$) indicated that the relationship between gender and attendance remained relatively constant across the 5-year period. When the predisposing factors, gender, race, education, and age were entered into the multivariable model, gender was not significant ($p = 0.618$).

Race

Race was dichotomized into two categories: Black and White. The participants in the sample were predominately White ($n = 232$, 73.1%). One participant chose the option "other" on the questionnaire and self-identified as Egyptian, and was excluded from analyses.

Over time, Blacks participated between 85.7% and 91.7% while Whites participated at slightly higher proportions during follow-up year 1, year 3, year 4, and year 5 (90.5%-94.0%). During follow-up year 2, retention was similar between Blacks and Whites with 89.3% retention and 89.2% retention, respectively. Across the 5 years, there were no significant differences in the odds of retention by race (OR for Whites/Blacks = 1.39; 95% CI [0.77, 2.51]; $p = 0.274$). A test of year-by-race interaction also showed a non-significant result (χ^2 (4) = 5.599; $p = 0.231$) meaning that the

relationship between race and attendance remained constant across the 5-year period. Race was not a significant predictor of retention in the multivariable model ($p = 0.383$).

Age

Age is a non-modifiable predisposing factor variable. However, unlike race and gender, age is a continuous variable that increases over time. In order to examine the relationship of age to retention over time, participants were grouped into two categories: (a) 45-59 year-olds and (b) 60-76 year-olds at the time of study enrollment.

The age group with the lowest follow-up proportion included participants from the 45-59 year-old category. The proportion of follow-up attendance for the younger group of participants over the 5-year period was 84.8% to 90.6% whereas the older group of participants attended follow-up visits consistently above 91%. Across the 5 years, a significant difference was noted in the odds of retention by age in the younger participants (OR for 45-59 year olds/60-76 year olds = 0.65; 95% CI [0.47, 0.88]; $p = 0.006$). A test of age-by-year interaction showed a non-significant result (χ^2 (4 df) = 5.607; $p = 0.230$). In the multivariable model, younger age (45-59 years) was a significant predictor of poor retention ($p = 0.023$).

Education

The participant questionnaire asked, *What is the most education you have completed?* One item on the questionnaire required the participant to identify the highest level of education that he or she completed. Education was divided into four categories: (a) high school diploma or less than high school education; (b) associate degree; (c)

bachelor degree; and (d) graduate degree. Participants with a high school diploma or less (n = 152) attended 86.8% or more of the visits over the 5-year span of the current study, with the lowest percentage occurring during the fourth year. Participants with an associate degree (n = 33) had the lowest participation at follow-up year 1 (n = 26; 78.8%) and the highest participation at follow-up year 3 (n = 32; 97%). Participants with a 4-year college degree (n = 79), Bachelor of Science (BS) or Bachelor of Arts (BA), attended at proportions from 88.6% (n = 70) for follow-up year 1 to 91.1% (n = 72) in follow-up year 5. Those participants with graduate degrees (n = 55) consistently maintained follow-up between 92.7% and 96.4% over the 5-year follow-up period.

These data trends suggest those with the highest level of education had a higher study participation than those with the lowest level of education. Over time, there was no significant difference in the odds of retention by education (OR for high school diploma and < high school diploma/graduate degree = 0.53; 95% CI [0.20, 1.39]; p = 0.198); (OR for associate degree/graduate degree = 0.37; 95% CI [0.12, 1.17]; p = 0.090); and (OR for BA and BS degree/graduate degree = 0.49; 95% CI [0.18, 1.37]; p = 0.173). A test of education-by-year interaction showed a non-significant result (χ^2 (12 df) = 14.56; p = 0.0266). The multivariable model including predisposing factors did not produce significant results for education.

Research Question 2

Enabling factors are identified as those characteristics that may facilitate or hinder participant retention. Both individual characteristics and follow-up visit characteristics are considered enabling factors in this study. Question 2 addressed the individual

characteristics of study participants, whereas Question 4 addressed follow-up visit characteristics.

The enabling factors that are grouped as individual characteristics are income, marital status, and depression. Results of the second research question are displayed in the following set of tables. Table 7 depicts the individual characteristics reported at baseline, and reflects how they related to participant retention over time. Table 8 depicts the bivariate models of individual characteristics controlling for follow-up year. Table 9 illustrates a multivariable model for retention using enabling factors as predictors. When all factors as predictors were entered into the multivariable model, no significant statistical associations were found.

Table 7

Enabling Factors and Participant Retention Over Time: Baseline Sample (N=316)

Variable	Y1	Y2	Y3	Y4	Y5
Attended Visit N (%)	282 (89.2)	282 (89.2)	293 (92.7)	282 (89.2)	291 (92.1)
Income					
<$10,000 - $49,999	97 (84.3)	101 (87.8)	104 (90.4)	100 (86.9)	101 (87.8)
$50,000 - $79,999	80 (96.4)	78 (94.0)	76 (91.6)	76 (91.6)	77 (92.8)
≥$80,000	60 (89.6)	57 (85.1)	63 (94.0)	59 (88.1)	63 (94.0)
Refused	45 (88.2)	46 (90.2)	50 (98.0)	47 (92.2)	50 (98.0)
Marital Status					
Not Married	78 (86.6)	83 (92.2)	82 (91.1)	77 (85.5)	79 (87.7)
Married	204 (90.2)	199 (88.4)	211(94.6)	205(91.9)	212 (95.0)
Depression Score					
None (0)	26 (92.9)	27 (96.4)	28 (100)	26 (92.9)	28 (100)
Minimal (1–13)	262 (89.7)	264 (90.4)	274 (93.8)	263 (90.1)	272 (93.2)
Mild/Moderate (14–26)	20 (83.3)	18 (75.0)	19 (79.2)	19 (79.2)	19 (79.2)

Table 8

Bivariate Longitudinal Models – Enabling Factors (Controlling for Follow-up Year)

	Time—averaged effect			Interaction with year		
Variable	Odds Ratio	95% CI	*p*	χ^2	*df*	*p*
Income						
<$10,000 - $49,999	0.54	0.29-1.03	0.060	6.482	8	0.593
$50,000 - $79,999	0.60	0.33-1.09	0.095			
≥$80,000	Ref	—	—			
Marital Status						
Not Married	0.63	0.38-1.03	0.068	8.422	4	0.077
Married	Ref	—	—			
Depression Score						
None (0)	2.25	1.12-4.50	0.022	19.979	14	0.131
Minimal (1–13)	1.62	0.96-2.71	0.069			
Mild/Moderate (14–26)	Ref	—	—			

Table 9

Multivariable Model for Retention using Enabling Factors as Predictors

	Time—averaged effect		
Variable	Odds Ratio	95% CI	*p*
Income			
<$10,000 - $49,999	0.57	0.27-1.22	0.149
$50,000 - $79,999	0.57	0.28-1.16	0.120
≥$80,000	Ref	—	—
Marital Status			
Not Married	0.69	0.40-1.20	0.189
Married	Ref	—	—
Depression Score			
None (0)	1.91	0.89-4.11	0.099
Minimal (1–13)	1.37	0.79-2.36	0.265
Mild/Moderate (14–26)	Ref	—	—

Income

An item in the parent study questionnaire assessed income. The question asked, *In the past 12 months, how much did you and others currently living in your household earn from all sources?* The parent study did not indicate an option to refuse; however 16.1% (n = 51) of the participants opted to leave this question blank. Income was the only item on the questionnaire that participants chose to not answer. In the present study,

income was divided into three categories: (a) < $10,000 - $49,999; (b) $50,000 - $79,999; and (c) ≥ $80,000.

Participants reporting an income of $50,000 - $79,999 consistently had the greatest participation, 91.6% or above, over the 5-year follow-up period. Participants reporting a household income level of ≥ $80,000 were retained in the study between 85.1% and 94.0%. Participants enrolled in the study who did not answer the income item on the questionnaire were retained between 88.2% and 98.0% over time. Across the 5 years, there were no significant differences in the odds of retention by income (OR for <$10,000 - $49,000 / ≥ $80,000 = 0.54; 95% CI [0.29, 1.03]; $p = 0.060$) and (OR for $50,000 - $79,999/ ≥ $80,000 = 0.60; 95% CI [0.33, 1.09]; $p = 0.095$). A test of income-by-year interaction showed a non-significant result (χ^2 (8 df) = 6.48; $p = 0.593$). Income did not emerge as a significant predictor of retention in the multivariable model.

Marital Status

In the parent study, marital status was divided into five categories: (a) single, (b) married, (c) separated, (d) divorced, and (e) widowed. However, because the single, separated, divorced, and widowed categories contained few participants, those groups were collapsed into one group. The marital status categories for this study identified participants as (a) married or (b) single, divorced, separated, or widowed. Married participants accounted for the majority of the sample ($n = 223$; 70.6%); retention among those participants remained high (>90%) at follow-up year 1, year 3, year 4, and year 5. Unmarried participants were retained at levels >90% only at follow-up year 2 and year 3.

Across the 5 years, there were no significant differences in the odds of retention by marital status (OR not married/married = 0.63; 95% CI [0.38, 1.03]; $p = 0.068$). A test of marital status-by-year interaction showed a non-significant result (χ^2 (4 df) = 8.422; $p = 0.077$). In the multivariable model marital status was not significant.

Depression

Using the BDI instrument, the baseline scores in this sample ranged from 0 to 26. These scores were categorized to examine depression status and its relationship to retention over time. Lower scores indicate a lower level of depression. For this dissertation research, participants scoring 0 were grouped as having no depression, participants scoring 1–13 were grouped as experiencing minimal depression, and participants scoring 14–26 were grouped as participants experiencing mild-to-moderate depression. The groupings for this dissertation research study differ from the standard cutoffs where 0–13 indicates minimal depression, 14–19 indicates mild depression, and 20–28 indicates moderate depression.

Participants reporting no depression at baseline, as evidenced by BDI scores, were retained at extraordinarily high proportions throughout the study. During follow-up year 5, 100% ($n = 28$) of those participants reporting no depression at baseline presented for an annual clinic visit.

Over the 5 years, there was a significant difference in the odds of retention by those reporting no depression (OR for no depression/mild-to-moderate = 2.25; 95% CI [1.12, 4.50]; $p = 0.022$). However, there was no significant difference in the odds of retention by those reporting minimal depression (OR for minimal depression / mild to moderate = 1.62; 95% CI [0.96, 2.71]; $p = 0.069$). A non-significant test of year-by-

depression level interaction (χ^2 (14) = 19.979; p = 0.131) indicated that the relationship between depression and attendance remained relatively constant across the five-year period. This finding of statistical significance was not replicated in the multivariable model (p = 0.099).

Research Question 3

Need factors are identified as those characteristics that motivate participants to seek health care or modify health behavior. These factors were examined to see how they relate to participant retention over time. In this study, the need factors were defined as BMI, hemoglobin A1c, and health status. Results of Research Question 3 are displayed in the following tables. Table 10 depicts the need factors at baseline and reflects how they relate to participant retention over time. Table 11 depicts the bivariate longitudinal model for need factors controlling for year. Table 12 illustrates the multivariable model where all need factor predictors were entered into the model.

Table 10

Need Factors and Participant Retention Over Time: Baseline Sample (N=316)

Variable	Y1	Y2	Y3	Y4	Y5
Attended Visit N (%)	282 (89.2)	282 (89.2)	293 (92.7)	282 (89.2)	291 (92.1)
BMI (kg/m^2)					
Overweight	53 (93.0)	53 (93.0)	55 (96.5)	53 (93.0)	55 (96.5)
Class I Obesity	101 (90.2)	99 (88.4)	102 (91.1)	96 (85.7)	99 (88.4)
Class II Obesity	71 (92.2)	74 (96.1)	73 (94.8)	70 (90.9)	74 (96.1)
Class III Obesity	57 (81.4)	56 (80.0)	63 (90.0)	63 (90.0)	63 (90.0)
HbA1c, %					
4.0-6.9	144 (90.0)	142 (88.8)	149 (93.1)	142 (88.8)	150 (93.8)
7.0-8.9	117 (90.0)	118 (90.8)	121 (93.1)	116 (89.2)	117 (90.0)
9.0-11.0	21 (80.8)	22 (84.6)	23 (88.5)	24 (92.3)	24 (92.3)
Health Status					
0-69.9	45 (78.9)	45 (78.9)	51 (89.5)	47 (82.5)	49 (85.9)
70.0-79.9	83 (89.2)	86 (92.5)	88 (94.6)	84 (90.3)	85 (91.4)
80.0-89.9	99 (94.3)	96 (91.4)	95 (90.5)	93 (88.6)	98 (93.3)
90.0-100	55 (90.2)	55 (90.2)	59 (96.7)	58 (95.1)	59 (96.7)

Table 11

Bivariate Longitudinal Models – Need Factors (Controlling for Follow-up Year)

	Time—averaged effect			Interaction with year		
Variable	Odds Ratio	95% CI	*p*	χ^2	*df*	*p*
BMI (kg/m^2)						
Overweight	3.01	1.52-5.96	0.002	26.570	12	0.009
Class I Obesity	1.29	0.70-2.36	0.410			
Class II Obesity	1.62	0.87-3.01	0.127			
Class III Obesity	Ref	—	—			
HbA1c, %						
4.0-6.9	1.75	0.99-3.11	0.056	13.265	8	0.103
7.0-8.9	2.11	1.17-3.18	0.013			
9.0-11.0	Ref	—	—			
Health Status						
0-69.9	0.43	0.23-0.81	0.009	14.831	12	0.251
70.0-79.9	0.63	0.38-1.09	0.080			
80.0-89.9	1.30	0.74-2.59	0.360			
90.0-100	Ref	—	—			

Table 12

Multivariable Model for Retention using Need Factors as Predictors

Variable	Odds Ratio	95% CI	*p*
BMI (kg/m^2)			
Overweight	2.82	1.28-6.21	0.010
Class I Obesity	1.31	0.67-2.54	0.433
Class II Obesity	1.72	0.91-3.25	0.095
Class III Obesity	Ref	—	—
HbA1c, %			
4.0-6.9	2.03	1.13-3.66	0.019
7.0-8.9	2.45	1.37-4.36	0.002
9.0-11.0	Ref	—	—
Health Status			
0-69.9	0.49	0.23-1.04	0.063
70.0-79.9	0.61	0.33-1.15	0.128
80.0-89.9	1.15	0.60-2.23	0.670
90.0-100	Ref	—	—

BMI

BMI was calculated by dividing participant baseline weight in kilograms by height in meters squared. In order to examine BMI over time as it relates to retention, participant baseline BMI was divided into four categories: (a) overweight participants

had a baseline BMI between 25.0 kg/m^2 and 29.9 kg/m^2; (b) class I obese participants had a baseline BMI between 30.0 kg/m^2 and 34.9 kg/m^2; (c) class II obese participants had a baseline BMI between 35.0 kg/m^2 and 39.9 kg/m^2; and (d) class III obese participants had a BMI greater than or equal to 40 kg/m^2. Participants who were overweight at baseline maintained a remarkably high retention, 93% or above, over the 5-year follow-up period. Participant identified as class I – class III obese were retained 88.4% or above, over the 5-year follow-up period. Across the 5 years, there was a significant difference in the odds of retention by obesity level. Odds ratio for class III obesity/overweight = 3.01; 95% CI [1.52, 5.96]; $p = 0.002$. These results indicate that the participants with greater levels of obesity were significantly less likely to be retained over time. These results were replicated in the multivariable model where all need factors as predictors were entered into the model ($p = 0.010$).

Hemoglobin A1c

Baseline hemoglobin A1c levels were examined in relationship to participant retention over time. The sample consisted of participants with a mean hemoglobin A1c of 7.2% (*SD* = 5.80%; range 4.9% – 11.0%). Participants with hemoglobin A1c levels ranging from 4.0% – 6.9% at baseline were retained at 88.8% ($n = 142$) in follow-up year 2 and year 4, but were retained at 93.8% in follow-up year 5. Participants with hemoglobin A1c levels ranging from 7.0% – 8.9% were consistently retained at proportions of 90% or above in year 1, year 2, year 3, and year 5. A slight dip in retention (89.2%; $n = 116$), occurred among those participants at follow-up year 4. The data indicated that participants with the highest levels of hemoglobin A1c at baseline

(9.0%-11.0%) were retained at 80.8% (n = 20) at follow-up year 1, but over time the retention among these participants gradually increased to 92.3% (n = 24) at follow-up year 5. A significant difference (p = 0.013) in the odds of retention by levels of hemoglobin A1c was noted among participants with a baseline level of hemoglobin A1c between 7.0% and 8.9% (OR for hemoglobin A1c 7.0% - 8.9%/hemoglobin A1c 9.0% - 11.0% = 2.11; 95% CI [1.17, 3.18]; p = 0.013). In the multivariable model, both categories of hemoglobin A1c were statistically significant for those with hemoglobin A1c levels between 4.0% and 6.9% (p = 0.019) and for those with hemoglobin A1c levels between 7.0% and 8.9 % (p = 0.002).

Health Status

Health status was measured using the Feeling Thermometer Rating Scale. Participants were instructed to draw a line to a point on a thermometer with gradients from 0 (*worst imaginable health state*) to 100 (*best imaginable health state*) indicating their health state at the time of the visit. Scores provided a single index value for health status. In the current study, health status scores were grouped into the following four categories: (a) 0-69.9; (b) 70-79.9; (c) 80-89.9; and (d) 90-100. Participants reporting a lower health status had the lowest retention (78.9%-89.5%; n = 57). Those participants reporting health status between 90 and 100 had consistently high retention (90.2% [n = 55]; to 96.7% [n = 59]) over the 5-year follow-up period.

Over the 5 years, a significant difference in the odds of retention by health status was noted among participants with health status values between 0 - 69.9. The OR for health status values 0-69.9/90.0-100 = 0.43; 95% CI [0.23, 0.81]; (p = 0.009). A non-

significant test of year-by-health status level interaction (χ^2 (12) = 14.831; p = 0.251) indicated that the relationship between health status and attendance remained relatively constant across the 5-year period. The statistical significance noted in the bivariate model was not replicated in the multivariable model.

Research Question 4

Research Question 4 further assesses enabling factors identified as follow-up visit characteristics. These factors include characteristics not related to participants, but pertaining to factors related to individual study visits. They include venipuncture, ECG, GXT, honorarium, and length of study visit. Table 13 describes the characteristics associated with each annual study visit. Table 14 displays the significant differences in the odds of retention that were associated with years that required an ECG (p = 0.006) and years where the length of visit was shortest (p = 0.003). The multivariable model could not be fitted due to multicollinearity.

Table 13

Follow-up Visit Characteristics

	Y1	Y2	Y3	Y4	Y5
Approximate length of visit	3 hours	2 hours	1 hour	3 hours	1 hour
Electrocardiogram	No	Yes	No	Yes	No
Venipuncture	Yes	Yes	Yes	Yes	No
Graded Exercise Test	Yes	No	No	Yes	No
Honorarium	No	No	Yes	Yes	Yes

Table 14

Bivariate Models - Follow-up Visit Characteristics

	Time—averaged effect		
Variable	Odds Ratio	95% CI	*p*
Venipuncture			
No	1.34	0.89-2.03	0.161
Yes	Ref	—	
Electrocardiogram			
No	1.28	1.07-1.52	0.006
Yes	Ref	—	
Graded Exercise Test			
No	1.19	0.93-1.52	0.165
Yes	Ref	—	
Honorarium			
No	0.69	0.45-1.06	0.093
Yes	Ref	—	
Length of Visit			
1 hour	1.48	1.15-1.92	0.003
2 hours	0.99	0.77-1.29	0.952
3 hours	Ref	—	—

Note. Interaction with year could not be tested due to collinearity between year and factors. Because of collinearity, year was controlled for assuming a linear trend.

Table 15 depicts the bivariate longitudinal model comparing treatment assignment controlling for year. The odds of retention in the control group were 60% the magnitude of the odds of retention in the intervention group (OR = 0.60). Conversely, the odds of retention in the intervention group were 1.66 times the odds of retention in the control group (1/0.604 = 1.66). However, the odds ratio is not significant at the 0.05 significance level ($p = 0.09$).

Table 15

Bivariate Longitudinal Model for Treatment Assignment (Controlling for Year)

	Time—averaged effect			Interaction with year		
Variable	Odds Ratio	95% CI	*p*	χ^2	*df*	*p*
Treatment Assignment						
Comparison Group	0.60	0.34-1.08	0.087	6.612	4	0.158
Intervention Group	Ref	—	—			

CHAPTER 5

DISCUSSION, IMPLICATIONS, LIMITATIONS, RECOMMENDATIONS, AND CONCLUSIONS

This chapter presents a discussion of the results of the study. Study conclusions, implications, limitations, and recommendations for future research are also presented.

Discussion

Research Question 1

Research Question 1 explored how predisposing factors, specifically gender, race, education, and age, relate to participant retention over time.

Gender. Participant retention among males and females was consistently high over time. Conflicting results were reported in previous clinical trials where both males and females were enrolled, making gender an inconsistent predictor of retention. Honas and colleagues (2003) found that females were less likely to be retained, whereas Glasgow and colleagues (2007) found that females were more likely to remain as participants in the research. Similar to the studies of Clark and colleagues (1996) and Fabricatore and colleagues (2009), findings from this study demonstrate that gender was not a factor associated with participant retention over time.

Race. Both Blacks and Whites were retained in the study at equally high proportions. These findings are supported by the literature in the study by Fabricatore

and colleagues (2009), where there was no association between race and retention. Previous studies reported that Blacks were more likely to drop out of behavioral weight-loss studies compared with Whites (Glasgow et al., 2007; Honas et al., 2003).

The fact that both Blacks and Whites were retained at equally high proportions could be related to the empathic staff members who are trained in cultural sensitivity issues. Another reason to consider for the equally high retention is that the present study explores not only an obese population but an obese population with type 2 diabetes. The combination of obesity and type 2 diabetes may be a contributing factor to these results. In other words, both Blacks and Whites may place equal value on the health benefit of remaining engaged in a research study that focuses on overweight and obese participants with type 2 diabetes. The present study sample had only 84 Black participants out of 316 participants. If race was more evenly distributed, the findings may have been different.

Age. Retention among older participants was high; whereas the younger participants in the study had lower attendance at annual follow-up visits. This result is similar to multiple findings in the literature where younger participants are less likely to be retained in weight-loss studies (Clark et al., 1996; Fabricatore et al., 2009; Glasgow et al., 2007; Honas et al., 2003). Honas and colleagues (2003) found that participants less than 50 years of age were significantly more likely to drop out of the program.

It may be that older individuals have less established schedules with fewer caretaking and work demands, thus allowing them to participate more consistently in activities of their choice, such as clinical research. Also, older participants may have more of an altruistic view of research, knowing that their participation now may benefit

the well-being of others in the future. Additionally, older participants may have multiple conditions threatening their health, whereas younger participants may have fewer adverse health conditions. Advanced age and multiple, adverse health conditions may enhance and inspire continual participation in a study focused on weight-loss and disease prevention.

Education. There was no association between retention and the level of education among participants. These results are supported by the literature in the study by Clark and colleagues (1996) that also did not find a significant association between participant education level and retention. Fabricatore and colleagues (2009) found that those with some college and college graduates were more likely to be retained when compared with those reporting a high school education or less. Over time, there was no significant association between retention and the level of education among participants.

In the parent study, participants were given educational materials and instructed on healthier life-styles in order to control obesity and diabetes. Perhaps a desire to increase knowledge about health conditions that affect individuals personally spans across all education levels.

Research Question 2

Research Question 2 asked how enabling factors, specifically income, marital status, and depression, relate to participant retention over time.

Income. Income was not significantly associated with retention. However, one might speculate that participants reporting lower levels of income would attend follow-up visits at significantly higher proportions compared with those reporting higher levels of income. The incentive of additional health information, education and an honorarium may be contributing factors. On the other hand, perhaps those with lower levels of income maintain jobs where they are less able to take time off to participate in clinical research. The fact that all of the participants in the study have type 2 diabetes may be a common factor regardless of income level. For example, all individuals diagnosed with type 2 diabetes may be interested in education, service, and benefit that are available with participation in a study focusing on weight-loss and diabetes control.

Marital Status. Findings showed no significant associations between retention and marital status. Fabricatore and colleagues (2009) found similar results. Conversely, Honas and colleagues (2003) found that retention among married individuals was higher at the last follow-up visit than that of those who reported being single, divorced, or widowed. In their 16-week study, Honas and colleagues (2003) reported retention at 74% for married participants, 68% for single participants, and 60% for divorced participants. The effect of an underlying disease process, such as type 2 diabetes, could affect the attitudes among participants toward the benefits of the parent study. Other studies did not explore retention in a cohort of participants with both obesity and type 2 diabetes.

Depression. Many studies in the literature suggest depression levels have a negative impact on participant retention (Clark et al., 1996; Fabricatore et al., 2009; Goldberg & Kiernan, 2005; Teixeira et al., 2006). Consistent with the previous literature, this study empirically demonstrates that individuals indicating no depressive symptoms on the BDI were retained at a significantly higher proportion than those whose scores indicated mild-to-moderate depression. Intuitively, it makes sense that participants experiencing greater levels of depression would be more likely to miss follow-up visits when compared to those participants reporting minimal to no depression. Depressed individuals may have more difficulty keeping appointments than non-depressed individuals because of the symptoms associated with depression. Addressing underlying depression prior to participant engagement in a behavioral weight-loss intervention may enhance participant retention over time.

Research Question 3

Research Question 3 explored how need factors (BMI, hemoglobin A1c, and health status) relate to participant retention over time.

BMI. Overweight individuals were more likely to present for follow-up visits over time than were individuals with class I, class II, and class III levels of obesity. The literature has conflicting findings regarding the significance of the relationship between obesity and participant retention. Carels and colleagues (2003) reported those individuals with a lower BMI were more likely to be retained in their study, while Honas and

colleagues (2003) did not find a significant association between participant retention and BMI.

Previous studies have been of shorter duration, unlike this study which examines BMI and participant retention over a 5-year period. It was interesting to discover that those participants who had the least amount of weight to lose maintained significantly higher levels of participation over time. Efforts could be made in future studies to incorporate targeted strategies to retain individuals with a greater BMI. Perhaps participants with greater levels of obesity have had less success at weight-loss attempts and therefore are less likely to stick with a long-term weight-loss intervention. The lower weight participants, as in the Carels and colleagues (2003) study, may have been able to achieve weight-loss success earlier in the program, thus providing a motivation to continue with the lifestyle strategies that contributed to their success.

Hemoglobin A1c. This study found individuals with hemoglobin A1c levels of 4.0% -8.9% were significantly more likely to attend annual study visits over time. The author was unable to identify studies in the literature that addressed the relationship between hemoglobin A1c levels and participant retention. Participants with values closer to normal were more likely to attend clinic visits, which is similar to results exploring the BMI variable. Perhaps individuals with lower hemoglobin A1c values are more motivated to continue participation in behavioral weight-loss studies because they are more diligent about maintaining glucose control.

Health Status. Findings showed that health status was not significantly related to participation. It seems likely that individuals who perceive and rank their health status low may be less likely to continue participation due to health conditions that prevent them from presenting for study visits. However, this was not found in this dissertation research study.

Research Question 4

Research Question 4 asked how follow-up visit characteristics (length of visit, honorarium, and study procedures) relate to participant retention over time.

There is no literature exploring the relationship between the length of study visit and participant retention. However, the findings are consistent with clinical observations that that study follow-up visits that are of longer duration and include multiple procedures are less appealing to study participants. Length of study visits and burden of multiple study procedures should be taken into account when designing research involving volunteers.

During the course of longitudinal research involving many study visits, participant retention could be improved if investigators considered offering shortened study visits to participants in order to decrease participant burden. For example, if a participant voiced concern over the length of a study visit, an investigator might consider splitting the visit or reducing the number of procedures in an effort to maintain participant retention.

In the parent study, an honorarium of $100 was not given until the third year of follow-up and every year thereafter. The shorter study visits had greater monetary value

because the amount of the honorarium was the same regardless of the length of the study visit. This could explain why people were more motivated to attend the shorter visits. For example, the shorter, one-hour visit occurred at the third year of follow-up which coincided with the first time the honorarium was given. The shorter visit, plus the honorarium, may have been a motivator for participants to attend the follow-up visit. During the fifth follow-up visit not only was an honorarium given but also there were no procedures or fasting required. This allowed flexibility in scheduling visits at the most convenient times for participants, possibly contributing to greater participation during that follow-up year. Ethically, honorariums should be modest and not used coercively to retain study participants. Variables associated with follow-up visit characteristics can be modified; examining factors associated with retention can inform researchers and may help increase participant retention.

Limitations

Some limitations inherent in a secondary analysis of existing data are noted. For example, data collected and measured for the parent study may not have the specificity to answer the questions posed in the secondary analysis. Some variable categories were collapsed, due to small numbers in specific categories, in order to provide meaningful statistical analyses and results. However, the Look AHEAD data set was rich with longitudinal data collected over a 5-year period and was available for analysis. A second potential limitation was that the author abstracted the data by hand and then entered the data into SPSS; this lends itself to the potential for transcription errors. However, care was taken to double-check all entries prior to data analysis. Findings reported in this

study relate to those in a behavioral weight-loss clinical trial and might not be generalizable to other clinical trials.

Implications for Research

Data generated from this study provided evidence that younger age, greater obesity, and longer study visits can negatively affect participant retention in longitudinal behavioral weight-loss studies. Further investigation is needed to explore targeted retention interventions in varied participant populations. Also, the unique role of the research team and their function as participant advocates should be explored.

Findings from this study support the need to minimize the length of visit for study volunteers to enhance participant retention. Results from this study are important when designing longitudinal research studies. Thoughtful evaluation of the amount of time spent during study visits and the number of procedures participants are required to undergo may significantly enhance participant retention. Research is needed to be able to implement these findings in future clinical trials.

Theoretically, because the Andersen Behavioral Model is well-suited to predict the use of discretionary health care services, the model adapted well to guide this exploratory study. Other theoretical models could potentially be used to examine predictors of retention in future behavioral weight-loss studies. For example, the Theory of Planned Behavior proposes that intention is a key determinant of action, and intention is determined by attitude (i.e., "What will happen if I participate in a research study to help me lose weight and how will I feel about participating?"), subjective norm (i.e., "What will people who are important to me think of my participating in a behavioral

weight-loss study?"), and perceived behavioral control (i.e., "It is up to me whether or not I participate in a behavioral weight-loss study.") (Ajzen, 1991). Because of the paucity of published theoretically-driven studies regarding participant retention in clinical research, a future study examining participation in a behavioral weight-loss study, guided by the Andersen Model, may be warranted.

Future Recommendations

Further analysis of these data could include additional variables that have been collected previously, such as quality of life questionnaire results, initial weight-loss success, and self-efficacy questionnaire results. These variables may explain additional variance in participant retention over time.

Prior to this study, visit characteristics defined by length of study visit and procedures required to complete the study visit had not been analyzed in such detail. Additional studies examining the effectiveness of participant retention strategies are needed. Because this study was a secondary data analysis and participant retention was not the main focus in the primary study, a randomized clinical trial aimed at examining participant retention in overweight and obese individuals is warranted. A randomized clinical trial would provide more information because the study aims would be specifically designed to examine participant retention over time. Last, future studies examining participant retention could be conducted in other areas of research.

Conclusions

The purpose of this dissertation research was to describe factors associated with participant retention in a behavioral weight-loss study. Three of the research questions were developed to explore how factors such as gender, race, age, income, marital status, depression level, BMI, hemoglobin A1c level, and health status relate to participant retention over time. The fourth research question was developed to explore how factors such as study visit length, study visit procedures (i.e., venipuncture, ECG, GXT), and honorarium relate to participant retention over time. In order to answer the study questions for this dissertation research, data were collected from participant study records, entered into a statistical software program, then analyzed.

Findings from this study showed age, BMI, and hemoglobin A1c, were factors significantly associated with participant retention over time. In contrast, race, gender, education, marital status, and income were factors not associated with participant retention over time. Depression was associated with participant retention a bivariate model, but not a multivariable model. Results indicated the length of a study visit was associated with participant retention over time, whereas an honorarium was not associated with participant retention over time.

Implications for research include a comprehensive investigation of factors associated with participant retention over time. Both individual characteristics and study visit characteristics need to be examined as factors associated with participant retention. One opportunity for further research would be to replicate the study using the entire Look AHEAD trial data to see what significant factors emerge. Continuing to investigate factors associated with participant retention in clinical trials may enable future

researchers to conduct efficient trials with enhanced participant retention, thus generating new knowledge aimed at promoting, protecting, and restoring health.

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APPENDIX A

DESCRIPTION OF THE PARENT STUDY

Description of Parent Study

The Look AHEAD Study is a prospective longitudinal, randomized clinical trial currently being conducted at 16 clinical sites in the U.S. The clinical sites are all located in urban settings at major university medical facilities. The Birmingham, Alabama clinical research site is located within the DOPM of the UAB School of Medicine.

Participants were randomized into one of two arms of the study: (1) intensive lifestyle or (2) a comparison group termed "Diabetes Support and Education." The intensive lifestyle intervention includes engaging in moderate physical activity of 200 minutes per week and a healthy, portion-controlled diet. The goal of the intervention is for participants to lose and maintain at least 10% of their body weight. The comparison group meets occasionally to provide diabetes education and social support. The primary study objective is to determine whether participation in a lifestyle intervention is effective in reducing the incidence of serious cardiovascular disease events in overweight and obese adults with type 2 diabetes.

The Look AHEAD Study is funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH). The author of this dissertation is involved in the research process with responsibilities of clinical research nurse and retention coordinator at the Birmingham site (UAB).

Sample

The study population, inclusion/exclusion criteria, sample size, and recruitment procedures for the parent study will be described. Additionally, the description will include details regarding the proposed secondary analysis.

A total of 5,145 volunteers with type 2 diabetes who were 45-75 years of age and overweight or obese (body mass index $\geq$ 25 kg/m^2) were recruited for the Look AHEAD Study over a 2.5-year time period. At the Birmingham site, 316 volunteers were enrolled in the study. Randomized participants are followed annually for a maximum of 13.5 years. Follow-up will continue through 2014. Potential volunteers who were unlikely to be able to carry out the components of the weight loss intervention were excluded.

Study Procedures

The individual clinical centers developed site-specific recruitment plans. Each site-specific recruitment plan reflected a variety of approaches directed both at population-based recruitment and at recruitment from identified diabetic patient groups. A central media group developed a variety of materials (e.g., brochures, media kits, video ads for television outlets, five-minute video tapes and slide sets for community events, newspaper ads, billboards, medical care setting displays, posters) for local-site production, as needed.

Multiple recruitment strategies were deployed in Birmingham, Alabama. Television advertisements were aired, advertisements were placed in local newspapers, billboards were placed on city buses, and staff attended and recruited at events such as the *Southern Women's Show*. Posters and brochures were placed in physicians' offices. Direct mail campaigns were used, where potential participants fitting the age demographic were mailed invitation letters and brochures. In addition to the previously-described recruitment techniques, participants were asked to "tell a friend" who might be eligible and interested in study participation.

The Look AHEAD Study was approved by the IRB at each clinical site. Participants signed a two-step informed consent document; initially they signed a consent form to be screened for eligibility, and if they met eligibility criteria, another consent document for the main study was signed at the randomization visit.

The screening process consisted of multiple steps. First, volunteers were preliminarily screened over the telephone or at community events to determine potential eligible volunteers. Second, volunteers attended an informational orientation visit where they received information about the study, a screening consent document to review, and an opportunity to ask questions of study staff. Third, once the screening consent document was signed, volunteers were scheduled for screening visit one (SV1). During SV1, laboratory tests, anthropometric measures, and questionnaires were completed. Also, a two-week run-in period was initiated. Participants were given a record book to record daily information about diet and physical activity. Successful recording was required for eligibility because if randomized to the intense lifestyle group it would be required. Fourth, before the end of the SV1 screening visit two (SV2) was scheduled. During SV2 the completion of the run-in was assessed, a GXT was performed, and a complete medical history was obtained. Finally, screening visit three (SV3) was scheduled, and during this visit randomization took place. Baseline data were collected during the screening visits and follow-up data were collected through annually-scheduled clinic visits and telephone interviews. Follow-up data collection will continue annually until study close-out in 2014.

All medical information and study charts are kept in locked file cabinets, in a locked office, on a floor that requires card key access. All study forms are identified by

participant identification number and acrostic only. Files containing names, addresses, or other identifiers are limited to authorized personnel.

A detailed protocol for the Look AHEAD clinical trial can be found at www.lookaheadtrial.org/public/lookAHEADProtocol.pdf.

APPENDIX B

INSTITUTIONAL REVIEW BOARD APPROVAL FORMS

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 September 29, 2013. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator:	ROCHE, CATHY C
Co-Investigator(s):	
Protocol Number:	**X110425004**
Protocol Title:	*Factors Associated with Retention in a Behavioral Weight Loss Study*

The IRB reviewed and approved the above named project on 5-18-11. 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: 5-18-11

Date IRB Approval Issued: 5-18-11

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.

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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 January 24, 2017. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator: ROCHE, CATHY C

Co-Investigator(s):

Protocol Number: **X110425004**

Protocol Title: *Factors Associated with Retention in a Behavioral Weight Loss Study*

The IRB reviewed and approved the above named project on 5-1-12. 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: 5-1-12

Date IRB Approval Issued: 5-1-12

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.

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APPENDIX C

DATA COLLECTION FORM

Factors Associated with Retention in a Behavioral Weight Loss Study: ***Data Collection Form***

ACROSTIC ___ ___ ___ ___ ___ ___ Date Completed: ___ ___/___ ___/___ ___ ___ ___

Baseline						No Honorarium
Marital Status:	1☐ Single	2☐ Married	3☐ Separated	4☐ Divorced	5☐ Widowed	
Education:	1☐ <HS	2☐ HS Diploma/GED	5☐ AS Degree	6☐ BA/BS	8☐ GradDegree	
Income:	1☐ <$10,000	2☐ $10,000-$49,999	3☐ $50,000-$79,999	4☐ ≥$80,000	5☐ PMD	
Moods:	___ ___	Health Status:	___ ___ ___			
Weight:	___ ___ ___ . ___ kg	Height:	___ ___ ___ . ___ cm	HbA1c:	___ ___ . ___ %	

FV 12 / Year 1						No Honorarium/Yes ECG/Yes GXT
Marital Status:	1☐ Single	2☐ Married	3☐ Separated	4☐ Divorced	5☐ Widowed	
Income:	1☐ <$10,000	2☐ $10,000-$49,999	3☐ $50,000-$79,999	4☐ ≥$80,000	5☐ PMD	
Moods:	___ ___	Health Status:	___ ___ ___			
Weight:	___ ___ ___ . ___ kg			HbA1c:	___ ___ . ___ %	

FV 24 / Year 2						No Honorarium
Marital Status:	1☐ Single	2☐ Married	3☐ Separated	4☐ Divorced	5☐ Widowed	
Income:	1☐ <$10,000	2☐ $10,000-$49,999	3☐ $50,000-$79,999	4☐ ≥$80,000	5☐ PMD	
Moods:	___ ___	Health Status:	___ ___ ___			
Weight:	___ ___ ___ . ___ kg			HbA1c:	___ ___ . ___ %	
ECG:	0☐ No	1☐ Yes		GXT:	0☐ No	1☐ Yes

FV 36 / Year 3						Yes Honorarium/ No ECG / No GXT
Marital Status:	1☐ Single	2☐ Married	3☐ Separated	4☐ Divorced	5☐ Widowed	
Income:	1☐ <$10,000	2☐ $10,000-$49,999	3☐ $50,000-$79,999	4☐ ≥$80,000	5☐ PMD	
Moods:	___ ___	Health Status:	___ ___ ___			
Weight:	___ ___ ___ . ___ kg			HbA1c:	___ ___ . ___ %	

FV 48 / Year 4						Yes Honorarium/ Yes ECG/ Yes GXT
Marital Status:	1☐ Single	2☐ Married	3☐ Separated	4☐ Divorced	5☐ Widowed	
Income:	1☐ <$10,000	2☐ $10,000-$49,999	3☐ $50,000-$79,999	4☐ ≥$80,000	5☐ PMD	
Moods:	___ ___	Health Status:	___ ___ ___			
Weight:	___ ___ ___ . ___ kg			HbA1c:	___ ___ . ___ %	

FV 60 / Year 5			Yes Honorarium/ No ECG/ No GXT
Weight:	___ ___ ___ . ___ kg	Health Status:	___ ___ ___