THE IMPACT OF THE HEALTHY LIVING PARTNERSHIPS TO PREVENT DIABETES (HELP PD) INTERVENTION ON MEASURES OF SELF-EFFICACY

BY

HEIDI SUSAN DOTSON

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Approved By:

Jeffrey A. Katula, Ph.D., Advisor

Shannon L. Mihalko, Ph. D.,Chair

Peter H. Brubaker, Ph. D.

DEDICATION

This thesis is dedicated to my incredible family. Mum, Dad, and Kerri you've helped make this possible through your continued support when things got tough. I'm blessed to draw strength and inspiration from you each day. I love you!

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LIST OF ABBREVIATIONS

ANCOVA – Analysis of Covariance

CHW – Community Health Worker

CVD – Cardiovascular Disease

DPP – Diabetes Prevention Program

DPPLI – Diabetes Prevention Program lifestyle intervention

ExSE – Exercise Self-Efficacy

FDPS – Finnish Diabetes Prevention Study

CHW – Community Health Workers

HELP PD – Healthy Living Partnerships to Prevent Diabetes

LWL – Lifestyle Weight Loss

N – Sample Size

M – Mean

SE – Self-Efficacy

UCC- Usual Care Control

WEL – Weight Efficacy Lifestyle

WL – Weight Loss

ABSTRACT

Although numerous diabetes prevention translational studies (DPPLI) have demonstrated weight loss effects, no studies have yet examined the theoretical mechanisms involved in those effects. The purpose of this study is to examine self-efficacy changes between groups across the 24-month HELP PD trial. The hypothesis is that the lifestyle weight loss (LWL) group will show greater changes than the usual care control (UCC) group at each time point for both measures of self-efficacy. HELP PD randomized 301 participants to either a community-based, community health worker (CHW)-led DPPLI translational LWL intervention, which was designed based on self-efficacy theory, or a UCC. Self-efficacy was measured using weight efficacy lifestyle, and task specific exercise self-efficacy. ANCOVAs show that for both measures the LWL significantly increased from baseline to 6 months (ΔWEL p= 0.000) (ΔexSE p=0.000) and 12 months (ΔWEL p= 0.007) (ΔexSE p= 0.000) compared to the UCC, but there were no significant differences between groups from baseline to 24 months (ΔWEL p= 0.121) (ΔexSE p= 0.505). Limitations include: uncontrolled moderators and an inability to determine which sources of self-efficacy were impacted by the intervention. These findings show that CHW-led, social cognitively-based DPPLI translation studies can target and influence self-efficacy.

INTRODUCTION

Approximately 8.3% of the US population has Diabetes Mellitus, and 90- 95% of diagnosed cases are Type II Diabetes (CDC, 2010). Another 29.5% of the population is pre-diabetic (Cowie et al., 2009). The Finnish Diabetes Prevention Study and Diabetes Prevention Program both found that the incidence of diabetes among pre-diabetics can be reduced by 58% with lifestyle modification and weight loss (Tuomilehto et al., 2001) (Knowler et al., 2002). A review of Diabetes Prevention Program lifestyle intervention (DPPLI) translational studies found that among the small number of randomized controlled trials, those interventions led by community health workers (CHWs) had a greater impact on body weight than those led by professional personnel (Ali et al., 2012). CHWs are community members working with the healthcare or research team to help in cultural translation, advocate for community needs, provide counseling on health behaviors, and deliver some direct healthcare services. Few studies have utilized CHWs in translation of the DPPLI, and only a limited number are randomized controlled trials (Ruggiero et al., 2011). The Healthy Living Partnership to Prevent Diabetes Project (HELP PD), is a randomized controlled trial, CHW-facilitated, translation of the DPPLI that demonstrated significant effects on body weight and numerous metabolic indicators. Participants in the lifestyle weight loss group attended weekly group meetings, led by a CHW, and founded in social cognitive and self-efficacy theories (Katula et al., 2010). Self-efficacy is defined as beliefs in one's abilities to overcome barriers and meet task demands. Self-efficacy is influenced by: performance accomplishments, vicarious experiences, verbal persuasion, and physiologic experiences (Bandura, 1989). Numerous studies have demonstrated that self-efficacy is a consistent predictor for weight loss

success (Palmeria et al., 2007; Shin et al., 2011; Annesi, 2010; Annesi, 2012; Byrne et al., 2012). Literature shows that self-efficacy tends to increase across weight loss interventions, and a number of studies target sources of self-efficacy through intervention design (Clark et al., 1996; Pinto et al., 1999; Focht et al., 2005; Zijlstra et al., 2006; Bas et al., 2009; Smith et al., 2010; Brawley et al., 2012; Staiano et al., 2013). None of these studies showing increases in self-efficacy are DPPLI translations, nor do they utilize CHWs. The timelines of these studies do not examine long-term maintenance of weight loss. Further understanding of self-efficacy changes will allow researchers and healthcare providers to impact self-efficacy to improve weight loss and battle chronic diseases including Type II Diabetes Mellitus. The purpose of this current study is to examine changes in two measures of self-efficacy between the lifestyle weight loss intervention and usual care condition over 24 months of the HELP PD project.

LITERATURE REVIEW

Background

There has been a linear increase in the prevalence of obesity for US adults aged 20-74 years since 1976. Today, more than one-third of US adults are obese, with a BMI ≥ 30 kg/m^2 (Flegal et al., 2010). Obesity is a major risk factor for Diabetes Mellitus, which is prevalent in 25.8 million Americans, roughly 8.3% of the US population, and 10.9 million Diabetics are 65 years or older. Individuals with diabetes have a risk for death twice that of non-diabetics of similar age (CDC, 2010; CDC, 2011). The addition of a 2 hour oral glucose tolerance test to the 2005-2006 NHANES survey shed light on a crude prevalence of undiagnosed diabetes among 4.9% of US adults > 20 years. Together with those undiagnosed diabetics recognized using a fasting blood glucose test, the total crude prevalence of undiagnosed diabetes is 5.1% among US adults over 20 years old. The prevalence of diabetes increases among older adults, peaking among adults 60-74 years old. Another 29.5% of the population is considered pre-diabetic (Cowie et al., 2009).

The widespread complications associated with diabetes creates a tremendous burden on the health care system: $174 billion annually, $52.8 billion of which are indirect costs such as absenteeism, presenteeism, disability, and early mortality (Dall et al., 2011). The remaining costs are due to medical care for diabetes-related complications, which can include but are not limited to: heart disease, stroke, hypertension, blindness, kidney disease, nervous system disease, amputations, dental disease, and pregnancy complications. Although Type I Diabetics are shown to incur greater medical expenses, approximately 90-95% of diagnosed cases are Type II Diabetes Mellitus, and thus it comprises the majority of the economic burden (Dall et al., 2009).

The growing prevalence, complications, and economic burden of Type II Diabetes Mellitus deserve some attention.

DPP and FDPS

Both the Finnish Diabetes Prevention Study and the Diabetes Prevention Program discovered that through lifestyle modification focused on weight loss, the incidence of Type II Diabetes Mellitus can be reduced by 58% in high risk pre-diabetic populations (Tuomilehto et al., 2001; Knowler et al., 2002). The Finnish Diabetes Prevention Study randomly assigned participants to either a control or intervention group. Participants in the intervention group were encouraged to lose at least 5% of their initial body weight through low-fat, high-fiber, and low-calorie dieting and regular moderate intensity exercise. Waist circumference, fasting blood glucose, 2 hour OGTT, and serum insulin concentration all decreased significantly in the intervention group compared to the controls. The average amount of weight lost in the intervention group was not large (5.4% of initial weight), but the incidence of diabetes was significantly reduced by 58% from the controls (Tuomilehto et al., 2001). The Diabetes Prevention Program randomly assigned participants to a placebo, metformin, or lifestyle modification group. Those in the metformin group were prescribed 850mg of metformin taken once daily, and placebo tablets also taken once daily. After the first month, the metformin was increased to 850 mg taken twice daily. Lifestyle modification participants were to achieve and maintain a weight reduction of at least 7% of their initial body weight through a low-calorie, low-fat diet and regular moderate intensity physical activity for at least 150 minutes each week. Participants in the lifestyle intervention group attended 16 one-to-one lessons on diet, exercise, and behavior modification during the first 24 weeks. Half of participants within

the lifestyle intervention achieved the weight loss goal at the close of the 24 week curriculum, and 38% had lost 7% of their initial body weight at the most recent visit. A greater proportion of 74% met the goal of 150 minutes of physical activity per week at 24 weeks, and 58% at the most recent visit. The incidence of diabetes was 58% lower in the lifestyle intervention and 31% lower in the metformin group when compared to the placebo group. Incidence of diabetes was 39% lower in the lifestyle intervention compared to metformin (Knowler et al., 2002). Table I compares the lifestyle interventions of the FDPS and DPP. The findings of the Diabetes Prevention Program and Finnish Diabetes Prevention Study have been widely accepted and led researchers to seek means of translating and disseminating similar weight loss programs to prevent diabetes.

Table I: Lifestyle Interventions of DPP vs. FDPS

Diabetes Prevention Program (DPP)	Finnish Diabetes Prevention Study (FDPS)
N= 3234	N= 523
Weight loss goal 7% +	Weight loss goal 5% +
Low calorie, Low fat diet	Low calorie, Low fat, high fiber diet
150 min of moderate PA / week	30 min of moderate PA / day
16 core sessions in first 24 weeks	7 sessions in first year, & 1 session every 3 months afterwards

Translation of DPP

There are several notable reviews that highlight the major themes within the DPP translation literature (Whittemore et al., 2011; Ali et al., 2012; Ruggiero et al., 2011). Studies vary in holding to the original DPP lifestyle intervention (DPPLI), and differ in the amount of weight lost among participants. Study design also varies, but there are a handful of randomized control trials translating the DPP.

Whittemore and colleagues (2011) performed a systematic review of 16

translational research studies of the Diabetes Prevention Program. The majority of studies were one-group designs varying in length of follow-up from 3 months to 2 years, but the review also included 2 pilot clinical trials and 1 cohort design trial. The studies were organized by setting: hospital outpatient or diabetes education, primary care, community setting, and church or workplace environment. Sample sizes ranged from 8 – 1,003 participants, and were predominately female but of diverse ethnicity. The primary outcome of weight loss varied at follow-up from -1.0 to -8.6 kg, but the reporting style differed with some studies reporting percent of participants who met the 5% weight loss goal ranging from 11% to 64%. This review was limited by studies predominately being one-group design, with small sample sizes. The variability in outcomes reported and follow-up timing eliminated the possibility of performing a meta-analysis (Whittemore et al., 2011).

A recent meta-analysis by Ali and colleagues (2012) highlighted 28 Diabetes Prevention Program translational studies, but limited the analysis to studies where participants received structured lifestyle interventions. Studies were primarily conducted in urban areas in a variety of settings: community environments, health care facilities, and 4 studies utilized electronic media. Among the 28 studies included in the review, only 4 were randomized controlled trials. The mean weight change seen across studies was -3.99% of initial body weight at 12-month follow-up visits. Interestingly, a sensitivity analysis indicated that those interventions led by community health workers (CHWs) resulted in greater weight loss. This review was limited by the small and predominantly female sample of some studies, heterogeneity in design, intervention, analyses, and outcomes, as well as the lack of description in some publications leading to

misclassification (Ali et al., 2012). However, it does appear that several models of community-based translations of diabetes prevention programs are feasible. Translational research of the Diabetes Prevention Program and Finnish Diabetes Prevention Study has struggled with finding the balance of intervention intensity needed to achieve significant weight lost. A theme across a number of these studies was the utilization of lay healthcare workers, community health workers, or peer leaders as a means to reach the larger populous and underserved communities. These trials have shown that perhaps a successful diabetes prevention program may include community health workers delivering a culturally tailored extensive curriculum to a large sample of the population with the greatest risk for developing diabetes.

Translation of DPP using CHWs

West et al. (2011) explored the effectiveness of a translation of the diabetes prevention program delivered by lay health educators within senior centers to promote weight loss among older adults. Senior centers across Arkansas were randomized to a diabetes prevention program or an attention control intervention. Participants at the senior centers randomized to the intervention group met in 12 weekly group sessions led by a lay health educator. These sessions were based off the diabetes prevention program to achieve 7% weight loss, calorie restriction including <25% of intake from fat, and increased physical activity graded to reach 150 minutes per week of moderate intensity activity. Those receiving the lifestyle intervention lost significantly more weight (38% lost ≥ 5% of baseline weight) than participants receiving the control (5% lost ≥ 5% of baseline weight). This trial shows that lay health educators provide a means to disseminate the diabetes prevention program and achieve meaningful weight loss success

(West et al., 2011).

Ruggiero and colleagues (2012) reviewed the literature to: define CHWs, describe their role and impact on diabetes care, and examine studies involving CHWs translating the DPPLI. CHWs represent motivated community members set to promote change. A number of DPP translational studies have utilized CHWs, but few are randomized control trials.

CHWs are lay members of the community who work/ volunteer in association with the local healthcare system. These individuals share language, ethnicity, socioeconomic status, and experiences with the community they serve. They provide translation, culturally appropriate health education, assistance in delivering healthcare to those who need it, counseling on health behaviors, advocate for community needs, and provide some direct health services. The worldwide shortage of health professionals and increasing rates of obesity and diabetes make CHWs a promising option for diabetes prevention weight loss programs (Ruggiero et al., 2012).

The American Association of Diabetes Education has recognized the importance of CHWs by defining them as frontline public health workers, who act as trusted members of their communities. They are called upon to serve as a link between the healthcare services and the community. In turn CHWs build community health knowledge and self-sufficiency. The literature shows that DPPLI programs utilizing CHWS can achieve significant weight loss (Ruggiero et al., 2012).

Ruggiero and colleagues (2012) reviewed 6 studies that have utilized CHWs in the translation of the DPP lifestyle intervention either as primary interventionists, or supportive team members. In the DEPLOY model a YMCA was used to translate the

DPPLI. This was a pilot cluster randomized trial involving 92 participants who were assigned to the lifestyle intervention or the counseling control group. The DPPLI core program was delivered by trained YMCA staff (CHWs). These results showed an average weight loss of 6% in the intervention group verses 2% in the control group (Ackermann et al., 2008). The HELP PD project was a randomized controlled trial with a community-based DPPLI translation. This sample was much larger with 301 participants who received either: the usual care control (UCC) or a 2-year, 24-session, group based, and CHW delivered intervention focused on nutrition and exercise. One-year results showed that those receiving the DPPLI lost significantly more weight and had significantly better clinical outcomes than those in the UCC (Katula et al., 2012). The POLI study was a community-based participatory research study investigating the translation of the DPPLI in a population of native Hawaiians and Other Pacific Islanders. The intervention was administered in groups, over 12 weeks, to 239 participants. There was a significant improvement in all clinical measures, and a mean weight loss of 1.5 kg (Mau et al., 2010). Making The Connection Study investigated a community-based participatory translation of the DPPLI in a Latino community. CHWs delivered a 1-year intervention to 69 participants. Results showed significant improvement across time for weight, waist circumference, and body fat (Ruggiero et al., 2011). Seidel and colleagues (2008) translated a DPPLI to an urban medically underserved community through a community hospital. This nonrandomized prospective study involved 88 participants. The intervention included 12 group sessions over 12-14 weeks delivered by an RD and an exercise specialist with support from CHWs. Percentages of participants who lost 5% and 7% of their initial weight were 46.4% and 26.1%, additionally the majority of

participants sustained their weight loss at 6 months (Seidel et al., 2008). The Senior Center Model was delivered by CHWs to 228 participants within 15 senior centers. This cluster randomized control trial assigned participants to an attention control group or the 12-session translated DPPLI. Compared to the control group the intervention achieved a significantly greater weight loss, and significantly greater proportion of participants reached either 5% or 7% weight loss (West et al., 2011).

These studies illustrate the valuable role of CHWs in translating the DPPLI in community settings and working with multi-disciplinary teams. Limitations to Ruggiero's review are the limited number of large randomized controlled trials, and inconsistency of outcome measures (Ruggiero et al., 2012).

This current study is based on the aforementioned HELP PD project. This was a community based implementation of the DPPLI conducted in community-based sites, implemented by a local Diabetes Care Center, and facilitated by CHWs. Registered Dietitians (RDs) were trained by study staff to train CHWs. The CHWs completed 36 hours of training involving: experiential learning, instruction, peer mentoring, and observation. The DPPLI translation was referred to as the lifestyle weight loss (LWL) intervention, which incorporated an increase in moderate physical activity along with a dietary weight loss program. CHWs led weekly group sessions during the first phase, and in the maintenance phase contacted participants twice monthly via 1 phone call and 1 group meeting. RDs held three meetings with each participant during the first phase. CHWs used a session intervention plan, DVD series, and toolkit of handouts to assist in the group meetings. The LWL was designed based on Self-Efficacy Theory (Katula et al., 2010).

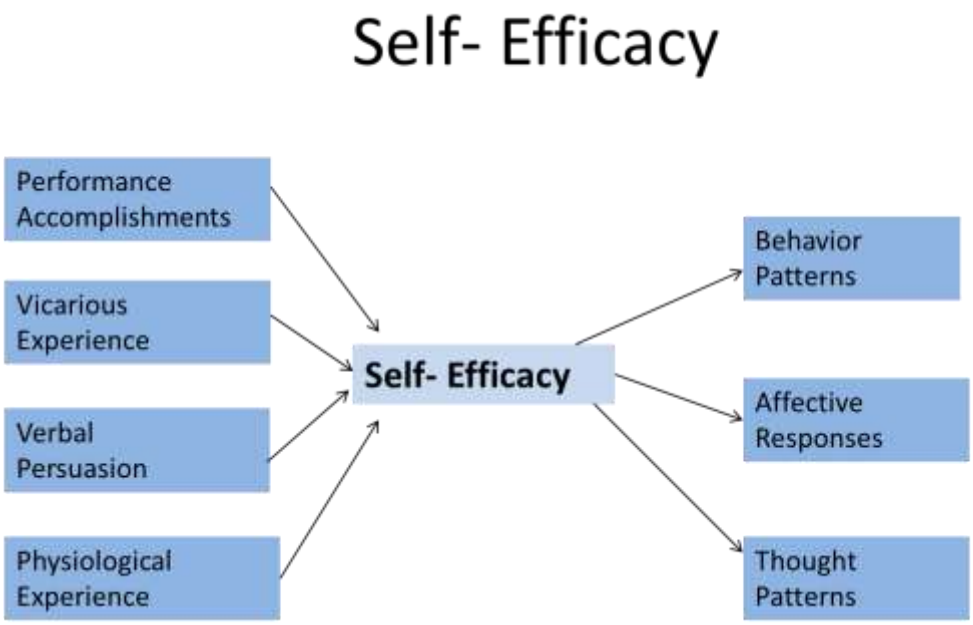
Self-Efficacy Theory

Albert Bandura (2004) points to Social Cognitive and Self-Efficacy Theories as a means for health promotion to battle chronic diseases like Type II Diabetes Mellitus (Bandura, 2004). Social Cognitive Theory states that a person, the environment, as well as the cognitive and emotional processes all interact to influence behavior. Self-Efficacy Theory is primarily concerned with the role of cognition in triadic reciprocal causation of Social Cognitive Theory. Understanding of self-efficacy began as: "People process, weigh, and integrate diverse sources of information concerning their capability, and they regulate their choice behavior and effort expenditure accordingly" (Bandura, 1977), and grew into "Beliefs in their capabilities to mobilize the motivation, cognitive resources, and courses of action needed to exercise control over task demands" (Bandura, 1990). Today self-efficacy can be understood as belief that one can exercise control over specific behaviors and overcome barriers.

Bandura (1989) outlined four primary sources that provide information and act as determinants of self-efficacy. Performance experiences are one's own life experiences. Particularly clear successes or failure can act as the most powerful sources of self-efficacy information. Vicarious Experiences take place through observational learning, modeling, and imitation. The impact of this depends upon the perception of the similarity between observer and model, the number and variety of models, perceived power of the models, and similarity between the problems faced by both the observer and the model. Verbal persuasion is influenced by expertise, trustworthiness, and attractiveness of the source. Verbal persuasion is not as strong sources of self-efficacy as performance experiences or vicarious experiences. Physiological states influence self-efficacy when

people associate aversive physiological responses with poor behavioral performance, or perceived incompetence or failure (Bandura, 1989). Figure 1 illustrates the sources of self-efficacy. Whichever of these sources is proximal will impact self-efficacy to a greater extent than those that are more distal (Maddox, 1995).

Figure 1: Self-Efficacy Theory



Self-efficacy beliefs influence behavior through four mediating processes (Maddox, 1995). Goal-setting and persistence stresses the importance of people's choice of goals, goal-directed activities, expenditure of effort, and persistence in the face of adversity. An example of this is: motivation to achieving difficult goals are influenced by overestimates of personal capabilities which become self-fulfilling prophecies. Self-efficacy beliefs influence cognition in four ways. Goals people set for themselves are impacted by self-efficacy, as are strategies people seek to attain these goals. Additionally, self-efficacy influences the development of rules for influencing events,

and self-efficacy for problem-solving influences efficacy and effectiveness of problem-solving. Self-efficacy beliefs are important determinants of affective responses to events, which can then influence cognition and action. One's self-efficacy beliefs about behavioral performance influences type and intensity of emotional response, which then impacts coping methods. Plus, self-efficacy for controlling the cognitions which influence affect can impact the emotional responses. Lastly, self-efficacy impacts people's selection of environments, which can in turn influence the continued development of these same beliefs (Maddox, 1995).

Bandura (2004) stresses the importance of health habits as a means to maintain health throughout life. This approach focuses upon the demand side of healthcare. Self-efficacy effects health behavior directly and indirectly through its impact on goals, outcome expectations, and perception of sociostructural facilitators and impediments to health- promoting behavior. However Bandura does admit that his theories over predict the resistance of health habits to change. Self- efficacy is specific to task and situation, meaning that self-efficacy may vary greatly within an individual from task to task. The specificity of self-efficacy distinguishes it from other cognitive constructs, and creates two distinct types of self-efficacy. Task self-efficacy is concerned with perceived competence at mastering the demands of a given task. Barriers self-efficacy focuses upon beliefs in one's capabilities to overcome barriers to a goal. The recognition that the weight of disease is shifting from acute to chronic illnesses points to the niche that self-efficacy theory can fulfill in self-management of chronic diseases and behavior change therapies (Bandura, 2004).

Self-efficacy has been examined as a valuable aspect of weight loss treatment.

Cochrane (2008) presents an anecdote that mimics the all too familiar patient whom has struggled with weight loss and believes that success is not possible. He suggests that this patient can in fact achieve successful weight loss once they improve their self-efficacy. Pointing out that self-efficacy comes from a sense of self-worth, which in turn promotes personal initiative, persistence, self-confidence, and optimism (Cochrane, 2008).

Self- Efficacy as Predictor of Successful Weight Loss

In fact, self-efficacy has been shown to predict weight loss. Palmeira and colleagues (2007) enrolled 142 overweight and obese women in a 16-week weight control program to examine how exercise and weight management psychosocial variables from the Social Cognitive Theory, the Transtheoretical Model, the Theory of Planned Behavior, and Self-Determination Theory predict short-term weight change. Participants achieved a significant mean decrease in weight. Social Cognitive Theory was shown to be the strongest model with self-efficacy as a predictive variable. Self-efficacy increases were shown to predict weight loss independently of baseline scores (Palmeira et al., 2007). Shin and colleagues (2011) examined whether self-efficacy was able to predict successful weight loss in 90 early postmenopausal women taking part in a 6-month weight loss program. The subjects who lost more weight reported higher scores on 2 and 5 subscales and total weight efficacy lifestyle at baseline, and higher scores on 4 and 5 subscales and the total weight efficacy lifestyle at 6 months. These results are consistent with previous findings, yet stand out by using the total weight efficacy lifestyle and 5 subscales to examine self-efficacy (Shin et al., 2011). In partnership with the YMCA of Atlanta, Annesi (2011) enrolled 183 obese participants in a 26-week exercise and nutrition treatment based upon self-efficacy theory. The double-blinded trial showed

statistically significant improvements in all variables following 26 weeks, with 26% of participants losing 5% or more of their initial weight. Improved self-efficacy significantly predicted increased fruit and vegetable intake, and increased exercise. Changes in self- regulatory skill usage accounted for the majority of the remaining variance, leaving the total indirect effect of the treatment on weight loss at 0.34. This shows that improvement of self-efficacy and self-regulatory skills are key to successful weight loss (Annesi, 2011). Annesi (2012) further examined associations of changes in exercise behavior, psychosocial factors, eating behaviors, and weight through a field based study of 430 obese adults. Participants took part in 26 weeks of cognitive-behaviorally supported exercise, and received either standard nutrition education, or cognitive- behavioral nutrition education. Results showed significant overall changes in all measures at 26 weeks. Changes in exercise, self-efficacy, and self-regulation for exercise significantly predicted change in exercise volume, as well as changes in weight efficacy lifestyle scores, and self-regulation for eating significantly predicted change in fruit and vegetable consumption (Annesi, 2012). Byrne and colleagues (2012) evaluated the effects of pre-treatment self-efficacy for diet and exercise as well as changes in self-efficacy during treatment upon weight loss success. Thirty participants took part in a 12-week weight loss treatment where they received the diabetes prevention program manual, and had weekly 30-minute counseling sessions. Additionally one group of participants was provided with tangible reinforcements for weight loss and activity completion. The mean weight loss across all participants was 4.9 lbs. Attendance and increased exercise self-efficacy were significantly associated with weight loss (Byrne et al., 2012). The results of these five studies have added to the discussion of self-efficacy acting as a

predictor for successful weight loss. This relationship has been widely accepted and many weight loss trials tailor towards boosting self-efficacy.

Self-Efficacy Changes Across Weight Loss Intervention

Clark and colleagues (1996) examined the construct validity of the weight efficacy lifestyle questionnaire by enrolling 26 obese subjects in a 26-week weight management program combining behavior therapy and a very-low calorie diet. Subjects lost a mean weight of 25.3kg and showed significant improvement on total WEL scores and all 5 subscales. These results provide construct validity, but also demonstrate improved self-efficacy following a weight loss intervention (Clark et al., 1996). Pinto and colleagues (1999) took these findings another step further by examining changes in eating and exercise self-efficacy, and decisional balance among 32 obese women enrolled in a 12-week multidisciplinary weight loss program. The treatment combined behavior therapy and a low-calorie diet. The intervention used the following cognitive behavioral strategies to target self-efficacy: stimulus control procedures, problem-solving training, stress management skills, goal setting, development of healthy eating habits, assertiveness training, facilitation of social supports, cognitive restructuring, and relapse prevention training. Results showed a significant mean weight loss of 14.6% of initial body weight, and significant improvements for eating and exercise self-efficacy. Improvements in eating self-efficacy were related to the improvement in exercise self-efficacy. The authors pointed to the need for research to investigate this relationship over a longer period of time and suggest the idea that relapse may occur (Pinto et al., 1999). At the end of the 1990s researchers had accepted that self-efficacy changed following weight loss interventions, yet the impact of time upon this change in self-efficacy was not

quite understood.

Over the following decade, researchers sought to further understand the role of self-efficacy in weight loss interventions. Focht and colleagues (2005) examined changes in mobility-related self-efficacy among overweight and obese subjects with knee osteoarthritis after exercise and dietary weight loss interventions. This was an 18-month, single blind, randomized, controlled trial. The dietary intervention was based upon principles of group dynamics and social cognitive theory, and the exercise intervention was also rooted in social cognitive theory (Miller et al., 2003). The exercise and dietary weight loss intervention group significantly improved in stair-climb self-efficacy over the control group, and both the exercise alone group, as well as the exercise and dietary weight loss group significantly improved walking self-efficacy compared with the control group. These results show that dietary weight loss and exercise together have a greater effect upon mobility related self-efficacy than exercise alone. The ADAPT trial supports previous research regarding the impact of weight loss upon self-efficacy (Focht et al., 2005). Zijlstra and colleagues (2006) investigated the association between weight loss and self-regulation cognitions pre and post-operative for obese individuals undergoing laparoscopic adjustable gastric banding. Seventy-seven patients completed the Obesity cognition questionnaire and an eating behavior self-efficacy scale both six months prior and one year following operation. Patients showed large individual differences in weight loss. The results of this study differ from the literature in that self-efficacy at 6 months pre-operative did not predict weight loss success. Self-efficacy was correlated with weight loss at one year post-operative, but as this was not a controlled experimental trial a causal relationship cannot be explored. These findings are in line with the bariatric

surgery literature, which shows that pre-operative psychological factors do not predict post-operative weight outcome (Zijlstra et al., 2006). Bas and colleagues (2009) examined potential improvements in eating self-efficacy, eating behavior, and other psychological factors in 96 obese subjects taking part in a 20-week weight loss program. Each session included activities to promote self-efficacy. The initial weight of subjects was negatively correlated to the total weight efficacy lifestyle questionnaire and the availability subscale of weight efficacy lifestyle. Weight change at 20 weeks showed a significant and positive relationship to eating self-efficacy and social physique anxiety, while demonstrating a significant negative relationship to social trait anxiety. This shows that self-efficacy significantly predicted weight loss in this trial. There was a significant main effect for time in total eating self-efficacy, demonstrating that self-efficacy increased over the course of obesity treatment (Bas et al., 2009).

In the past few years a number of studies stand out in how they incorporated self-efficacy theory within interventions to explore self-efficacy changes. Smith and colleagues (2010) worked with 23 obese children at risk for Type II Diabetes to improve physical activity and nutrition behaviors through a 12-week weight loss intervention based upon social cognitive theory. The intervention focused on the following to enhance self-efficacy: development of self-regulation and self-management skills, foster sense of progress, competence, and mastery, group setting, non-threatening environment. Subjects had a significant reduction in BMI and significant within-group increase in voluntary physical activity. Results showed that changes in physical self -concept and exercise self-efficacy scores accounted for variance in changes in voluntary physical activity. The small sample size and limited power of this study suggest that more

research is needed (Smith et al., 2010). Brawley and colleagues (2012) designed a translational randomized controlled trial of physical activity and weight loss to examine changes in self-efficacy, satisfaction with function and appearance, and whether self-efficacy mediated change in 400-meter walk time. Participants were recruited from three counties in North Carolina and randomized into three treatment groups: physical activity, weight loss and physical activity, or successful aging education. Outcome expectancies were targeted as outcomes. The intervention utilized self-efficacy theory and group dynamics to improve self-efficacy in a number of ways: developing a group-focused learning environment to foster instruction and encourage at-home practice, and development of self-regulatory skills, social reinforcement through group sessions. Improvements in satisfaction with function and appearance in the weight loss and physical activity group did result in increased physical activity and weight loss success. Participants in the weight loss and physical activity group significantly improved their walking self-efficacy, and satisfaction with physical function and appearance at levels beyond both of the other treatment groups. This group showed improvements in walking self-efficacy at 6 months and maintained this improvement through to 18 months. The improvement in self-efficacy across all 18 months of the study paralleled improvements in the 400-meter walk time, showing a mediation effect (Brawley et al., 2012). Staiano and colleagues (2013) worked with 54 overweight adolescents, using a randomized controlled trial design, to examine whether a 20-week exergame intervention could impact weight loss and psychosocial outcomes. Social cognitive theory influenced the hypothesis and the design of the exergame interventions. Baseline self-efficacy did not predict or mediate weight loss. The adolescents assigned to the cooperative exergame

intervention arm lost significantly more weight than both the control and competitive exergame arms. Cooperative exergamers showed significant improvement in self-efficacy at both 10 and 20 weeks (Staiano et al., 2013). Today researchers know that self-efficacy can predict weight loss, it improves across a weight loss intervention, and it can act as a mediator for other behaviors.

Table II outlines the self-efficacy changes across weight loss interventions in the literature. This literature shows a consensus in improvement of self-efficacy following a weight loss intervention. The weight efficacy lifestyle questionnaire has been shown to be a valid and reliable measure of self-efficacy. It is used in a number of studies to assess 5 main factors of self-efficacy pre and post-intervention. Researchers applied self-efficacy changes to other social cognitive constructs. When working with obese children, similar relationships were observed.

Table II: Self-Efficacy Changes across Weight Loss Interventions in Literature

Citation	Sample Size	Study Design	Intervention Length	Analysis	SE change
Clark et al., 1996	N=26 M age= 44 years	Quasi-experimental study	26 weeks	Repeated measures t-test	↑ total WEL score and all components
Pinto et al., 1999	N=36 females M age= 43 years	Longitudinal Cohort Study	16 weeks	Pearson Correlation	↑ SE for eat and exercise
Focht et al., 2005	N= 316 w/ knee arthritis	Single blind, Randomized Controlled trial	18 months	Mixed Model ANCOVA	↑ SE for stair-climb and walk
Zijlstra et al., 2006	N=77 gastric band surgery	Longitudinal Cohort Study	6 months pre -12 months post-op	Pearson Correlation, t-tests, Effect Sizes	SE 6 months pre did not predict WL
Bas et al., 2009	N= 96	Longitudinal Cohort Study	20 weeks	Pearson Correlation, Regression, 2x2 ANCOVA	↑SE for eat, SE sig, predict WL
Smith et al., 2012	N= 23 children	Pilot, Longitudinal Cohort Study	12 weeks	Dependent t-tests, Linear bivariate correlation, Multiple regression	↑ SE for exercise
Brawley et al., 2012	N= 288 w/ cardiovascular disease, and mobility limits	Translational, Block randomization Controlled trial	18 months	Linear mixed model ANCOVA	WL + physical activity arm ↑ SE for walk across 18 months
Staiano et al., 2013	N= 54 African-American adolescents	Randomized Controlled trial	20 weeks	Growth curve analysis, Structural equation modeling	Cooperative arm ↑ SE at 10 and 20 weeks

Table III depicts the ways in which the literature targeted each of the sources of self-efficacy. Zijlstra et al. (2006) did not target any sources of self-efficacy, as it was a pre-post analysis of bariatric surgery patients' weight loss success. Focht et al. (2005), Smith et al. (2012), and Brawley et al. (2012) targeted all four sources of self-efficacy. It is important to note the ways in which these studies built their interventions.

Table III: How the Literature Targeted Self-Efficacy

Citation	Performance Experience	Vicarious Experience	Verbal Persuasion	Physiological States
Clark et al., 1996	-Goal-setting -Problem solving	X	-Social supports	-Stress management skills
Pinto et al., 1999	-Weekly Progress -Goal-setting -Problem solving	X	-Social supports	-Stress management skills
Focht et al., 2005 / Miller et al., 2003	-Weekly progress -Self-monitoring -Goal- setting -Problem solving	-Group Support	-Encouragement	-Group Discussion of exercise
Zijlstra et al., 2006	X	X	X	X
Bas et al., 2009	-Weekly Progress -Self-monitoring -Goal-setting	-Group support	X	X
Smith et al., 2012	-Weekly Progress -Goal-setting -Problem solving	-Group support	-Encouragement -Social supports	-Feelings during exercise
Brawley et al., 2012	-Weekly progress -Self-monitoring -Goal-setting -Problem solving	-Group support	-Encouragement -Social Supports	-Group Discussion of exercise
Staiano et al., 2013	-Progress	-Group support	-Encouragement	X

Rationale

Studies based in social cognitive theory which target sources of self-efficacy have been successful in improving self-efficacy following weight loss interventions. However, this literature is limited by relatively brief follow-up periods. Thus, the effects of weight loss interventions over extended time frames (i.e., maintenance phase) is unknown. Additionally, no community-based DPPLI translational study has reported the impact of translational DPPLI on self-efficacy. With further understanding of the self-efficacy changes that take place, researchers may be able to impact self-efficacy to further improve weight loss. This in turn will impact obesity and chronic diseases including Type II Diabetes Mellitus.

Hypothesis

The LWL group will experience greater improvements in exercise self-efficacy at 6, 12, and 24 months as compared to the UCC group. The LWL group will also experience greater improvements in weight efficacy lifestyle at 6, 12, and 24 months as compared to the UCC group.

METHODS

Overview

The Healthy Living Partnership to Prevent Diabetes (HELP PD) trial translated the diabetes prevention program using community health workers (CHWs) in community settings (Katula et al., 2010). The purpose of this study is to examine the changes in self-efficacy that took place between groups as participants completed the 6-month intensive weight loss phase and 18-month weight maintenance phase of HELP PD.

Participants

Recruitment for HELP PD was completed over the course of 2 years (Blackwell et al., 2011). Eligibility criteria for HELP PD was designed to target a sample representing Forsyth County at risk for developing Type II Diabetes Mellitus without contraindications for participation in weight loss. Participants were required to have an initial pre-diabetic qualifying glucose checked on two separate occasions as either: fasting blood glucose 95-125 mg/dl collected in previous 3 months or at the general clinical research center, or non-fasting blood glucose 120-199 mg/dl collected at the study information session. Participants also needed to be older than 21 years or age and overweight or obese, with a BMI between 25.0 kg/m^2 and 39.9 kg/m^2. Recruitment was completed via referrals from primary care providers, community screenings, mass mailings, and group presentations to the community. A tiered screening process was used. This started with an original telephone screening, information session, and completion of a non-fasting blood glucose sample, resting blood pressure, and physical activity readiness questionnaire. A question and answer period and the informed consent process followed the information session for those that qualified and chose to participate

in the study. Nearly one-fourth of excluded participants failed to qualify during the telephone screening, while others declined participation at this point. Exclusion criteria included: current enrollment in a weight loss program, diagnosed diabetes, uncontrolled hypertension, recent cardiovascular disease, pregnancy or breastfeeding, use of hypoglycemic medication or another drug that significantly affects glucose metabolism, behavioral or psychiatric condition, and inability to exercise (Blackwell et al., 2010).

Treatment Arms

Lifestyle Weight Loss (LWL)

The conceptual basis for the LWL intervention was founded in social cognitive theory, group dynamics literature, and research experience involving lifestyle interventions, with particular focus on self-efficacy. According to Bandura's theory, self-efficacy is influenced by performance accomplishments, vicarious experience, verbal persuasion, and physiologic experience; while self- efficacy in turn influencing behavior patterns, affective responses, and thought patterns (Bandura, 1989; Bandura, 2004). Literature in lifestyle behavior change shows that self-efficacy beliefs are influenced by prior behavior, physical symptoms, appetite, affect, and environmental/ social factors (Bandura et al., 2004).

In addition to explicitly targeting sources of self-efficacy, the LWL also included education on self-regulatory skills. Self-regulatory skills allow individuals to exercise control over their behavior, cognitions, and environment. The LWL targeted self-efficacy in relation to a number of self-regulatory behaviors including: goal setting, self-monitoring, and problem solving skills. Group-mediated interventions have been shown to support social problem solving, and play a role in reinforcing behavior (Katula et al.,

2010). Table IV illustrates how the HELP PD LWL intervention influenced sources of self-efficacy.

Table IV: Sources of Self-Efficacy and HELP PD LWL Intervention

Sources of Self- Efficacy	LWL Intervention
Performance Accomplishments	-Progress checks during weekly meetings -Weekly weigh ins -Shared successes -Goal setting -Problem solving -Self-monitoring -Performance feedback
Vicarious Experience	-Group discussion of success and barriers -CHW led group meetings -Group support
Verbal Persuasion	-Progress checks during weekly meetings -Encouragement from group and CHWs -Fostering social support
Interpretations of Physiologic Experience	-Group discussion of cravings/ hunger -Group discussion of physical activity success

Participants randomized into the LWL intervention group underwent an intensive weight loss program for the first 6 months, followed by a weight maintenance program for 18 months. They were encouraged to lose 5-7% of their initial body weight through low-calorie dieting and engaging in moderate physical activity for at least 180 minutes every week. During the first phase of the intervention, participants met weekly for group sessions led by a CHW, and all participants met individually with a registered dietician 3 times. In the second phase, participants were contacted twice with the CHW each month via one meeting and one phone interview. The intervention was delivered in 14 groups of 8-12 participants (Katula et al., 2012).

Community Health Worker (CHW) Training

The CHWs were responsible for conducting the intervention group sessions, managing their group participants, and data entry of participant body weights obtained at each group session. Each CHW was responsible for 1 group during the intensive phase (1 meeting/ week) of the intervention, and were assigned a new group when his/her group transitioned to the maintenance phase (1 meeting/ month). Therefore, each CHW was ultimately responsible for 1 group in the intensive phase and 1 group in the maintenance phase. CHWs were compensated $100/ week for their participation in the intensive phase and $200/ month in the maintenance phase.

The CHW training program consisted of a 36-hour program over the course of 6-9 weeks of experiential learning, didactic instruction, peer mentoring, and observation. To provide experiential learning, CHWs participated in a compressed form of the intensive phase of the LWL in which they self-monitored calories and physical activity, tracked weight, and took part in group sessions. Each training session began with an intervention session, and two sessions were presented in didactic format. Additionally the CHW training consisted of instruction on: study protocol; intervention philosophy, goals and procedures; weight loss; physical activity basics; nutrition basics; group facilitation; social-cognitive/ self-efficacy principles; participant monitoring and tool kit methods; and data entry. CHWs were trained to target sources of self-efficacy. A formal certification process, in which the study investigators observed CHWs conduct a mock group consisting of other CHWs and RDs as group members. CHWs received feedback and coaching on their performance.

Usual Care Condition (UCC)

Enhanced usual care group participants had 2 individual meetings with a

nutritionist in the first 3 months to review healthy eating and provide information on community resources. These participants received a quarterly newsletter educating them on living a healthy lifestyle (Katula et al., 2012).

Measures

Self-efficacy was measured in two ways: barriers efficacy for diet using weight efficacy lifestyle, and task efficacy related to specific exercise. Both assessments were self-administered at 6 month intervals for 24 months (Katula et al., 2010). Additionally, both self-efficacy measures were created in a manner consistent with recommendations put forth by Bandura (Bandura et al., 1989).

Weight Efficacy Lifestyle

Clark and colleagues (1991) developed and validated a 20-item weight efficacy lifestyle questionnaire examining 5 situational factors: negative emotions, availability, social pressure, physical discomfort, and positive activities. This measure was tested in two separate clinical treatment studies involving 382 participants. Results indicated that the measure is sensitive to changes in total scores and five situational factor scores (Clark et al., 19991). This study modified the original weight efficacy lifestyle questionnaire into a 6-item scale representing common barriers in managing diet, and addressing the five situational factors of the original measure. A sample of one of the items form the Weight Efficacy Lifestyle questionnaire is “I can resist eating when there is a lot of food available” (Katula et al., 2010). Participants ranked their confidence in their ability to self-regulate barriers and manage their diet on a scale from 1-10. Number 1 represented the phrase “No Confidence”, while number 5 represented “Moderately Confident”, and number 10 stood for “Complete Confidence”. Responses for each of the 6 items were

summed and averaged to give a total score, in which higher scores indicated a stronger efficacy to manage diet barriers (Katula et al., 2010). This measure possessed adequate reliability (all α's >0.9).

Task Specific Exercise Self-Efficacy

The task specific exercise self-efficacy measure used in this study was based off of the measure implemented by McAuley in his investigation of the role played by exercise self-efficacy in the maintenance of exercise participation (McAuley, 1993). Efficacy associated with physical activity performance was assessed as the level of confidence that participants' held in their ability to exercise at a moderate intensity without stopping for a specific amount of time: 10 minutes, 20 minutes, 30 minutes, 40 minutes, and 50 minutes. Each time point was rated on a scale from 1-10. The phrase "No Confidence" was represented by number 1, while number 5 represented "Moderately Confident", and number 10 stood for "Complete Confidence". The ratings were summed and averaged to give a total score with higher scores indicating higher exercise efficacy (Katula et al., 2010). This measure possessed adequate reliability (all α's >0.9).

Statistical Analysis

The purpose of this statistical analysis is to examine the effect of the HELP PD LWL intervention on both measures of self-efficacy. A series of ANCOVAs were conducted to compare between group differences in change at each time point. Separate models were run for each measure of self-efficacy. In each model the self-efficacy change score was the dependent variable and baseline levels of the dependent variable served as covariates. This analysis controls for differences at baseline in both measure of self-efficacy. Effect sizes were also calculated as Cohen's d

RESULTS

Descriptive statistics illustrated baseline characteristics of the HELP PD sample. The sample of 301 participants consisted of middle-aged or elderly men and women with a mean BMI of 32.7 kg/m^2. The group was well-educated, racially representative of the community (with 24.8% African Americans), and predominantly female (57.5%). Table V further outlines baseline sample characteristics (Katula et al., 2012). Additionally, means and standard deviations of baseline self-efficacy for each treatment group are presented in Table VI. No between group differences were found at baseline.

Table V: Baseline Sample Characteristics, n (%) or M ± SD

Variable	LWL	UC	Total	p-value
Number	151	150	301	
Gender				1.00
Male	64 (42.4)	64 (42.7)	128 (42.5)	
Female	87 (57.6)	86 (57.3)	173 (57.5)	
Race				0.43
African-American	39 (25.8)	35 (23.3)	74 (24.6)	
White	111 (73.5)	111 (74.0)	222 (73.8)	
Other / refused	1 (0.7)	4 (2.7)	5 (1.6)	
Age (years)	57.3 ± 10.1	58.5 ± 9.0	57.9 ± 9.5	0.28
Educational attainment				0.97
High school or less	29 (19.2)	32 (21.3)	61 (20.3)	
Associate degree or other	49 (32.5)	47 (31.3)	96 (31.9)	
Bachelor's degree	37 (24.5)	37 (24.7)	74 (24.6)	
Beyond Bachelor's degree	36 (23.8)	34 (22.7)	70 (23.3)	
Weight (kg)	94.4 ± 14.7	93.0 ± 16.2	93.7 ± 15.5	0.44
BMI (kg/m^2)	32.8 ± 3.9	32.6 ± 4.1	32.7 ± 4.0	0.54
Glucose (mg/dl)	105.4 ± 12.5	105.7 ± 10.0	105.5 ± 11.3	0.79
Insulin (μU/ml)	16.7 ± 9.7	16.7 ± 10.0	16.7 ± 9.8	0.95
HOMA IR	4.4 ± 3.0	4.4 ± 2.9	4.4 ± 2.9	0.99

Table VI: Descriptive Statistics for Baseline Self-Efficacy

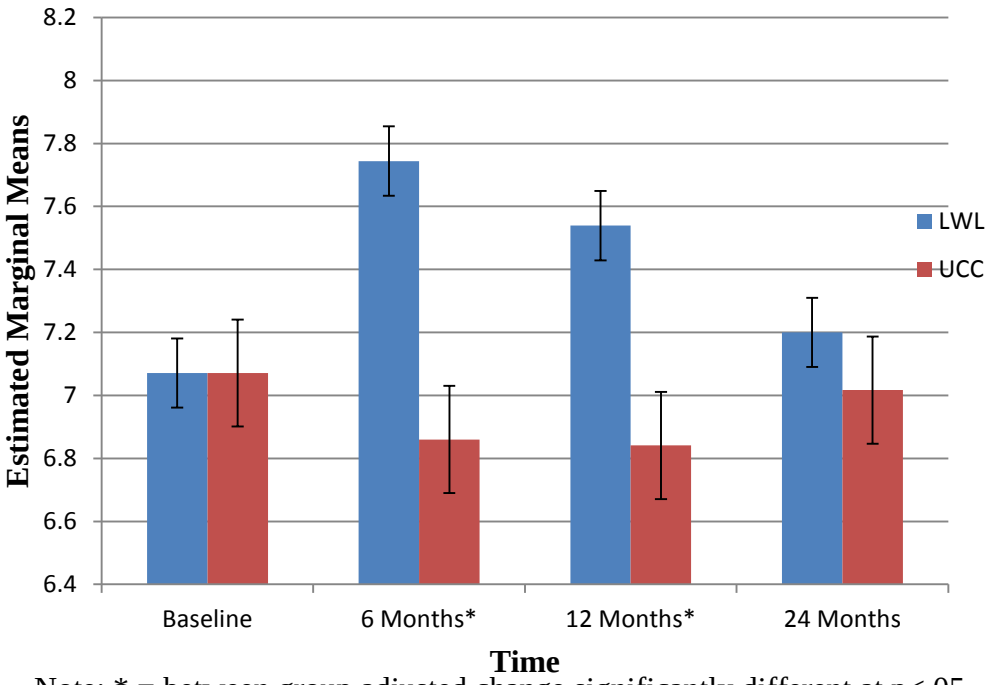
Measure	Randomization	Mean	Standard Deviation	Sample Size
Exercise Self-Efficacy	LWL	6.885	2.245	119
	UCC	7.269	1.909	129
Weight Efficacy Lifestyle	LWL	7.255	1.763	119
	UCC	7.511	1.735	129

A series of ANCOVAs tested the hypothesis that the lifestyle weight loss intervention (LWL) group would have greater changes in both measures of self-efficacy at each time point than the usual care condition (UCC) group. Covariates included the dependent measures of self-efficacy changes from baseline over the 24 month HELP PD project. The analysis controlled for baseline measures of self-efficacy.

Exercise Self-Efficacy

Figure 2 and Table VIII show the changes in exercise self-efficacy over time between the LWL and UCC groups. The ANCOVA showed statistically significant differences in changes between groups in exercise self-efficacy at 6 and 12 months. Table VII shows effect sizes indicating that the LWL produced small to moderate increases in exercise self-efficacy (6 month ES =0.398; 12 month ES = 0.303). Yet, the LWL and UCC groups did not differ in change at 24 months. Therefore, the LWL appears to have produced increased exercise self-efficacy in the first 6 months that it remained elevated at 12 months, and decreased to near baseline level at 24 months.

Figure 2: Estimated Marginal Means of Exercise Self-Efficacy over Time



Note: * = between group adjusted change significantly different at p<.05

Table VII: Estimates and Significance of Exercise Self-Efficacy from Baseline

	ΔBL-6	SE	p*	d	ΔBL-12	SE	p*	d	ΔBL-24	SE	p*	d
LWL	0.61	0.16	p<.001	0.40	0.49	0.17	p<.001	0.30	0.13	0.2	p=0.51	0.07
UCC	-0.25	0.16			-0.37	0.17			-0.05	0.19		

Note: *= statistical test of the between group difference in adjusted change scores.

Table VIII: Estimates of Exercise Self-Efficacy over Time*

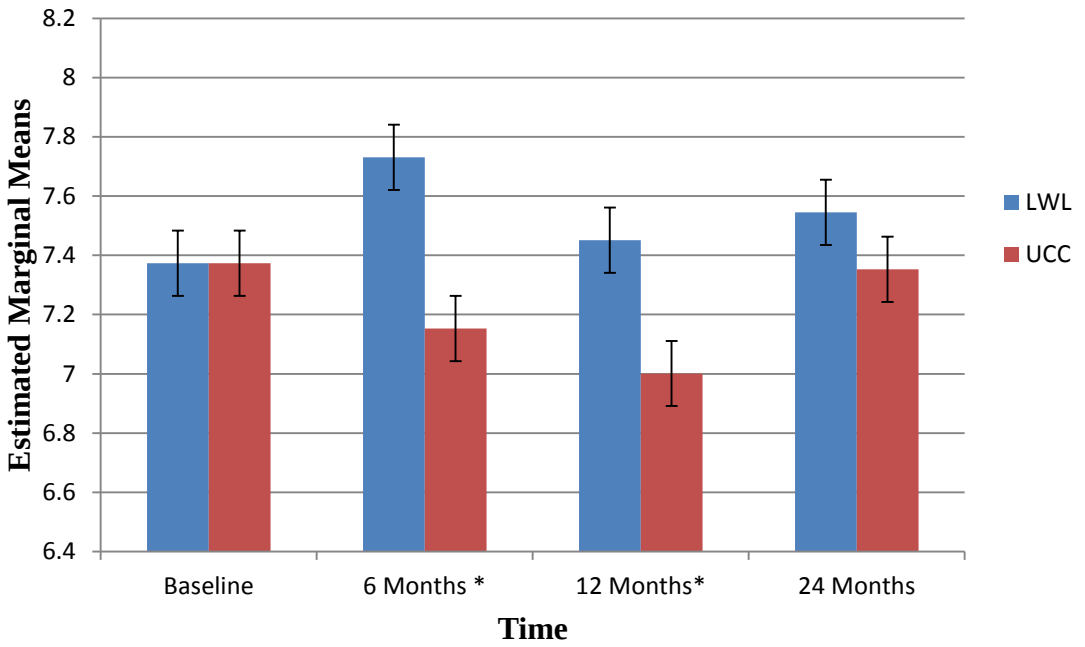
Randomization	Time	Mean	Standard Error	95% Confidence Interval	
				Lower Bound	Upper Bound
Lifestyle Weight Loss	Baseline	7.071	0.000	7.071	7.071
	6 mth	7.744	0.168	7.413	8.075
	12 mth	7.539	0.175	7.195	7.884
	24 mth	7.200	0.197	6.813	7.587
Usual Care Condition	Baseline	7.071	0.000	7.071	7.071
	6 mth	6.860	0.164	6.538	7.182
	12 mth	6.841	0.170	6.506	7.176
	24 mth	7.017	0.191	6.640	7.393

Note: * = values represent estimated marginal means adjusting for baseline values.

Weight Efficacy Lifestyle

Figure 4 and Table X depict changes in weight efficacy lifestyle over time between the LWL and UCC groups. The ANCOVA indicated that the adjusted change in weight efficacy lifestyle was significantly different between groups at 6 and 12 months. Effect sizes shown in Table IX indicate that the LWL produced small to moderate increases in weight efficacy lifestyle (6 months ES =0.341; 12 month ES =0.264). However, the groups did not differ in change at 24 months, but the effect decreased over time such that the weight efficacy lifestyle was essentially at baseline levels at 24 months.

Figure 3: Estimated Marginal Means of Weight Efficacy Lifestyle over Time



Note: * = between group adjusted change significantly different at p<.05

Table IX: Estimates and Significance of Weight Efficacy Lifestyle from Baseline*

	ΔBL-6	SE	p*	d	ΔBL-12	SE	p*	d	ΔBL-24	SE	p*	d
LWL	0.42	0.12	p<.001	0.34	0.14	0.12	p<.01	0.26	0.21	0.12	p=0.12	0.12
UCC	-0.17	0.11			-0.31	0.12			-0.04	0.12		

Note: *= statistical test of the between group difference in adjusted change scores

Table X: Estimates of Weight Efficacy Lifestyle Over Time*

Randomization	Time	Mean	Standard Error	95% Confidence Interval	
				Lower Bound	Upper Bound
Lifestyle Weight Loss	Baseline	7.373	0.000	7.373	7.373
	6 mth	7.731	0.108	7.518	7.944
	12 mth	7.451	0.113	7.228	7.674
	24 mth	7.545	0.108	7.334	7.757
Usual Care Condition	Baseline	7.373	0.000	7.373	7.373
	6 mth	7.153	0.105	6.946	7.360
	12 mth	7.001	0.110	6.785	7.218
	24 mth	7.353	0.105	7.147	7.559

Note: *= Covariates appearing are evaluated at Weight Efficacy Lifestyle Baseline = 7.37

These findings partially support the hypothesis. There was a statistically significant difference in change between the LWL and UCC groups from baseline to 6 months and baseline to 12 months in both measures of self-efficacy. Changes between baseline and 24 months did not show a significant difference between the treatment groups in either measure.

DISCUSSION

Summarized Findings

The purpose of this study was to examine the impact of the HELP PD lifestyle weight loss intervention (LWL) on self-efficacy measured at baseline, 6-months, 12-months, and 24-months. The results of this study revealed that the LWL group experienced significantly greater exercise self-efficacy and weight efficacy lifestyle at 6 months and 12 months as compared to the usual care condition (UCC) group, but those differences were not maintained at 24 months. Differences between groups showed small to moderate effect sizes at 6 and 12-months, making these findings meaningful. To our knowledge, this is the first translational diabetes prevention study utilizing community health workers (CHWs) to document significant changes in theoretically relevant constructs.

Is Hypothesis Supported?

The hypothesis was that the LWL intervention group would experience greater changes in both measures of self-efficacy than the UCC group at each time point. The LWL group showed statistically significant changes and small to moderate effect sizes from baseline to 6 months and baseline to 12 months compared to the UCC. However, there were non-significant changes from baseline to 24 months between the two intervention groups.

The greater change in both measures of self-efficacy experienced by the LWL group compared to the UCC group is not surprising, as this finding has been consistent in the literature. This supports the hypothesis and concurs with the majority of the

literature. A quasi-experimental study combined self-efficacy theory- based behavior change therapy and a very low calorie diet in a 26 week weight loss program. Results from 26 participants showed improvement in total weight efficacy lifestyle scores and across all 5 components pre-to-post intervention (Clark et al, 1996). The ADAPT trial showed not only the possibility for increases in self-efficacy following behavior change interventions, but pointed out that dietary weight loss and exercise have a greater impact upon self-efficacy increases than dietary weight loss alone, exercise alone, or healthy lifestyle control groups (Focht et al, 2005). A pilot longitudinal cohort study involving 23 obese children undergoing an self-efficacy theory- based weight loss intervention showed an increased exercise self-efficacy (Smith et al, 2010). In another study, 288 older obese adults in poor cardiovascular health were block randomized into either a physical activity group, a weight loss and physical activity group, or a successful aging education group. Participants in the weight loss and physical activity group significantly improved walking self-efficacy above the other groups (Brawley et al, 2012). A number of studies had similar findings to the current results of this trial, in which self-efficacy measures increased in the lifestyle change intervention groups compared to control groups. However none of the aforementioned studies were translational diabetes prevention studies nor utilized CHWs to deliver the intervention. The literature and current results give support for the hypothesis.

Contrary to what was hypothesized, the improvements in self-efficacy experienced at 6 and 12 months were not maintained at 24 months. Although this was not expected, other studies have found similar results. A two-year follow-up of the MOBILIS (Multi-center Self-Directed Lifestyle Change) program, an interdisciplinary

cognitive behavioral weight loss intervention, displayed similar results. The 385 individuals in the intervention group took part in an exercise program, received dietary advice, and attended group meetings focusing on motivational and volitional behavior change. The intervention differed significantly from the control group at baseline, 6 months, and 12 months in diet self-efficacy. However the increases in the intervention group dropped at 24 months, and the difference between groups was not significant any longer (Göhner et al., 2012). McAuley and colleagues (2011) examined trajectories of exercise related self-efficacy across a 12 month randomized controlled trial. All measures of self-efficacy increased significantly at 6 months, before decreasing significantly at program conclusion (McAuley et al., 2011). These results demonstrate that increases in self-efficacy as a result of behavior change intervention may not last long term. Exercise and weight loss behavior change is often more challenging to maintain than participants expect, and self-efficacy for these behaviors may drop as maintenance continues long term.

Implications

Theoretically these changes in self-efficacy illustrate a positive impact of the LWL intervention upon self-efficacy. The larger changes seen in the LWL group compared to the UCC group show that self-efficacy was indeed influenced as a result of the behavioral intervention. The impact of time across these results shows the need for greater influence of self-management and problem-solving skills in the maintenance phase of weight loss. The results of this study demonstrate the impact of weight loss behavioral change interventions on two separate measures of self-efficacy.

Weight Efficacy Lifestyle

The weight efficacy lifestyle questionnaire is a common self- efficacy measure involving 5 situational factors: negative emotions, availability, social pressure, physical discomfort, and positive activities. This measure has been widely used and validated across literature (Clark et al, 1991). The increase in weight efficacy lifestyle in the LWL group reflects the consensus of the literature (Clark et al, 1996; Pinto et al, 1999; Palmeira et al, 2007; Bas et al, 2009; Shin et al, 2011; Annesi, 2011; Byrne et al, 2012; Annesi et al, 2012). Changes in weight efficacy lifestyle support the hypothesis and agree with the literature.

Task Specific Exercise Self-Efficacy

This measure was based on the design by McAuley (1993) and adapted to the HELP PD study (McAuley, 1993; Katula et al, 2009). Other studies showed similar increases in exercise self-efficacy following an exercise intervention (Pinto et al, 1999; McAuley et al, 2007; Bas et al, 2008; Annesi, 2011; Byrne et al, 2012; Phillips et al, 2013). The findings in task specific exercise self-efficacy are similar to what has been seen across the literature.

More research is needed to show the long-term impact of cognitive-based weight loss interventions on measures of self-efficacy. With this knowledge future studies can incorporate further self-efficacy enhancing components to achieve further success in weight loss interventions.

Self-Efficacy and Other Variables

Literature has shown that self-efficacy can influence a number of other variables. It has been widely accepted that self-efficacy increases significantly predict weight loss success (Palmeira et al, 2007; Bas et al, 2008; Shin et al, 2011; Annesi, 2011; Annesi, 2012; Byrne et al, 2012). Previously, data from the HELP PD study demonstrated that baseline to 6-month changes in self-efficacy significantly predicted successful weight loss at 6 and 12-months. (Squires, 2012). Improvements in self-efficacy predict changes in self-esteem (McAuley et al, 1996; McAuley et al, 2000). Self-efficacy has been shown to mediate quality of life following physical activity interventions (Phillips et al, 2014; Phillips et al, 2013; Motl et al, 2009). Quality of life was measured in the HELP PD trial, but the influence of self-efficacy upon quality of life has yet to be determined. Literature has consistently shown that self-efficacy can predict physical activity adoption and maintenance (McAuley et al, 1993; Trost et al, 1997; McAuley et al, 2007). The ADAPT trial noted in the literature review demonstrated that self-efficacy mediated both pain and performance measures of mobility (Focht et al, 2005). There is nothing to suggest that self-efficacy may impact glucose, a major outcome of the HELP PD trial. The relationship of self-efficacy to other variables is important when implementing a theoretically based behavior change intervention.

Community Health Worker (CHW) Delivered Intervention

CHWs directly delivered the LWL intervention to participants of HELP PD, while the RD provided support and study staff remained behind the scenes. Ruggiero (2012) cited HELP PD as an important randomized controlled trial supporting CHW translation of the DPPLI. Other studies reviewed showed the growing role of CHWs in translating the DPPLI within community settings and working with multidisciplinary healthcare

teams (Ruggiero, 2012). The current study demonstrates that training community members to implement a theoretically- based weight loss intervention in a community setting can achieve predicted changes in theoretically relevant variables. This is a promising step towards further dissemination of the DPPLI.

These results can be used to impact how weight loss is approached within the coordinated care setting. The impact of self-efficacy through weight loss programs based in social cognitive theory demonstrates a means for encouraging successful weight loss. Perhaps if patients are enrolled in weight loss programs which monitor and address changes in self-efficacy, more of these patients will successfully lose weight and simultaneously reduce their risk for many chronic diseases including T2DM.

Strengths and Limitations

Two measures of self-efficacy (both task and barriers efficacy) were separately measured and analyzed. Weight Efficacy Lifestyle was measured by addressing 9 common barriers, giving this measure high validity. This measure is supported throughout the literature (Clark et al, 1996; Pinto et al, 1999; Palmeira et al, 2007; Bas et al, 2009; Shin et al, 2011; Annesi, 2011; Byrne et al, 2012; Annesi et al, 2012). Task Specific Exercise Self-Efficacy was assessed by individuals' confidence in performing moderate intensity exercise for a variety of time intervals. This measurement is supported by both exercise literature and Bandura (Pinto et al, 1999; McAuley et al, 2007; Bas et al, 2009; Annesi, 2011; Byrne et al, 2012; Phillips et al, 2013; Bandura, 1986). The variety of self-efficacy measures used as well as each measure's validity supported through literature are strengths of this study.

The LWL intervention design stands out in that it targeted key concepts of Self-Efficacy Theory and group dynamics. This was achieved by: increasing health knowledge, promoting a series of successful experiences in changing eating and exercise behaviors, incentive motivation through assessment and feedback on key behaviors, utilizing the group setting as motivation, improvement of self-regulatory skills, and incorporating a continuous problem-solving model. The CHWs followed a standard framework for each group meeting where they: reviewed participants' progress, privately weighed participants and discussed problems, and delivered core content based upon cognitive-behavioral self-management skills (Katula et al, 2010). The strong influence of Self-Efficacy Theory woven deep into the framework of the LWL intervention is a unique strength of this study.

The LWL intervention was designed to target sources of self-efficacy. Performance accomplishments, vicarious experience, verbal persuasion, and interpretations of physiologic experience were all impacted at each weekly group meeting facilitated by the CHWs. There is no indication as to which sources of self-efficacy improved as a result of the LWL intervention. Some sources may have increased while others did not. This study could not adequately measure such variables with the intervention design. Future research may investigate which sources of self-efficacy are influenced by a weight loss intervention, by randomizing participants to multiple intervention groups where each one focuses upon improving one source of self-efficacy. The inability to specify which sources of self-efficacy improved as a result of the LWL is a limitation to our study.

The present study also did not examine potential moderators of the treatment effect. It is unknown as to what factors may have influenced for whom and under what conditions the LWL intervention was successful at improving self-efficacy measures. The sample was predominantly White, with nearly 25% of participants identifying as African- American. This reflects the geographical area where the study was conducted, but not the population as a whole. Ethnicity may be a moderator, and it certainly limits the translatability of the intervention to more diverse areas. The sample was 57.5% female which is similar to other weight loss trials, but gender may moderate the effectiveness of the intervention. The CHWs were recruited from the community and trained by a registered dietician. Each CHW interacted with a different group of participants. CHW personnel delivering the intervention to participants may also serve as a moderator. Participants encouraged one another within the group setting, but relationships among participants may not always have been beneficial to everyone. Some participants may simply have not seen eye to eye, or may have become very close friends. Relationships among group members also may have moderated self-efficacy changes. The fact that moderators were not analyzed serves as a limitation to our study.

Conclusions

To the best of my knowledge, this is the first study to examine changes in weight efficacy lifestyle, and task specific exercise self-efficacy in a pre-diabetic population across a weight loss intervention based in Self-Efficacy Theory. Future research should investigate: which sources of self-efficacy respond to weight loss interventions, possible moderators, the possibility of a dose-response relationship, and long-term impact on self-efficacy. The impact of time across these results shows the need for greater focus on

self-management and problem-solving skills in the long-term maintenance of weight loss. This study demonstrates the ability of a diabetes prevention program translational CHW-delivered intervention to target and influence self-efficacy measures. These findings may help to influence weight loss in both the research and clinical care settings.

APPENDIX A

Wake Forest University Health Sciences

Informed Consent Document

Healthy Living Partnership to Prevent Diabetes (HELP Prevent Diabetes) Study
(Consent version date: 09/05/08)
Principal Investigator: David C. Goff, MD, PhD

You are being invited to take part in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You may or may not receive any benefit from being part of the study. There may also be risks due to being part of research studies. You are being asked to take part because you weigh more than is ideal and you have high blood sugar (pre-diabetes). Your participation is voluntary. Please take your time to make up your mind. Ask the study doctor or the study staff to explain any words or information that you do not understand. The doctor listed above is in charge of the study. Other study staff will help him.

Increased weight is a major health problem in the United States. The long-term health risks from being overweight are high among people with pre-diabetes, and include developing diabetes. The current problem with diabetes in the United States is largely the result of more people being overweight.

Before you make up your mind whether or not you should join the HELP PREVENT DIABETES study, you should learn about its risks and benefits. This step is called informed consent. The consent form you are reading describes the study. Study staff will talk with you and answer any questions you may have. If you decide to join the study, you will be asked to sign this form. You will be given a signed copy for your records.

PURPOSE OF THE STUDY

The HELP PREVENT DIABETES study will look at the health effects of weight loss in men and women who are overweight and have pre-diabetes. Three hundred people in Forsyth County will take part in the study. Your participation in this study will last two years. Previous studies have shown that weight loss has many benefits, including preventing diabetes. Most of these studies have used professional staff, such as dietitians and doctors, and one-on-one counseling. We do not know if a group-based weight loss program led by a lay (non-professional) person would also help people lose weight. The HELP PREVENT DIABETES Study will look at whether our weight-loss program leads to weight loss.

We hope to learn the benefits and risks of a group-based weight-loss-program led by a lay health counselor under the supervision of a dietitian. The study will consist of two groups of volunteers. Both groups will be involved in a physical activity and dietary intervention. Group A will be involved in a weight loss program that combines dietitian-led sessions with group lay-health counseling sessions (a small group led by a trained member of the community with diabetes). Group B will receive two individual sessions with a registered dietitian and written information about programs in the area. Both groups will receive the same medical monitoring.

STUDY PROCEDURES

Screening Visit 1

If you agree to be in the study, you will come to the General Clinical Research Center (GCRC) at Wake Forest University Baptist Medical Center for a screening visit. During this visit, we will ask you to fill out some forms about your health, review your current medications and to have your height, weight, waist, and blood pressure measured. This visit will take about one hour. If you might be eligible for the study, you will be asked to have a blood test of about two tablespoons of blood to measure your blood sugar level. These tests will help the doctors decide if you qualify for the study.

Screening Visit 2, if needed

A second screening visit may be needed to re-check your blood sugar level. If you have had a blood sugar measured in the recent past, you may not need this second screening visit. If needed, the second screening clinic visit will last about 30 minutes. You will have your weight and blood pressure measured. In addition, two tablespoons of blood

will be collected to measure blood sugar. If you are still eligible, you will be asked to attend a third visit, the Randomization Visit.

Randomization Visit

The Randomization Visit will last approximately 2 hours. This visit will also occur in the GCRC. You will have a brief physical exam, and have your weight, height, waist and blood pressure measured. Two tablespoons of blood will be collected to measure blood sugar, insulin, and lipids. Some of this blood will also be stored for possible future research. You will fill out forms about your usual activities and ideas about health. During this visit you will be randomly assigned to one of two groups. By "random" we mean that neither you nor any of the clinic staff (including your doctor) can select which group you will be in. Using a procedure like flipping a coin, a computer program assigns you to one of the groups (equal chance of being placed in either group). The two possible groups are a dietitian-led intervention and a weight loss intervention group that combines dietitian-led sessions with group lay-health counseling sessions (a small peer group with a trained peer leader). By signing this consent, you are agreeing that you are willing to be placed in either of the two groups. Both of these groups and what they will do are described below.

Intervention Visits

If you are randomized to Group A, you will receive three individual sessions with a registered dietitian during the first six months. You will also meet once a week with a peer group and lay-health counselor who will consult with a dietitian (when needed) for the first six months. These meetings will take place at a location that is convenient for your group. Information about diet and weight loss will either be delivered by your lay-health counselor, an expert from the community or by a DVD presentation. During the next eighteen months, you will only meet with your lay-health counselor and group once a month. You will receive a small number of low cost items chosen to help you with lifestyle change. These items will be provided to you at no cost. Additionally, you may receive items to assist in removing barriers to meeting study goals such as weight loss supplements, sports gear, transportation assistance, or other similar items. These items will not exceed $100 per participant without prior approval from the study Steering Committee and will be provided at no cost to you.

If you are randomized to Group B, you will have two individual meetings with a registered dietitian during the first three months of the study and then you will be given information on a variety of low cost community programs. You will also receive a newsletter monthly with information about healthy living. At the end of the study, we will share information we have learned about successful strategies to change lifestyle and reduce the risk of developing diabetes.

Both groups in the HELP PREVENT DIABETES Study are offered at no cost to you. *Whichever group you are assigned to (A or B), you will continue to see your regular doctor for routine (primary) care.*

If your primary care doctor feels you need additional education about weight loss, you are free to do so. However, any additional education and counseling will not be paid for by the HELP PREVENT DIABETES study.

Follow-Up Visits

Your health and progress will be monitored every six months during the study. Each of these visits will last approximately 2 hours and will also take place in the GCRC. At these visits you will again have a brief physical exam, and have your weight, height, waist size and blood pressure measured. About two tablespoons of blood will be collected to measure blood sugar and insulin. At the 12 month visit, lipids will also be measured. You will fill out forms about your usual activities and ideas about health.

You will be asked not to eat or drink anything but water after midnight the night before each of your clinic visits (Screening Visits 1 and 2, Randomization and Follow-up Visits).

Like the randomization visit, some of the blood that is collected at the follow-up visits will be stored for future possible research. Your tissue sample will be stored with a unique identifier and will not include any identifiable information about you, such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule regulations. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social

security number, etc. will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

The research that may be done with your blood sample is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research done with your blood sample will not be given to you or your doctor. These results will not be put in your medical records. The research using your blood sample will not affect your care. Your blood sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of this research.

Sometimes blood samples used for genetic research may provide information about diseases that are passed on in families. Even if your blood sample is used for this kind of research, the results will not be told to you or members of your family, and will not be put in your health records.

The choice to let your blood sample be kept for future use is up to you. No matter what you decide to do, it will not affect your care in this study. If you decide now that your blood sample can be kept for research, you can change your mind at any time. Just contact your study investigator, David Goff, MD (336) 716-9837, and let him know that you do not want your blood sample used and it will no longer be used for research. Otherwise, the blood sample may be kept until it is used up or it is destroyed.

POTENTIAL RISKS AND DISCOMFORTS

There are no major risks associated with the data collection visits. All medical tests and care may involve some minor risks or discomforts. These include:

Risks of Blood Draw: The risks of drawing blood are rare and include feeling brief pain, becoming faint during the blood draw or developing a bruise or bump following the blood draw. There is a slight risk of infection at the site where blood was drawn.

Risks of Blood Pressure Assessment: You may feel brief discomfort during blood pressure readings due to the pressure of the cuff on your arm.

Risks of Increasing Physical Activity: Increasing your physical activity may increase your risk of injuries to the muscles, ligaments, tendons and joints of the body. Other risks include abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, and very rare instances of heart attack, stroke, or even death. To help ensure your safety, the study will check your readiness to become more active. A study doctor will see you if your readiness is in doubt.

Risks of Hypotension (Low Blood Pressure): If you do lose weight while you take medicines to control your blood pressure, there is a chance you may have episodes of feeling light-headed, dizzy or nauseous from a drop in blood pressure. Low blood pressure is also known as hypotension. To reduce the chance of hypotension, please report any feelings dizziness, nausea, or light-headedness to study staff. If you develop low blood pressure, the study doctors will contact your doctor to discuss adjustment of your blood pressure medicine.

Pregnant women are excluded from participation in this study. Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), DepoProvera, Norplant, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. If you are a sexually active woman of childbearing potential and have not been using an accepted method of birth control, two negative pregnancy tests performed 15 days apart are required to check for possible early pregnancy prior to starting treatment. We encourage you to discuss this issue further with your physician if you have any questions.

POTENTIAL BENEFITS

There may or may not be any direct benefit to you from this study. You will receive regular medical tests relating to pre-diabetes. We will learn more about the short-term effects of two different weight loss programs. This information can be provided to people who have pre-diabetes and the medical community.

ALTERNATIVE TREATMENT

If you choose not to join this study, you may talk to your doctor about the benefits of weight loss and exercise and other programs to lose weight. We encourage you to continue with your usual health care, whether you join the study or not.

WHAT ABOUT THE USE, DISCLOSURE AND CONFIDENTIALITY OF HEALTH INFORMATION?

By taking part in this research study, your personal health information and other information that directly identifies you may be used and shared. Information that identifies you includes, but is not limited to, such things as your name, address, telephone number, and date of birth. Your personal health information includes all information about you that is collected or created during the study for research purposes. It also includes your personal health information that is related to this study and that is maintained in your medical records at this institution and at other places such as other hospitals and clinics where you may have received medical care. Examples of your personal health information include your health history, your family health history, how you respond to study activities or procedures, laboratory and other test results, medical images, and information from study visits, phone calls, surveys, and physical examinations.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products. In addition to the study doctors and staff, some of the people, agencies and businesses that may receive and use your health information are the central laboratories, the institutional review board, representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by

federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study.

This research study could lead to the treatment or diagnosis of a medical problem. If so, then information collected or created as part of the study may be placed in your medical record. This information may be discussed with individuals caring for you who are not part of the study. This will help in providing you with good medical care. In addition, all or part of your research related health information may be used or disclosed for treatment, payment, or healthcare operations purposes related to providing you with medical care.

Laboratory test results and other medical reports will be created as a result of your taking part in the research study. This information may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These results will be kept secure. Access to this information will be limited to individuals with proper authority. Some people with access may not be directly involved with this research study.

In the future, people who do research may need to know more about your health. While the study investigator may give reports about your health, he/she will NOT be given your name, address, phone number, or any other identifying information about who you are, unless you agree to being contacted in the future.

When you sign this consent and authorization form you authorize or give permission for the use of your health information as described in the consent form. This authorization does not have an expiration date. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

David Goff, MD, PhD

Wake Forest University Health Sciences

Division of Public Health Sciences- Epidemiology

Medical Center Blvd

Winston-Salem, NC 27157

If you withdraw your authorization you will not be able to be in this study. If you withdraw your authorization, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. You will not have access to your health information that is included in the research study records until the end of the study.

COSTS AND PAYMENTS

There are no costs to you for taking part in this study. All the study costs, including any study visits and procedures related directly to the study, will be paid for by the study. Travel costs associated with trips to and from study assessment visits at the GCRC will be paid for by the study. However, travel costs to and from group meetings and dietitian sessions will not be paid for by the study. Your HELP PREVENT DIABETES Lifestyle or Dietitian sessions, clinic visits and study tests are free. All other treatments, procedures, and clinic visits for your medical care are considered usual medical care. Their costs are expected to be covered by your insurance company or you. You will receive no payment or other compensation for taking part in this study.

INJURY

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of

$25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at (336) 716-3467.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr David Goff at (336) 716-9837 or the Project Manager, Caroline Blackwell, at (336) 713-4061. After hours please call the PAL line at (336) 716-7654.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, you should contact the Chairman of the IRB at (336) 716-4542.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to take part in or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because you had an unexpected reaction, have failed to follow instructions or because the entire study has been stopped. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study. You will be given a signed copy of this consent form.

Do you request that we send important medical findings from your study tests/exams to your personal physician? ____Yes ____ No

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. As a participant in this study, a copy of this signed consent form will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

a. I agree that my blood sample and health records may be kept for use in research on diabetes and diabetes prevention. Yes __ No __

b. I agree that my blood sample and health records may also be kept for use in future research to learn about, detect, prevent, treat or cure other health problems.
Yes __ No __

c. I agree that David Goff, MD, PhD or someone whom he/she chooses may contact me in the future to ask about taking part in more research.
Yes __ No __

_____

Subject Name (Printed)

Subject Signature	**Date**
Person Obtaining Consent	**Date**

APPENDIX B

Measures of Self-Efficacy

Task-specific Exercise Self-efficacy
We are going to ask you about your participation in moderate intensity exercise. These are activities that take some physical effort, and increase your heart rate and breathing above resting levels, but is not as hard as vigorous exercise. Examples of these activities might include, brisk walking, carrying light loads, playing doubles tennis, or regular bicycling.

Please indicate below how confident you are that you can successfully carry out each of the following activities.

"I BELIEVE THAT I COULD EXERCISE…"

1. For **5 minutes at a moderate intensity** without stopping? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 No Confidence — Moderate Confidence — Complete Confidence
2. For **10 minutes at a moderate intensity** without stopping? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 No Confidence — Moderate Confidence — Complete Confidence
3. For **15 minutes at a moderate intensity** without stopping? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 No Confidence — Moderate Confidence — Complete Confidence
4. For **20 minutes at a moderate intensity** without stopping ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 No Confidence — Moderate Confidence — Complete Confidence
5. For **25 minutes at a moderate intensity** without stopping? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 No Confidence — Moderate Confidence — Complete Confidence

6. For **30 minutes at a moderate intensity** without stopping

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

7. For **35 minutes at a moderate intensity** without stopping?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

8. For **40 minutes at a moderate intensity** without stopping

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

9. For **45 minutes at a moderate intensity** without stopping?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

10. For **50 minutes at a moderate intensity** without stopping

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

11. For **55 minutes at a moderate intensity** without stopping?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

12. For **60 minutes at a moderate intensity** without stopping

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

Weight Efficacy Lifestyle

The following items represent a number of situations that may be difficult to stick with a healthy diet. Please rate your confidence about being able to successfully resist the desire to eat under each condition.

1. I can resist eating when I am **anxious (nervous)**.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

2. I can resist eating when I am **depressed**.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

3. I can resist eating when I am **dining out**.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

4. I can resist eating when **there is a lot of food available**.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

5. I can resist eating even when **I have to say "no" to others**.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

6. I can resist eating when **others are pressuring me to eat**.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Confidence — Moderate Confidence — Complete Confidence

7. I can resist eating when **I am watching TV**.

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 2 3 4 5 6 7 8 9 10

No Confidence — Moderate Confidence — Complete Confidence

8. I can resist eating **just before going to bed.**

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 2 3 4 5 6 7 8 9 10

No Confidence — Moderate Confidence — Complete Confidence

9. I can resist eating **between meals.**

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 2 3 4 5 6 7 8 9 10

No Confidence — Moderate Confidence — Complete Confidence

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SCHOLASTIC VITAE

Heidi Dotson

Personal Information

Birth date: August 20, 1989

Undergraduate History

2007 – 2011 University of Rhode Island

Kingston, Rhode Island

B.S. Kinesiology / Exercise Science

Minor in German

Graduate Study

2011 – 2014 Wake Forest University

Winston- Salem, North Carolina

M.S. Health and Exercise Science

Advisor: Jeffrey Katula, Ph. D.

Thesis: The Impact of Healthy Living Partnership to Prevent Diabetes (HELP PD) Intervention on Measures of Self-Efficacy

Professional Experience

2011- 2012 Exercise Specialist and Patient Coordinator

Healthy Exercise and Lifestyle Programs (HELPS)

Wake Forest University Department of Health and Exercise Science

Winston-Salem, North Carolina

2011 – 2012 Research Assistant

Wake Forest University Department of Health and Exercise Science

Winston- Salem, North Carolina

2012	Exercise Specialist
	Physical Activity, Lifestyle and Nutrition Program (PLAN)
	Action Health: Wake Forest University Baptist Medical Center
	Winston- Salem, North Carolina
2011 – 2012	Lecturer
	Wake Forest University Department of Health and Exercise Science
	Winston- Salem, North Carolina
2010	Undergraduate Intern
	Noninvasive Cardiovascular Imaging Center
	Brigham and Women's Hospital
	Boston, Massachusetts
2010	Undergraduate Shadow
	Cardiac Rehab
	St. Joseph's Hospital
	Nashua, New Hampshire

Memberships

2011- 2014	American College of Sports Medicine

Certifications

2013- 2015	BLS for Healthcare Providers CPR/AED American Heart Association